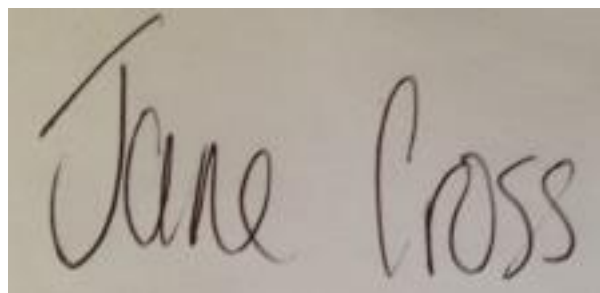


Fenestrated Endovascular Aneurysm Repair – Validation of Current UK Practise

I, Jane Elizabeth Cross, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

A photograph of a handwritten signature in black ink on a light-colored surface. The signature reads "Jane Cross" in a cursive, flowing script.

Abstract

EVAR has revolutionised aneurysm management; level one evidence shows advantages of endovascular repair over open repair. However, analysis of the EUROSTAR database of >11,000 aneurysms shows that use of EVAR outside manufacturer's instructions for use is associated with a significant risk of aneurysm related mortality and type 1 endoleak.

Recent advances have seen the evolution of fenestrated endografts (FEVAR) to enable endovascular repair of aneurysms with a compromised proximal neck. However, these complex endografts are often technically difficult to insert and long term durability is unknown. In this thesis I hypothesise that all abdominal aortic aneurysms should be treated endovascularly and aim to determine the indications for fenestrated endografts.

A meta-analysis found current evidence for FEVAR to be limited. A weakness in current evidence base is lack of concurrence between definition of juxta/para and supra-renal aneurysms leading to difficulty in comparison between series. A new classification system of aneurysm necks based on the endograft seal zone is proposed. Further adjuncts to complex endograft insertion are discussed including use of CO₂ angiography to reduce incidence of contrast induced nephropathy and use of temporary axillo-bifemoral grafts to reduce reperfusion injury.

Indications for FEVAR based on current evidence are unclear and a consensus statement to determine the indications was undertaken. An initial survey outlined current UK practise of aneurysm management. The consensus statement using RAND methodology determined the indications for FEVAR in approximately two thirds of all scenarios but outlined a grey area of equipoise in almost one third of scenarios.

In conclusion, whilst most aneurysms are technically suitable for endovascular repair, it is not possible to conclude that FEVAR is superior to open repair in the long term. A grey area of equipoise was highlighted for the indications of EVAR; further evidence is required to determine guidelines for patient suitability.

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Part 1

Chapter 1

Introduction: Background to Standard EVAR

Introduction: Background to Standard EVAR

EVAR (endovascular aneurysm repair) has changed the management of aortic aneurysms. The key principle to successful EVAR is aneurysm exclusion from the circulation by forming an effective seal between implanted endograft fabric and native vessel wall.

Initially conceived as a treatment for patients unfit for open surgery, it was a decade after Parodi's(1) first case that EVAR emerged as a viable treatment option for infra-renal AAA (abdominal aortic aneurysm) (Figure 1a). Prototypes in the early 1990s were often 'home made' and predisposed to complications. Two registries launched in 1996 documented these learning curves; Registry for Endovascular Treatment of Aneurysms (UK) (RETA) and EUROSTAR from 14 European countries.

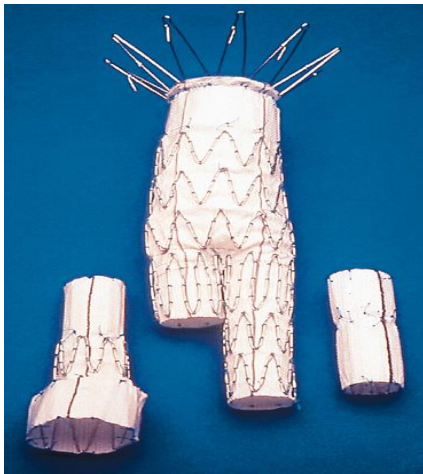
Early enthusiasm was tempered by results; Vanguard showed poor proximal fixation, stent graft migration and delayed AAA rupture. By its closure in 2006 EUROSTAR had produced data on 11,208 EVAR, this level two evidence influenced patient management, second generation graft designs and with RETA, provided methodology for two UK randomised EndoVascular Aneurysm Repair trials (EVAR I & II). Started in 1999 as second generation devices became available, these trials combined with the

Dutch Randomized Endovascular Aneurysm Management Trial (DREAM) produced level one evidence for EVAR in 2004 and 2005.

Since then, recent years have seen a steady expansion of EVAR use which is now regarded as standard management for AAA (figure 1b). Next generation infra-renal devices include modifications in graft flexibility and lower profile design to increase ease of use and applicability. Developments of fenestrated and branched graft design show recent advances in EVAR in complex AAA.

Fig 1a:

Some commercially available modular infra renal EVAR devices



i) The Cook Zenith device. This is made up of three parts: a main body and two “legs”. The graft itself is made of polyester and prolene suture is used to sew the graft material to a frame of stainless steel stents. The uncovered stents at proximal end are designed to sit above the renal arteries (supra-renal fixation). The graft has several gold markers to aid orientation.



ii) The GORE Excluder device. The graft is made from PTFE with outer self-expanding nitinol stents.

Fig 1b:

Completion angiography following infra-renal EVAR.



1.1 Level one evidence for EVAR

1.1a EVAR I & II(2) Trial design

Between September 1999 and December 2003 patients aged over 60, with an AAA > 5.5cm, anatomically suitable for EVAR were included. EVAR I comprised patients considered fit for open repair and EVAR II those considered unfit. 41 centres were eligible as defined by completion of 20 previous cases (entered to RETA). EVAR I randomly allocated patients to open or endovascular repair whereas EVAR II compared EVAR with conservative management. Primary outcome in both trials was all cause mortality, secondary outcomes were aneurysm related mortality, post-operative complications, secondary interventions, quality of life scores and cost effectiveness.

1.1b DREAM(3) Trial design

Between November 2000 and December 2003 patients with AAA > 5cm and anatomically suitable for EVAR were included if deemed fit for open surgery as defined by a cardiologist/internalist. As with EVAR I, EVAR was compared to open surgery. There were 26 participating centres in Holland and 4 in Belgium. Teams had performed at least five EVAR and were proctored until they had performed 20. Primary endpoints were operative mortality and morbidity, secondary endpoints and additional assessments were event free survival, quality of life, length of hospital stay and costs. Each complication was assessed by an independent blinded assessor.

1.1c EVAR I(4) Early results

These were reported in 2004 on patients recruited by December 31st 2003. Of all screened individuals 54% of were anatomically suitable for EVAR. A total 1082 patients were randomised in EVAR Trial I, 543 allocated EVAR and 539 allocated open repair. Demographic profiles were similar. 30-day mortality was lower in the EVAR group 1.7% (9/531) versus 4.7% (24/516) in the open group (odds ratio 0.35 [95% CI 0.16-0.77] $P=0.009$). Secondary interventions were more common in patients allocated to EVAR (9.8% versus 5.8%, $P=0.02$).

1.1d DREAM(5) Early results

DREAM also reported in 2004 with 351 patients randomised, 174 to open repair and 171 patients EVAR. Patient demographics were similar. 30-day mortality was again lower in the EVAR group 1.2% (2/171) versus 4.6% (8/174) for open repair (risk ratio 3.9 [95% CI 0.9 to 32.9, $P=0.10$]). The combined rates of operative mortality and severe complications were 4.7% (8/171) in EVAR and 9.8% (17/174) in open repair (risk ratio 2.1 [95% CI 0.9 to 5.4, $P=0.10$]). EVAR was associated with shorter duration of surgery, less blood loss and blood replacement, less post-operative respiratory ventilation, less change in haematocrit, shorter ITU/HDU stay and shorter hospital stay than open repair.

Publication of these trials in 2004 provided level one evidence for reduced early mortality from EVAR compared to open repair. DREAM was not statistically significant, due to low numbers (a third that of EVAR I). One reason suggested was withdrawal of funding for DREAM, as EVAR I had recruited and outcomes looked similar. These early results were augmented in 2005 with publication of EVAR I midterm results and those from EVAR II and together were a turning point in EVAR use. Although the first commercially available device was launched in 1999 it was not until publication of EVAR I and DREAM results that most vascular surgeons took EVAR as a valid alternative to open repair. The UK National Vascular Database(6) report in 2004 did not report EVAR in the management of 3,444 AAA. In 2008, 1,580 EVAR were reported in 3,614 AAA (44%). Leading manufacturers have seen over 100,000 of their second generation devices deployed.

1.1e EVAR I(7) midterm results

EVAR I reported four year outcomes. Overall at median follow-up of 2.9 years 209 of 1082 patients had died, 53 from aneurysm-related causes. Primary outcome of all-cause mortality was similar in both groups (about 28% $P=0.46$). Secondary outcome of aneurysm-related death was reduced following EVAR (4% versus 7%, $P=0.04$).

Complications were more common following EVAR (41% versus 9% for open, $P=0.04$).

Re-intervention occurred in 15% following EVAR and 7% of open repairs. 14 patients in the EVAR group were converted to open, 6 early and 8 late. Midterm results also

reported improved initial quality of life scores following EVAR at 3 months, with no differences seen after 12 months. EVAR was associated with increased costs of £13257 versus £9946 for the open repair group.

1.1f EVAR Trial II(8)

338 patients were entered by December 31st 2003, 166 were allocated EVAR.

Demographic profiles of the groups were similar. 14 patients died before intervention (6 ruptured), 146 underwent EVAR (90%), 4 had open repair (2 for rupture), 2 were managed conservatively. Of 150 patients, median time from randomisation to surgery was 57 days. Of 172 patients randomised to no intervention, 125 (73%) adhered to protocol, 47 crossed over (35 EVAR and 12 open repair). On intention to treat, 30 day EVAR group mortality was 9% (n=13/150). At 4 years 64% of patients had died (n=142), 42 (30%) of these from aneurysm-related causes. There was no significant difference between the EVAR group and the no-intervention group for all-cause mortality (HR 1.21, P=0.25) or for aneurysm related mortality. Post Hoc per protocol analysis showed no difference in all-cause mortality (HR 1.07 P=0.7) or aneurysm related mortality (HR 0.77 P=0.43). Quality of Life was no different between the groups and EVAR more expensive (£13632 v £4983).

Outcomes of EVAR I and II cemented the early benefit for EVAR in 'fit patients' and clarified indications for EVAR in those 'unfit'. Criticisms of EVAR included the high rates of re-intervention, the need for long term surveillance and increased costs. Re-

intervention was high but reflected treatment of type II endoleaks. These are now regarded as benign, the majority resolving over six months and requiring re-intervention in the minority of cases. Cost have fallen with increasing use of duplex instead of CT for follow up, reduced hospital stay (median 6 days in EVAR I) and reduction in device costs. EVAR II had methodological criticisms on delay to treatment and large number of cross over cases between groups. Nevertheless post hoc analysis showed no advantage from EVAR. Early mortality in EVAR II was very high, significantly more than EVAR I perhaps suggesting poor patient selection; patients with very limited life expectancy. Definition by what is 'unfit' was confused by functional results (cardiac and lung function) that overlapped with those regarded 'fit' in EVAR I.

The EVAR trials demonstrated that doctors can effectively identify those patients in whom EVAR is not appropriate and in those appropriate there was a better early outcome with reduced AAA related mortality.

1.1g Long term results for EVAR I Trial(9)

In total 1252 patients were recruited by 31st August 2004, 626 assigned to each group. Patients were followed up for a minimum of 5 years (mean 6 years, max 10 years). Of 524 deaths, 76 were aneurysm related. 30 day mortality remained improved for EVAR (1.8% (11/614) versus 4.3% (26/602); $P=0.02$). Although the endovascular group had an early benefit in terms of aneurysm related mortality, by the end of the study there was no difference between groups ($P=0.73$). There was no difference in all-cause mortality

($P=0.72$). Complications were higher following EVAR (45.0% versus 12.4%; $P=0.01$). Re-intervention was also higher following EVAR (23.1% versus 8.8%; $P=0.001$). By the end of the study, 18 EVAR patients had been converted to open repair and delayed rupture following EVAR had occurred in 25 patients of whom 17 died.

1.1h Long term results for EVAR II Trial(10)

In total 404 patients were recruited by 31st August 2004, 197 to EVAR and 207 to no intervention. During follow up, median 3.1 years, 305 deaths occurred, 78 of which were aneurysm related. Primary endpoint of all-cause mortality did not differ ($P=0.97$). Aneurysm related mortality was reduced with EVAR ($P=0.02$) despite a 30 day operative mortality of 7.3% ($n=13$). Overall the rate of aneurysm rupture in the no-intervention group was 12.4 per 100 person years. 70 patients in the no intervention group crossed over to the intervention group. During 8 years of follow up the average cost difference between each group was £9,826.

1.1i Long term results for DREAM trial (11)

The median follow up was 6.4 years and all patients were followed up for a minimum of 5 years. There was no difference in overall survival (69.9% for open repair and 68.9% for EVAR, $P=0.97$). Aneurysm related mortality was not reported. The cumulative rates of freedom from secondary interventions were 81.9% for open repair and 70.4% for endovascular repair (95% CI, 2.0 to 21.0; $P = 0.03$). Incisional hernia repair was the

commonest intervention in the open group and endoleak or graft migration in the EVAR group.

Despite the results from these trials showing no long term benefit from EVAR there has been little influence on current practise in the UK. Following early and midterm results in 2004 and 2005 there was a significant rise in EVAR use throughout the UK. EVAR offered reduced postoperative mortality. EVAR II suggested futility of offering elective intervention to unfit patients, a practise that has been adopted with conservative management for those with significant co-morbidities likely to live less than two to three years. However, EVAR is now firmly established in the management of AAA. For patients able to attend follow up with anatomically suitable AAA, EVAR is now the preferred first line treatment.

1.2 EVAR for small aneurysms

The UK small aneurysm trial(12) (UKSAT) and Aneurysm Detection and Management(13) (ADAM) trial showed no long term survival benefit of early open surgery for patients with small (4.0-5.5cm) symptomless AAA. These data have set the benchmark for AAA intervention over the last decade but results from EVAR have questioned this; lower mortality rates from intervention, smaller AAA are more likely to be anatomically suitable for EVAR(14) and that in long term follow up the majority small AAA underwent intervention(15). Two trials were undertaken to assess the role

of EVAR for small AAA; Comparison of surveillance versus Aortic Endografting for Small Aneurysm Repair trial (CAESAR) (16) and Positive Impact of endoVascular Options for Treating Aneurysms early PIVOTAL (17, 18) trial.

CAESAR randomised 360 patients between 2004 and 2008 with 4.1-5.4cm AAA to early EVAR (n=182) or surveillance and repair at a defined threshold (diameter ≥ 5.5 cm, enlargement >1 cm/year, symptoms) (n=178). Primary endpoint of all-cause mortality showed no difference (P=0.6) at 54 months. Aneurysm related mortality, aneurysm rupture and major morbidity rates were similar. PIVOTAL was a prospective 70 site trial of patients aged 40-90, morphologically suitable for EVAR with low risk co-morbidities, randomised to early EVAR versus surveillance for aneurysms 4-5cm in diameter. Of 728 patients, with a mean diameter of 4.5cm, 362 were randomised to surveillance and 326 patients underwent intervention (EVAR n=322 and open repair n=4), although 112 patients assigned to surveillance underwent intervention (109 EVAR, 3 open). Primary endpoint of all-cause mortality showed no difference at 20 months with 15 deaths in each group (4.1%) (HR for mortality in the early EVAR group was 1.01 (P=0.98)). Other endpoints rates were similar.

These trials suggested that EVAR could be undertaken in patients with small aneurysms but there was no benefit compared to surveillance in the endpoints assessed. Risk of rupture was lower than predicted in surveillance giving no advantage to EVAR. PIVOTAL was stopped early because of this. Debate on whether small AAA

may 'grow out of' anatomical suitability for EVAR was assessed in 221 patients under surveillance (14). Smaller AAA were more likely to be anatomically suitable for EVAR, 76% at mean 52 ± 9 mm, but rate of suitability did not decrease until the aneurysm measured 57 mm by CT scanning. These data imply that waiting until 5.5cm does not result in loss of suitability for EVAR. Any benefit from early intervention in small AAA is also affected by patient co-morbidities, 40% of those in follow up in the UKSAT died from other causes. Further optimal risk factor management with statins and ace inhibitors may also slow AAA progression and delay rupture.

1.3 Summary

In summary, EVAR has changed the management of AAA. EVAR is associated with shorter operation time, decreased blood loss, reduced hospital stay and improved 30 day operative mortality. Level one evidence supports the use of EVAR for infra-renal AAA and it is emerging as the lead option for all aneurysm repairs.

In this thesis I will outline an alternative endovascular option for AAA with an adverse neck in the form of fenestrated endovascular aneurysm repair (FEVAR). The next chapter demonstrates why standard EVAR is unsuitable in the adverse neck. The following chapters discuss FEVAR and some adjunct procedures. Part three of the thesis presents a consensus statement to illicit the indications for FEVAR and validate

current practise. I hypothesise that all abdominal aortic aneurysms should be treated endovascularly and the aim of this thesis is to determine the indications for FEVAR.

Chapter 2

Endovascular Repair of Abdominal Aortic Aneurysms with Adverse Necks: Infra- renal Sealing is not a Safe Option

Endovascular Repair of Abdominal Aortic Aneurysms with Adverse Necks: Infra-renal Sealing is not a Safe Option

2.1 Introduction

Following publication of the EVAR(4, 7) and DREAM(5) trials in 2004/5, EVAR became widely accepted in the UK as a viable alternative to open repair. Since then, use has increased rapidly and it is now the treatment of choice in most UK centres. Data published from the 2009 National Vascular Database(19) showed that EVAR was used in 44% of aneurysm cases. However, the long term outcomes from the EVAR I trial(9) have raised questions as to the long term durability of EVAR.

Suitability for EVAR is defined by anatomical criteria and approximately 25-50% of aneurysms conform. Most commercial grafts are licensed for a neck length of >15mm and angulation of <60 degrees; specific brands licensed for a straight neck up to 10mm or a long neck of angulation up to 90 degrees are available. Short and angulated aneurysm necks are associated with an increased endoleak and reintervention rate (20, 21). Manufacturers have developed instructions for use recommending minimum anatomical conditions for the use of their graft; these are developed following extensive bench testing by engineers. However, as clinicians have become skilled in EVAR techniques, standard stent grafts have been inserted for shorter, more angulated necks and potentially used outside manufacturer's instructions for use.

Options for endovascular repair of aortic aneurysms with an adverse neck are 1) “off-label” use of an infra-renal device and 2) use of a fenestrated endograft to extend the sealing zone proximal to the level of the renal arteries. However fenestrated endografts are not universally available and at present evidence for their benefit is limited.

Little data has been published on the long term outcome of endografts inserted “off label”. The aim of this study is to investigate the long term outcome of patients with adverse neck anatomy in whom a standard infra-renal EVAR was inserted outside manufacturer’s instructions for use.

2.2 Methods

The EUROSTAR database is a multi-centre European collaborative. Data was collected from Jan 1994 to Nov 2006. Asymptomatic, non-ruptured patients were prospectively entered from 165 institutions. Details entered included patient risk factors, anatomical parameters, operative details, and intraoperative and perioperative complications. Patients were followed up at 1, 3, 6, 12, 18 and 24 months and annually thereafter for a maximum of 10 years. Adverse events reported during follow up were endoleaks, migration, kinking, occlusion, aneurysm rupture, conversion and death.

We extracted data for all patients with an adverse neck in whom a standard infra-renal graft had been inserted outside manufacturer's instructions for use. Short-term outcome together with all available follow up data were obtained. Infra-renal neck length was generally measured by CT and defined as the distance between the lowest renal artery and the onset of the aneurysm. The onset of the aneurysm was defined as a diameter increase of 4mm between 2 axial CT cuts. Neck angulation was defined as the angle between the infra-renal aortic neck and the longitudinal axis of the aneurysm.

Primary outcome was aneurysm related mortality. Secondary outcomes were all cause mortality, incidence of proximal type 1 endoleak and secondary intervention. Patients were categorised according to their infra-renal neck morphology and graft type used. Group 1 had an infra-renal graft inserted within manufacturer's instructions for use and in group 2 an infra-renal graft was inserted outside manufacturer's maximum anatomical constraints. Patients were excluded if graft type was unrecorded, if less than 10 grafts of a particular type had been inserted or if data regarding neck length and angulation were not documented.

Statistical Analysis

Normally distributed continuous variables are described using means and standard deviations and analysed using one sample student's T test or two sample T-tests. Non-

normal continuous variables are described using medians and inter-quartile ranges and were compared using a Mann-Whitney test. Categorical variables are described using numbers and percentages and compared using chi-square or Fisher's exact tests. Survival curves were plotted using the Kaplan-Meier method. Multivariable cox regression model was fitted for long-term outcome and hazard ratios (HR) with corresponding 95% confidence intervals (CI) were obtained. P-values <0.05 were considered to be statistically significant.

2.3 Results

Data from a total of 11208 patients undergoing endovascular repair of abdominal aortic aneurysms were entered into the database. 1,321 patients were excluded due to missing data or inadequate sample size of graft type. The remaining patients were divided into 2 groups; group 1 (n=7238) consisted of patients with a graft inserted within manufacturer's instructions for use, and group 2 (n= 2649) of patients with a graft inserted outside manufacturer's instructions for use. Figure 2.1 shows the graft type used. Table 2.1 presents the baseline demographics and pre-op comorbidities.

Figure 2.1 Graft Type Inserted

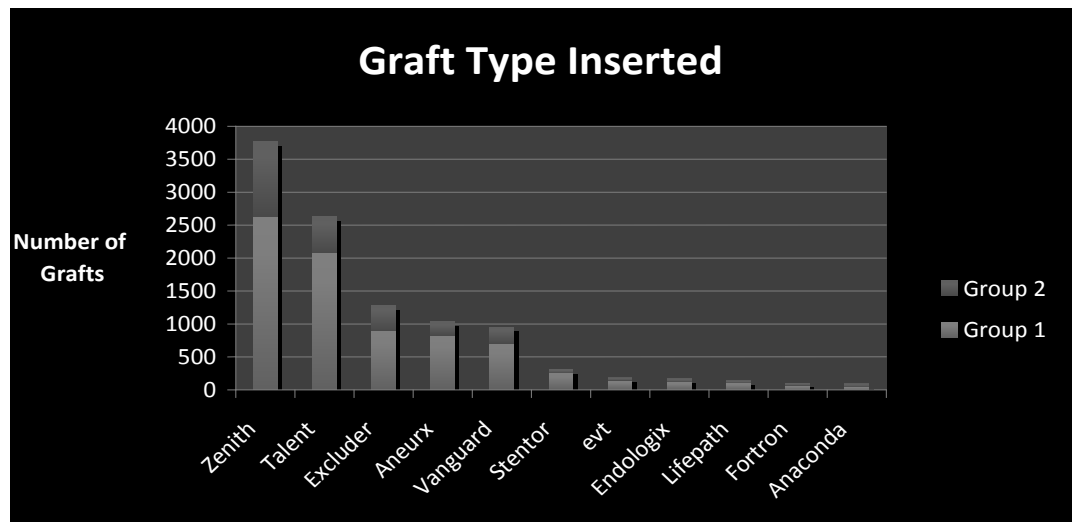


Table 2.1 Baseline demographics

	Group 1 (n=7238)	Group 2 (n=2649)	P value
Mean aneurysm diameter mm(SD)	56.3(11.1)	62.1(13.0)	<0.0001
Mean age yrs (SD)	71.7(7.9)	73.6(7.5)	<0.0001
Male (%)	93.9	89.9	<0.0001
ASA grade 1 (%)	8.0	6.1	0.0015
ASA grade 2 (%)	42.0	37.5	<0.001
ASA grade 3 (%)	43.8	48.4	<0.001

ASA grade 4 (%)	6.2	8.0	0.002
Diabetes (%)	13.1	12.1	0.18
Smoking history (%)	52.1	51.9	0.86
Hypertension (%)	65.6	65.7	0.92
Hyperlipidaemia (%)	47.5	44.1	0.002
Pre existing cardiac history (%)	61.0	61.7	0.53
Pre existing pulmonary disease	41.8	43.7	0.09
Pre-existing renal failure (%)	19.0	19.2	0.83
Unfit for open AAA (%)	22.2	26.2	<0.0001
Unfit for GA (%)	8.2	11.1	<0.0001

Patients in group 2 were significantly older, were more likely to be female and had a greater mean aneurysm diameter compared to group 1 (all $p < 0.0001$). Although there were significant differences in ASA grade and fitness for surgery, individual co-morbidities were similar in each group with the exception of hyperlipidaemia. (Table 2.1).

Patients in group 2 had a longer operating time, a higher blood transfusion requirement and were less likely to have a general anaesthetic (Table 2.2). Patients in group 2 were significantly more likely to have a proximal endoleak at completion angiography but there was no difference in the rates of intraoperative conversion to open repair.

Table 2.2 Operative details

	Group 1 (n=7238)	Group 2 (n=2649)	P value
Mean operative time (mins) (SD)	128.5 (58.3)	140.8 (64.1)	<0.001
Median blood transfusion (mls) (IQR)	400 (200-600)	500 (200-800)	0.0041
Local anaesthesia (%)	5.7	6.3	0.29
Regional anaesthesia (%)	24.8	30.0	<0.001
General anaesthesia (%)	69.5	63.7	<0.001
Proximal endoleak at completion angiography (%)	1.90	5.55	<0.0001
Intraoperative conversion to open (%)	0.67	0.89	0.29

Postoperative morbidity included cardiac, cerebral, pulmonary, renal, hepatobiliary, gastrointestinal, and septic complications. This was significantly higher in group 2 (table 2.3), however in hospital secondary interventions were similar in both groups. There was a significant difference in 30-day mortality with a mortality rate of 1.9% for group 1 and 3.2% for group 2. Although median length of hospital stay was similar in both groups, there was a statistically significant difference between the two groups.

Table 2.3 Post op (from operation to discharge)

	Group 1 (n=7238)	Group 2 (n=2649)	P value
Post op morbidity (%)	3.0	4.2	0.0043
Transfemoral secondary intervention (%)	1.0	1.5	0.051
30 day Mortality (%)	1.9	3.2	0.0001
Median length of hospital stay (days) (range)	4 (0-183)	4 (0-106)	0.02

The survival curve for the primary endpoint of aneurysm related mortality (fig 2.2) shows a significant increase in the mortality rate in group 2 over a 10 year period. The secondary endpoint of all cause mortality (fig 2.3) was also significantly increased in the adverse neck group as was incidence of proximal type 1 endoleak (fig 2.4). There was no significant difference between the two groups for secondary intervention (fig 2.5).

Fig 2.2 Kaplan Meier survival curve for aneurysm related mortality

$P=0.0012$, $HR=0.60$ ($CI=0.40-0.80$)

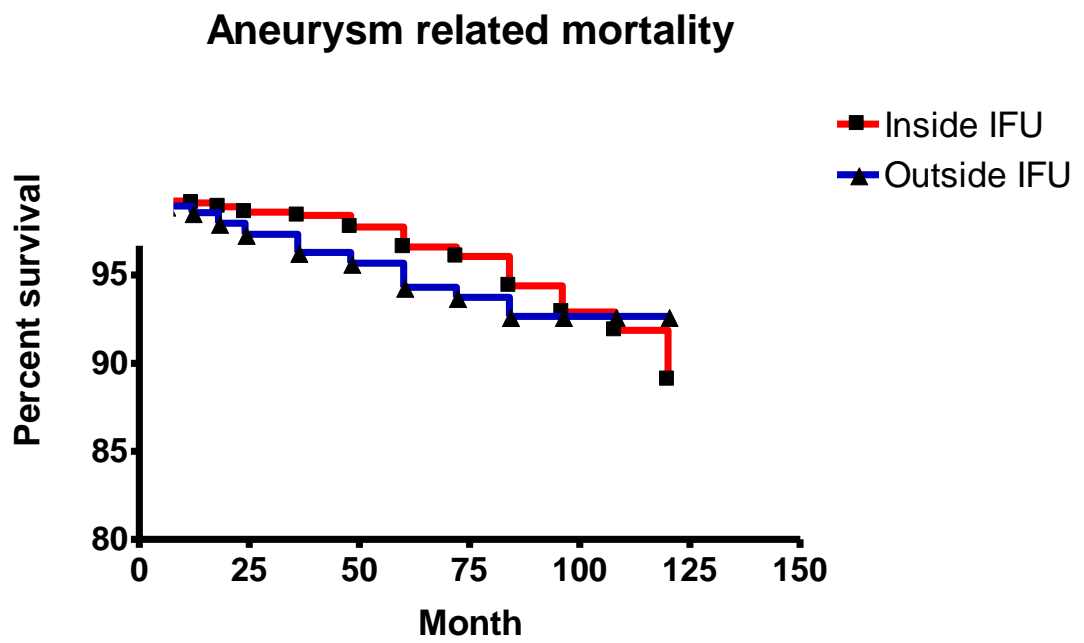
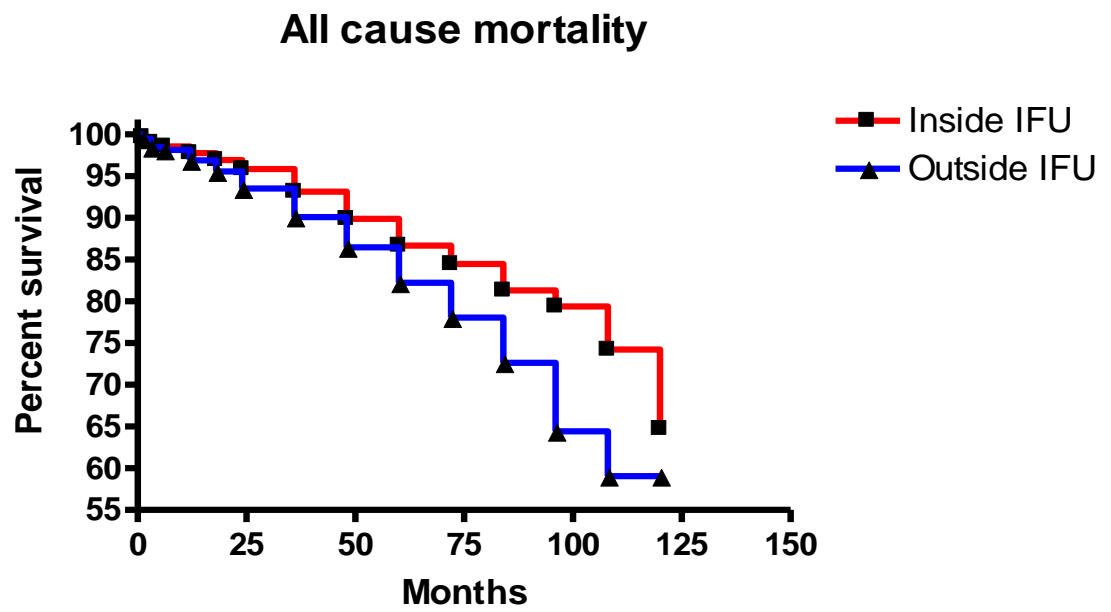
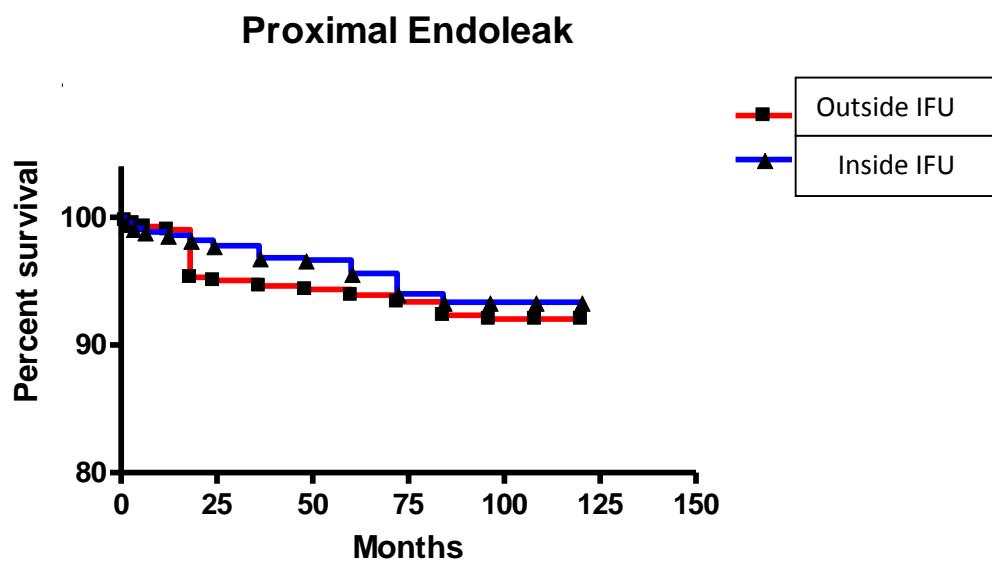


Fig 2.3 Kaplan Meier survival curve for all-cause mortality



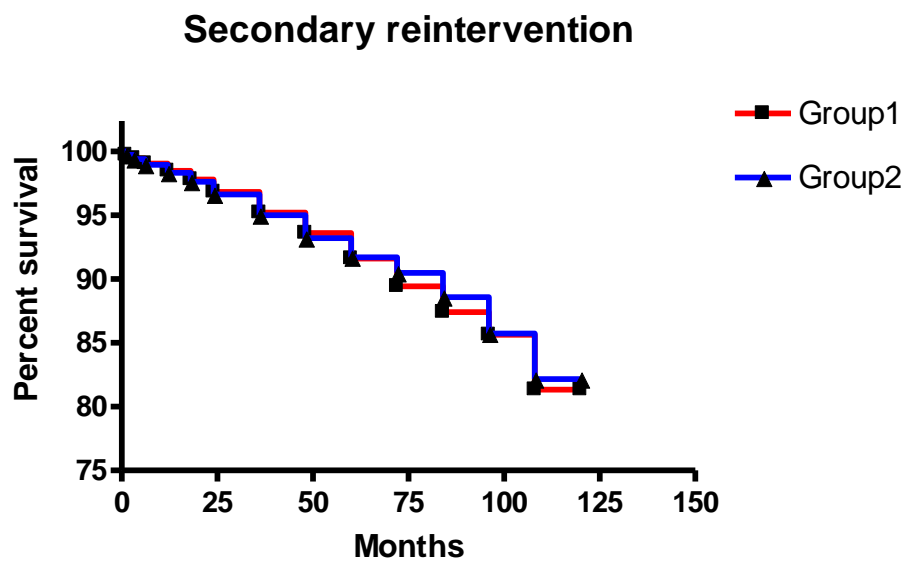
P<0.001, HR=0.69 (CI 0.59-0.74)

Fig 2.4 Kaplan Meier survival curve for proximal type 1 endoleak



P=0.005, HR 1.36 (CI 1.14-1.58)

Fig 2.5 Kaplan Meier survival curve for secondary intervention



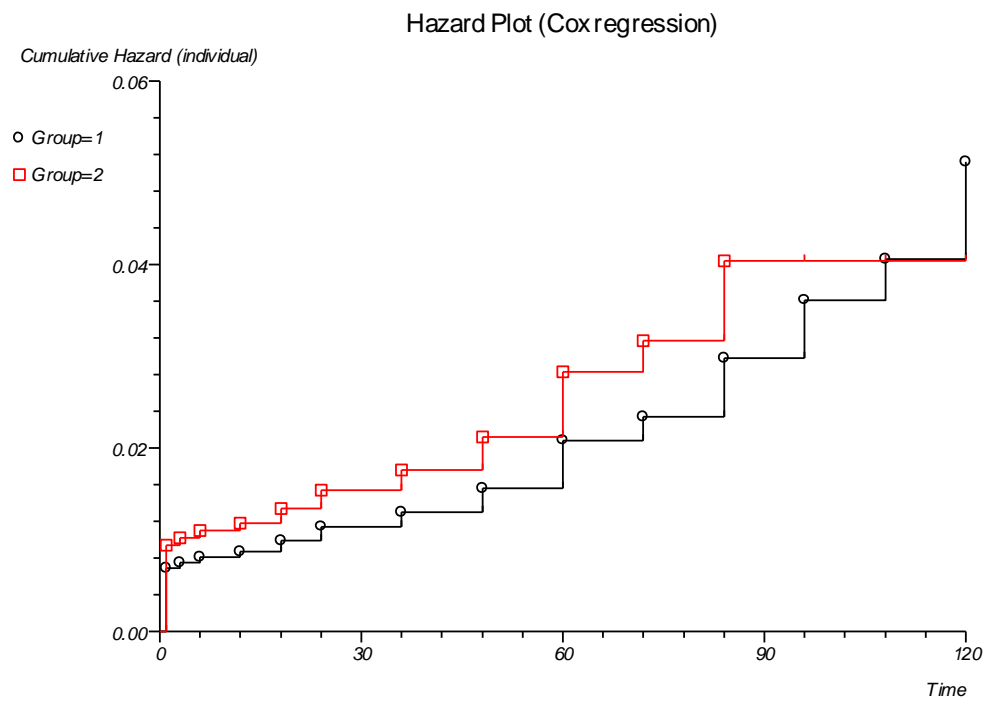
P=0.66, HR=0.98 (CI 0.89-1.12)

The results from the multivariable cox regression model are shown in Table 2.4 and the regression hazard plot in fig 2.6. Insertion of grafts outside manufacturer's instructions for use was a significant predictor for aneurysm related death.

Table 2.4 Multi variable Cox Regression

	HR (95% CI)	P value
Outside IFU	1.36 (1.08 - 1.70)	0.0078
Patient Age	1.06 (1.05 - 1.08)	0.0001
Female sex	0.78 (0.52 - 1.17)	0.24
Unfit for GA	0.92 (0.65 - 1.32)	0.67
Operation time	1.01 (1.00 - 1.01)	0.0001
Endoleak at completion	1.22 (0.76 - 1.98)	0.41
ASA 2	1.54 (0.80 - 2.99)	0.19
ASA 3	2.61 (1.37 - 4.94)	0.0034
ASA 4	6.34 (3.23 - 12.46)	<0.0001

Fig 2.6 Cox regression hazard plot



2.4 Discussion

This chapter determined the long-term outcome for grafts inserted outside manufacturer's IFU in the aneurysm with an adverse neck. It demonstrated that insertion of a graft in this cohort is a significant risk factor for long term aneurysm related mortality.

The principle of the aortic stent graft is aneurysm exclusion from circulation. The key factor in success is provision of an adequate seal both proximally and distally.

Proximally the main seal force is provided by radial force of the stent against the aortic wall. Both a short neck length or neck angulation may limit the contact of the stent with the aortic wall thereby compromising this radial strength. Over time, further dilation of the neck decreases wall contact and thus weakens the seal strength, potentially leading to sac repressurisation and subsequent rupture.

A recent short term study(22) describing the use of the Endurant graft outside instructions for use did not find a significant increase in aneurysm related mortality, and although the incidence of type 1 endoleak was increased this was not statistically significant. However, their follow up was only for 1 year and cohort numbers were small. A larger study (23) of 10228 patients found use of stent grafts outside IFU was

an independent predictor for post EVAR sac enlargement. Although mortality was not included in their outcomes, aortic sac enlargement has previously been associated with an increased risk subsequent open repair and aneurysm rupture (24, 25).

Patients in this study with adverse necks were older, with higher ASA grades and were more likely to be unfit for open surgery or for a general anaesthetic. Operations in aneurysms with compromised anatomy are harder to perform and were therefore longer and have increased blood transfusion requirements. It is unclear from our study how much of a cumulative effect this had on the primary outcome of aneurysm related mortality in the long term.

It is unclear why there was no difference in secondary re-intervention rates. This may have been an error in the data collection coding. The database collected data for treated type 1 endoleaks and a separate data entry point for secondary re-intervention. Potentially some centres may not have included intervention for a type 1 endoleak in their secondary re-intervention data as they believed that they had already entered the data in the treated type 1 endoleak category.

A limitation of this study is that many of the grafts used were older generation and are not still in production. It may be argued that improvements in graft design have improved proximal seal strength. However, when by Schanzer(23) et al removed the

earlier grafts from their results, they found an even greater difference between use of EVAR outside IFU and higher incidence of post EVAR sac enlargement. In our study we determined a long-term follow up of 10 years. Stent graft technology is rapidly evolving and it is impossible to produce any long-term data without analysing old technology.

These datasets support the fact that use of EVAR outside IFU can be done but short term results that may appear satisfactory are in fact significantly worse in long term follow up. EVAR is an excellent prophylactic treatment for infrarenal AAA when undertaken correctly, however it appears less effective if outside IFU and increases the risk for long-term failure.

In conclusion, infra-renal aortic stent grafts inserted outside manufacturer's IFU are a significant long-term risk factor for aneurysm related mortality. EVAR for asymptomatic aneurysms is a prophylactic procedure and consequences of "off-label" use may have resulted in steadily increased numbers of ruptured aneurysms over the long-term period. This must be considered when assessing aneurysm suitability for EVAR and alternative options should be considered.

Chapter 3

Endovascular alternatives to standard EVAR in the adverse neck

Endovascular alternatives to standard EVAR in the adverse neck

3.1 Fenestrated endografts

Recently, endovascular management of juxta- and suprarenal aortic aneurysmal disease has advanced through the use of fenestrated endografts (fig 3.1). The same basic principles of aneurysm exclusion apply for these newer endografts, however the seal-zone, instead of being infrarenal is now within the visceral segment and incorporates side-branches such as renal arteries. Flow to these visceral arteries is preserved through fenestrations in the endograft, or branches from the endograft being bridged to the visceral artery with covered stents. Careful preoperative planning allows the proximal seal zone for these endografts to incorporate any visceral vessel or anatomical variation.

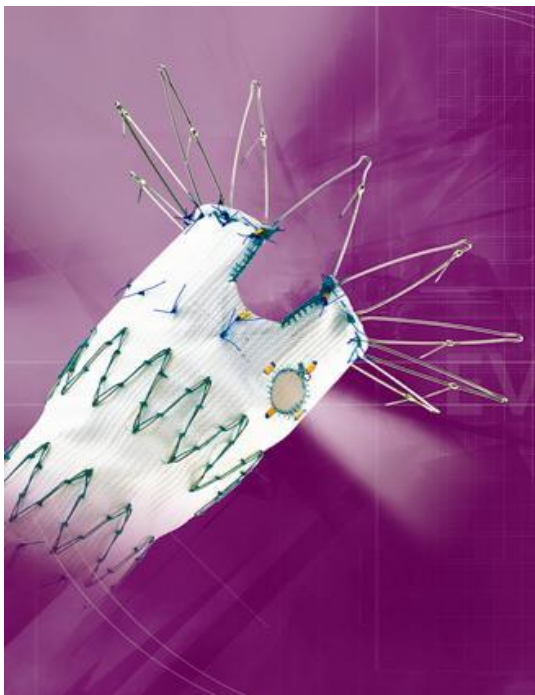


Fig 3.1

A fenestrated endograft showing a scallop for the SMA and a renal fenestration

At present, fenestrated endografts must be individually manufactured according to specific patient anatomy, taking into account differences in the locations of visceral vessel origins and aortic size and shape; the manufacturing process presents delays of weeks to months. This individual manufacturing also makes the grafts significantly more expensive than standard infra-renal grafts. Patients with large aneurysms are at risk of rupture during the manufacturing period; for symptomatic or rupture patients, in experienced hands, it is feasible to make a “home-made” fenestrated graft (26, 27).

Emerging device advances include “off-the-shelf” availability of fenestrated endografts. Despite anatomical variation, the majority of renal arteries lie within a predictable region that can be accessed by pivoting fenestrations, rendering them suitable for pre-fabricated endografts in greater than 80% of cases(28). These “off-the-shelf” devices avoid the delay in manufacturing that custom-made devices require, and will reduce cost.

Current fenestrated systems include modular components to aid alignment of the graft, diameter reducing restraining ties, (these limit the initial stent-graft expansion to assist alignment of the stent-graft prior to catheterization of target vessels), gold markers to define the edges of the fenestrations and nitinol reinforced fenestrations to facilitate catheterization.

Use of fenestrated grafts is restricted in the US to a few institutions for patients who are prospectively enrolled in physician-initiated Investigational Device Exemption (IDE) protocols. In the UK, availability is variable as funding is often limited by local health authorities.

3.1a Indications

Patient

At present open repair remains the gold standard for juxta renal aneurysms due to the limited evidence base for FEAVR. However, patients with symptomatic aneurysms who are not physiologically fit for open repair and anatomically unsuitable for standard EVAR may be considered for a fenestrated endograft.

Aneurysm morphology

Morphological indications for a fenestrated graft include: (1) A neck length of < 10mm (2) angulation of >60 degrees between the proximal aorta and the long axis angle of the aneurysm sac (3) infra-renal neck thrombus covering >50% of the proximal neck (4) infra-renal neck diameter of >32 mm or (5) inverse conical shape of the proximal aneurysm neck.

The key to successful FEVAR is meticulous planning and design of the graft. High resolution, 2mm multi-slice CT angio is performed and then reconstructed into a 3D

orientation; the technique of “centre-lining” is utilised to determine the exact relation of the target vessels. The aortic diameter at the level of the renal arteries and the length of the aneurysm neck is calculated. Distances between the ostia of the coeliac axis, the superior mesenteric and renal arteries are measured. The distance between fenestrations should be measured from the centre of the ostium whereas those target vessels receiving scallops should be measured from the most caudal point of the ostium. The location and relationship of the renal and visceral ostia are recorded in a clock-dial configuration. For a successful fenestrated graft the aortic diameter should be less than 31mm at the level of the target vessels (normally the renal arteries); diameters greater than this require a branched stent graft. There must also be an uncompromised proximal landing zone with at least a 2cm length of “normal”, non-calcified, parallel aortic wall. Stent-grafts should be oversized by 10 – 20% in the aortic neck.

Graft orientation in both in a vertical and a rotational plane is vital to success. This is aided by the placement of numerous gold markers around each orifice or branch. These markers are then aligned to visceral vessels, which are seen on intra-operative angiogram.

Angulation of the aortic neck makes sizing of the stent-graft difficult. There may be significant discrepancy between distances measured from orthogonal (mid flow-line) and axial views. It is also difficult to predict the lie of the stent-graft in vivo. Further,

the angulation of the neck increases the technical demands of fenestration catheterisation.

Increasing number of fenestrations increases the complexity of planning and deployment. Multiple renal vessels, especially if less than 4mm diameter (accessory) or stenosed are associated with catheterisation failure or subsequent occlusion.

Thrombus in the aneurysm neck is not necessarily, in itself, a contraindication to FEVAR but is associated with an increased risk of embolisation.

Anatomical limitations to the use of fenestrated grafts are excessive aortic tortuosity in the visceral segment, presence of multiple arteries that require revascularization, and vessels that arise separately from the true or false lumen in the setting of chronic aortic dissections(27).

Diameter reducing ties allow easier graft manipulation when there is a narrow segment in the visceral aorta. The narrower graft is also held away from the aortic wall allowing easier side-branch cannulation, especially if there is shuttering of the fenestration and the branch orifice.

A large amount of operative time may be spent cannulating fenestrations or branches and their target vessels, especially if there is any inaccuracy in target vessel alignment to the endograft. This time may be reduced by the use of preloaded wires – these are threaded through the fenestrations at the time of manufacture and allow rapid passage of catheters directly to the fenestration or branch.

Reduced delivery system size and greater sheath flexibility allow easier iliac access, reducing the need for iliac conduits.

3.1b Manufacturing a "home-made" fenestrated stent graft

The concept of home-made fenestrated stent grafts for EVAR is not new having first been described by Parks in 1996(29). Since then fenestrated EVAR (FEVAR) has developed as an emerging field and refined into a commercially available system.

Manufacturing the “home-made” fenestrated graft is technically challenging taking approximately 2-3 hours to complete, depending on the number of fenestrations(27). Thorough knowledge of the stent graft used and its delivery system is paramount. The operator must be experienced in elective EVAR and in planning elective fenestrated stent-graft procedures. Errors in device design and implantation may result in stent

graft misalignment between the fenestration and the origin of the target vessel (26, 27).

The stent graft cannot be re-sterilised and must therefore be prepared in a sterile environment, usually the operating theatre, immediately prior to use (fig 3.2). Our technique is based on the Zenith stent-graft, bifurcated main body (Cook Europe, Bjaereskov, Denmark) and is selected according to the proximal neck diameter and renal artery to aortic bifurcation length. Alternatively, a thoracic stent graft may be used.

Fig 3.2. Preparation of the stent graft



The graft can either be prepared “muzzle loaded” whereby the sheath of the main delivery system is withdrawn such that the first two covered stents are deployed, or the stent can be completely unsheathed. In the former method, the supra-renal stent is restrained within the top cap. The safety trigger wire is partially removed to permit deployment of the uncovered supra-renal stent. The inner cannula which is attached

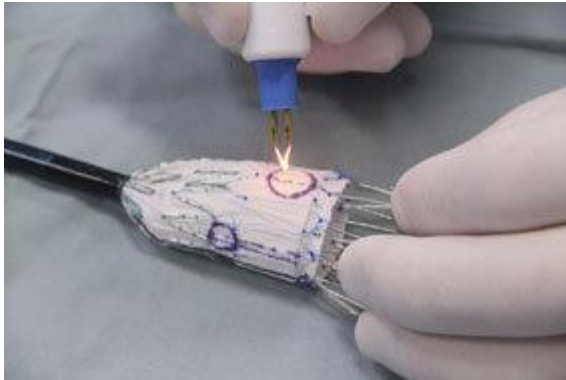
to the top cap is then advanced to deploy the supra-renal stent. This is a quicker method than completely unsheathing, however orientation is easier with the graft completely unsheathed.

Ex vivo graft fluoroscopy identifies the orientation of the stent-graft markers, particularly the lateral markers identifying the contralateral iliac stump. These markers will be helpful later to aid orientation at the aortic bifurcation and to ensure the stent-graft is not twisted when re-loaded. Use of a thoracic graft allows incorporation of a composite graft whereby independent alignment of the fenestrations and the contralateral stump at the aortic bifurcation is permitted. However, there is the potential drawback of modular disconnection between the two components.

An indelible marker pen is used to mark the Dacron. The longitudinal axis is marked in the 12 o'clock position and all measurements are taken from this mark. Callipers are used to precisely mark out the exact site of the fenestrations. The fenestrations or scallops are then burnt into the fabric using a low-power ophthalmic cautery device (Medtronic Xomed, Jacksonville, FL) (fig 3.3). Dacron is flammable and care should be taken to avoid uncontrolled burning of the fabric. It is important to mark out the exact size of the fenestration/scallop required to avoid overzealous cautery and creation of fenestrations that are too large. Most fenestrations have a diameter of 6 – 8mm and are located at a minimum of 15mm distal to the top of the fabric. They are placed between stent struts to allow unimpeded access to the target vessel. Should the

anatomy be such that the fenestration lies over a strut then the strut must be bent away from the fenestration. Scallops are hemi-oval, 6 – 10mm in height and 8 – 12mm in diameter and are located on the proximal portion of the graft.

Fig 3.3



A cautery device is used to create the fenestrations in the fabric

The fenestrations are reinforced by nitinol rings. These aid cannulation and provide a buttress to secure the bridging stent. They may either be harvested from unused fenestrated grafts which may be in stock or alternatively the goose neck snare may be used; this can also accommodate varying diameters of fenestration. The ring is secured to the graft by locking fine non-absorbable monofilament sutures. Scallops do not require reinforcement.

Gold markers are used to mark the exact sites of the fenestration; four markers are placed at the edges of each fenestration, one in each quadrant, to aid orientation.

Scallops are marked with three gold markers. The top markers from the standard graft are used; these are moved down to surround the fenestrations/scallops. The markers are sutured close to, but not on the edge of the fabric using a monofilament non-absorbable suture. Additional markers may be used to assist in correct axial alignment of the stent-graft. These markers are placed on the body of the graft. Three gold markers are sutured vertically on the anterior of the graft and three markers sutured horizontally on the posterior aspect. Once the stent-graft is orientated correctly in vivo the markers will align to form a cross. Fluoroscopy of the stent-graft confirms the position and identification of the markers.

Diameter reducing ties facilitate longitudinal and rotational movement prior to target vessel catheterisation. Movement of the stent-graft is very difficult in vivo without partial constraint, especially in patients with tortuous vessels. Manipulation of a fully expanded stent-graft also increases the risk of embolisation. The ties consist of looped 3-0 reabsorbable sutures attached to the posterior of the stent-graft (sutured to adjacent Z-stents) so as not to interfere with any of the fenestrations. Once the diameter reducing ties have been placed a 0.014" coronary wire is threaded alternately through the graft and then through opposite loops. The wire is threaded through the graft using an angiographic needle. As the wire passes through adjacent suture loops it is pulled tight and the graft is reduced in diameter to approx. 2/3 of the full diameter. The coronary wire is then passed on the outside of the inner cannula through the external sheath and exits through the back of the delivery system. A

similar technique has been described by withdrawing one of the nitinol wires located in the inner cannula and redirecting it externally through and through the fabric of the stent graft. Each Z stent is then constrained using the nitinol wire for support and two non-locking polypropylene loops(30).

When graft production is finished it must then be re-loaded in to the delivery system. The bare stent is re-captured in the top cap by using a 2-0 polypropylene suture intertwined within the struts and pulled together. The suture is passed within the lumen of the delivery system and exteriorised through the hole intended for the safety trigger wire. The stent is pulled carefully back in to the top restraining cap and the metal core tubing replaced to its original position. The safety trigger wire is then repositioned in to the top cap. The covered stents are now withdrawn in to the delivery system. Each stent is sequentially and concentrically collapsed using umbilical tapes. The procedure is facilitated by using a stiff 180cm guidewire (Amplatz) passed through the delivery system and clamped at both ends (nose cone and rear of inner cannula). This makes advancing the outer sheath over the covered stents somewhat easier.

When re-loading the covered stents, it is vital to ensure correct alignment and avoid twisting of the stent-graft. It is crucial to check alignment of the multiple markers at the joints of the Z stents (leading down to the contralateral iliac limb stump) with

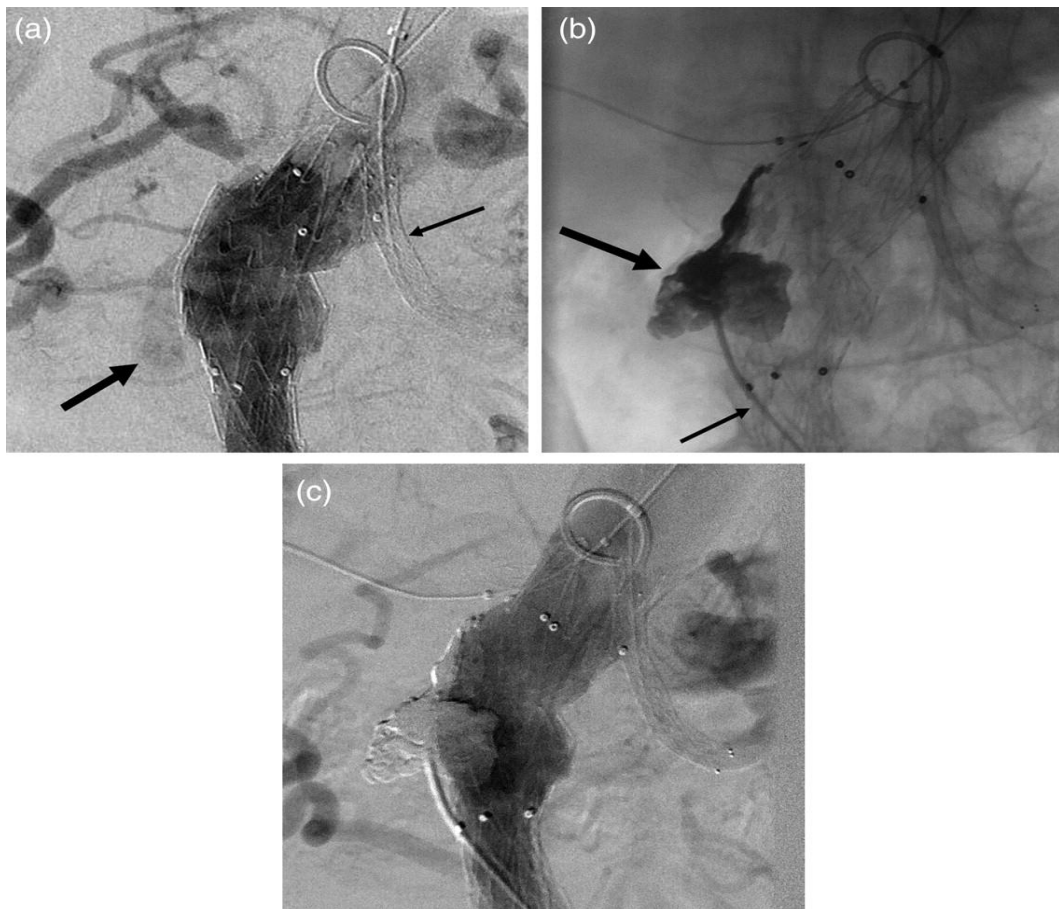
fluoroscopy before the stent-graft is inserted in to the patient. Failure to do so may result in incorrect fenestration or contralateral stump alignment.

3.2 Chimney graft (aka the snorkel graft)

The concept of the chimney graft (CG) was first introduced by Greenberg et al(31) with the use of renal stents to depress the proximal edge of stent graft fabric that protruded a few millimetres above the renal artery ostium. This idea was further developed into the CG technique.

The CG involves concurrent deployment of a standard aortic endograft and covered stents into the visceral arteries such that the proximal portion of the visceral stent lies parallel to the aortic stent with the distal portion preserving flow to the over-stented visceral vessel (fig 3.3). This technique has been used in renal arteries (RA), superior mesenteric artery(SMA), left subclavian artery, left common carotid, and brachiocephalic artery(32).

Fig 3.4 Chimney technique showing a chimney graft in the left renal artery



Indications for CG include restoration of flow in aortic branches accidentally or intentionally covered during TEVAR in the aortic arch(33-35) or juxta renal AAA, in cases unsuitable for branched/fenestrated EVAR due to anatomical tortuosity, and in urgent cases when it is not possible to delay for the manufacture of a branched graft such as symptomatic or ruptured AAA. It is also significantly cheaper than branched/fenestrated endografts. Ideal anatomy includes down going RA and a minimum 20mm of disease free proximal seal zone. Bruen et al (36) describe a “sealing

ring” to be desirable below the chimney, i.e. a funnel shaped neck, for optimal suitability of anatomy.

Planned procedures involve either retrograde (branches of the aortic arch) or antegrade (renal arteries/SMA) visceral vessel cannulation via the brachial or carotid artery. The visceral stent is placed, aortic stent released and then the visceral stent deployed. In the emergency setting, salvage of a renal artery following inadvertent covering may be done via an antegrade approach. Salvage of the SMA has been reported by open retrograde cannulation via a laparotomy, passing the guide wire into the aorta, snaring the guidewire using a brachial approach and then inserting the chimney graft in an antegrade direction from the arm(37, 38).

Evidence surrounding the use of CG consists of case reports and small case series only. Published series range from 2 – 21 patients (32, 36, 39-42), including both thoracic and abdominal aneurysms. 30 day mortality ranged from 0-12.5%. Reported type 1a endoleak at completion angiography was up to 25% and up to 6% over the follow up period; post op renal impairment was up to 29%. Primary graft patency ranged from 84.8-96% during follow up. The maximum follow up was a median of 12 months.

Advantages of the CG over open repair remain unclear. Bruen et al (36) report a series of 42 anatomically matched patients undergoing either open (low surgical risk) repair or CG (high surgical risk). Despite higher co-morbidities in the CG group, the mortality rate was identical with one death in each group. 6 patients in the CG group developed post op renal impairment compared to 4 in the open group. There was only 1 type 1 endoleak which resolved spontaneously. However this is a small series and the CG technique is generally used in the high risk setting; data for open repair of high risk juxta renal aneurysms is scarce.

Although technically the direct cannulation of the visceral vessels with CG may be easier than the indirect cannulation of fenestrated and branched grafts, there may be potential difficulties of arch navigation through brachial arteries and difficulties in target vessel cannulation. However, patients selected for this technique are anatomically complex and it is difficult to judge whether this is an easier technique than that of branched/fenestrated grafts.

The long term durability for CG is unclear. Intuitively they have design flaws compared to branched/fenestrated grafts. The contact of the endograft to the vessel wall may be decreased by the visceral grafts; subsequently there is a poorer graft/wall interface and therefore a reduction in the radial sealing force.

“Gutters” between the vessel wall, the stents, and the endografts may be difficult to seal and lead to subsequent endoleaks. The mechanism of seal around the CG stents and gutters is likely to be multifactorial. Cross sectional imaging suggests local deformation of the native aortic wall by the chimney graft and that this gives some conformation around the graph and aids the seal. A hard calcified wall may therefore be a higher risk for type 1a endoleak. The length of the gutter may also contribute to the seal; the longer gutter is more likely to promote thrombosis within the gutter itself. There are no studies to determine minimum length of the gutter. Larger CG will have larger gutters along the device; this indicates a limit to the diameter of the CG. There is no evidence as to the maximum number of CG that can be used. Bruen et al (36) assumed that 2 CG was the maximum and therefore covered a RA in cases where the SMA required a stent. Others have successfully used 3 or more stents (39, 43).

Branched/fenestrated grafts are mated and sealed within integral constructs of the endograft; CG are positioned along the outside of the endografts and the aortic wall around the chimney graft. There are therefore fewer constraints to migration.

Interestingly, this lack of constraint may decrease the risk of stenosis by removing the potential external compression from a branch/fenestration which has migrated or rotated, Coscas et al(39) advocate the use of reinforcing the balloon expandable covered stents with uncovered self-expanding stents to improve long term patency rates. The distance between RA and SMA is often very small and accidental coverage of the SMA should be borne in mind when performing renal CG.

3.3 Conclusion

Endovascular repair in the setting of adverse anatomy has been the focus of much research over the past decade and is an evolving field. This review outlines alternative techniques for complex aneurysm repair. Avoidance of aortic cross clamping is an attractive option and use of endovascular alternatives to open repair is growing. However, use of these techniques is technically challenging and requires considerable endovascular experience, excellent imaging and a good working knowledge of the stent-graft system. Although they are technically feasible with low morbidity and mortality, robust data supporting their use is lacking. Long term durability and target vessel patency are still to be determined.

CG make it possible to use standard off the shelf stent grafts to treat lesions with inadequate fixation zones, this is particularly useful in the emergency setting. They may be used in selective elective cases which are unsuitable for fenestrated EVAR and in rescue procedures to salvage aortic side branches over-stented during endovascular stent graft repairs. These techniques should be viewed as complementary techniques to fenestrated and branched stent grafts; the larger series of short and medium term results reported with these grafts make these the treatment of choice and CG should not compete for superiority. CG are significantly cheaper than branched/fenestrated grafts. However, the ideal candidate and procedural steps for these techniques remain to be defined. Use of these techniques should be confined to specialist centres.

Chapter 4

A Meta-analysis of Observational Studies in Epidemiology: Fenestrated Endovascular Aneurysm Repair

A Meta-analysis of Observational Studies in Epidemiology: Fenestrated Endovascular Aneurysm Repair

4.1 Introduction

Fenestrated endografts are an evolving technology specifically designed for the aneurysm with the adverse neck (fig 4.1/2). However, they are technically challenging to insert and length of operation is often much longer than for standard EVAR. Subsequently blood loss, limb ischaemia, renal dysfunction(44) and reperfusion injury are likely to be higher with FEVAR than standard EVAR. It can therefore be argued that benefits of FEVAR over open repair may be less than those seen with standard infra-renal EVAR.

Fig. 4.1a

3D imaging of a juxta renal aneurysm - pre FEVAR



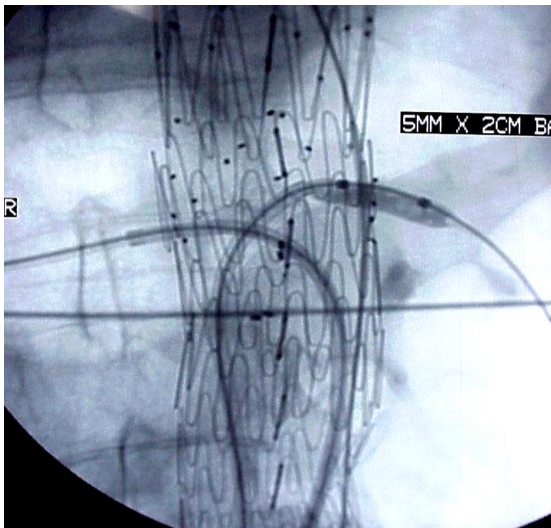
Fig. 4.1 b

Juxta renal aneurysm post FEVAR



Fig. 4.2

Insertion of the fenestrated graft showing cannulation of and bridging stents to the renal arteries



The technology associated with fenestrated endografting has advanced prior to clinical trials. There is currently no level 1 evidence for the use of FEVAR; evidence is poor

quality relying only on published case series. Previous reviews have been published. Nordon et al(45) compared FEVAR (8 studies with a total of 368 patients) with open repair (12 studies with a total of 1164 patients). They found a 1.4% vs 3.6% 30 day mortality in favour of FEVAR. A further analysis by the Ontario Health Technology(46) compared five FEVAR studies with seven open studies giving a 1.8% vs 3.1% 30 day mortality in favour of FEVAR and a 12.8% vs 23.7% late mortality in favour of FEVAR. However these studies are flawed with inaccurate statistical methods and possible duplication of patient data due to overlapping cohort studies. Further case series have been published since these reviews were written.

This chapter is a MOOSE (Meta-analysis of Observational Studies in Epidemiology) on all published data for FEVAR and aims to highlight current issues around the evidence for FEVAR.

4.2 Methods

A computer-assisted search was performed (from January 2000 to Oct 2011) of the medical databases Medline, Embase, Science Citation Index and the Cochrane database of systematic reviews, using the keywords “fenestrated endovascular stent graft”, “fenestrated endovascular aneurysm repair”, and “juxta-renal abdominal aortic aneurysm”. An additional extensive search was performed using a combination of the following Medical Subject Heading (MeSH) terms; juxta-renal aortic surgery,

fenestrated aneurysm repair, fenestrated stent grafts, type 4 thoraco-abdominal aortic surgery, thoraco-abdominal aneurysms. After identifying relevant titles, abstracts of these studies were read by two of the authors (JC/TR) to decide study suitability. Abstracts of articles printed in languages other than English were translated using "Google translate" and if suitable underwent a more accurate formal translation of the full paper. (See Appendix C)

Clinical studies eligible for inclusion were those that described use of fenestrated endovascular stent-graft technology for juxta-renal aortic aneurysms. Eligible articles described original patient series with information of operative technique, operative time, hospital stay, mortality, complications, conversions and follow up outcomes. Small series of less than 10 cases and studies describing the use of predominantly branched endovascular stent-graft technology or use of fenestrated technology in aortic dissections were excluded. Authors of the included papers were contacted and replicate data from overlapping cohort studies were excluded. Outcomes assessed were intra-operative complications, target vessel patency, mortality, morbidity and late outcomes. Outcomes were analysed using a meta-analysis of proportion calculation (Stats direct software statistical software, version 1.0).

4.3 Results

11 studies were identified which met the inclusion criteria. The flow diagram for included and excluded studies is shown in fig 4.3. See Table 4.1 for characteristics of the studies.

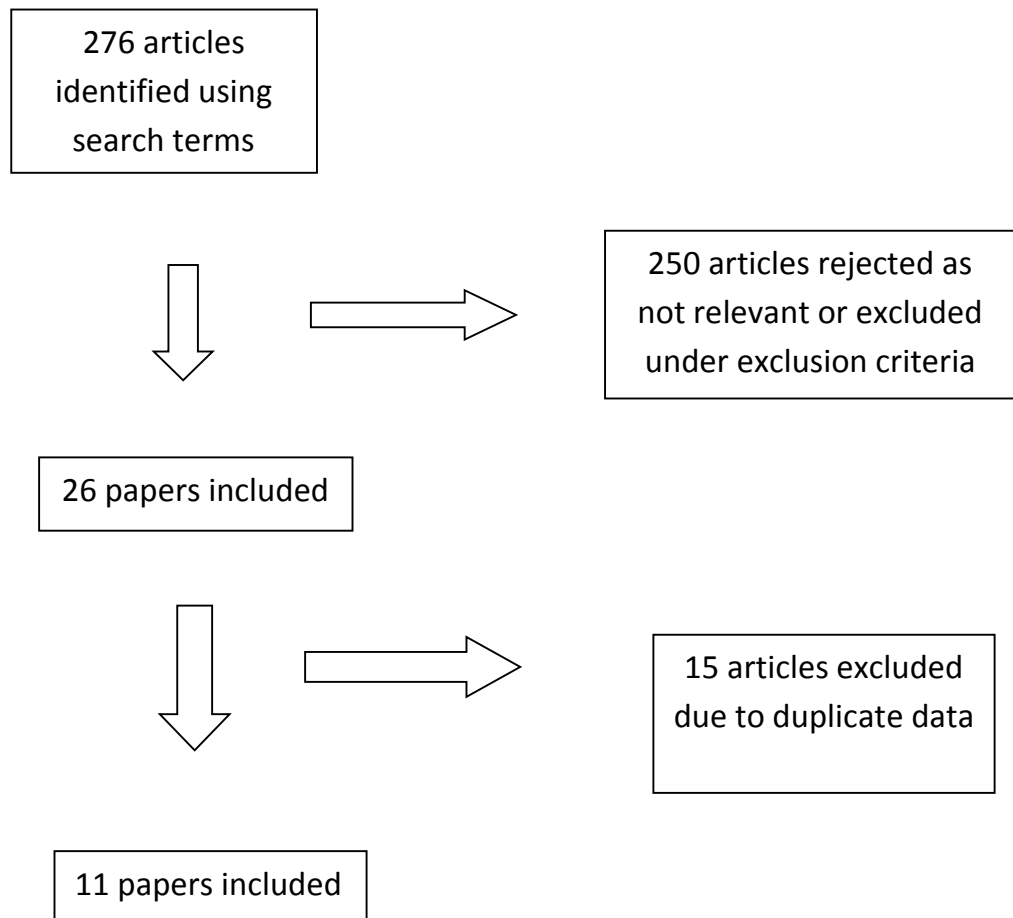
Table 4.1

Patient demographics

Centre	Single/multi centre	No of patients	N=Male	Age yrs	Aneurysm diameter
Groningen/Utrecht Holland(47)	single	100	87	72.6 mean	60mm median
WA - Australia(48)	multiple	58	51	75.5 mean	ND
South Australia(49)	single	13	10	74 mean	6.5cm mean
France(50)	multiple	134	129	73 median	56mm median
Malmo - Sweden(51)	single	54	46	72 median	60mm median
Cleveland Ohio - US(52)	single	119	98	75 mean	65mm mean
Germany(53)	single	63	57	70.5 mean	55.1 mm mean
Liverpool - UK(54)	single	45	41	73 median	68mm median
St Mary's, London - UK(55)	single	15	12	70 mean	64mm median
US Multicentre(56)	multiple	30	24	75 mean	61.4mm mean
Leicester - UK(57)	single	29	27	74 median	68mm mean

Fig. 4.3

Literature search



Patient factors

A total of 660 patients were included (582=male). Although the ages were similar (table 4a), reports included both mean and median. Nine papers reported information on patient co-morbidities and all nine specified coronary artery disease giving a pooled proportion of 0.525 (52.5%) (95% CI 0.484 – 0.564) patients with coronary artery disease. A pooled proportion of 0.730 (73.0%) (CI 0.693 – 0.765) patients had hypertension, 0.397 (39.7%) (CI 0.358-0.437) had COPD, and 0.172 (17.2%) (CI 0.148-0.204) with diabetes. Although data was given on renal impairment, comparison is difficult as definitions of renal impairment varied (definitions used include creat > than 100, 105 and 120, e GFR<60 ml/min and serum creat > 2.0mg/dl). Only one paper reported that 87% of their patients were taking a statin and none documented anti-platelet, beta blocker or ACE inhibitor medication usage. Five papers documented smoking status giving a pooled proportion of 0.643 (64.3%) (CI 0.594 – 0.691) patients with a smoking history. Previous major abdominal surgery was reported in five papers with a pooled proportion of 0.346 (34.6%) (95% CI 0.230 – 0.395) patients having previously had a laparotomy and 21 patients were reported to have previously had an open AAA repair. ASA grade was poorly reported and groups were often combined making it difficult to extrapolate exact numbers. ASA grade 3 was the modal grade. No papers reported other pre-op scoring systems such as POSSUM.

Anatomical factors

Definitions of aneurysm morphology were variable and clear inclusion/exclusion criteria were not always documented. 20 were defined as Crawford type IV, 165 were defined as short neck, 228 were defined as juxta-renal and 27 were described as supra-renal. There was some variation in the diameter of aneurysm treated and again reports of both mean and medians preclude statistical comparison (table 4.1).

Procedure details

Five papers commented on anaesthesia. There was some variation, presumably due to unit policies. In France(50) the procedure was carried out under general anaesthetic in 96.3% of patients whereas in the US(52) only 18.4 % of patients had a GA and 81.5% of patients had the procedure done under regional blockade. No record was made of anaesthetic monitoring.

Femoral access was documented in 3 papers, with 77 patients having open femoral cut downs and 35 successful percutaneous approach. A planned ilial conduit was used in seven patients. The number of fenestrations is given in table 4.2. Although the breakdown was not available for all papers, grafts with double fenestrations (i.e. a fenestration for each renal artery) were used more commonly than a triple fenestration (i.e. a graft incorporating fenestrations for both renals and the SMA).

Interestingly the ratios of double:triple fenestrations varied; one centre performed more than half their FEVAR as triple fenestrations where as another centre only used triple fenestrations for 4% of cases. A quadruple fenestration graft was only reported for seven grafts.

Table 4.2

Total number of fenestrations and scallops in each study

Centre	RA		SMA		Coeliac		Combined total
	S	F	S	F	S	F	
Groningen/Utrecht	27	165	74	4	5	0	169F & 106S
WA - Australia	25	66	21	3	0	1	70F & 46S
South Australia	0	24	0	9	ND	ND	33F
France	ND	ND	ND	ND	ND	ND	269F & 133S
Malmo - Sweden	ND	ND	ND	ND	ND	ND	91F & 133S
Cleveland Ohio - US	231	Combined scallops and fenestrations	76	Combined scallops and fenestrations	0	1	308
Germany	24	64	10	12	7	2	78F & 41S

Liverpool - UK	10	68	28	7	1	1	76F & 29S
St Mary's, London - UK	1	29	5	8	4	1	38F & 10S
US Multi-centre	10	47	20	0	0	0	47F & 30S
Leicester - UK	4	48	23	2	0	2	52F & 27S

RA Right renal artery

S Scallop

F Fenestration

SMA Superior mesenteric artery

ND Not documented

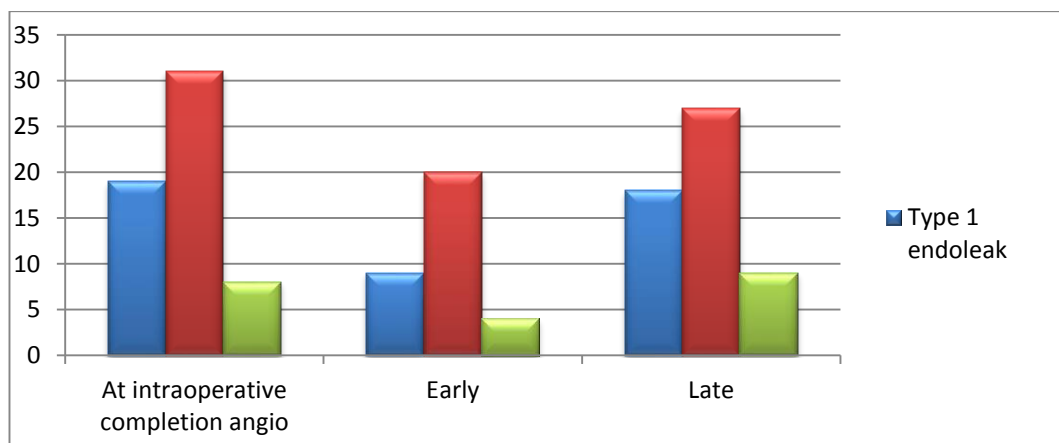
Operation time was reported using both means and median. The median operation times ranged from 180 – 375 mins. Median fluoroscopy times ranged from 26 – 111 mins and the fluoroscopy times were proportional to the median operation times.

Target vessel cannulation was reported in seven papers, with failure of target vessel cannulation in 21 vessels. There were five reports of arterial perforation (1 requiring conversion to laparotomy), four intra-operative stent occlusions, three arterial dissections and one stent dislocation. There were 3 reports of intra-operative kidney loss, and 6 segmental renal infarcts were shown but none showed renal impairment

(definitions varied but most commonly defined as post-operative rise in creatinine of > 30% of baseline). Overall target vessel perfusion rates ranged from 90.5 – 100%. See Figure 4.4 for endoleaks reported on completion imaging. 67 additional intra-operative procedures were reported including Palmaz stent, extension grafts, junctional stents and covered stent placement.

Fig 4.4

Total number of reported endoleaks



Other reported immediate complications included three reports of leg ischaemia, one requiring a fem-fem cross over following iliac limb occlusion secondary to graft malplacement, and two requiring a femoral embolectomy; one patient required fasciotomies, and one patient developed skin necrosis of the buttocks and leg weakness following over-stenting of the internal iliac artery. There were 6 reports of external iliac rupture. Blood loss was only reported in 4 papers with mean losses of 739

and 601ml and two median losses of 200 and 600ml. 4 procedures were converted to open intra-operatively.

Morbidity and mortality

Morbidity was not reported in all series and was selectively reported in others; it is likely to be under represented. Commonest peri-operative morbidity was renal impairment (n=81) with 10 patients requiring early dialysis, 8 permanently. 53 patients remained with permanent reduction in renal function. 15 patients developed cardiac events and 9 respiratory events. There were only 8 reported wound problems. Length of hospital stay was reported in seven papers and the median stay ranged from 3 – 9 days.

11 deaths occurred within 30 days, giving a 30 day pooled proportion mortality rate of 0.020 (2.0%) (95% CI = 0.011 to 0.032) (fig. 4.5). (See table 4.3 for cause of death).

During the follow up period there were 92 deaths after 30 days. Of these 6 were reported aneurysm related deaths.

Fig 4.5

Meta-analysis of mortality

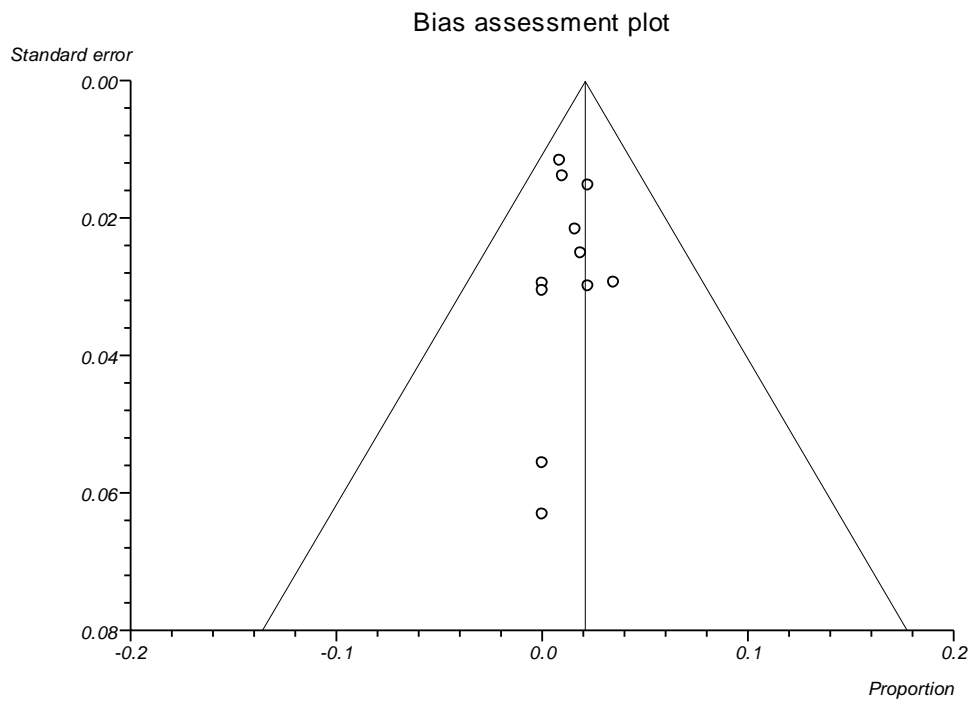
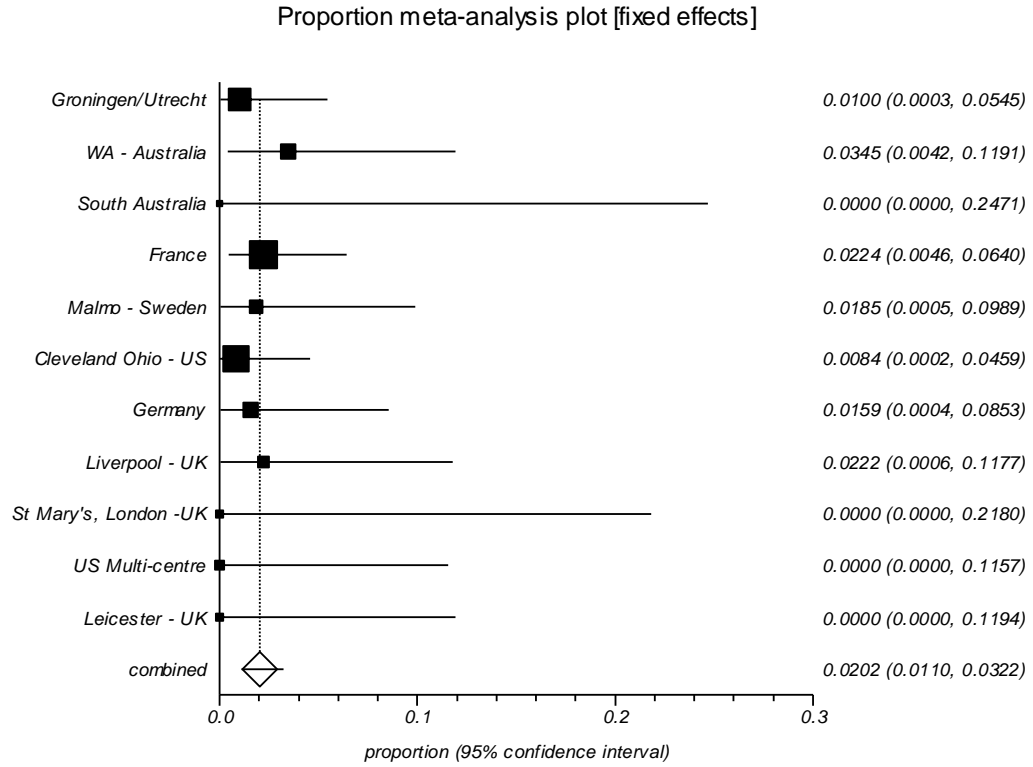


Table 4.3

Deaths at <30 days

	Patient details
1	Co-morbidities included an ejection fraction of 23%, no intra-operative difficulties, readmitted at day 6, died from colonic ischaemia, autopsy showed a patent SMA
2	Sudden death from Myocardial infarction/Pulmonary embolus
3	Co-morbidities included aortic valve stenosis and chronic renal failure, underwent prolonged procedure, died from MI and subsequent multi-organ failure
4	Large vessel blood loss following iliac rupture, developed subsequent MOF
5	Died following pulmonary oedema
6	Large vessel blood loss following iliac rupture, developed subsequent MOF
7	Bowel ischaemia secondary to mesenteric embolization
8	Uncontrollable retroperitoneal bleed
9	Known COPD, aspirated and developed subsequent sepsis and multi organ failure
10	Mesenteric ischaemia
11	Myocardial infarction

Median length of follow up ranged from 12 – 25 months with a modal follow up of 24 months. Reports on late morbidity include 54 late target vessels lost, 10 stent fractures, 9 significant stent migration and 1 distraction of the modular components. Figure 4b shows the total number of reported endoleaks. Patient survival was not widely reported; Verhoeven(47) reports a 1 year survival of 90.3%, 84.4% at 2 years and 58.5% at 5 years.

4.4 Discussion

This paper presents an overview of the published case series for FEVAR. FEVAR is a viable alternative to open surgical repair for juxta renal/short neck aneurysms. In this review, the 30 day pooled proportional mortality rate of 2.0% compares favourably with that of open surgical repair which has reported 30 day mortality rates of 2.5- 5.8% (58, 59).

A significant problem with current published case series of FEVAR is the differing definitions of juxta-renal/short neck aneurysms. Previously, with open surgery, a juxta-renal aneurysm or a short neck was defined as one in which the surgeon was unable to safely place an infra-renal clamp; commonly this was 5 mm. It is not so clear with FEVAR and there is currently no universal classification system to allow accurate anatomical comparison. This has led to wide variations between centres in the

indications for use of fenestrated grafts which are highlighted in table 4.4. Although we have pooled the data for the same treatment modality, it is not clear that we are comparing aneurysms of the same anatomical parameters. Aneurysm anatomy differentiates an "easy" repair from a "difficult" one, therefore true comparisons of FEVAR can only be made with anatomical homogeneity. Recently several classification systems have been proposed including a fenestration based system(60) and a "sealing zone" system proposed by the authors(61).

Table 4.4

Definition of juxta-renal aneurysm used / indications for FEVAR

Germany	"inadequate proximal sealing zone"
Holland	Short neck – 4-12mm below RA Juxta-renal - neck of < 4mm below RA
Liverpool	Juxta-renal – Infra-renal neck of <10mm
St Mary's	Juxta-renal - 4mm or less below RA
Sweden	Neck < 8mm
France	Short neck <10mm Juxta-renal – "short neck extending to but not involving RA"
Cleveland Ohio	"Compromised proximal neck anatomy"
US Multi-centre	Proximal neck 4-15mm in length
Australia	Juxta-renal not defined
Leicester	Neck "too short for standard EVAR"

It is not possible to differentiate the outcome between patients with double, triple and quadruple fenestrations in these papers due to data presentation. Increasing number of fenestrations lead to longer operation length and higher risk of cannulation failure or target vessel loss(62). It is misrepresentative to group double/triple/quadruple fenestrations together. The difference in ratio between double and triple fenestration grafts used between centres indicates that different units may have different planning policies again indicating heterogeneity.

FEVAR is a new technique with small numbers performed worldwide each year. Each series had a relatively small number of patients. There is a learning curve associated with the technique and as larger numbers are performed results may improve. No series compared the results from early in their series with those at the end of their series. The small numbers performed each year suggest that this intervention should be confined to specialist referral centres that perform a minimum number/year.

Other than current anatomical licensing guidelines, there are currently no guidelines on patient factors used to decide suitability for FEVAR. EVAR II trial(44) showed no short term survival benefit for EVAR in those deemed unfit for surgery and logic would dictate the same to be true for FEVAR. However, selection criteria for open repair of a juxta/supra-renal aneurysm are rigorous and in this review there are a number of patients who would not have been deemed suitable for open repair. If the cohort of patients in this review have, in general, a worse co-morbid status than those

undergoing open repair then the results do further support an advantage towards FEVAR. However, no series compared co-morbidities with patient outcome and the reporting of the co-morbidities in these series made a direct comparison impossible.

A good indication for FEVAR would be the presence of a hostile abdomen (i.e. previous laparotomy). It is interesting to note that approximately one third of patients had a hostile abdomen. With increasing age, the prevalence of previous abdominal surgery increases and this figure probably represents the elderly age group that are affected by aneurysms.

The number of cardiac/respiratory events appears to be much lower than expected for a major procedure. The level of detail in reporting complications varied between papers and is probably under reported. However, 1.2% of patients needed permanent renal dialysis. This is likely to be multifactorial, being a combination of contrast induced nephropathy, intra-operative hypotension and micro-emboli following manipulation of the renal arteries. Although some papers reported contrast usage, reporting methods precluded relating contrast volumes to post op renal function and it is also unclear whether renal stent problems occurred in this dialysis group. Details of intra-operative blood loss and operation length were given, however, again it was not possible to relate these to outcome.

In the UK, the UK small aneurysm trial(12) has led to an almost universal of adoption of 5.5 cm being the intervention size. In this review, one series had a mean diameter of 5.51cm and another median diameter of 5.6cm. (It is not clear whether diameters were assessed using ultrasound or CT.) This indicates that intervention in these centres must be occurring on a significant number of aneurysms with a diameter of <5.5cm. Potentially this may affect aneurysm morphology and ease of procedure; small aneurysms may have less neck angulation or iliac tortuosity. However, the CAESAR(63) trial failed to show an advantage to early EVAR in small aneurysms; it is unclear why so many small aneurysms are being intervened on in these series.

Unit policies are likely to account for the variation in anaesthetic type. Undoubtedly there are benefits to avoiding a general anaesthetic in these patients, however this is potentially a long intervention and patients may struggle without a GA.

A criticisms of EVAR compared to open repair is the higher re-intervention rate in the EVAR group. Unfortunately in many papers re-intervention was not clearly documented making a true comparison with EVAR or open repair impossible. It is unknown whether FEVAR has a higher re-intervention rate than EVAR and it may be that the addition of side branches makes FEVAR a much more stable structure.

Comparison with open repair is difficult as complications such as hernias and small bowel obstruction are often under-reported following open surgery. Future data needs to assess endpoints for further analysis as re-intervention following EVAR is

increasingly less common; for example type 2 endoleak is now managed conservatively in the majority of cases. Further data are required to assess the effect of re-intervention rates.

At present FEVAR is an expensive procedure due to the unit price of the graft. Each graft is specifically manufactured to individual patient anatomy. A formal cost-effectiveness analysis is needed to compare costs with open repair; FEVAR is likely to be initially more expensive but savings may be made in reduced ITU or hospital length of stay. "Off the shelf" FEVAR devices(28), suitable for approximately 80% of patients who currently require a fenestrated graft are in development. As with EVAR, it is likely that the cost of each graft will decrease with mass production.

In conclusion, FEVAR is a relatively new technique for repair of supra and juxta-renal aneurysms which may be a viable alternative to open repair. There are currently no randomised controlled trials comparing FEVAR with open repair and current evidence is weak with many unanswered questions. Clear indications for use of FEVAR, anatomical classification of the aortic neck to clarify anatomical comparisons and further trials are needed to define a benefit.

Chapter 5

Summary of Part 1

Endovascular repair has revolutionised the management of aortic aneurysms. EVAR, first described in 1991(1), has now become the modality of choice in most UK centres. Advantages of over open repair include reduced early aneurysm mortality (5, 7), decreased length of stay, reduced blood loss, shorter operation time, avoidance of laparotomy and improved short-term quality of life.

The key principle of endovascular aneurysm repair, is aneurysm exclusion by forming an effective seal between the implanted graft and native vessel. This relies on adequate neck morphology and an inadequate graft/wall interface compromises longevity of the proximal or distal seal. Suitability for endovascular repair is therefore defined by anatomical criteria.

There is much debate regarding use of EVAR in the adverse neck aneurysm and there may be overlap between units in the use of EVAR/FEVAR/open repair in these patients. Current commercially available grafts are licensed for neck lengths of >10mm or angulation of <90 degrees. Standard EVAR in short and angulated aneurysm necks are associated with an increased endoleak and reintervention rate (20, 21). Although some authors have advocated use of standard EVAR outside IFU(22) for juxta renal aneurysms, results which appear satisfactory in the short term may be significantly worse in long term follow up. Analysis of the Eurostar database found an increased risk of aneurysm related mortality over long term follow up for grafts inserted outside manufacturer's instructions for use. FEVAR may be a good alternative for the short

neck/juxta renal aneurysm. Long-term data is limited but fenestrated grafts may be more stable devices in the short neck aneurysm, being anchored by the bridging stents.

Endovascular alternatives to standard EVAR have evolved to enable repair of those aneurysms with a compromised proximal neck; endovascular treatment of juxta renal and suprarenal aneurysmal disease is now possible. However, fenestrated devices are technically challenging to insert, are significantly more expensive than standard endografts and benefits may not be as clear as for standard endografting.

Initially both EVAR and FEVAR were reserved for patients unfit for conventional surgery. However encouraging early results led to the expansion of these techniques. Avoidance of aortic cross clamping is very attractive and aneurysms anatomically requiring FEVAR may be technically difficult for open repair with potentially higher morbidity and mortality than open infra-renal aneurysms.

Current anatomical indications for FEVAR include: (1) neck length of < 10mm (2) angulation of >60 degrees between the proximal aorta and the long axis angle of the aneurysm sac (3)infra-renal neck thrombus covering >50% of the proximal neck (4)infra-renal neck diameter of >32 mm or (5)inverse conical shape of the proximal aneurysm neck. FEVAR is generally indicated for asymptomatic patients only due to

manufacturing delays, however, there have also been reports of the use of "home-made" fenestrated grafts for symptomatic aneurysms(27).

Evidence for FEVAR is limited to case series only and there are currently no randomised controlled trials or level one evidence. Data to date reflects selection bias and development of an emerging technology. Many cases were undertaken in patients deemed 'unfit' for open repair, reflecting a similar approach to when EVAR started.

The meta-analysis of the current evidence for FEVAR identified 11 studies with a total of 660 patients. There were 11 deaths within 30 days, giving a 30 day pooled proportion mortality rate of 2.0%. This compares favourably with that of open surgical repair with reported 30 day mortality rates of 2.5- 5.8% (58, 59).

However, there is much heterogeneity between case series and patient demographics and indications for use of FEVAR varied. There is no universal definition of juxta-renal/short neck aneurysms in the endovascular setting making comparison of case series difficult.

In summary, fenestrated devices have been developed to extend the graft seal zone proximally, above the level of the renal arteries, thereby increasing the number of patients suitable for endovascular intervention. Current evidence is limited, however mortality rates appear favourable to open repair particularly for high-risk patients. I

hypothesise that all abdominal aortic aneurysms should be treated endovascularly and the aim of this thesis is to determine the indications for FEVAR.

Part 2

FEVAR Adjuncts

Chapter 6

**A new classification
of AAA based upon
proximal sealing
zones: Results of
complex aortic stent-
grafting in 100
consecutive patients**

A new classification of AAA based upon proximal sealing zones: Results of complex aortic stent-grafting in 100 consecutive patients

6.1 Introduction

Previous chapters have demonstrated that fenestrated grafts are technically more challenging than standard endografts, may have a higher morbidity rate and current evidence is limited to case series and systematic reviews(45, 64, 65).

Comparison between these case series is particularly difficult however, as there is no consensus on what constitutes a juxta-renal, para-renal or supra-renal aneurysm. Additionally, there is emerging evidence that the extent of the aneurysm repair as determined by the number of fenestrations is associated with outcome (66).

In this chapter, we propose a classification system in which the aorta is divided into Zones. Each zone relates to the level at which the proximal aortic seal is achieved. This classification system is suitable for both open and endovascular aneurysm repair thereby enabling comparison of anatomically matched aneurysms for all treatment modalities. This classification system is used to present the outcomes of 100 consecutive aneurysm cases.

6.2 Methods

6.2a Patient Selection

All patients included were referred to a single tertiary centre for consideration of endovascular aortic aneurysm repair. Each patient had contrast enhanced computed tomographic angiography (CTA) of their arterial anatomy assessed on a TeraRecon (TeraRecon, CA, USA) 3D workstation. Patients underwent an anaesthetic assessment for fitness for surgery (standard clinical and physiological assessment parameters and all patients underwent a cardio-pulmonary exercise test (CPEX) as an adjunct assessment) and patients were subsequently discussed at a Multi-Disciplinary Team (MDT) meeting where a consensus was reached for inclusion or exclusion into the programme. 100 consecutive patients with short necked, juxta-renal or thoraco-abdominal aortic aneurysms between April 2008 and October 2011 were retrospectively analysed (See table 1 for inclusion criteria). All patients deemed "unfit" for endovascular surgery were excluded. No patients were excluded for technical reasons. Informed consent was obtained for all patients.

Table 6.1 Inclusion criteria for branched/fenestrated grafts

Infra-renal neck length < 10mm
Angle between proximal aorta and long axis angle of aneurysm sac >60 degrees
Infra-renal neck thrombus covering > 50% of proximal neck
Infra-renal neck diameter >32mm
Inverse conical shape of proximal neck
Sufficient fitness for endovascular surgery

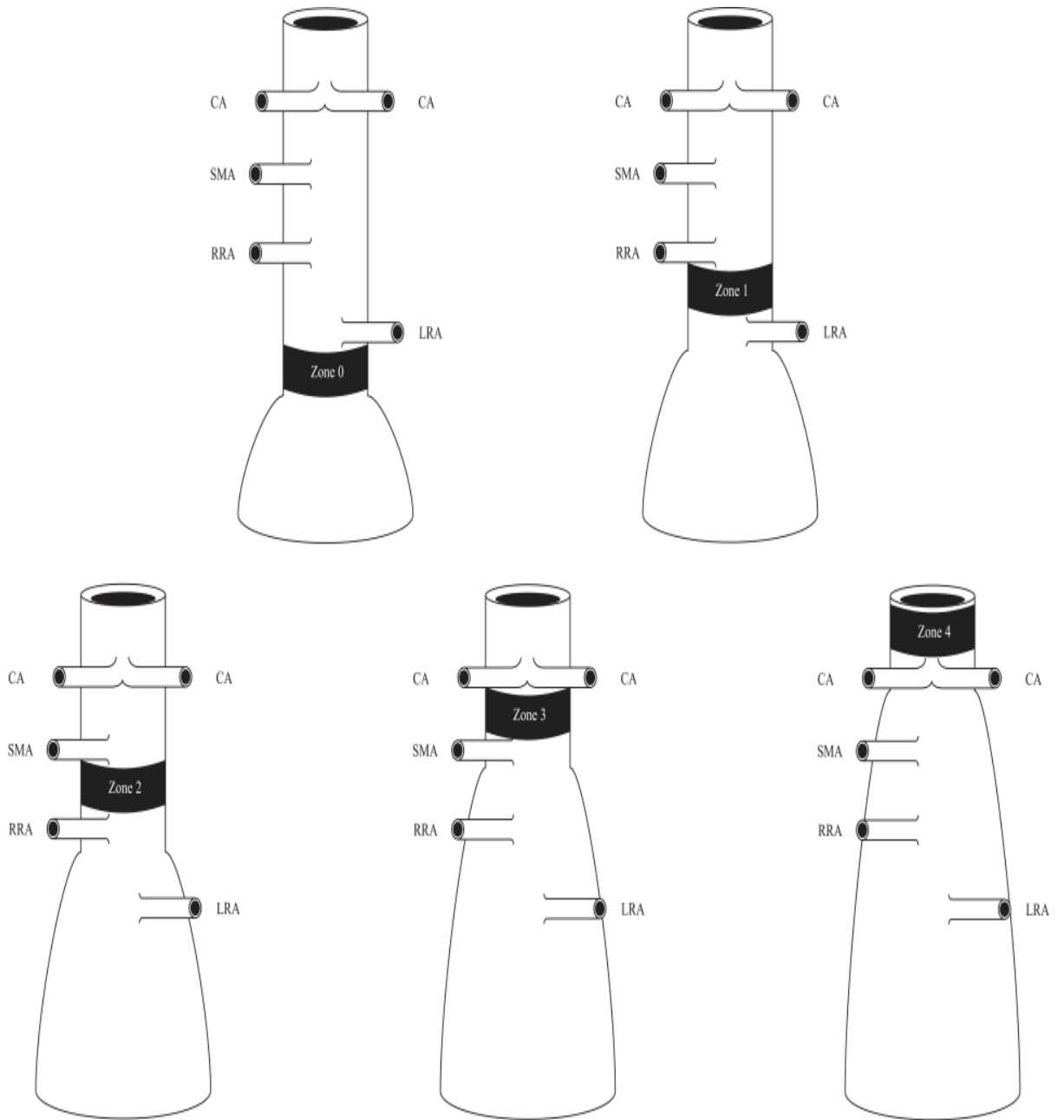
6.2 b Pre-operative imaging assessment and Zone Classification

Aneurysm morphology was assessed in all patients using thin slice (maximum thickness 1.5mm) CTA images reformatted on a TeraRecon 3D workstation, with manually corrected centre-line reconstruction of the aorta. Aneurysms were sub-divided into Zones according to the position of the proximal seal in relation to the visceral arteries: Zone 0 is a seal below the lowest preserved renal artery, Zone 1 is between renal arteries at different levels, Zone 2 is above the renal arteries but below the superior mesenteric artery (SMA), Zone 3 is above the SMA but below the celiac axis (CA) and Zone 4 is above the CA and may incorporate the arch (Fig 6.1).

6.2 c Devices

Custom made fenestrated and branched devices manufactured by Zenith (Cook Medical, Perth, Australia) were planned “in-house” based on CTA reconstructions on the TeraRecon workstation or at the Zenith Planning Centre (Cook Medical, London UK). All local planning was undertaken by consultant vascular surgeons and interventional radiologists following the guidelines for graft planning produced by Cook Medical, with a combination of scallops, fenestrations and branches incorporated to ensure continued visceral flow whilst obtaining an adequate aortic seal. Incorporation of modifications such as diameter reducing ties, paraplegia prevention branches, preloaded fenestrations and preloaded branches were decided on a case-by-case basis.

Figure 6.1 Proposed new Endo-classification based on proximal sealing zones



- Zone 0 Below the lowest preserved RA
- Zone 1 Between RA's at different levels
- Zone 2 Between RA's and SMA
- Zone 3 Between SMA and CA
- Zone 4 Above the CA
(possibly incorporating the Arch)

6.2 d Methods – statistical analysis

Normally distributed continuous variables are reported using means and standard deviations and analysed using unpaired ANOVA test; non-normal continuous variables as medians and interquartile ranges and compared using a Kruskal-Wallis test.

Categorical variables are described using numbers and percentages with chi-square comparisons. P-values <0.05 were considered to be statistically significant.

6.3 Results

100 consecutive patients underwent complex endografting during the above period. Fenestrated only endografts were used for all Zone 1/ 2 patients and the majority of zone 3 patients. Branched only endografts were used for the majority of zone 4 patients (Table 6.2).

Four cases were performed as emergencies either using a “home-made” fenestrated graft, ‘off-the-shelf’ branch grafts were used in 2 cases and in one case a graft had been manufactured and was available when the patient presented with a ruptured aneurysm. These emergencies have been included in the analysis.

Table 6.2 Graft type by Zone

	Zone 1 (n=3)	Zone 2 (n=29)	Zone 3 (n=41)	Zone 4 (n=27)
1 fenestration	3	0	0	0
2 fenestrations	0	26	3	1
3 fenestrations	0	3	36	0
4 fenestrations	0	0	1	1
Fenestration/branch combination	0	0	0	4
Branches only	0	0	1	21

Patient demographics are shown in table 6.3. The only significant difference between groups was prevalence of previous aortic surgery and aneurysm diameter.

Table 6.3 Pre-operative characteristics

	Zone 1&2 (n=32)	Zone 3 (n=41)	Zone 4 (n=27)	P-value
Median age (range)	74(56-86)	76(60-86)	71(48-84)	0.47
Sex (M/F)	27/5	33/8	20/7	0.45
IHD (%)	55	54	37	0.3
CCF (%)	12	21	15	0.56
Prev. aortic surgery (%)	18	17	48	0.01

Median aneurysm diameter (mm) (range)	65 (54-91)	69 (53-113)	73 (57-109)	0.04
Current smoker (%)	16	14	24	0.6

13/22 patients with a past history of aortic surgery had previously had an EVAR in which the sac had repressurised due to Type 1a endoleak. 9 of the 13 with prior EVAR were classified as Zone 2 or 3; all 9 prior open surgical repairs were classified as Zone 4.

Across the four Zones, comparisons were made for age, maximal aneurysm diameter, estimated blood loss and operative time. While there was no difference in the age of patients across the Zones, there was significantly increased aneurysm diameter, blood loss and operative time as the Zone ascended. Zone 4 aneurysms had the largest median diameter (73mm), estimated blood loss (2083ml), longest operative time (503 minutes) and lowest target vessel patency (TVP) (70/100) at case completion (Table 6.4).

Table 6.4

Zone	Blood Loss (median/range)	Operation time (Median/range)	TVP	% TVP
1&2	857(300-1500)	295(145-630)	61/64	95.3
3	2029(200-5000)	419(210-720)	119/121	98.3
4	2083(500-5000)	503(240-720)	98/106	92.4
	p<0.001	p=0.01		

There were 9 in-patient deaths recorded across all Zones (Table 6.5).

Table 6.5 Morbidity and Mortality

Zone	Mortality	Morbidity
2	1(29)	4(29)
3	4(41)	13(41)
4	4(27)	11(27)

There was one death in the zone 2 group. In this case, the patient presented with an expanding aneurysm one year after an episode of sepsis from an infected pacemaker. Despite antibiotic prophylaxis, the patient developed abdominal pain and sepsis post-EVAR and developed a frank rupture on the 32nd post-operative day. The patient had

an extra-anatomic bypass to the superior mesenteric artery and stent-graft coverage of the rupture at the visceral segment with a snorkel for the right renal artery, the left renal artery was sacrificed. He died 2 days later.

There were four deaths in the Zone 3 group. The first patient experienced an ischemic injury to the lower limbs after prolonged (450 minute) procedure complicated by rupture of an iliac artery. Post-operatively he developed acute renal impairment requiring haemofiltration; he went on to develop multi organ failure with respiratory impairment and had a fatal myocardial infarction on day 3 post op. The second patient also developed lower limb ischemia after a 660 minute procedure. He required haemofiltration and ultimately developed severe respiratory impairment; on cessation of sedation he was found to have had an intracerebral event. He died from multi organ failure 11 days post op. The third patient also developed lower limb ischemia after a 550 minute procedure due to a ruptured left renal artery. Day one post op he was noted to have an ischaemic leg and required an emergency fem-pop bypass and fasciotomies. He went on to develop multi-organ failure and ischemic colitis with death from respiratory failure on day 18. The fourth patient suffered a myocardial infarction on the 6th post-operative day; persistent hypotension caused an ischemic colitis which resulted in death on day 10.

There were four deaths in Zone 4. The first patient woke with lower limb paralysis. She then suffered a stroke followed by acute pancreatitis and eventually died from

respiratory impairment. The second patient was operated on as an emergency (rupture) whilst awaiting elective surgery with a custom-made graft already in the hospital. She died on the first post-operative day from a myocardial event. The third patient had severe micro-embolic “trashing” of the lower limbs and abdominal viscera resulting in haemofiltration, colectomy and splenectomy – he died from multi-organ failure on day 14. The final patient developed paraplegia, and subsequently had a myocardial infarction and pneumonia. After a prolonged ICU and ward stay, the patient died whilst attending in-patient rehabilitation on day 118.

Major morbidity amongst patients who survived, defined as an unplanned return to the operating theatre or clinical event that prolonged hospital stay was high across all the Zones with a significantly greater number of events in Zones 3 and 4. The distribution of morbidity by patient is shown in table 6.6.

Table 6.6 Morbidity in survivors

Zone 1	Bleeding from renal artery requiring coiling Brachial artery embolus
Zone 2	Groin haematoma Renal impairment (n=2) Spinal cord ischaemia – resolved spontaneously Perforated branch of renal artery requiring coiling

<p>Zone 3</p>	<p>Renal failure requiring dialysis (n=7)</p> <p>ARF not requiring dialysis (n=18)</p> <p>Respiratory event (n=10)</p> <p>Lower limb ischaemia (n=3)</p> <p>Bowel ischemia requiring resection and stoma (n=1)</p> <p>Paraparesis (n=1)</p> <p>Brachial artery false aneurysm (n=1)</p> <p>Pulmonary Embolus (n=1)</p> <p>Cardiac event (n=7)</p> <p>Sepsis (n=5)</p> <p>Wound issue (n=4)</p>
<p>Zone 4</p>	<p>Paraparesis (n=2)</p> <p>Bleeding DU (n=1)</p> <p>Type 1B endoleak requiring further stenting</p> <p>Dialysis (n=3)</p> <p>Myocardial Infarction (n=4)</p> <p>Pneumonia (n=3)</p> <p>ARF (n=7)</p> <p>Groin hematoma requiring evacuation</p> <p>EIA dissection requiring stenting</p> <p>Pancreatitis</p> <p>Lower limb ischemia</p>

When assessing complications occurring in all patients regardless of survival, acute renal impairment (defined as a rise in serum creatinine of >25%) was most common in Zone 3. Lower limb ischemia occurred mainly in zone 3. Paraparesis or paraplegia was, however, more common in Zone 4.

6.4 Discussion

Current classification relates to the ability to place an aortic cross-clamp at open surgery, for example, a juxta-renal aneurysm is varyingly defined as one which is within 5mm of the renal arteries, reflecting the distance needed to place a clamp and sew a graft. This differs from the aortic requirements for successful endovascular seal of a standard infra-renal aortic stent-graft, usually 10 or 15mm of good quality aortic wall.

The concept of endovascular Zones within the aorta is not new – Ishimaru(67) divided the aortic arch into Zones for defining the site of proximal fixation of thoracic endografts, based on the location of the great vessels. This firstly recognises that cases which require more proximal stent-grafts are more complex and as debranching is required, are associated with greater morbidity and mortality(68). It also recognises that different Zones have their own particular problems, such as bird-beaking or mal-apposition. This work was expanded by Criado to include the visceral aorta in what was termed the *visceral zone map* marking out the distal landing zone for thoracic stent grafts using vertebral levels and visceral vessels as dividing lines. The purpose of this

visceral map was to allow planning, documenting and reporting the extent of aortic coverage and the distal landing site, though Criado(69) acknowledges the variability of spinal vertebral anatomy and aortic branches constitutes a weakness.

The proposed classification system divides the visceral aortic segment into Zones for the intended proximal endovascular seal zone for treatment of abdominal and thoraco-abdominal aortic aneurysms with FEVAR and BEVAR specifically in mind, using visceral vessel origins as the landmarks between Zones. Zone 0 is below the renal arteries, Zone 1 lies between renal arteries, Zone 2 is above the renal arteries but below the superior mesenteric artery, Zone 3 lies between the SMA and celiac axis and Zone 4 is above the celiac axis and may be in the aortic arch. Accordingly, Zone 0 corresponds with an infra-renal aneurysm and Zones 1, 2 and 3 collectively replace the terms juxta-renal, para-renal and supra-renal. Zone 4 corresponds with a Crawford 2, 3 or 4 thoraco-abdominal aneurysm (TAA).

Classifying these aneurysms by the number of fenestrations may be a valid alternative as the outcomes for double-fenestrated grafts have been shown to be different than for triple-fenestrated grafts (66). One weakness with this, however, is that the number of fenestrations or branches does not necessarily reflect the extent or complexity of

the repair. For example in our series, whilst the majority of Zone 2 repairs utilised double-fenestrated grafts, three used grafts with three fenestrations reflecting anatomical variation that is often encountered (Table 6.2). The Zonal classification allows flexibility for this variation whilst still grouping aneurysms of similar extent together. At the same time it can be seen that the different Zones are likely to require different grafts, such as triple-fenestrations for Zone 3 and branched grafts for Zone 4. This takes on additional importance as the technical process and challenges for fenestrated and branched grafts are quite different, and each has problems that are unique to their method of implantation.

In addition to providing reproducible morphological differentiation between aneurysms, results from our series demonstrate that clinical outcomes between Zones differ. Aneurysms that require higher seal-zones that incorporate additional visceral vessel origins are associated with significantly increased morbidity. This is reflected in longer operating times, increased blood loss, increased length of stay and reduced target vessel patency. The highest seal-zones, however, are not necessarily associated with all complications and particular problems may be associated with particular Zones. For example, the incidence of renal impairment was highest in Zone 3 reflecting that this particular Zone may be vulnerable to these kinds of injury. Similarly, paraparesis or paraplegia was more common in Zone 4 reflecting the surgical experience of increased spinal cord events in aneurysms that are more extensive.

One problem encountered particularly in Zone 3 is lower limb ischemia in lengthy cases, despite Zone 4 cases also being lengthy, this seems not to be a problem and the difference can be explained by technical differences in the implantation of fenestrated and branched grafts. Zone 3 cases, usually requiring triple-fenestrated grafts, would normally require large (20-22 French) sheaths in both iliac systems obstructing flow to both femoral (and often both internal iliac) arteries. These need to be in place until all the viscera have been cannulated and stented, an often lengthy process and in these cases a temporary axillo-bifemoral bypass can be performed. On the other hand, Zone 4 aneurysms usually requiring branched endografts require only one large sheath (leaving one iliac system open) and this may be removed prior to branch vessel cannulation, so that lower limb blood flow is restored much earlier. Zone 4 aneurysms had the highest number of spinal cord ischemic injuries, as might be expected in parallel with open surgical experience.

The overall morbidity and mortality particularly in Zones 3 and 4 is high in our case series. However, as previously shown, it is difficult to compare our results to other data sets due to the heterogeneity in reporting. However, the majority of previously reported cases are generally for aneurysms that require double-fenestrations which

are likely to be Zone 2. The comparison of our Zone 2 outcomes with other series is then more favourable; this further highlights the need for a classification system that differentiates between complex aneurysm repairs so meaningful comparisons may be made between centres.

Zone 4 is clearly a large territory especially as it may incorporate the arch, and as the open surgical outcomes for a Crawford 2 TAA are different to a Crawford Type 4 TAA (70) this is likely to be the same for endovascular repairs as well. It is anticipated that as more aneurysms are added to the series that this large Zone may be further differentiated.

In summary, a clear reproducible classification system is required for juxta/para-renal/supra-renal aneurysm surgery, to allow accurate comparison between cases. We have designed a classification system which can be applied to both open and endovascular surgery and which we feel should replace the previously used outdated terminology.

Please note:

The concept of the zones classification was a joint project between myself and two other surgeons. The data analysis and writing of the chapter is my own work.

Chapter 7

**Use of CO₂
angiography for
complex
endovascular
aneurysm repair**

Use of CO₂ angiography for complex endovascular aneurysm repair

7.1 Introduction

Complex endografts are challenging to insert with increased number of technical steps and their use is therefore associated with a greater volume of contrast (47) than with standard infra-renal grafts. Postoperative renal dysfunction and renal failure in these patients has previously been reported (44, 45, 47).

Current standard angiography utilises iodinated contrast agents; potential complications include contrast induced nephropathy (CIN). CIN occurs in approximately 15% of radio-contrast procedures with less than 1% requiring dialysis(71). Incidence of CIN is directly proportional to volume of iodinated contrast media used (72) and severity of pre-existing renal disease (73). Mortality is significantly increased in patients with CIN particularly if renal dialysis is required (73) and even transient renal dysfunction may lead to poor clinical outcomes.

Various prophylactic regimes have been used; pre and post angiography intra-venous hydration (74, 75) significantly decreases incidence of CIN especially in those with pre-existing renal disease. Some benefit has been shown with both oral and intravenous N-

acetylcysteine (76, 77), sodium bicarbonate(78), theophylline(79) and prophylactic haemofiltration(80).

Carbon dioxide is an alternative contrast medium to iodinated contrast. When injected into the aorta, CO₂ bubbles coalesce into larger bubbles, producing a continuous gas column; the blood displacement by CO₂ can be imaged using digital subtraction angiography. CO₂ is highly soluble in blood in which it inter-converts between CO₂ and carbonic acid before being excreted in the lungs. Although there are few complications associated with the use of CO₂ such as “vapour lock” (gas trapping causing arterial occlusion) and gas embolisation, its usage is limited due to inferior picture quality compared to iodinated contrast agents.

Use of CO₂ as primary contrast agent in standard EVAR has previously been described (81), however to our knowledge, its use in branched and fenestrated EVAR has not previously been reported. The aim of this study is to determine a reduction in the incidence of post-operative renal dysfunction with use of CO₂ as primary contrast agent.

7.2 Methods

This is a retrospective study of all patients undergoing complex EVAR at a tertiary referral centre. Two cohorts of consecutive patients undergoing fenestrated and branched EVAR between April 2008 – July 2011 were compared. Patients undergoing arch or proximal thoracic endografting, or those who had a known contrast allergy were excluded. Patients were grouped according to time period. Group 1 underwent aneurysm repair between April 2008-January 2010 and group 2 between January 2010-July 2011. In group 1, iodinated contrast media (Omnipaque 240, GE Healthcare, Europe) was sole contrast agent. In group 2, CO₂ was used as primary contrast agent and iodinated contrast (Omnipaque 240) as an adjunct when enhanced graphical resolution was required. All aortic stent grafts were custom made by Cook Medical; Atrium Advanta stents were used to bridge fenestrations and Fluency stents for branches.

All patients underwent standard preparation for complex EVAR, routine intra-operative monitoring for complex endograft procedures and pre-op rehydration; patients with pre-existing renal disease also received intravenous sodium bicarbonate. Figure 7.1 demonstrates the equipment set up. A CO₂ canister filled with medically approved 99.99% laboratory grade CO₂ is attached to a filter (standard filter from a laparoscopic set). The cylinder has a standard valve, regulator, gas gauge and metal

diaphragm. The regulator used is specific for these CO₂ cylinders thereby eliminating risk of inadvertent use of an incorrect gas.

Fig. 7.1a

The CO₂ delivery system is filled with 99.99% laboratory grade CO₂. The cylinder has a standard valve, regulator, gas gauge and metal diaphragm

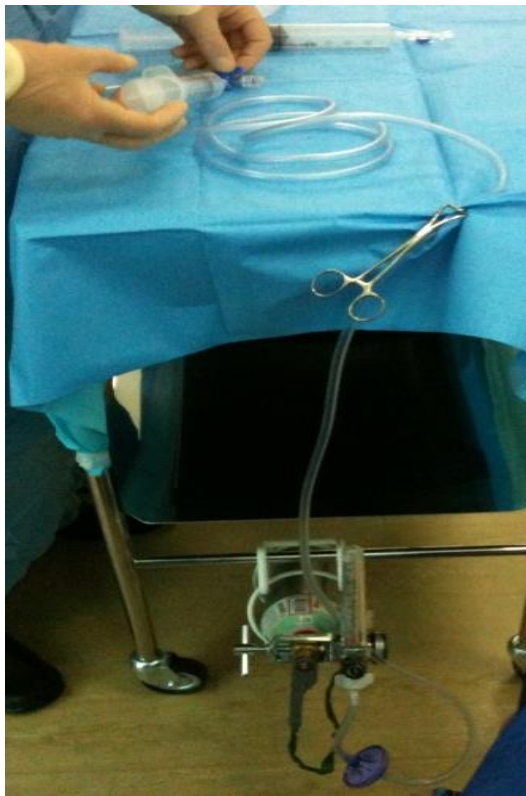


Fig. 7.1b

The cylinder is attached to a filter (from a laparoscopy set) and then to a 3-way tap. A 50 ml syringe is connected to the 3 way tap using a Floswitch.



Fig. 7.1c

A Floswitch connector. The switch can be clicked open with the operators thumb whilst compressing the syringe thereby allowing rapid injection of CO₂.



Tubing then connects the filter to a standard 50 ml syringe with a louver lock via a 3 way tap. The syringe is attached to the 3 way tap using a flow switch. The system is completely disconnected from the patient. The 50 ml syringe is filled with CO₂ using pressure (no higher than 1 atmosphere) from the cylinder to displace the plunger and aspiration is not performed to prevent air contamination. Volume of CO₂ injected is limited to 50ml by the syringe thus preventing a dangerously large volume.

Hand-delivered counter pressure prevents full plunger displacement. Air is poorly soluble and air contamination must be avoided to prevent air embolus. The syringe is filled with CO₂ and purged three times to remove any residual air before filling and then locking with the floswitch as a further measure to prevent air contamination. The locked 50 ml syringe filled with uncontaminated CO₂ is then disconnected from the 3 way tap and attached to the angiographic catheter. Blood in the catheter is flushed out using heparinised saline via a 3 way tap. The connection to the CO₂ syringe is then opened, the CO₂ syringe is manually compressed to one third of its volume, floswitch opened and gaseous CO₂ is injected directly into the aorta as 30-50ml aliquots under x-ray visualisation. Use of CO₂ as a contrast agent is contra-indicated above the diaphragm. We do not inject CO₂ if the systolic blood pressure is less than 70mm Hg to ensure sufficient flow prevents supra-diaphragmatic reflux.

Calibrated pigtail catheters are used for aortograms, and selective catheters for target vessels such as SMA or renal arteries. Calibrated pigtail catheters easily demonstrate

coeliac axis and SMA as they are ventral and therefore opacify well with buoyant CO₂ in lateral views. Other target vessels such as renal arteries that are dorsally oriented are less easy to opacify. They may be catheterised using a 4Fr catheter and then a 0.014 coronary guide wire is passed through the catheter, into the periphery of the renal artery, to stabilise the catheter position. The catheter is then pulled back into the origin of the target vessel. The catheter is attached to a 3-way stopcock, a Flexor valve (COOK), which substitutes for the Touhy Borst adapter; this 3-way tap also allows locking of the 0.014 wire. CO₂ is then injected directly into the orifice of the renal arteries thereby safely outlining their anatomy.

Digital subtraction angiography (DSA) was used for both groups; the iodinated-contrast DSA runs were acquired at 2 frames per second (FPS). CO₂ rapidly dissipates and therefore CO₂ runs require 4 FPS runs. Our radiographic equipment (Siemens) has a setting for abdominal CO₂ angiography which automatically makes these adjustments.

Primary endpoint was incidence of postoperative renal impairment. Renal impairment was defined as an increase of more than 25% from baseline creatinine during the in-hospital perioperative period. Secondary endpoints were need for renal support (dialysis/ haemofiltration), grams of contrast iodine used, fluoroscopy time, and radiation exposure.

Statistical analysis

Normally distributed continuous variables are reported using means and standard deviations and analysed using two sample t-tests; non-normal continuous variables as medians and inter-quartile ranges and compared using a Mann-Whitney test.

Categorical variables are described using numbers and percentages with chi-square or Fisher's exact test comparisons. P-values <0.05 were considered to be statistically significant.

7.3 Results:

86 complex endografts were implanted between 2008 and 2011; 39 in group 1 and 47 in group 2. Patient demographics were similar (Table 7.1) as was baseline renal function. Pre-existing chronic renal failure was defined as a baseline creatinine of >120 micromoles/litre.

Table 7.1

Patient baseline demographics

	Group 1 (n=39)	Group 2 (n=47)	P value
% Male	76.9	85.1	0.33
Median age yrs	77	75	0.44
Age range	63-86	48-85	
Median Baseline creatinine (micromole/L)	94	104	0.59
% pre-existing chronic renal failure	33.3	36.2	0.78

Mean post-operative creatinine was reduced in group 2 (see table 7.2), although the incidence of post-operative renal impairment was similar in both groups. Requirement for renal support (haemofiltration/dialysis) was significantly less in group 2 and the median number of days of renal support was also less in group 2.

Table 7.2

	Group 1 (n=39)	Group 2 (n=47)	P value
Mean post-operative creatinine (micromols/L)	175.9 (SD 117.4)	163.2 (SD 85.2)	0.56
Post-operative renal impairment	11 (28.2%)	13 (27.7%)	0.95
Post-operative renal support (haemofiltration/dialysis)	8 (20.5%)	2 (4.3%)	0.039
Median numbers of days of renal support	6.5	2.5	0.33
Median grams of contrast iodine used (range)	61.2 (12-141.6)	26.4 (0.7-84)	0.038
Median fluoroscopy time (mins)(range)	117 (56-404)	94 (50-218)	0.62
Median radiation dose (Gy)	52005	41836	0.22

Median grams of contrast iodine used was significantly reduced with use of CO₂. There was no significant difference in either fluoroscopy times or radiation dose between each group).

There were no complications associated with the use of CO₂.

7.4 Discussion

We have demonstrated successful use of CO₂ as primary contrast agent for complex endografts and subsequent reduction in use of post-operative renal support. CO₂ use is effectively “limitless” with our system with no maximum dose. It is safe, easy to use and we experienced no complications associated with its use.

Use of CO₂ as a contrast agent dates back to the 1950s when it was used to diagnose pericardial effusions. Iodinated contrast pre dates CO₂ as a contrast medium and the superior picture quality and definition make it the medium of choice. However, iodinated contrast when used in high volumes is associated with significant morbidity, our study showing an incidence of 28.2% of renal impairment in the iodinated contrast only group.

Renal impairment following complex EVAR is likely to be multi-factorial being a combination of micro-embolisation following renal artery catheterisation, pre-renal failure secondary to intra-operative hypotension and contrast induced nephropathy (CIN). This is reflected in our study by the similar incidence of post-operative renal impairment in each group. However we demonstrated a significant reduction in post-operative haemofiltration/ dialysis requirement with use of CO₂. Duration of renal

support was also less in the CO₂ group; although this was not statistically significant this is likely to be a reflection of the small cohort involved.

We demonstrated a significant reduction in contrast usage in group 2. Graphical definition in CO₂ angiography is inferior to that with iodinated contrast (Fig 7.2) and iodinated contrast was therefore needed as an adjunct to define fine anatomical detail in every case. This is due partly to the partial displacement of blood by CO₂ as opposed to full displacement with iodinated contrast medium, and partly to reflux or rapid dissipation of CO₂. However, as familiarity with use of CO₂ improved, we noted that iodinated contrast usage decreased further and later patients in the series required only very small volumes of iodinated contrast (3 mls being the lowest volume used).

Fig. 7.2

Fig. 2a and 2b, are taken with iodinated contrast medium, Omnipaque 240 mg/ml diluted to 50 % with saline. They show the left renal artery targeted with a 4Fr catheter stabilised in position with a 0,014 wire, and further to that a 6Fr sheath at the orifice of the left renal artery. Nb the contrast medium firstly fills the proximal part of the left renal artery, and then subsequently the more peripheral part of the left renal artery.

Fig. 7.2a

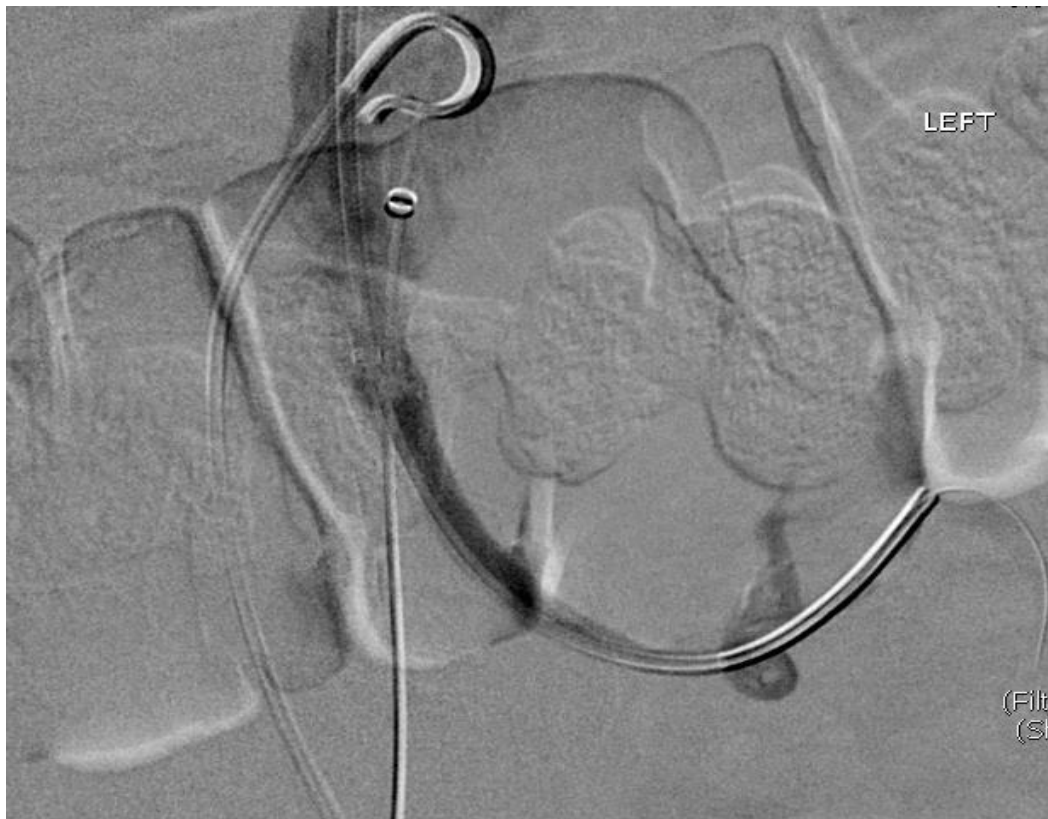


Fig. 7.2b



Fig. 7.2c

Fig. 2c is the same renal artery outlined with CO₂. Gas fills the entire left renal artery including the peripheral branches, and because it is gas, then refluxes into the aorta and adjacent vessels. The amount of refluxed gas depends on the pressure that is applied during delivery of the gas. There is a partially deployed SG with fenestrations marked with gold markers.



Our delivery method for CO₂ angiography is a safe and effective system. The cylinder and filter are medically approved for CO₂ and the same as those used for laparoscopy.

The specific CO₂ regulator prevents the inadvertent use of other gases and the pressure limit and maximum volume of the syringe prevent the injection of excess volumes of CO₂. The delivery system is totally disconnected from the patient. Use of the flow switch on the CO₂ containing syringe prevents air contamination and is further complimented by filling of the syringe by pressure from the gas canister only and by filling and purging 3 times prior to use. AngioDynamics have previously developed a dedicated computer-controlled failsafe injector, however FDA approval was not obtained and so it was abandoned. This injector eliminated the explosive delivery associated with previous handheld systems and aimed to reduce patient discomfort, CO₂ break up into small bubbles and reflux into potentially dangerous i.e. cerebral and coronary circulation.

Another delivery system consisting of a flaccid plastic bag to eliminate the possibility of delivering excessive volumes of CO₂ was developed(82) after a near fatal complication in which several thousand mL of CO₂ were inadvertently injected into the inferior vena cava when the system was connected directly to the CO₂ cylinder. Volume of CO₂ aspirated from the plastic bag is the exact amount that is delivered. The commercially available system includes check valves that eliminate stopcock manipulation and reflux of blood into the catheter. An extension tube also allows the operator to stand behind a lead screen to reduce operator radiation exposure. Before making definitive injections, the catheter is purged to prevent explosive delivery. A distal check valve prevents reflux of blood into the catheter. However, air contamination is possible if

there is a defect in the wall of the connectors between bag and delivery syringe and the system is generally cumbersome to use.

CO₂ is less dense than blood. With the patient supine, bubbles of CO₂ bubbles flow along the anterior part of the vessel, with incomplete blood displacement along the posterior portion. The celiac and superior mesenteric arteries fill well with small volumes of CO₂ due to their anterior position; it is often difficult to clearly visualise the renal arteries due to their relatively posterior position and in our experience selective catheterisation of the renal arteries is required. However, selective catheterisation gives good image quality and significantly decreases contrast usage.

Although elevating the feet has been shown to improve both extremity filling and aortic filling(83), we did not find this helpful in our series of juxta/para-renal and thoraco-abdominal aneurysms. Dorsally oriented renal arteries that were difficult to visualise using CO₂ were identified by direct catheterisation and arterial ostia targeting with CO₂. Our technique for this improved with experience significantly reducing requirement for iodinated contrast to demonstrate the renal arteries in the later patients. It is extremely cumbersome to elevate any side of the patient, particularly when orientating fenestrations and branches and makes it impossible to interpret the clock-face positions of fenestrations/branches.

The rapid dissipation of CO₂ necessitates double the number of frames per second for CO₂ angiography compared to standard iodinated contrast. Also, inferior picture quality may lead to multiple injections with CO₂; these both potentially increase patient radiation exposure compared to iodinated contrast. However, direct, repeated target vessel runs identify the most suitable angle for catheterisation thereby aiding and decreasing catheterisation time. Despite higher radiation exposure per run, we did not find a difference in radiation exposure between the two groups.

If awake, patients with stenotic/occlusive disease may experience abdominal pain due to temporary occlusion/ischemia of mesenteric vessels. If gas is trapped in a large abdominal aneurysm, it may persist allowing gas exchange between CO₂ and nitrogen in the blood. Embolic occlusion of side branches such as inferior mesenteric artery may occur leading to colonic ischaemia. However, occlusive disease in target vessels of aneurysm patients is uncommon and small volumes of CO₂ used in each run make this complication rare.

CO₂ is a naturally occurring by-product of aerobic metabolism and therefore does not cause hypersensitivity reactions. It is not known to cause renal or hepatic injuries. An unlimited intra-operative volume can be used in patients without mesenteric occlusive disease. Although there are no absolute contra-indications to the use of CO₂, it should

not be used above the diaphragm because of the risk of spinal, coronary and carotid artery gas embolisation.

In conclusion CO₂ is a good, safe alternative to iodinated contrast agents for complex endovascular aneurysm repair and significantly reduced requirement for post-operative renal support and usage of iodinated contrast. Renal impairment is a common post-operative complication amongst patients undergoing complex EVAR; cause appears to be multifactorial in origin and use of CO₂ angiography may aid risk reduction.

Chapter 8

**Temporary axillo-
bifemoral bypass
during complex
fenestrated aortic
aneurysm repair**

Temporary axillo-bifemoral bypass during complex fenestrated aortic aneurysm repair

8.1 Introduction

Insertion of fenestrated endografts and target vessel cannulation is technically challenging and requires many more procedural steps than standard EVAR. There is also a steep learning curve associated with this procedure and currently few operators in the UK have significant experience of the technique. Operation time may subsequently be much longer than for standard EVAR. Moreover, as the number of target vessels increase, so does the complexity of the procedure; consequently operation length increases further (84).

Fenestrated endografts require the simultaneous insertion of bilateral large calibre femoral sheaths. These may occlude the common femoral and iliac systems, particularly in patients with concurrent stenotic disease. The risk of lower limb ischaemia is therefore high. This, combined with a long operation length, may initiate a reperfusion injury on completion of the procedure.

Reperfusion injury occurs when the blood supply to a tissue is interrupted. Acute ischaemia of the limb results in anaerobic metabolism and an increased local

concentration of lactic acid. The resulting acidosis alters normal enzyme kinetics leading to cellular dysfunction. Disruption of the cell membrane pump allows sodium ions to move into the cell, osmotically drawing water molecules with them, and potassium ions to escape from the cell. Cellular and interstitial oedema, cell chaos and ultimately cell death occur.

When the blood supply is re-established, toxic metabolites are flushed from the limb into the systemic circulation and endothelial and white cells become activated inducing a cascade of inflammatory reactions. Consequences of this include sudden cardiac arrest and death from hyperkalaemia, renal failure secondary to rhabdomyolysis, myoglobinaemia and myoglobinuria, compartment syndrome secondary to local inflammation and acute lung injury and multi organ failure as a result of the systemic inflammatory response syndrome.

We hypothesise that the more complex the procedure the greater the risk of developing a reperfusion injury and that this may be reduced by the use of a temporary axillo-bifemoral bypass. The aim of this study is to determine the outcome of the use of an adjunct temporary axillo-bifemoral bypass with complex fenestrated endovascular aneurysm repair.

8.2 Methods

This is a retrospective observational study of consecutive patients undergoing FEVAR at a tertiary referral centre from October 2008-July 2011. All patients undergoing FEVAR involving the superior mesenteric artery (SMA) and the renal arteries were included. Patients with a scallop only for the SMA, those requiring a fenestration for the coeliac axis or a branched graft were excluded.

Patients with lower limb stenotic /occlusive disease (confirmed by pre-op arterial duplex), or those with complex anatomy such that a long procedure was anticipated, underwent an adjunct temporary axillo-bifemoral graft. Patients were divided into two groups. Group 1 consisted of patients who did not undergo a temporary axillo-bifemoral graft. This included all patients between October 2008 and December 2009, (it was at this point, following a reperfusion injury that we decided to implement this adjunct procedure) and those patients who did not meet the inclusion criteria for group 2. Group 2 consisted of patients who underwent a temporary axillo-bifemoral bypass graft. Primary outcome was patient mortality. Secondary outcomes were patient morbidity and the need for renal support.

8.2a Procedure details

All procedures were carried out under general anaesthesia. The axillo-bifemoral bypass was performed at the start of the procedure. An 8 mm Dacron graft was anastomosed (end to side) proximally to the right axillary artery just below the clavicle and passed extra corporeal to anastomose to the distal common femoral arteries (end to side). Subsequent cannulation of the common femoral arteries and graft introduction was performed just proximal to the bypass.

The Dacron graft itself was used as a proximal conduit allowing antegrade catheterisation and also the introduction of a "through and through" wire as an adjunct device. Standard cannulation of the fenestrations and graft deployment was performed (85, 86). When successful aneurysm exclusion was confirmed by completion angiography, the temporary bypass was amputated; a small remaining cuff of Dacron at each anastomosis was utilised as a patch for closure.

8.2b Follow up

Postoperatively, patients were prescribed dual antiplatelet therapy (aspirin lifelong and clopidogrel for two months). Routine follow up consisted of abdominal radiography at 1 and 6 months, and yearly thereafter and yearly arterial duplex.

8.3 Results

34 patients with juxta renal aneurysms requiring renal and SMA fenestrations underwent FEVAR during this period. See table 8.1 for patient demographics. Gender and age were not significantly different between the two groups. Comorbidities were similar between each group except pre-existing hypertension which was significantly higher in group 2.

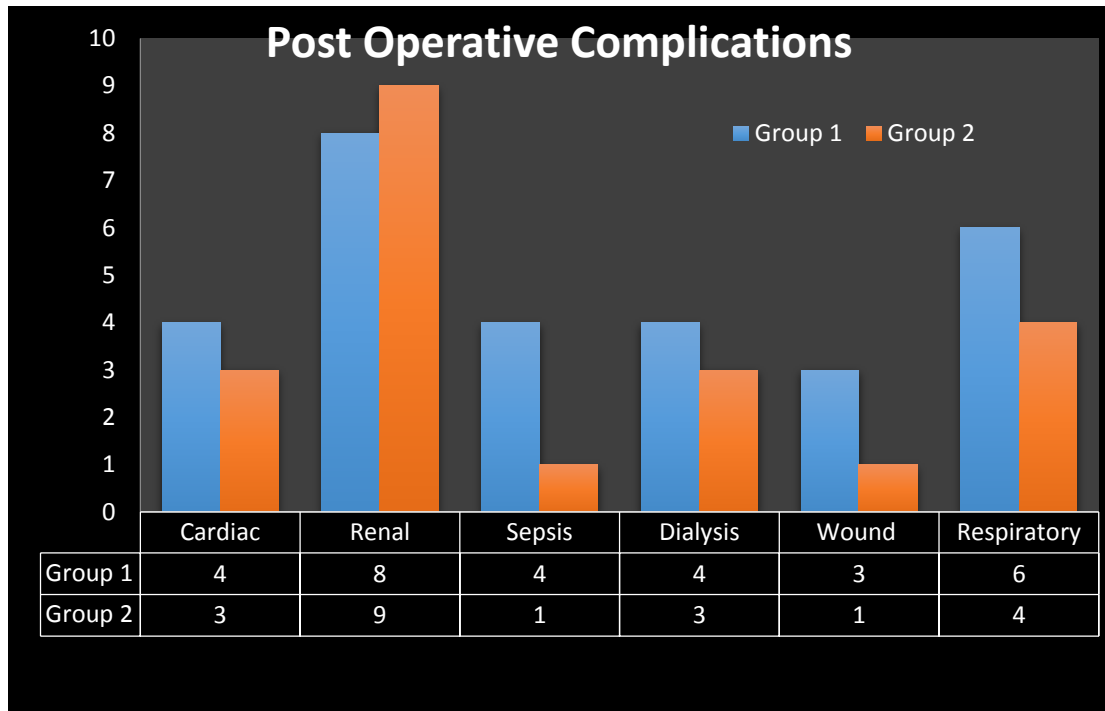
Table 8.1

	Group 1 (n=16)	Group 2 (n=18)	P value
% male	81.3	94.4	0.23
Median age (range) yrs	78.5 (66-86)	73.5(60-83)	0.16
Pre-op diabetes %	25.0	16.6	0.54
Pre-op hypertension	68.8	100	0.02
Current smoker	18.8	16.7	0.87
Pre-op cardiac history	37.5	66.7	0.08
ASA 2 (%)	12.5	0	0.55
ASA 3 (%)	68.7	88.9	0.12
ASA 4(%)	18.8	11.1	0.31
Pre-op hx COPD	31.3	22.2	0.53
Pre-op hx PVD	6.3	22.2	0.82
Pre-op hx chronic renal failure	31.3	27.8	0.19

No procedures required conversion to open repair. Total number of target vessels is shown in table 8.2. Two patients in each group had an accessory renal artery requiring fenestration, and one patient from group 1 and two from group 2 had a non-functioning kidney which did not require a fenestration. Although median procedural time was longer for group 2 this was not statistically significant. Only one unplanned additional intra-operative procedure was required and that was the use of an atrium covered stent following a ruptured renal artery.

Table 8.2

	Group 1 (n=16)	Group 2 (n=18)	P value
Median procedural time (mins) (range)	340 (210-660)	425 (240-660)	0.12
Median blood loss (mls) (range)	1,000 (200-4500)	2,500 (240-4,000)	0.53
Total number of target vessels	48	53	
Target vessel cannulation (%)	100	96.2	
Median ITU length of stay (range)	6 (1-35)	3 (1-38)	0.47
In hospital length of stay (range)	11 (2-54)	11.5 (4-100)	0.52
30 day mortality %	18.8 (n=3)	0	0.046

Figure 8.1*Morbidity and mortality*

30 day mortality was 18.8% (n=3) in group 1 and 0% in group 2 (P=0.046). The first patient had a prolonged procedure (>450 mins) due to an intraoperative common iliac artery rupture; he was noted intra-operatively to have ischaemic legs and post operatively developed a reperfusion injury requiring fasciotomies, and haemofiltration. He went on to develop multi-organ failure with respiratory impairment and had a fatal

myocardial infarction on day 3 post op. The second patient was noted to have ischaemic legs at the end of the operation which slowly improved and did not require further intervention. However he went on to develop renal and respiratory failure and on cessation of sedation was found to have had an intracerebral event. He died from MOF day 11 post op. The third patient had an intra-operative complication of a ruptured left renal artery which required a covered stent. He lost 450 mls of blood during the procedure and was hypothermic on arrival in ITU. Day one post op he was noted to have an ischaemic leg and required an emergency fem-pop bypass and fasciotomies. Post op he was coagulopathic and went on to develop MOF with ischaemic colitis, and respiratory failure. He died day 18 post op.

Morbidities were similar in both groups (fig 8.1). 50% of patients in each group developed renal impairment post op (defined as a creatinine rise of >20% from baseline). However of these only 16% of group 2 required dialysis compared to 25% of group 1 ($p=0.54$). There were no morbidities related to the use of the temporary axillo-bifemoral graft.

8.4 Discussion

FEVAR for short-necked and juxta renal aneurysms is a complex procedure with significantly higher morbidity and mortality than standard EVAR. Reperfusion injury is a considerable risk in this cohort of patients and we have demonstrated that the mortality from this may be reduced by the use of a temporary axillo-bifemoral bypass graft.

In our series, a 20 or 22 Fr sheath was introduced to the ipsilateral side and a 20 or 24 Fr sheath placed in the contralateral femoral artery. This was necessary to allow access for the small sheaths required for target vessel cannulation. Alternatively, the contralateral femoral artery could be punctured separately for each 6 or 7Fr sheath, however this is unpractical and compromises arterial wall integrity. The presence of large sheaths in both femoral arteries, in combination with prolonged operative time and peripheral vascular disease, is likely to lead to lower limb ischemia and the subsequent risk of reperfusion injury. It has been reported that lower limb lactate is significantly higher after EVAR than after open AAA repair, and remains elevated for at least 48h post op(87).

All three patients who died developed multi-organ failure. This was perceived to be directly related to a reperfusion injury in two of these patients. As a result of these deaths our policy regarding adjunct temporary axillo-bifemoral graft was implemented. No patient who underwent this adjunct procedure developed post-operative reperfusion syndrome and we had no morbidities as a result of this adjunct procedure. Renal dysfunction is a common morbidity post FEVAR, as shown in our series. This is likely to be multi-factorial being a combination of micro-embolisation following renal artery catheterisation and contrast induced nephropathy. We did demonstrate a reduction in the need for renal support in group 2; the small numbers in each group may account for the lack of statistical significance.

In our series, although the median procedure time was longer for group 2 this was not statistically significant. This may be a reflection of the small sample size. However, the axillo-femoral graft, served as an additional access site allowing antegrade catheterisation of the target vessels prior to stent graft deployment. These were then used as markers making orientation the stent graft easier and potentially shortening procedure time. Moreover, it allowed the option of antegrade target vessel cannulation in cases where retrograde cannulation proved difficult.

In some complex cases, multiple wires and catheters from the axillary artery are necessary for the completion of the procedure. Puncture of the Dacron graft, at the

site of axillary anastomosis, is a simple and safe procedure. Conversely, multiple puncture sites at the axillary artery may be dangerous, given the fragility of this vessel.

Tortuous iliac arteries and severe neck angulation are considered to be relative contraindications to FEVAR (88). Axillary access, facilitated by the axillo-bifemoral graft, enables the use of a through and through guidewire technique. A floppy guidewire is advanced through the right axillary artery and into the abdominal aorta. This is then exchanged, using a 5Fr catheter, for a Super Stiff wire, which is pulled down from the aorta or the iliacs, and out of the femoral sheath, by a loop snare. This can then be used to straighten a tortuous aorta or iliac arteries thereby aiding the procedure.

Temporary axillo-femoral bypass has previously been described as an adjunctive procedure to open aortic aneurysm repair. Further, it has been shown to reduce left-ventricular afterload (89-93). Aortic cross clamping increases mean aortic pressure and heart rate, increasing the metabolic requirements of the heart and subsequently increasing the risk of cardiac ischaemia. Despite lack of data regarding the hemodynamic effect of large sheaths in the iliac arteries, it is possible that the axillo-bifemoral bypass reduces cardiac afterload during FEVAR.

In our unit we do not routinely use an axillo-bifemoral graft for patients requiring renal fenestrations only because this is a shorter, simpler procedure and the risk of reperfusion injury is therefore much less. Similarly, we do not routinely use it for branched devices because this does not require bilateral large bore femoral catheterisation as target vessel catheterisation of the branches is antegrade from the brachial/axillary artery.

In conclusion, FEVAR is technically challenging. The procedure is often long and potentially involves occluding the arterial supply to the legs. This, combined with concomitant peripheral vascular disease, increases the risk of intra-operative limb ischaemia and subsequent postoperative reperfusion syndrome. Use of an adjunct temporary axillo-bifemoral bypass, decreases this risk and may reduce mortality without contributing to overall morbidity.

Part 3

Consensus Statement

Chapter 9

“The post code Lottery” of aneurysms – current practise of aneurysm management in the UK

“The post code Lottery” of aneurysms – current practise of aneurysm management in the UK

9.1 Introduction

The process of introducing new surgical techniques is much debated in recent years. Traditional methods consisted of presentations at surgical meetings, publication of case reports and case series and the development of large observational (often retrospective) studies. As modern surgery has developed, newer innovations may be refinements of previous techniques which often confer smaller and less striking improvements than those previously reported.

Randomised controlled trials (RCT) are commonly described as the “gold standard” of surgical research and are designed to clearly show any benefit imparted by an intervention. However, good quality trials usually take time to set up, require a large number of patients, are expensive and results may not be immediately apparent. Technology may evolve too fast for RCTs to be useful and there may be situations where they are not possible or appropriate to perform. Management of complex aneurysms is an example where technology has currently exceeded good quality clinical research evidence.

Endovascular aneurysm repair (EVAR) has revolutionised the management of aneurysm disease. There is now level one evidence establishing it as a viable alternative to open repair(7) for infra-renal aneurysms. Its use has increased rapidly and the National Vascular Database Audit 2009(94) showed over 44% of AAA (abdominal aortic aneurysms) in the UK underwent EVAR. Although it was first described by Parodi in 1991(1), guidelines establishing EVAR criteria were not published until 2003(95) and have only recently been updated(96) to incorporate later generation graft design.

The development of fenestrated and branched endografts has enabled endovascular intervention for juxta-renal/thoraco-abdominal aneurysms. However, benefits of FEVAR over open repair may be less than those seen with standard infra-renal EVAR and questions on the validity of FEVAR for juxta-renal aneurysms have arisen. The heterogeneity between the case series and lack of high quality evidence have made the indications and role of FEVAR unclear. Consequently, in the UK FEVAR is not universally available. The aim of this study is to establish current practise of aneurysm management, to assess the introduction of FEVAR and to establish the criteria for use and its role in the UK.

9.2 Methods

This project was co-ordinated through the British Society of Endovascular Therapy (BSET) thereby ensuring representation of at least one individual from each UK vascular centre specialising in complex aneurysm repair. The COOK database of FEVAR users was also interrogated to gain a full list of UK FEVAR centres. All UK centres performing fenestrated EVAR and centres with an established interest in infra-renal EVAR were invited to participate.

An open ended questionnaire was developed regarding current practise of AAA management (See appendix D). The questionnaire was undertaken either as a telephone interview or in email format. Both consultant vascular surgeons and consultant interventional radiologists were invited to participate.

The questions were broadly divided into 4 sections:

1. Previous aneurysm experience
2. Current practise of aneurysm management
3. Definition of juxta-renal aneurysm
4. Indications for FEVAR

The questions were specifically open ended and the wording designed to avoid prompting answers.

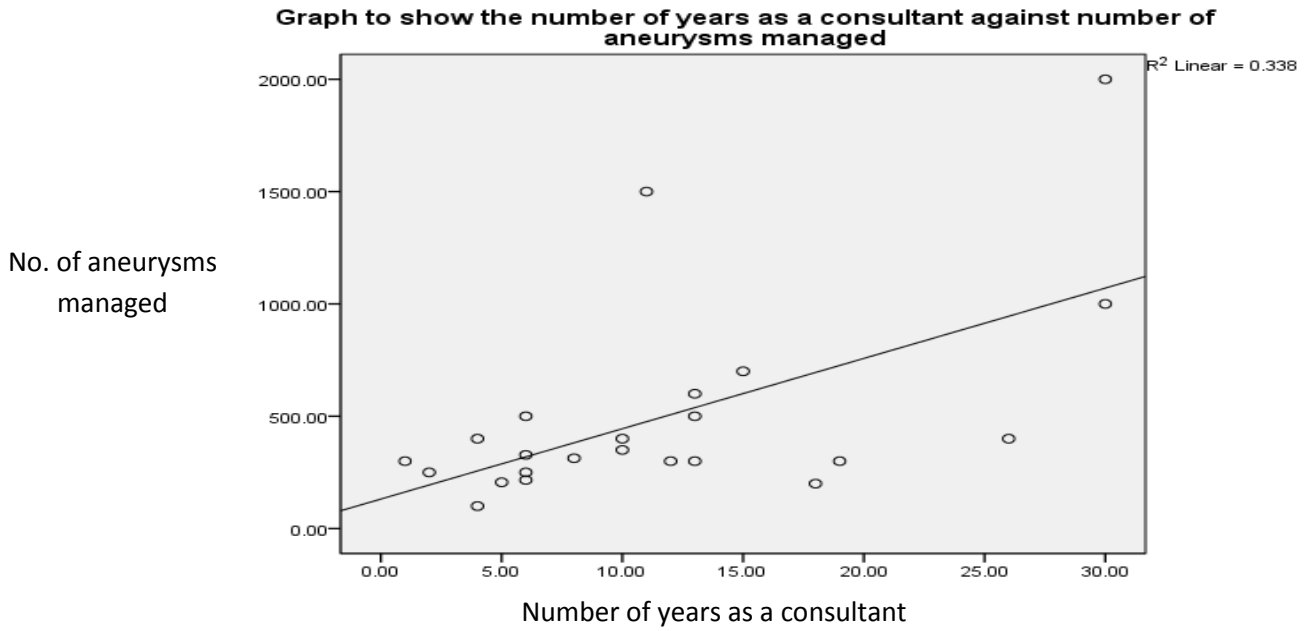
9.3 Results

9.3 1. Previous aneurysm experience

45 UK consultants were invited to participate. 26 responded and of these, 4 were primarily consultant radiologists and 22 were primarily vascular surgeons. A response was obtained from over 90% of the current UK FEVAR centres.

The median number of years in consultant position was 10.5 (range 1-30). The median total number of aneurysms managed was 328 (range 100-2,000). See Fig 9.1. The majority of surgeons had managed less than 500 aneurysms. There was a significant correlation between years of experience and number of aneurysms managed (Pearson Correlation coefficient 0.581, P=0.004)

Fig 9.1 Graph showing years of consultant experience against number of aneurysms managed



The median number of open infra-renal aneurysms managed was 125 (range 20-400) and median number of infra-renal EVAR managed was 160 (range 8-800). Most consultants had limited experience of fenestrated EVAR; over half (54%, n=14) had been involved with 10 or under, and only 23% (n=6) had been involved with 50 or more. The median number of open supra-renal aneurysms managed was 14 (range 1-400).

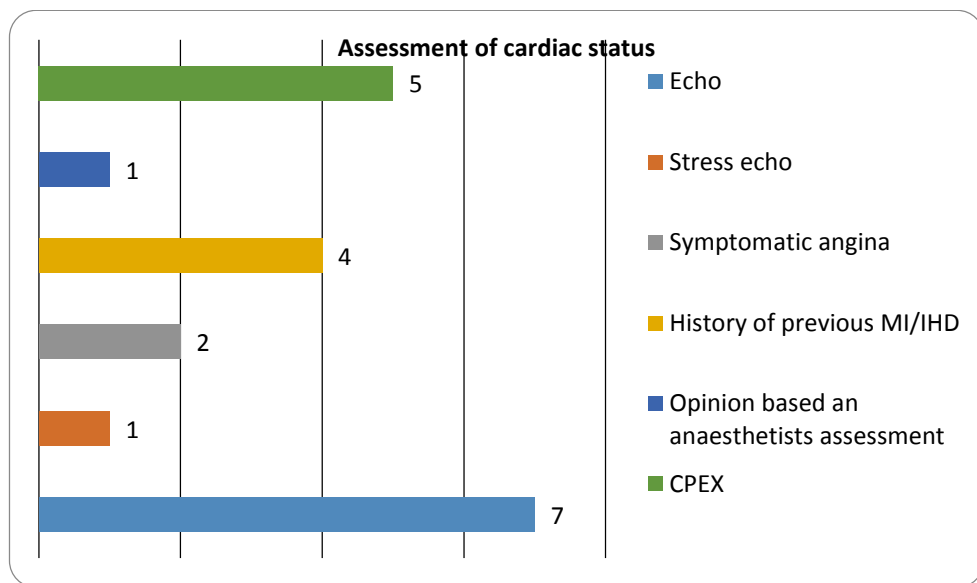
9.3 2. Current Practise

Standard Practise

10/26 consultants stated that EVAR was their first choice preference. Almost all consultants stated that they would discuss both options with the patient and would generally recommend a modality based on patient fitness. Only 3 consultants specifically said that the management decisions were made after an MDT discussion. 4 consultants said they used scoring systems to help predict patient outcomes.

Patient factors

All consultants sited fitness for surgery as a factor taken into consideration when deciding management options for aneurysms. However, defining "fitness" for surgery varied considerably.



There was no concurrence on assessment of cardiac status. A cardiac echo was the most commonly sited investigation, however a significant ejection fraction was not universally agreed. Although respiratory disease was sited by 9 consultants and renal disease by 11 consultants, the cut off levels for significant parameters varied considerably. 7 consultants sited exercise tolerance and it was generally agreed that patients should be able to climb 1 flight of stairs. Other factors taken into consideration were the ability to self care, life expectancy, obesity, symptomatic aneurysms, claudication, scoring systems and the presence of a hostile abdomen.

Aneurysm size

Aneurysm size was universally agreed as 5.5 cm being the cut off for a fit male, however, 2 consultants said they would consider repair in females at 5.0cm. Most consultants stated they would wait until the aneurysm had reached 6-7cm before intervening on an unfit patient.

Age

4 consultants specifically stated that age alone was not considered when deciding aneurysm management. Of the consultants that mentioned age, it was generally

agreed that under the age of 60, open repair was preferable and that over the age of 80 EVAR was preferable. However opinions varied as to best practise for the 60-80 yr age group.

EVAR Morphology

Definition of an acceptable neck length for standard infra-renal EVAR varied considerably. Although it was universally agreed that a straight, thrombus free neck of >15mm was suitable, 12 consultants said they would accept a neck length of 10mm, and 3 said they would accept a neck length of up to 8mm. Only 5 consultants stated they would not accept angulation of more than 60 degrees and 4 consultants said they would accept neck angulation of up to 90 degrees. Where cited it was generally agreed that the iliacs should be greater than 6mm and not heavily calcified.

Graft Type

The most commonly used graft was the Cook zenith (n=17 consultants used as first line graft) followed by the medtronic enduring (n=10). The Aorfix was commonly cited as being used for angulated necks.

9.3 3. Juxta renal definition

Definition of a "juxtarenal aneurysm" was variable. 14 consultants defined this as being the need to clamp above one or more renal arteries. 2 consultants defined juxtarenal as a Crawford type 4 aneurysm, 3 only as "short neck ", 6 defined it as a neck length of less than 10mm, 2 defined it as a neck length of <5mm and 1 as less than 3mm. 1 consultant defined as "seal zone above the renal arteries".

9.3 4. Indications for FEVAR

There was little agreement on the indications for fenestrated EVAR (FEVAR). 2 consultants were unsure when to use FEVAR, 10 consultants felt they should be used for patients who were unfit for open repair if standard EVAR was not suitable, "complex aneurysm"/ thoracoabdominal aneurysm/juxtarenal aneurysm was cited by 15 consultants and short/hostile neck was used by 10 consultants however only 4 gave a neck length, 3 stated less than 10mm and 1 stated less than 15mm.

9.4 Discussion

This audit presents a snap shot of current practise of aneurysm management in the UK. The results show a wide variation in aneurysm management. Of particular interest is the poor concurrence on the indications for FEVAR and definition of juxta-renal aneurysm.

The questions were deliberately open ended to prevent prompting answers. This may however, have limited the responses for each answer and led to mis-understandings in relation to expected answers. Respondants may have also elaborated more on various aspects if prompts had been given and may have omitted some answers due to the nature of the questions. The questionnaires conducted as a telephone interview were less likely to have misunderstandings.

Defining "fitness for surgery" and standard pre-op investigations varied between institutions. Whilst severe cardiac disease is a contra-indication, the methods of defining and the cut off level at which it was deemed too unsafe were not universal. This was also the case for respiratory and renal disease. Exercise tolerance and the "ability to climb stairs" although very subjective are commonly used parameters. However, EVAR II(8) trial, showed clinical judgement to be a satisfactory method of deciding patient "fitness". There was agreement that an unfit patient, should wait until

the aneurysm had reached >6cm, regardless of intervention modality. Although EVAR II showed a lower than anticipated rupture rate, the all cause mortality in this group was high and the benefit of EVAR in someone with a limited life expectancy is not clear.

Aneurysm size was generally agreed as 5.5cm being the size to intervene in a fit patient regardless of treatment modality. This is generally based on the results from the UKSAT(12) and the results results from the CESAR(63) and PIVOTAL(17) have not shown any benefit for EVAR with early intervention.

Patient age is a controversial area and opinion varied particularly in the management of the 60-80 year old group. Although it is generally agreed that EVAR is the better option for older patients, there has been some reluctance to insert grafts into young patients. This is based on the high reintervention rates associated with EVAR and the radiation dose with repeated surveillance CT scans. Recently surveillance duplex is becoming the modality of choice and as graft design is improving, reintervention rates are decreasing.

Acceptable aneurysm morphology suitable for a standard infra-renal graft varied considerably and over half the consultants would be prepared to insert a standard infra-renal graft outside the manufacturers instructions for use. Some consultants would not consider a standard EVAR in a neck of less than 15mm whilst others would be prepared to accept a neck length of up to 8mm. Whilst graft design has improved considerably and grafts are now licensed for up to a 10mm neck, previous studies have shown that short and/or angulated necks(20, 21)are associated with a higher endoleak and subsequent re-intervention rate.

This also showed a large overlap with the indications for FEVAR. Whilst FEVAR is often considered for aneurysms that do not conform with manufacturers instructions for use for standard infra-renal grafts, our survey showed that in a significant number of cases standard grafts are being used where other centres would consider a fenestrated graft to be the most suitable option. It is interesting to note that FEVAR use was often considered for unfit patients. Evidence for a benefit for unfit patients is poor and given the EVAR II data it is unclear whether we should be considering FEVAR in unfit patients at all.

There was no clear definition of a "juxta-renal" aneurysm. The old definition relating to clamp placement is now obsolete in the endovascular era and a new common

definition should be agreed to enable uniformity in management and the ability to accurately compare morphology. This is particularly apparent in the use of FEVAR. Experience of FEVAR was variable and indications were not clear.

This survey has highlighted that the indications for use and the role of FEVAR are unclear. At present only a small number of UK consultants have significant experience of FEVAR and although its use is increasing its introduction remains haphazard with no current guidelines. Opinion differences are usually an indication of lack of good quality evidence and the need for further research.

It appears the trend in the UK is now heading towards endovascular repair, with 10/26 consultants specifically stating that this was their first choice preference. However there are still variations in unit policies indicating regional differences in patient management. This study has highlighted the need for further guidelines regarding the role of FEVAR.

Chapter 10

UK Multi- Institutional Consensus Statement: Indications for Fenestrated Endovascular Aneurysm Repair

UK Multi-Institutional Consensus Statement:

Indications for Fenestrated Endovascular Aneurysm Repair

10.1 Introduction

The management of infra-renal abdominal aortic aneurysms (AAA) is a highly researched field with level one evidence to guide practise. Over the last decade endovascular aneurysm repair (EVAR) has emerged as a viable alternative to open repair(7). Use of EVAR has increased rapidly and the National Vascular Database 2009 audit(94) showed EVAR to be the management choice of approximately 44% of all aneurysms.

Approximately 25-75% of all AAA remain unsuitable for standard EVAR (14, 97) and in these patients options include open repair, conservative management or complex endograft repair. Fenestrated endografts are the most commonly used complex endovascular technique in the UK. However, morbidity and mortality (44) is higher with FEVAR than standard EVAR and questions on the validity of FEVAR for juxta-renal aneurysms have arisen.

These technological advances have exceeded evidence for use in the area of FEVAR. Current evidence is poor quality; there is likely bias in reporting of cases, particularly in open repair and these results do not necessarily represent a real world experience.

The IDEAL model (98) (Innovation, Development, Exploration, Assessment and Long term study) suggests a staged approach for introduction of new clinical practise. Part of this is the development of recommendations for use. Guidelines for clinical practice may be developed using formal consensus methods (99, 100). The recommendations produced by consensus methods represent the views of groups about current research evidence and clinical opinion (101, 102). These methods identify where there is consensus, or whether individual views diverge to such an extent that no recommendation can be made. Consensus methodology is a validated technique, in particular for areas lacking in research evidence or where randomised controlled trial may not be possible. Consensus methodology has been previously used to produce guidelines by national bodies such as NICE and an example of previous use in vascular surgery was in the setup of the BASIL trial(103) to define areas to be requiring further focused research.

Current evidence for FEVAR indicates that its role is unclear. It is too early in its development to deliver a good randomised controlled trial. Whilst this may evolve in the future, at present a consensus statement is a suitable alternative for clarification of

the role of FEVAR. The aim of this study was to develop a consensus opinion on the current indications of FEVAR.

10.2 Methods

This consensus statement was performed using a modified form of the RAND appropriateness technique. The method used is a validated and reliable technique for formal consensus decision making(104) and is the basis of methodology employed by NICE. RAND is a hybrid of the Delphi survey and the nominal group technique. The process involves a series of surveys, the results of which are fed back to all participants. Time is then allowed for discussion before further surveys are undertaken. The key features are feedback and discussion of results in a non-dominant and independent manner. Participants should represent a breadth of experience, opinions, knowledge and enthusiasm of the larger professional body, thereby avoiding bias. The consensus process employs anonymous scoring thereby not allowing domination by individual 'enthusiasts'. The numbers on the final discussion panel are limited at this stage to allow optimal debate and discussion.

There were five key steps in the development of the FEVAR consensus process:

1. Review of current literature
2. Survey of current practise
3. Establishment of the nominal group and definitions of clinical attributes

4. RAND – Round 1

5. RAND – Round 2

10.2 1. Literature Review of Published work

A Meta-analysis of Observational Studies in Epidemiology (MOOSE) of the current evidence for FEVAR was undertaken (see chapter 4). Eleven studies were identified which met the inclusion criteria.

10.2 2. Survey of current practice

The aim of this round was to assess responses from a full range of UK vascular surgeons and interventional radiologists representing a breadth of experience and enthusiasm for all types of AAA management. A questionnaire on current practice of AAA management was completed (see chapter 9). This was designed as a scoping strategy to establish areas of opinion using open ended non quantifiable questions. At the time of writing only one company supplied complex endografts in the UK.

Interrogation of their database determined a full list of those centres in the UK who had ordered a fenestrated endograft. These centres and a nationwide spread of centres with high volume open or infra renal endovascular aneurysm surgery were contacted and invited to participate. The questionnaire was undertaken either as a telephone interview or in email format.

10.2 3. Establishment of the nominal group and defining the clinical attributes

All those who participated in the survey were invited to attend a meeting in August 2010 (see Appendix E), the aim of which was to establish areas requiring consensus agreement, define the clinical attributes which would make up the clinical scenarios and form an “expert panel” for the data collection. The aim of the expert panel was to include a group of professionals’ representative of current UK practise with a range of experience and knowledge of the clinical choices in AAA management (i.e. including those with considerable open surgery experience for infra-renal and complex AAA, those with both open and infrarenal EVAR experience and FEVAR users).

The results of the MOOSE on the current evidence for FEVAR were first presented to the experts together with the results from the current practise survey. A structured group discussion followed; the minutes of which were fully transcribed and clear definitions of the clinical attributes were established. Four main clinical attribute groups were identified and each group was further sub-categorised; from these, the clinical scenarios which formed the basis of the consensus process were developed. See Table 10.1 and Appendix F.

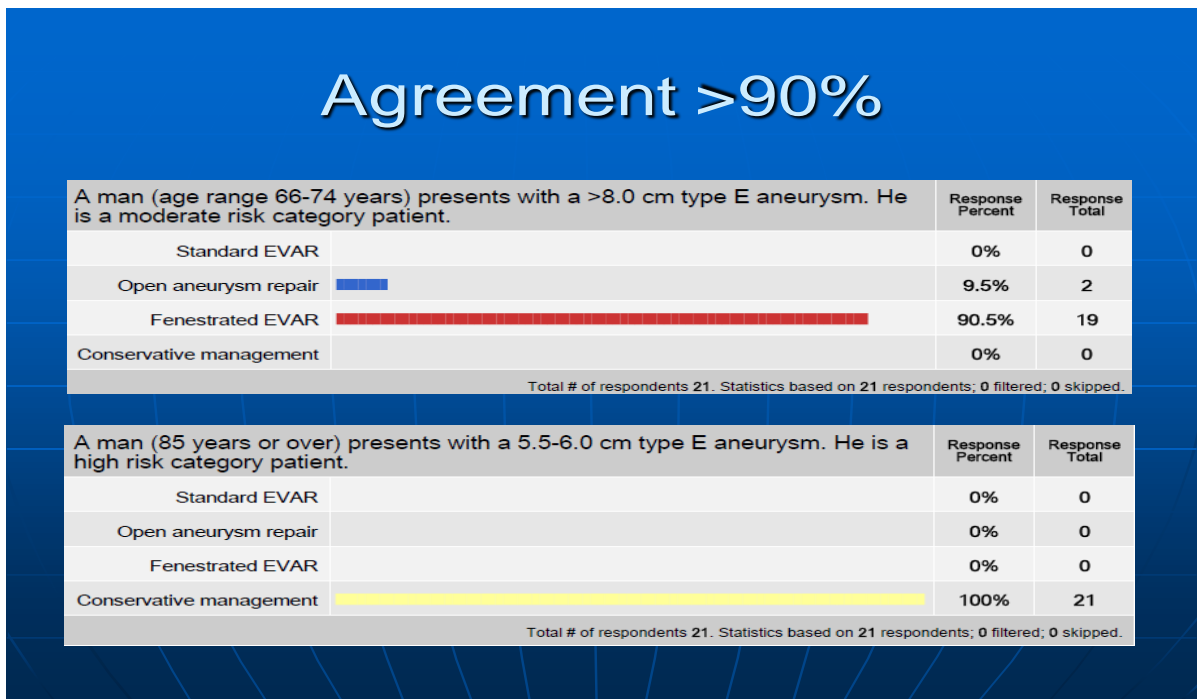
Table 10.1

Age in years	less than 65 yrs
	65-74 yrs
	75-84 yrs
	more than or equal to 85 yrs
Aneurysm size in cm	<5.5
	5.5-6.0
	6.1-7.9
	>8cm
Co-morbidities/risk of surgery (after pre-op assessment and optimisation):	Low risk (no significant PMH, <5% mortality risk of surgery)
	Mild Risk (some mild co-morbidities or reduced exercise tolerance or 5-10% mortality risk of open surgery)
	Moderate Risk (Some significant co-morbidities etc. or > 10% open mortality risk)
	High Risk (house bound etc. unfit for open)
AAA Morphology	Type A aneurysm - AAA with long infra-renal neck that is suitable for EVAR by manufacturers guidelines of the graft of your choice
	Type B aneurysm - AAA that lies outside manufactures IFU but in your opinion EVAR is feasible (may be conical, thrombus lined, short neck angulated etc.). Technically suitable for standard open repair involving an infra-renal clamp
	Type C aneurysm - Standard EVAR not feasible but infra-renal clamp possible, abutting but below renals or suitable for a fenestrated graft
	Type D aneurysm - AAA where, if open, suprarenal clamp necessary or double fenestrated EVAR
	Type E aneurysm – Supra-renal/ Type IV AAA or AAA that requires supra-coeliac clamp/medial visceral rotation +/- reconstruction of renal/visceral arteries or 4 fenestrations / branches

10.2 4. Round 1

Round 1 of the consensus development was performed as an on line survey to all participants from the survey. Every combination of the clinical attribute groups were used in a factorial design providing 192 case vignettes (i.e. 4 age groups, x 3 aneurysm size groups, x 4 co-morbidity groups, x 4 aneurysm morphology groups = 192). For each case vignette, participants were given four management options (open aneurysm repair, standard EVAR, conservative management or FEVAR) reflecting normal clinical situations and were asked which option they felt was most appropriate. The results were presented as percentage agreement for each option. Consensus was defined where there was > 90% agreement for one option and these vignettes were then excluded from further discussions at round 2. On completion, results from Round 1 were e-mailed back to all participants. See fig 10.1

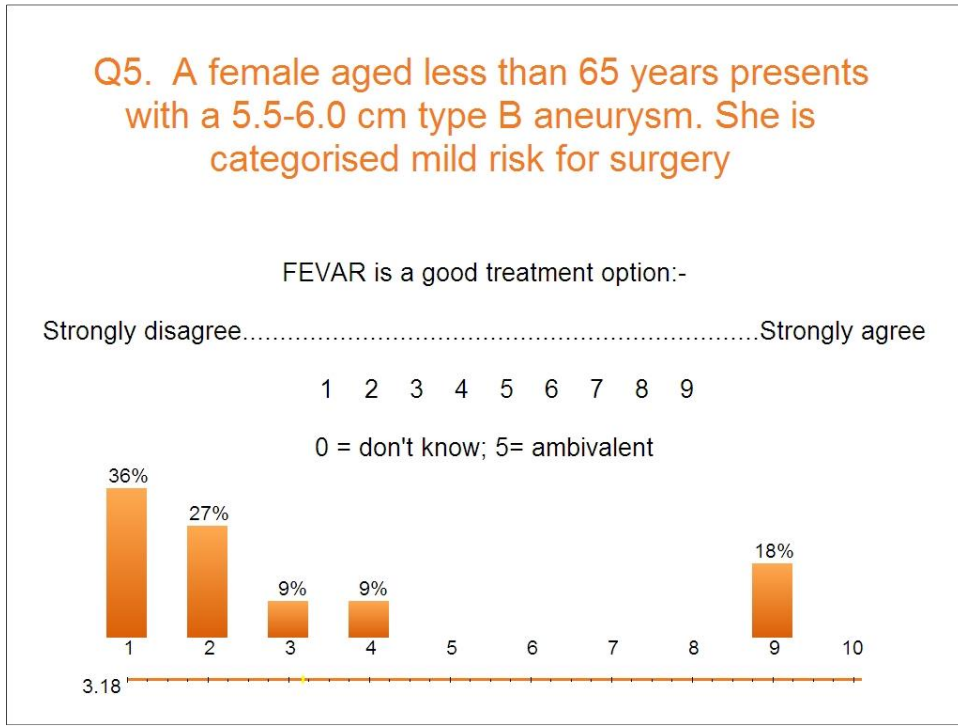
Figure 10.1



10.2 5. Round 2

Round 2 consisted of a meeting, attended by members of the expert panel. The results from Round 1 were shown for each case vignette in which consensus had not been reached. The results were discussed, reasons for divergence were analysed and any ambiguities were clarified and if necessary re-worded before re-scoring. To avoid the effect of a dominant personality, each participant was given a sixty second uninterrupted opportunity to present their opinions. The panel was then asked to re-score each scenario's suitability for FEVAR using a Likert scale of 1-9 where 1 was considered very unsuitable and 9 considered very suitable. Rating was done using a simultaneous electronic voting system to avoid peer influence. Anonymised results were immediately fed back to the panel. See fig 10.2

Figure 10.2



The results from the consensus were then sent back to the entire cohort of participants. Any comments and disagreements were incorporated into the final analysis with the aim of producing a paper representative of the group as a whole.

10.2 6. Analysis

A median rating for each of the 192 vignettes was calculated. The median score reflects the strength of support for each vignette. These were then categorised into one of three groups. Group medians of 1-3.5 were considered good agreement: “suitable not for FEVAR”, 3.6-6.5 no agreement on suitability for FEVAR, and 6.6-9 good agreement: “suitable for FEVAR”. For transparency of results, the group's mean absolute deviation from the median (MADM) (i.e. the average distance (on the nine-point Likert scale) of the participants' ratings from the group's median rating) was also calculated. The MADM defines the extent of support of the group. Consensus was considered to have been achieved in those vignettes with a median rating of 6.6-9 or 1-3.5 and a high extent of support reflected by a MADM of <1.41.

10.3 Results

10.3.1 Survey of Current Practise

22 centres in the UK performing FEVAR were identified. 26 of the 45 UK consultants (57.8%) invited to participate took part. This expert panel consisted of 4 consultant radiologists and 22 vascular surgeons. Representation was obtained from over 90% of current UK FEVAR centres. All consultants cited fitness for surgery as a key factor in aneurysm management, however, definition of "fitness" varied considerably.

Aneurysm size was universally agreed as 5.5 cm being the cut off for a fit male. There was much variation in defining an acceptable neck length for standard infra-renal EVAR and over half the consultants would be prepared to insert a standard infra-renal graft outside instructions for use. There was no clear agreement on the definition of a "juxtarenal aneurysm" and there was poor concordance on the indications for FEVAR.

10.3.2 Initial meeting

At the initial meeting, clinical attributes agreed for aneurysm management were patient age, aneurysm size, "fitness for surgery" and aneurysm morphology. (Table 10.1). It was decided that type A aneurysms and aneurysms of less than 5.5cm were to be excluded from further discussion because it was universally agreed that type A aneurysms were not suitable for FEVAR and that aneurysms of less than 5.5 cm should be managed conservatively. No clear agreement could be made on definitions for

fitness for surgery and it was therefore established that this should be left to the individual. A similar strategy was adopted in the EVAR II trial(8).

10.3 3 Round 1

21 of the 26 members (80.8%) of the expert panel completed surveys of the case vignettes. In several cases the case vignettes were completed simultaneously by more than one person reflecting an MDT viewpoint.

There was disagreement in 137/192 (71.3%) of the scenarios. The highest level of agreement was seen in type B aneurysms (24/48, 50%) and age >85yrs (19/48, 39.6%). The lowest agreement was seen in the mild risk category (7/48, 14.6%)

10.3 4 Round 2

12 members of the expert panel convened to discuss the Round 1 results. Following peer discussions and feedback from the first round, agreement was improved to 68.8% of vignettes (Figure 10.3).

Figure 10.3a

% agreement of aneurysm management based on age

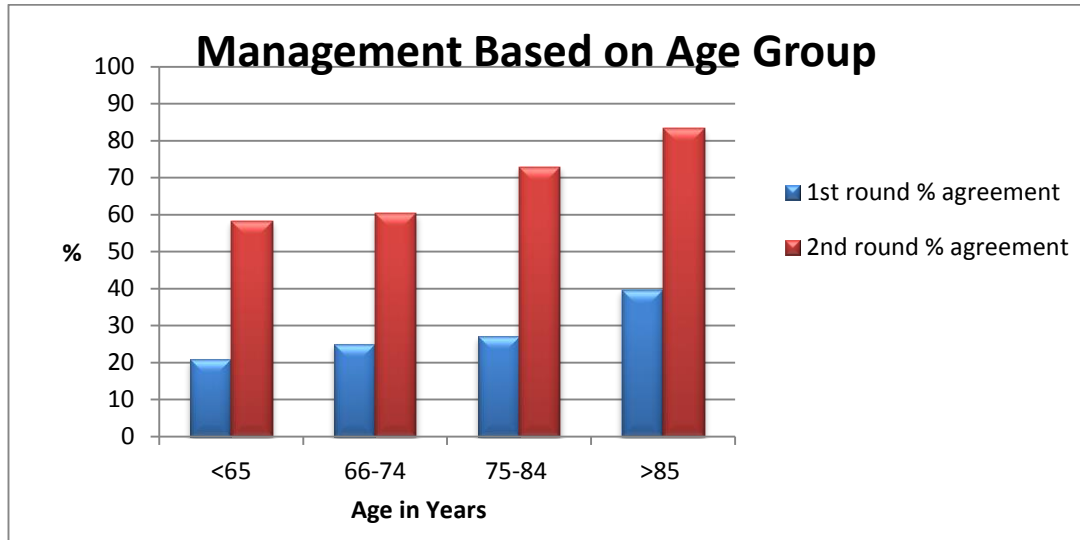


Figure 10.3b

% agreement of aneurysm management based on aneurysm size

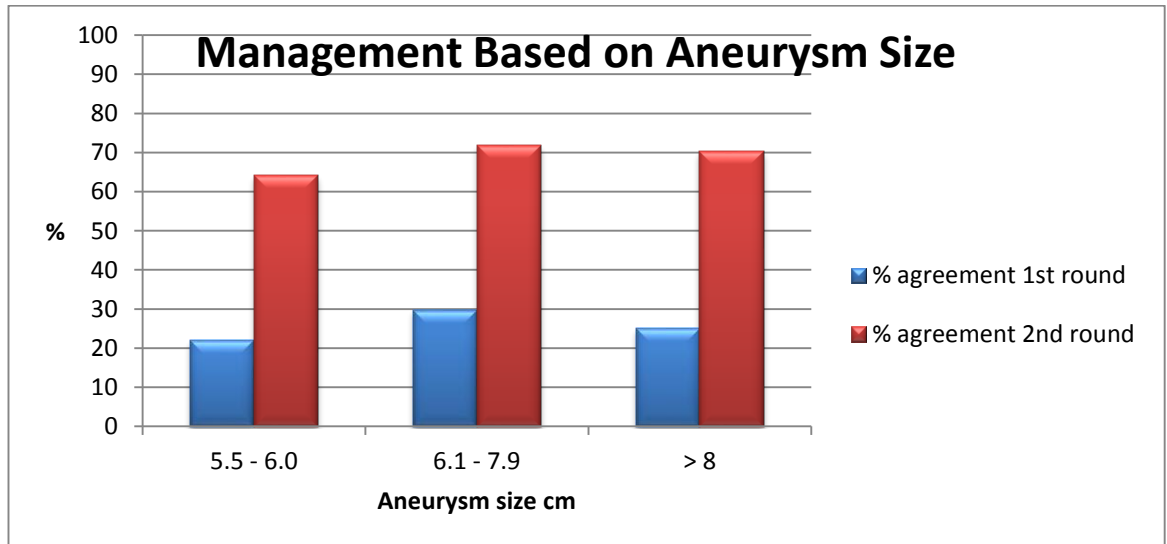


Figure 10.3c

% agreement of aneurysm management operation risk

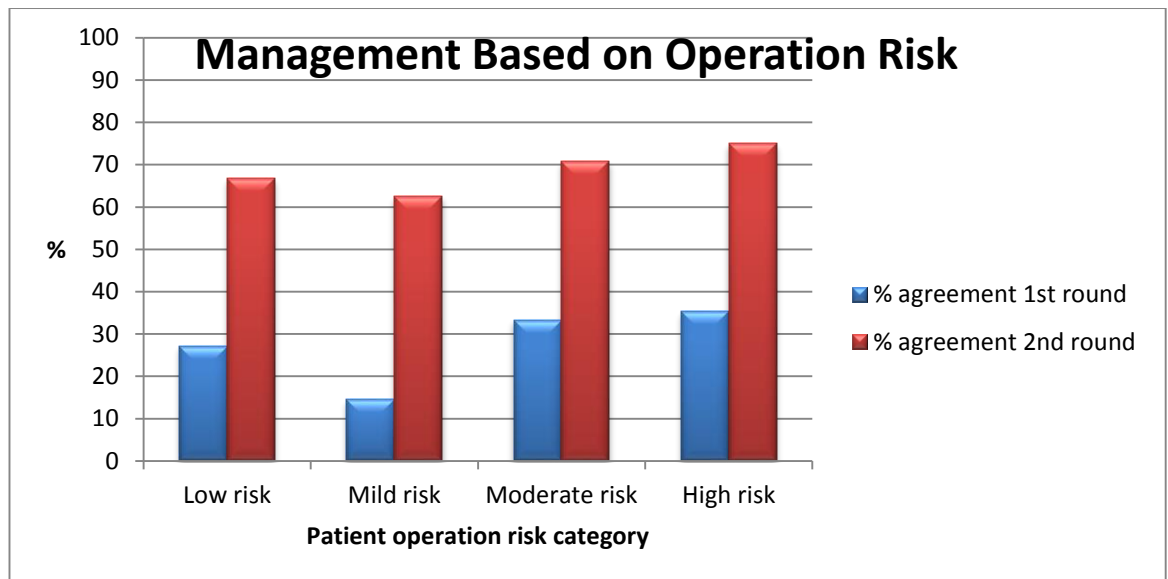
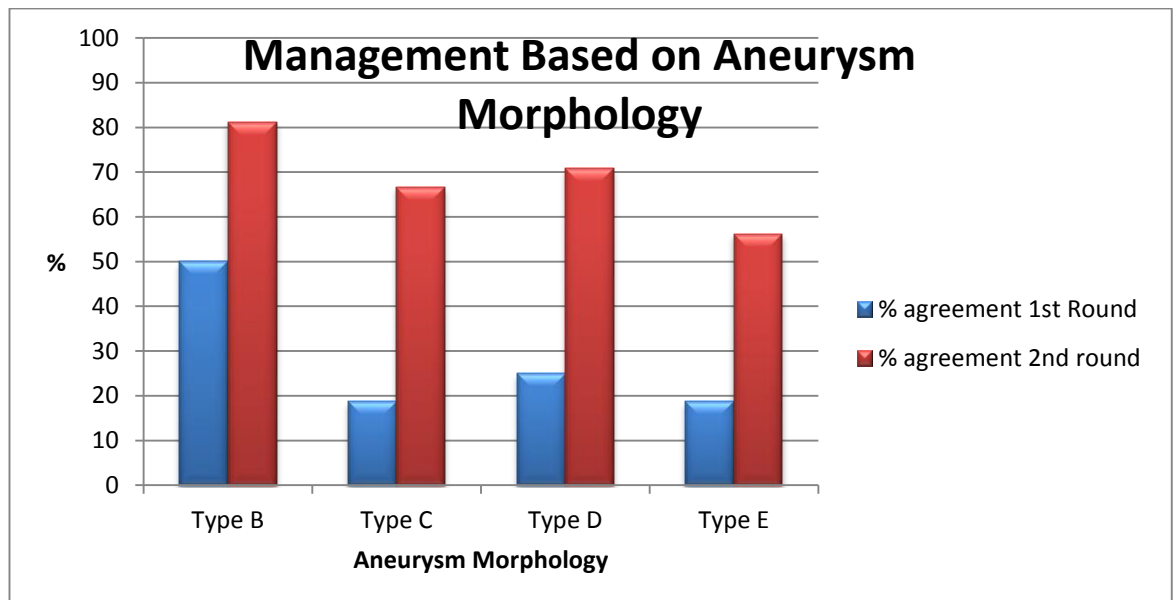


Figure 10.3d

% agreement of aneurysm management based on aneurysm morphology



The highest level of agreement seen was again in aneurysms over the age of 85 years (40/48, 83.3%) and the management of type B aneurysms (39/48, 81.2%). The lowest agreement was now seen in the management of type E aneurysms (27/48, 56.2%) and management of young patients (age <65 years) (28/48, 58.3%). The categories achieving 100% consensus agreement were patients over the age of 85 years with a type B aneurysm and high risk patients age >85years; consensus agreed that they were not indicated for FEVAR. See table 10.2 a-d

Table 10.2

Tables show the consensus views on appropriateness for EVAR

Table 10.2a

FEVAR

NO FEVAR

No Consensus

Type B Aneurysms

		Age <65 yrs	Age 65-74 yrs	Age 75-84 yrs	Age >85 yrs
5.5-6.0cm	Low risk	Red	Red	Red	Red
	Mild risk	Grey	Red	Red	Red
	Moderate risk	Red	Red	Red	Red
	High risk	Red	Red	Red	Red
6.1-7.9cm	Low risk	Red	Red	Red	Red
	Mild risk	Grey	Grey	Grey	Red
	Moderate risk	Grey	Grey	Red	Red
	High risk	Red	Red	Red	Red
>8cm	Low risk	Red	Red	Red	Red
	Mild risk	Grey	Red	Red	Red
	Moderate risk	Grey	Red	Grey	Red
	High risk	Red	Red	Red	Red

Table 10.2b

FEVAR
NO FEVAR
 No Consensus Type C Aneurysms

		Age <65 yrs	Age 65-74 yrs	Age 75-84 yrs	Age >85 yrs
5.5-6.0cm	Low risk	Red	Red	Grey	Red
	Mild risk	Red	Red	Green	Red
	Moderate risk	Green	Green	Grey	Red
	High risk	Grey	Grey	Grey	Red
6.1-7.9cm	Low risk	Grey	Grey	Green	Green
	Mild risk	Grey	Grey	Green	Green
	Moderate risk	Green	Green	Green	Grey
	High risk	Green	Grey	Green	Red
>8cm	Low risk	Red	Grey	Grey	Green
	Mild risk	Grey	Grey	Green	Green
	Moderate risk	Green	Green	Green	Grey
	High risk	Green	Green	Green	Green

Table 10.2c

FEVAR
NO FEVAR
 No Consensus **Type D Aneurysms**

		Age <65 yrs	Age 65-74yrs	Age 75-84 yrs	Age >85 yrs
5.5-6.0cm	Low risk	Grey	Grey	Grey	Red
	Mild risk	Grey	Grey	Grey	Red
	Moderate risk	Green	Green	Grey	Red
	High risk	Red	Grey	Red	Red
6.1-7.9cm	Low risk	Grey	Grey	Green	Green
	Mild risk	Green	Green	Green	Green
	Moderate risk	Green	Green	Green	Grey
	High risk	Green	Green	Green	Red
>8cm	Low risk	Grey	Green	Green	Green
	Mild risk	Grey	Green	Green	Green
	Moderate risk	Green	Green	Green	Grey
	High risk	Green	Green	Green	Red

Table 10.2d

FEVAR
NO FEVAR
 No Consensus **Type E Aneurysms**

		Age <65 yrs	Age 65-74 yrs	Age 75-84 yrs	Age >85 yrs
5.5-6.0cm	Low risk				
	Mild risk				
	Moderate risk				
	High risk				
6.1-7.9cm	Low risk				
	Mild risk				
	Moderate risk				
	High risk				
>8cm	Low risk				
	Mild risk				
	Moderate risk				
	High risk				

Equipoise was defined as existing if the median score fell in the 3.5-6.5 range or the MADM was > 1.41 (i.e. the spread of the votes, was too large). By the end of the second round, the grey area of equipoise had dropped from 71.3% to 31.2%.

10.4 Discussion

This paper presents the results of a consensus statement undertaken to reflect the views of UK vascular interventionalists on the indications for FEVAR. This study highlights those clinical scenarios where FEVAR is currently regarded as the preferred treatment of choice and where it not regarded as appropriate. Despite presentation of current research evidence and extensive structured discussions of an expert panel, agreement regarding best practise was not achieved in almost one third of case vignettes.

This consensus statement was formed by an even spread of vascular experts with differing opinions. An equal number of perceived “pro-EVAR” and “pro open” enthusiasts together with “midway” experts made up the expert panel. The RAND methodology relies on a core group of experts to facilitate purposeful discussions. However, the final results and paper were re-circulated to the entire group for comments before publication. This statement is therefore likely to represent national practice. This was a clinical appropriateness based paper and although, health economics may limit availability, this should not have had an influence on decision making in these clinical scenarios.

Consensus opinion is that FEVAR is not indicated for > 80% type B aneurysms (Table 10.2a). This may reflect limited availability of FEVAR or could relate to improvements in standard graft design and durability. Despite evidence that late endoleak and reintervention rate is higher in short/angulated necks (20, 21), this result indicates that a significant proportion of consultants may be using standard infra-renal devices outside manufacturer's instructions for use. Interestingly much of the current data is for FEVAR in type B aneurysms. Over 90% of current UK FEVAR centres contributed and the results are likely to represent national practise.

Consensus opinion is also that FEVAR is not indicated for elderly (>85yrs) high risk patients. In the initial survey, high surgical risk was commonly cited as an indication for FEVAR. However, the expert panel stated that FEVAR was only appropriate in patients with a reasonable life expectancy. EVAR II(8) showed high all-cause mortality in "unfit" patients and the benefit of EVAR in someone with limited life expectancy is not clear.

The key to acceptance of a new procedure is the apparent effect and as surgical specialities have evolved, innovations have led to smaller increments and less striking improvements than those previously reported. The IDEAL model has been developed as series of five recommended stages for the implementation of new surgical innovations. Stage 1 is the "proof of concept" phase where the procedure is tried on a small number of patients for the first time. If early reports suggest benefit then the innovation may progress to stage 2a (innovation stage) where the focus is on the

technical development of the intervention. Subsequently stage 2b (development stage) investigates the indications for use, understanding the benefits and harm and optimising effectiveness. Stage 3 establishes the clinical efficacy and cost effectiveness.

Currently the development of FEVAR is at stage 2b. As part of the evolution, an important part of the development is defining the indications for use. Prospective research databases are often employed at this stage, however these take time to accrue meaningful data. A consensus statement is a validated alternative method to guiding clinical practise particularly when research evidence is limited.

The use of expert consensus in guideline development is based on the assumption that the views of the group have greater validity and reliability than the judgement of an individual. Structured methods for developing a consensus should offer a transparent way of producing judgements, reduce the influence of dominating personalities and peer influence on decision making and can provide valuable information on the extent and reasons for differences of opinion.

The RAND appropriateness method allows a large, geographically dispersed group to participate in the first round thus avoiding the effect of a dominant personality. The use of a formal meeting for the second round aims to reduce the risk of misunderstandings and may expose the reasons for opinion differences. Although, this

is an accepted, validated methodology, outcomes may be biased by composition of the expert group. The level of resources available in a healthcare system may also influence recommendations. Future developments are not always predicted correctly by the “expert” group particularly if panellists are misinformed about a topic. Judgements may be unreliable and un-reproducible, particularly in the second round where group discussions can lead to unrepresentative and therefore unreliable outcomes.

Although the RAND appropriateness method uses a Likert scale for round 1, we used the four management options to better reflect decision making in clinical practise. A limitation of the study is that not everyone who participated in Round 1 was able to attend Round 2 and that two people who participated in Round 2 had not completed Round 1. Given geographical and time restraints, this is what was practical and feasible. However, recirculation of the results and inclusion of comments from the entire group aimed to achieve group representation.

These data provide a base whereby a professional body of opinion agrees on indications for FEVAR and when not to undertake a FEVAR, and could be developed to provide guidelines and recommendations to clinicians, purchasers and health economists. The grey area of equipoise identified in this study indicates the need for clarification of the indications for FEVAR and these results could be used to define inclusion criteria for future studies.

Chapter 11

RAND Consensus Statement on the Indications for Fenestrated Endovascular Aneurysm Repair: Reliability and Validity

RAND Consensus Statement on the Indications for Fenestrated Endovascular Aneurysm Repair: Reliability and Validity

11.1 Introduction

Given the benefits of standard EVAR (5), endovascular repair of the juxta renal aneurysm logically seems an attractive option. However, this involves the use of fenestrated endografts; benefits of FEVAR over open repair may be less than those seen with standard infra-renal EVAR and evidence for their use is limited.

The decision to perform clinical interventions is commonly based on knowledge from clinical evidence, often involving the gold standard of a randomised controlled trial. Practise involving a limited evidence base may have major consequences in terms of clinical and economical outcomes. However, introduction of new health technology often involves a limited evidence base and in certain circumstances randomised controlled trials may not be possible or ethical.

Fenestrated endografts are an example of this. At present, current evidence consists of small case series only. Devices are costly as they must be custom made and the lifelong follow up needed means this is a much more expensive option than the current gold

standard of an open repair. Ultimately, as a prophylactic procedure, we must be confident of achieving aneurysm exclusion; at present there is limited evidence for long term durability.

Clinical guidelines are developed to aid the clinician, particularly in this field of limited evidence. A consensus approach can be used as part of the guideline process based on the assumption that the views of the group have greater validity and reliability than the judgement of an individual. Chapter 10 presents a consensus statement outlining the indications for FEVAR. However, in order to develop these further into guidelines we must determine their reliability and validity.

Firstly, are the recommendations for or against intervention reproducible by independent groups? This is a measure of reliability and good levels of agreement are essential for clinical credibility and accurate measurement of the frequency of under or over use. Secondly, setting the level of the thresholds of benefit is crucial, particularly when, as with FEVAR a number of different factors are involved in determining the management option. Thirdly, are the recommendations valid in terms of prognosis? If so, then clinical outcomes should be better amongst patients undergoing the recommended procedure.

The aim of this paper is to address these questions by matching a patient cohort to the hypothetical patients discussed during the RAND appropriateness consensus statement.

11.2 Methods

The RAND appropriateness methodology and the development of the consensus statement on the indications for FEVAR have been described in chapter 10.

The database from a tertiary referral vascular centre of all patients treated using a fenestrated endograft was interrogated. Patient details including co-morbidities, aneurysm morphology, graft morphology, and operative outcomes were retrospectively entered and analysed. Patients involving predominantly branched endografts were excluded.

Patients were matched to a category using the parameters used to create the case vignettes, i.e. age, aneurysm size, aneurysm morphology and operation risk based on comorbidities. This was then linked to the consensus recommendation for those specific conditions. 3 patient groups were identified; group 1 (the intervention was performed as recommended by consensus opinion, i.e. the intervention was deemed appropriate), group 2 (the intervention was performed against the recommendation of consensus opinion, i.e. the intervention was deemed inappropriate), group 3 (consensus opinion was not reached regarding management of those criteria i.e. there was equipoise regarding the management). Patient outcomes were analysed according

to cohort group. Primary outcome was 30 day mortality. Secondary outcomes were patient morbidity and length of stay. All decisions made regarding patient management were independent of the consensus appropriateness statement. Decisions on patient management were made in a multidisciplinary team environment by a combination of vascular surgeons and interventional radiologists.

Statistical analysis

Reliability of the consensus statement was analysed using the appropriateness scores of the 3-level categories (inappropriately inappropriate, uncertain, or appropriate) and agreement between clinicians and the consensus assessed in percentage terms.

Validity of the consensus statement was assessed using chi squared comparing the results of use of FEVAR outside consensus opinion compared to those within consensus opinion. Stats direct version 1 was used for all analyses.

11.3 Results

84 patients were treated for a juxta/para/supra-renal aneurysm using a fenestrated endograft. 14% of patients were female. Median age was 74 (range 48-87). Figure 11.1 shows the distribution of the age ranges by group.

Figure 11.1 Patient age range

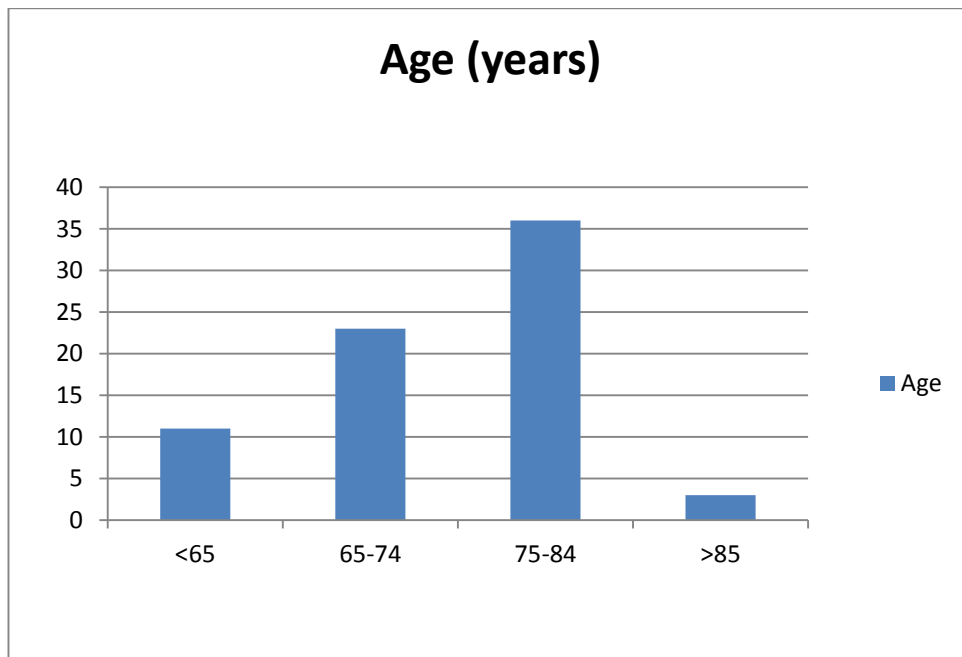


Figure 11.2 shows the distribution of aneurysm size.

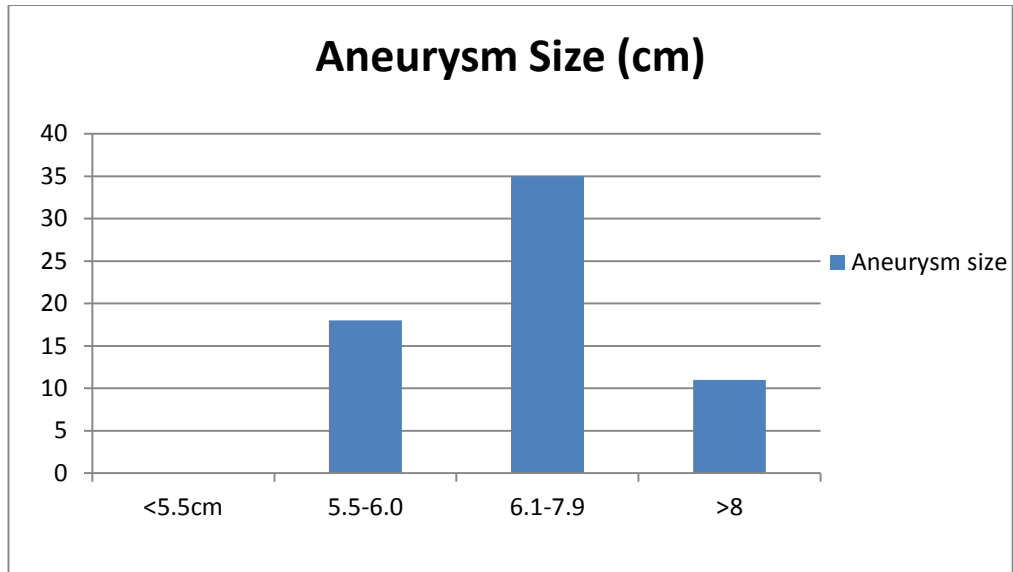


Figure 11.3 shows the distribution of aneurysm morphology

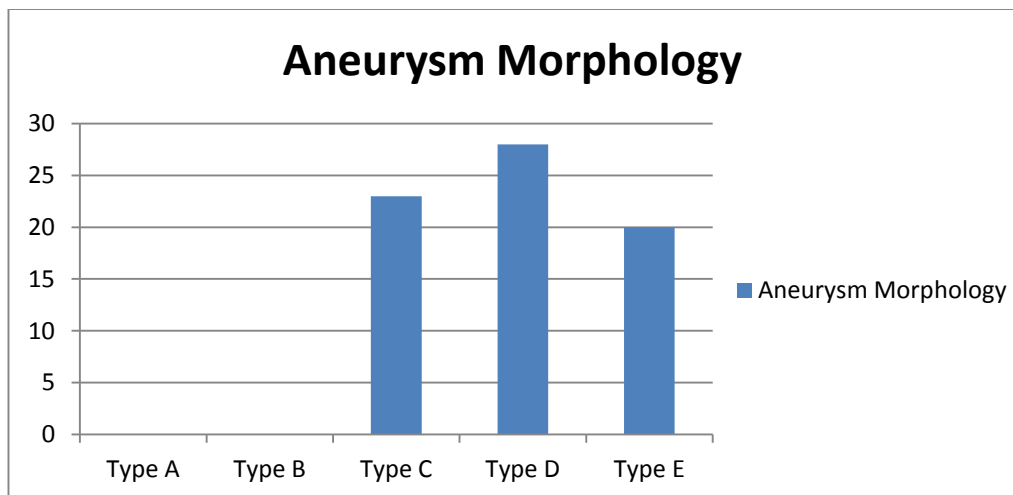


Figure 11.4 shows the distribution of risk stratification according to patient comorbidities.

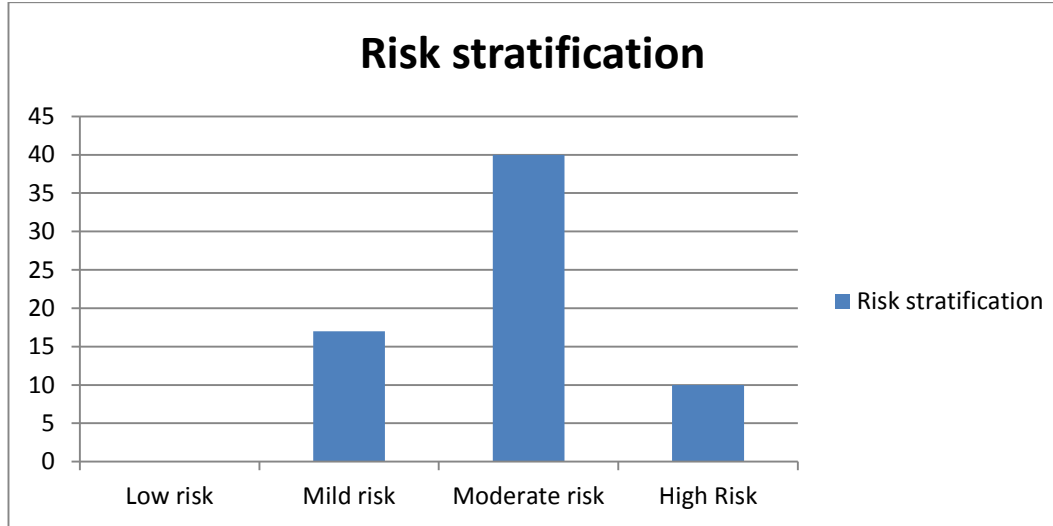
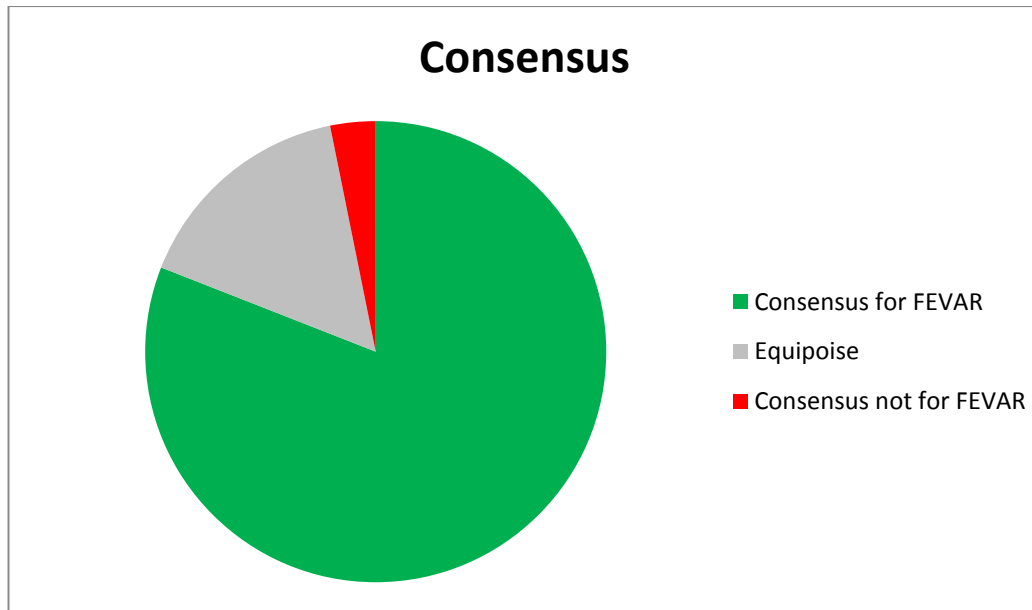


Figure 11.5 shows the percentage of patients whose management decisions concurred with the consensus statement. 80.9% of patients were independently managed as recommended by the consensus panel. Only 2 patients (2.4%) had FEVAR against the recommendation of the consensus group and 16.7% of patients fell into the area of equipoise.

Figure 11.5*Table 11.1**Peri-operative data*

	Appropriate by consensus N=68	Inappropriate by consensus N=2	Equipoise by consensus N=14	P value
30 day Mortality	N=6	N=0	N=0	0.042
Mortality at 6 months	N=10	N=0	N=0	0.02
Mortality at 12 months	N=10	N=0	N=0	0.02
Median LOS ITU (days)	3	1	4	0.45
Median total LOS (days)	10	8	9.5	0.20
Cardiac morbidity (%)	18.8	0	11.1	0.031
Renal complication (%)	22.9	0	11.1	0.022
Renal support (Dialysis/haemofiltration)	20.8	0	11.1	0.028

11.4 Discussion

In this paper we have attempted to determine the reliability and validity of the consensus statement regarding the indications for FEVAR. Although we have demonstrated good reliability, with agreement by independent clinicians of over 80%, we failed to demonstrate the validity of the study.

Only two patients underwent intervention against the recommendations of the FEVAR consensus statement. This is clearly too small a cohort to draw any meaningful conclusion. However, this does demonstrate one of the most controversial areas of FEVAR. Both these patients were young (age <74), with aneurysms that were relatively straight forward for open repair and had few co-morbidities. Neither patients suffered any complication and both had short hospital stays; at present there is no data for the longevity of these grafts and both these patients had a good life expectancy. Longevity for standard grafts used in open repair has been demonstrated and it is anticipated that the graft would outlast the patients. Early standard EVAR grafts showed many long term issues and this has led to significant improvements in design and the materials used. All initial grafts have been superseded by superior designs which have improved their longevity. Until long term data is available for FEVAR, many physicians

are reluctant to place a fenestrated graft into a young patient who is perceived to be a low risk for open repair.

Although we demonstrated good reliability, this may be a reflection of the small numbers of clinicians with significant experience with FEVAR. Many operators were trained from the same background with the same trainers. The good reliability may therefore be a reflection of the limited evidence base. However most decisions were made in a multi-disciplinary team setting consisting of vascular surgeons, interventional radiologists and intensivists. It is likely therefore that this is a true reflection of perceived current best practise.

One of the weaknesses of this study is the subjective nature of the risk stratification category. When defining the risk categories during the consensus process, it was decided that it should be left to the individual clinician to categorise the patient risk based on the standard investigations that they perform at their own institution. However, we categorised the patients for this validation study, we used criteria from our institution. This may not always have concurred with the same categorisation strategies of other institutions.

The threshold of benefit has also not been clarified by this study. This again relates to the previous argument that the most unclear management is that of the young patient

with few co-morbidities who would be a low risk candidate for open repair. However, just because the consensus opinion states that FEVAR is inappropriate, this does not indicate the best alternative management. A period of conservative management may be more appropriate than open repair in some scenarios.

In conclusion, a consensus statement is a validated tool for working towards guidelines for a new technology/treatment in an area of limited evidence. Although we have shown the statement produced on the indications for FEVAR to be reliable, we have been unable to prove its validity. This is a reflection of the lack of long term evidence for FEVAR and indicates the need for further studies.

Part 4

Conclusion

Chapter 12

Discussion and conclusion

Discussion and conclusion

12.1 Discussion

Surgery for abdominal aortic aneurismal disease is traditionally considered high risk. High morbidity and mortality rates had previously ensured it was reserved only for fit patients. Endovascular interventions that are associated with lower peri-operative major complications have been met with great enthusiasm. EVAR has revolutionised aneurysm management.

The aim of this thesis is to determine whether all abdominal aortic aneurysms should be treated endovascularly. A literature review detailed the history and current evidence for standard EVAR. Level one evidence shows significant advantages of endovascular repair compared to open repair.

However, as use of EVAR has increased, boundaries have been pushed; analysis of the EUROSTAR database found that use of EVAR outside manufacturer's instructions for use is associated with a significant risk of aneurysm related mortality and type 1 endoleak.

Recent advances have seen the evolution of fenestrated endografts from standard EVAR to enable endovascular repair of those aneurysms with a compromised proximal neck. Fenestrated grafts are typically required for juxta/para-renal aneurysms with narrower visceral aortic diameters whereas the larger aortic diameter at the visceral segment seen in thoraco-abdominal aneurysms generally require a branched graft. Endovascular repair of juxta/para and supra-renal aneurysms is now possible.

However, although avoidance of aortic cross clamping and associated haemodynamic insult is an attractive option, there are still significant issues surrounding complex endovascular repair. These complex aneurysms often require technically difficult endovascular procedures with long operating times and a significant intra-operative blood loss; evidence base is currently limited and long term durability is untested.

The meta-analysis of current evidence for fenestrated endografts found evidence to be limited to case series only with no randomised controlled trials or level one evidence. The first reported use of a fenestrated graft was by Parks in 1996(29), followed by a series of 13 patients by Anderson(49) in 2001. Similar to EVAR, early prototypes were often 'home made' and predisposed to complications.

In Europe several case series have been reported, often with a mix of indications and devices. Chisci et al reported their centres' selected outcomes in patients undergoing

open repair, off license infrarenal EVAR or if high risk FEVAR(105). In the United States two centres are licensed for complex EVAR; Cleveland has the largest FEVAR worldwide experience with 119 patients reported(52) and a further combined series of both branched EVAR and FEVAR of 633 patients(64). However, no trial has been undertaken to compare complex EVAR with open repair. Nordon et al(45) reviewed FEVAR (8 studies, n=368 patients) with historical open repair (12 studies, n=1164 patients), finding a 1.4% versus 3.6% 30 day mortality in favour of FEVAR. The Ontario Health Technology(106) compared 5 FEVAR studies with 7 open studies giving a 1.8% versus 3.1% 30 day mortality in favour of FEVAR and a 12.8% versus 23.7% late mortality in favour of FEVAR.

Not all series have shown an advantage for the endovascular approach. Greenberg(64) did not demonstrate a significant difference in 30 day mortality rate for endovascular repair of thoraco-abdominal aneurysms compared to anatomically matched open repair (5.7% vs 8.3%, P=0.2); the endovascular group however, were an average 9 years older and sicker than the open group. A further review (107) of both fenestrated and branched grafts of 155 patients found a 7.1% 30 day mortality for complex EVAR. A meta-analysis by Jonkind et al(108) of 1256 patients undergoing an open repair involving a suprarenal clamp for a juxta renal aortic (JAA) aneurysm found a perioperative mortality rate of only 2.9% (95% confidence interval [CI], 1.8%-4.6%). Furthermore, operative mortality in the open group might be overestimated; a short neck JAA which is unsuitable for EVAR and would therefore be classified as requiring a

complex endovascular graft may be a straightforward open repair without the need for supra-renal clamping. One aspect missing from analyses to date is the natural history of these “complex AAA”. As the technical boundaries are pushed, results should be compared to the natural history of the untreated aneurysm as many may have non AAA related outcomes.

Previous national registries have provided vital evidence for EVAR outcomes and have been used to set up formal trials. The British Society of Endovascular Therapy has launched Globalstar, a national registry for FEVAR; the early results for FEVAR in juxta renal aneurysms have been published(109); 14 UK centres, having each performed at least 10 complex EAVR submitted data for a retrospective analysis. Data from 318 patients were analysed. Patient cohort was generally high risk with over 55% having an estimated operative mortality of >10%. Mean operating time was 4h 31 min, mean intra-operative blood loss was 807 ml and completion target vessel patency 99.4%. The commonest graft configuration was of two renal fenestrations and a scallop for the SMA (36.1%) and quadruple fenestrations was only performed in 8 (2.5%) patients. Peri-operative mortality was 4.1%, however mortality was significantly higher in grafts extending to the celiac axis compared to those extending to the SMA only. The V-POSSUM (a validated peri-operative mortality score for open repair) was applied to the results. Comparison of the observed 4.1% death rate following FEVAR with the estimated 11% V-POSSUM prediction of open repair gives a risk reduction of 6.9% attributable to FEVAR.

These data to date reflect selection bias and development of an emerging technology. Many cases were undertaken in patients deemed 'unfit' for open repair, reflecting a similar approach to when EVAR started. Our meta-analysis of the current evidence for FEVAR found a 30-day mortality rate of 2.0%. This compares favourably with that of open surgical repair with reported 30-day mortality rates of 2.5- 5.8% (58, 59). Despite the lack of level 1 evidence, FEVAR appears to be a viable alternative to open surgical repair for juxta renal/short neck aneurysms and to offer a favourable mortality rate particularly for high-risk cases.

However, we identified much heterogeneity between case series and patient demographics and indications for use of FEVAR varied. There is no universal definition of juxta-renal/short neck aneurysms in the endovascular setting making comparison of case series difficult. In chapter 6 we presented a new classification system of aortic aneurysms based on the level of the proximal seal zone to allow homogeneity in comparisons and give more accurate results.

Published evidence reports only short to midterm results and there are currently no long term published series. Long term durability is therefore questionable; history tells

us that results which seem favourable initially may fail to show a long term benefit, an example being the 10 year results for EVAR I trial(9).

A recognised complication of complex endovascular aneurysm repair is postoperative renal impairment. This is likely to be multi-factorial, being a combination of contrast induced nephropathy, intra-operative hypotension and micro-emboli following manipulation of the renal arteries. Chapter 7 presents the use of CO₂ as the contrast agent during complex endovascular repair and demonstrates a significant decrease in the need for renal support and contrast use in this cohort of patients. FEVAR is technically challenging and may have a prolonged procedure time. Chapter 8 describes the use of a temporary axilla-bifemoral bypass graft in patients with peripheral vascular disease or an anticipated long procedure time and showed a reduction in morbidity related to reperfusion injury.

Complex endografting requires highly developed endovascular skills and there is an associated steep learning curve; it has been suggested that use should therefore be limited to specialist centres. However, open aneurysm repair performed in specialized centres with high quality intensive peri-operative care may have a much lower complication rate than in earlier reports (110), particularly in selected patients. Late results and durability of open repair are also excellent (111) and benefits of FEVAR in low risk patients are questionable.

FEVAR was initially conceived as a treatment option for patients considered unfit for open repair. The technique has been refined and developed and these grafts are now commonly used in patients suitable for open repair. However, data from standard EVAR questions the validity of this. Although EVAR II study compared only standard EVAR with open repair, the results showed this cohort of patients to have a limited life expectancy and that surgical intervention conferred no survival benefit at a very high economic burden. It is possible then that complex endografting in high-risk patients is also unlikely to confer a survival benefit.

Perversely, a randomised trial for non-ruptured aneurysms (112) found no difference in mortality or major events between open repair and EVAR in patients with low to intermediate risk factors. However, there was a significantly higher re-intervention rate in the EVAR group. These results indicate that open repair is as safe as EVAR and remains a more durable option in low/intermediate risk patients. The same may apply to complex endografts.

Further, the consensus statement on the indications for FEVAR(113) failed to agree on suitability for FEVAR in approximately one third of clinical scenarios. Consensus methodology is a validated technique for defining areas of equipoise that need further research and potential clinical trials. These data were recently presented at the UK

Vascular Society Annual Meeting (2011) and a vote overwhelmingly agreed that a randomised controlled trial for FEVAR was needed. Although this uncertainty indicates a lack of evidence surrounding FEVAR, introduction of any new device is often accompanied by a limited evidence base and learning curve. Consensus methodology can also be used to produce guidelines particularly in areas lacking clinical evidence. The areas of equipoise highlighted require targeted research and indicate potential areas for future trials. However, randomised controlled trials are not always possible or ethical; complex aneurysms represent a small percentage of the total aortic aneurysm cohort and recruitment for a well-run RCT may be problematic, particularly in the face of evolving devices. An alternative would be an observational study based on the Consensus data but relies on inclusion of all cases considered for repair including those turned down.

At present complex endografts must be custom made to individual patient anatomy and device manufacture takes between 6-12 weeks. Clearly this is not an option for the symptomatic/ruptured aneurysm. Although "home-made fenestrated grafts" (26, 27) have been successful for these aneurysms, fabrication should only be undertaken by experienced operators and there are few individuals worldwide who possess these skills.

Scurr et al point out the long term uncertainties of the effect of sac modification and graft movement on the bridging stents (held only by friction forces) leading to

potential compression, stenosis and eventual occlusion(54). Further, morphological modifications may lead to stent disconnection, abrupt re-pressurisation of the aortic sac [Fig 1] and potential rupture. Use then seems paradoxical as a prophylactic procedure in an asymptomatic patient. Conversely, open surgery securely sews in the visceral branches leading to a stable, durable structure.

A meta-analysis of FEVAR(114) found a re-intervention rate at one year of 15%. Longer term rates are unclear. One third of patients in EVAR I trial underwent a secondary intervention which was significantly higher than the open cohort. There is no evidence that these more complex endografts are stable structures and it is likely that long term re-intervention rates will be higher still. Complications involving visceral arteries have a high mortality rate. In our unit series of one hundred fenestrated/branched endografts, two acute SMA/coeliac occlusions led to death despite early and aggressive management.

Questions have also arisen regarding long term durability of the graft material particularly when a large area of aorta is covered. Stent grafts are tested to fulfil ISO 9001 criteria; these require only laboratory device testing to resist a period of ten years. Grafts consisting of two materials, e.g. a polyester body with a metal alloy framework are likely to wear differently to polyester/dacron grafts alone; it may be that constant friction of fabric against a relatively fixed frame leads to faster fabric degradation. Complex endografts have accessory components such as bridging stents,

which are also under constant stress and risk of degradation. Further we do not know the effect of abdominal flexion and extension on the graft. We do know that covered stents used for popliteal aneurysms fair badly to repetitive flexion training and are prone to fracture particularly at the junction segment(115).

Fenestrated grafts are currently excessively expensive (approximately four to six times the price of a standard aorto bi-iliac Dacron graft). The preliminary results of the on-going French medical and economic evaluation of fenestrated and branched stent graft shows that the mean cost of FEVAR for juxta renal aneurysms is over 40,000 Euros at 30 days. This doesn't include potential re-intervention or long-term surveillance costs. Although "off the shelf" devices are predicted to reduce device costs, these are still in development and not currently on the open market. A formal cost-effectiveness analysis is needed to compare costs with open repair; FEVAR is likely to be initially more expensive but savings may be made in reduced ITU or hospital length of stay.

Cheaper, rapidly available endovascular alternatives to FEVAR exist in the form of Chimney grafts using off the shelf devices; reported series are small and follow up is limited. Provisional results however are favourable (116, 117). Emerging device advances include "off-the-shelf" availability of fenestrated and branched endografts. Despite anatomical variation, the majority of renal arteries lie within a predictable region that can be accessed by pivoting fenestrations, rendering them suitable for pre-

fabricated endografts in >80% of cases(118). These “off-the-shelf” devices avoid the current manufacturing delays of between 6-12 weeks and will reduce device costs.

FEVAR can be performed under GA, regional blockade or even local anaesthetic.

Undoubtedly there are benefits to avoiding a general anaesthetic in patients with significant co-morbidities, however this is potentially a very long intervention and not all patients will tolerate it without general anaesthesia.

12.2 Future experiments

1. Cochrane systematic review

- The Cochrane Database of Systematic Reviews is the leading resource for systematic reviews in health care. We have recently co-ordinated a review author team and registered the title with the Cochrane Library for a systematic review of current evidence for fenestrated endografts. Our initial protocol has been submitted to the Cochrane library and study selection and evaluation is underway.

2. Validation of results from the consensus statement against a large database

- Chapter 11 of this thesis was an attempt at validating the results of the consensus statement using a small single centre database with short term follow up only. However we were unable to demonstrate validity because of a lack of long term evidence. Several large national databases have now been setup and will eventually provide long follow up and data for a large number of patients. We plan to interrogate the UK British Society for Endovascular Therapy (BSET) Globalstar database and also the Australian National Vascular Database. Both will provide comprehensive datasets for fenestrated endografts.

3. Submit the results of the consensus statement to NICE (National Institute of Clinical Excellence) to formulate national UK guidelines for the indications for fenestrated endografts

- Consensus methodology is a validated tool used to produce clinical guidelines and has previously been employed by NICE for this purpose. At present guidelines regarding the areas of consensus could be developed,

however further evidence is required for guideline development of the equipoise categories.

4. Future trials

- This thesis has identified where the professional body of opinion lies and defined the grey area of equipoise on the indications for fenestrated endografts. The next step logically therefore is to determine best outcome for patients in the equipoise group. The gold standard for answering this question is a randomised controlled trial (RCT). However, given the heterogeneity of the patient cohort in terms of both physiological and anatomical factors this may not be possible or even ethical. A well run RCT is expensive; fenestrated endografts are already a costly technology and a trial of this nature would be very expensive with potential funding issues. A large national RCT would take time to set up, develop protocols, and gain ethics approval and funding. Graft technology, materials and design are rapidly evolving; it is very likely that technological advances would progress faster than the trial thereby rendering the trial using technologically outdated grafts and the results redundant. A small number of specialists in the UK have the expertise to utilise this technology; selection bias could be a

potential problem with a high crossover rate similar to EVAR II. An alternative, whilst less scientific, could be an observational trial. Data registries, such as the Globalstar registry, can produce valuable data, provided that data collection and follow up is rigorous. Important questions to answer include 30 and 90 day mortality, re-intervention rates, cost benefit analysis, a multidimensional quality of life years analysis (social, physical and psychological outcomes) and return to independent living.

12.3 Conclusion

In conclusion, the technology exists to treat most AAA by endovascular means. Infrarenal EVAR is the accepted normal practice. For those AAA which are outside IFU for EVAR then it is inadvisable to use off label EVAR. Complex endografts are an evolving field; at present current evidence is weak and does not support superiority over open repair. Although short-term results may be promising, long-term durability is untested and further research is required for a definitive answer.

Our hypothesis that all abdominal aortic aneurysms should be effectively treated endovascularly cannot be accepted. Whilst we have shown that technically most aneurysms are suitable for endovascular repair, we cannot conclude that this is

superior to open repair in the long term and have shown that further evidence is required to determine guidelines for patient suitability.

Appendix A

Published chapters from this thesis

Peer Reviewed Journals

1. **Fenestrated endovascular aneurysm repair**
 1. Br J Surg. 2012 Feb; 99(2);152-9 Dec 19.
 2. Chapter 4

2. **Temporary axillo-bifemoral bypass during fenestrated aortic aneurysm repair**
 - J Vasc Surg. 2012 Dec;56(6):1544-8
 - Chapter 8 (revised version published)

3. **Current practise of aneurysm management in the UK**
 - Ann R Coll Engl.2014 Jan;96(1):27-31
 - Chapter 9

4. **Indications for Fenestrated Endovascular Aneurysm Repair**
 - Br J Surg. 2012 Feb;99(2):217-24
 - Chapter 10

5. **Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom**
 - Circulation. 2012 Jun 5;125(22):2707-15
 - Data collected in this thesis was used by the British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry

Book Chapters

1. **“Recent Advances in Endovascular management of Aortic Aneurysms”**
 - “Recent Advances in Surgery 34”
 - Editors: Irving Taylor and Colin Johnson
 - ISBN-13:978-9350253557
 - Chapter 1

2. **Fenestrated and branched EVAR are worthwhile – for the motion**
 - Vascular and Endovascular controversies update
 - 34th Charing Cross Symposium
 - Chapter 12

3. **Fenestrated and branched EVAR are worthwhile – against the motion**
 - Vascular and Endovascular controversies update
 - 34th Charing Cross Symposium
 - Chapter 12

Published abstracts

- 1. Classification of the aortic visceral segment by zones**
International Journal of Surgery 01/2011; 9(7):568-569

- 2. Morbidity following complex EVAR**
International Journal of Surgery 01/2011; 9(7):576

- 3. Use of CO2 angiography for complex endovascular aneurysm repair**
International Journal of Surgery 01/2011; 9(7):495

- 4. Use of CO2 Angiography for Complex Endovascular Aneurysm Repair**
J Vasc Surg Jun 2011, 53(6); 33S

- 5. Use of CO2 angiography for fenestrated endovascular aneurysm repair**
Vascular Society Yearbook 2010

- 6. Endovascular repair of abdominal aortic aneurysms (AAA) outside manufacturer's instructions for use: Infra-renal sealing is not a safe option**
International Journal of Surgery 01/2011; 9(7):499

- 7. Endovascular repair of Abdominal aortic aneurysms (AAA) with short and/or angulated necks: infra-renal sealing is not a safe option**
Vascular Society Yearbook 2010

- 8. First Description Of The Surgeon-Made Fenestrated Graft**
Vascular and Endovascular Issues, Techniques and Horizons, VEITH Symposium 2011

Appendix B

Presentations

Presentations

1. **Endovascular Repair of Abdominal Aortic Aneurysms (AAA) outside manufacturer's Instructions for Use: Infra-renal sealing is not a safe option (Oral)**
European Society of Vascular Surgery Meeting 2011 Athens, Greece

2. **Classification of the Aortic Visceral Segment by zones (Oral)**
Vascular Annual Meeting 2011, Chicago, USA

3. **Use of CO2 angiography for complex endovascular aneurysm repair (Oral poster)**
Vascular Annual Meeting 2011, Chicago, USA

4. **Use of CO2 angiography for complex endovascular aneurysm repair (Oral)**
International Symposium on Endovascular Therapy 2011, Miami, USA

5. **Endovascular repair of abdominal aortic aneurysms (AAA) with short and /or angulated necks : Infra-renal sealing is not a safe option (poster)**
International Symposium on Endovascular Therapy 2011, Miami, USA

6. **Classification of the Aortic Visceral Segment by zones (poster)**
International Symposium on Endovascular Therapy 2011, Miami, USA

7. **There is no consensus in the UK on the role of fenestrated endovascular aortic aneurysm repair (FEVAR): The case for a randomised trial (Oral)**
Vascular Society Conference, Edinburgh 2011

8. **Use of CO2 angiography for complex endovascular aneurysm repair (Oral)**
British Society of Endovascular Therapy, Warwickshire, 2011

9. **Endovascular repair of abdominal aortic aneurysms (AAA) outside manufacturer's Instructions for Use: Infra-renal sealing is not a safe option (Oral)**
British Society of Endovascular Therapy, Warwickshire, 2011

10. **Use of CO2 angiography for complex endovascular aneurysm repair (Oral)**
Association of Surgeons in Training Conference, Sheffield, 2011

11. **Endovascular repair of abdominal aortic aneurysms (AAA) with short and /or angulated necks : Infra-renal sealing is not a safe option (Oral)**
Vascular Society Conference, Brighton, 2010

12. **Use of CO2 angiography for Fenestrated Endovascular Aneurysm Repair (Oral)**
Vascular Society Conference, Brighton, 2010

13. **Use of CO2 angiography for complex endovascular aneurysm repair (Poster)**
Association of Surgeons of Great Britain and Ireland, Bournemouth, 2011

14. **Endovascular repair of abdominal aortic aneurysms (AAA) outside manufacturer's Instructions for Use: Infra-renal sealing is not a safe option (Poster)**
Association of Surgeons of Great Britain and Ireland, Bournemouth, 2011

15. **Classification of the Aortic Visceral Segment by zones (Poster)**
Association of Surgeons in Training Conference, Sheffield, 2011

16. **Morbidity following complex EVAR (Poster)**
Association of Surgeons in Training Conference, Sheffield, 2011

Appendix C

Search methodology for Meta-analysis of Observational studies in Epidemiology

Search methodology for Meta-analysis of Observational studies in Epidemiology

A computer-assisted search was performed in the medical databases Medline (from January 2000 to Dec 2010) and the Cochrane database of systematic reviews, using the keywords “fenestrated endovascular stent graft”, “fenestrated endovascular aneurysm repair”, and “juxta-renal abdominal aortic aneurysm”. An additional extensive search was performed using a combination of the following Medical Subject Heading (MeSH) terms; juxta-renal aortic surgery, fenestrated aneurysm repair, fenestrated stent grafts, type 4 thoraco-abdominal aortic surgery, thoraco-abdominal aneurysms. After identifying relevant titles, the abstracts of these studies were read by two of the authors (JC/TR) to decide if the study was suitable.

Criteria for Inclusion

Clinical studies eligible for inclusion were those that described the use of fenestrated endovascular stent-graft technology for juxta-renal aortic aneurysms.

Eligible articles described original patient series with information of the operative technique, operative time, hospital stay, mortality, complications, conversions and follow up outcomes.

Criteria for exclusion

Small series of less than 10 cases and studies describing the use of predominantly branched endovascular stent-graft technology or use of fenestrated technology in aortic dissections were excluded. Replicate data was also excluded.

Study Quality

Each article selected was appraised and ranked for homogeneity in accordance with the Cochrane centre critical review checklist. The list evaluates the quality of each study using yes / no answers for individual statements.

- Clear definition of the study population
 - Size and type of aneurysm.
 - Patient demographics.
- Can selection bias be excluded and the cohort data analysed on an intention to treat basis.
- Clear description of the surgical technique used, for example scallop and number of fenestrations.
- Clear definition of outcomes and outcome assessments with objective numeric information. Outcome measures included clinical parameters, biochemistry data and radiological imaging.
- Adequate follow up period during duration of patient stay and long term follow up.
- Selective loss to follow up if entire patient cohort information not available
- Confounding and prognostic factors identified

Each study was evaluated further using the Meta-Analysis of Observational Studies in Epidemiology group scoring system (Cochrane analysis tool) using 8 individual criteria scored out of 2 points with a potential maximum score of 16.

- Consecutive study; 0- not reported, 1- not consecutive, 2- consecutive
- Prospective series; 0- not reported, 1- retrospective, 2- prospective
- Report on excluded patients; 0- not reported, 1- number only, 2- number and reason of exclusion
- Surgical indications; 0- not reported, 1- general description- aneurysmal disease, 2- aneurysm morphology, aneurysm size

- Surgical procedures; 0- not reported, 1- total number only, 2- number of each procedure and type of FEVAR graft
- Conversion; 0- not reported, 1- number only, 2- number and reason given
- Morbidity; 0- not reported, 1- number, 2- number and complications
- Mortality; 0- not reported, 1- number, 2- number and cause of death

Study Data

The following data was extracted from each study:

- Number of patients
- Patient demographics – gender, age, co-morbidities and risk prediction scores
- Type of disease and morphology aneurysmal disease
- Anaesthetic technique / monitoring
- Femoral artery access used - open or percutaneous groin insertion
- Operative time
- Radiation time / dose
- Stent-graft type/no of fenestrations/scallops
- Intra-operative complications / conversion to open / technical problems
- Blood loss
- Hospital stay
- Mortality
- Morbidity
 - Ischaemia- need for further intervention
 - Mesenteric
 - Limb
 - Renal
 - Clinical- anuria / oliguria

- Biochemical change
 - Cardiac
 - Spinal
 - Respiratory/other
 - Target vessel loss
 - Endoleak
- Long term follow up and technique

The authors of the included papers were contacted to ensure no duplication of patient entries.

Appendix D

Questionnaire – Audit of current practise

<p>How many years have you been a consultant?</p>		
<p>What is your experience of: -</p>	<p>All AAA</p>	
	<p>Open infra renal AAA</p>	
	<p>Infra renal EVAR</p>	
	<p>Conservative care</p>	
	<p>Open suprarenal AAA</p>	
	<p>Fenestrated EVAR</p>	
	<p>Other (mycotic etc.)</p>	
<p>When considering the options for a patient with an AAA what (factors/attributes) do you take into consideration? For each of these attributes please could you break these down (grade) as much as possible? (i.e. if the attribute is 'size of AAA' the grading would be any different sizes you regard significant in your decision making)</p>		
Empty space for response		

<p>What is your current practice for AAA management</p> <p>If John Smith walks into your clinic with a letter from his GP saying he has an AAA what is your normal management of this patient (open surgery / EVAR / conservative)</p>													
<p>What is your definition of a Juxta renal AAA</p>													
<p>What morphological criteria do you consider acceptable for EVAR</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 30px;"></td><td style="width: 50%;"></td></tr> </table>												
<p>Which endograft do you commonly use</p> <p>Do you use different grafts for different circumstances (please specify)</p>													

What would you consider the indications for fenestrated or branched EVAR?

Appendix E

Consensus Meeting Discussions

FEVAR consensus meeting UCLH

August 31st 2010

Minutes of meeting

10.30 Introduction – Geoff Bellingham (medical Director)

Peter Harris – Overview of the day

10.45 Literature review on current evidence for FEVAR – Jane Cross

11.00 Review of Current Practise – results of pre-consensus questionnaire – Toby Richards

Discussion:

- Morphology of aneurysm is a predictor of outcome
- We do not know what happens to the patients who are turned down for intervention
 - GP asked to palliate
 - Do not know if they die from their rupture or other pathology
 - Actual rupture rates
- Paper from Edinburgh – Rod Chalvers – Series of thoraco-abdominal aneurysms – approx. 120 type IV turned down for surgery as unfit – approx. 70% had aortic related deaths at 2 years
- What happens to people who are turned down for FEVAR on the basis of funding?

11.15 How a consensus works – Harry Hemingway

Discussion:

- The knowledge distilled from the expert panel of the consensus is better than the ubiquitous practise of the general clinicians
- Selection of the panel - ? bias by panel members
- Should the panel consist of a wide cross section of specialists or be confined to those with a knowledge of FEVAR
- Delphi – needs a balanced group of nine
 - ? 3 general vascular surgeons/3 vascular surgeons with an interest in EVAR/3 experts in FEVAR

11.30 Consensus discussion – defining clinical attributes

Proposed clinical attribute groups for aneurysm management are:

- **Aneurysm size**
 - Consensus reached that this should be an attribute
- **Patient age/life expectancy**
 - Agreed that life expectancy should be considered in fitness for surgery attribute
 - Consensus reached that Patient age should be a clinical attribute
- **Fitness for surgery/co-morbidities/life expectancy**
 - When assessing fitness for surgery many aspects of “fitness” are taken into account, not just one
 - EVAR II – fitness defined locally in the institution
 - Showed that physicians with no guidelines were good at picking out unfit patients
 - Subjective impressions of patients are fairly accurate
 - All the aneurysm trials to date show that the subjective impression of the physician is the best assessment and better than an scoring systems
 - The purchasers only care about outcome at 1 year – is this better than if they hadn’t had the procedure?
 - What is the benefit of the procedure?
 - Without risk prediction models it is difficult to see how we can move forward
 - Should we make the attribute fitness for open surgery?
 - Feasibility of grading system 1-4 to define fitness
 - What is the definition of fitness
 - Need to use the word risk
 - Assessing the risk of an open procedure is assessing the risk for a procedure that is not required in this case
 - Co-morbidity scores – the difference between consensus and what happens in real life for example -a particular PCT will only consider an aneurysm if the vPOSSUM score is attached regardless of whether the clinician is actually going to use the score
 - Assumption that the risk of EVAR is less but not proved with FEVAR
 - Wording of the co-morbidity/risk category not agreed
- **Aneurysm Morphology**
 - Consensus reached that this should be an attribute
- **Hostile abdomen**
 - Obesity/redo surgery/UML +/- stoma

- All agreed that this is a special case and should be a separate attribute

A) Discussing regarding aneurysm size

- All agreed that all aneurysms under 5.5cm in men should be managed conservatively unless there are exceptional circumstances such as extremely young age
- Some women may be treated under 5.5cm
- Aneurysms >8cm are less likely to be managed with a FEVAR as the rupture risk is approx. 50% per annum and so the risk of leaving the aneurysm for 3 months while the graft is made is not acceptable
- Kronenberg paper stratifies rupture risk against size
- EVAR 2 trial showed the median rupture size was 6.5cm
- Supra-renal aneurysm repair is a high risk procedure – at 7cm the rupture risk is approx. 20% which is generally higher than the operative risk
- Consensus reached that size should be:
 - <5.5cm
 - 5.5-6.0
 - 6.1-7.9
 - >8.0cm

B) Discussion regarding Age

- Mortality for 80 yr. olds is getting better by 1% per year
- At aged 80 the average man has a 13 yr. life expectancy
- However aneurysm population is not the average population – it is a marker for cardiac disease and they are often smokers
- Consensus reached that age should be:
 - <65
 - 66-74
 - 75-84
 - >85

13.30 Consensus and Basil Trial – Donald Adam

Discussion:

- Importance of who the “experts “ on the panel are
- Importance of global clinical assessment and who is making that decision i.e. radiologists are not usually involved in the physical assessment. Clinician in clinic are the ones who make the decisions – radiologists make decisions re technical feasibility
- Should radiologists be on the panel?

- Should be combination of technical and clinical info
- Patient's wishes
- For vignettes - assume that patients are keen to be treated and has no strong opinions on either treatment
- Cannot change what you do for the purpose of the consensus
- ?could have surgeon and radiologists sitting together and fill in vignettes
- ?role of panel members who have no experience of FEVAR
- Established senior members who have >decade of both open/EVAR, Young group of dual trained, Established DGH general vascular surgeons who have some experience of EVAR but most experience of open
- Option of referral/consideration to FEVAR expert
- FEVAR experts will have differing views on people with little experience of FEVAR
- Methodology of ways to improve agreement between surgeons/radiologists

C) Discussion – Fitness for surgery

- Agreement between first 2 attributes
- Should be leave it up to the individual decision as to what is high and low risk
- Should we have a scoring system/estimated mortality risk – should we use this as a guide?
- Impossible to define objectively
- ?can define when we do the retrospective study
- 1/3/4 system disorder
- ? risk of creating a new scoring system
- How should we grade these?
- Use of estimated possum mortality
- Use low /med/ high risk
- Low<5%, moderate 5-10%, high >10% mortality risk
- Simple gradation based on clinical assessment
- Add in group – considered unfit for open repair
- If patient unfit for open repair should they be referred for FEVAR
- Ethically immoral to withhold EVAR from patients who are not fit for open

Fitness after pre-operative assessment

- Agreement that should classify according to risk
 - 1.No PMH, fit and healthy
 - Mort<5%
 - ASA 1
 - No SOBOE

- No renal /cardiac/resp dysfunction
- 2. Some PMH that does not limit activity of daily living
 - Mort 5-10%
 - ASA2
 - SOB 2 flights of stairs
- 3. Illness that limits ADL
 - Mort >10%
 - ASA3
 - SOBOE – some stairs
- 4. Housebound by comorbidities
 - ASA4
 - Not for open surgery

Classification of the visceral aorta by zones – Dominic Simring

D) Discussion - EVAR Morphology

- Long infra-renal neck, no disease, straight – all agreed – Can do EVAR
- No infra-renal neck, - only endovascular option as fenestrated
- Assume undiseased renals and position is such that fenestration is possible
- Assume that iliacs are suitable
- Are all fenestrations equal?
- Does no of fenestrations affect the decision making?
- Many confounding variables so need a simple grading system
- ? possible to have a morphological classification that applies to both open and FEVAR
- Majority of fenestrations are 2 fen and a scallop
- For purposes of a vignette must be told that this patients is suitable for FEVAR
- If multiple vessels need to be revascularised i.e. > 2 then difficulty of procedure increases significantly
- There will be a range of opinions of the panel as to what is anatomically suitable for FEVAR
- What constitutes an adequate infra-renal neck
- Idea of contact zone being greater than 10mm – use cone of conical neck as part of contact zone
- Aneurysm that has a sufficient neck that allows you to put in the device of your choice
- IFU that meets the grafts that are on the market
- Don't need a consensus for standard EVAR – level 1 evidence for this
- If have a neck that falls outside the recommendations of the IFU – many people who do not have access to FEVAR are still treating these with EVAR
- Shouldn't have within IFU in the consensus

- Group1 EVAR within IFU guidelines – everyone will agree on this and so ?should be taken out of Vignettes – to be discussed with HH
 - Group2 EVAR is possible but it's outside the IFU recommendations, - conical, neck 10-15mm, angulation60-90' FEVAR possible
 - Group3 Infra-renal EVAR not possible – Neck <5mm, angulation>90', swan neck – can still do open repair and FEVAR possible, but can do open infra-renal clamp
 - Group 4 All 4 vessels need revascularising, surgery requires visceral rotation, needs supra-renal clamp FEVAR technically possible
 - Group 5
- If someone in their 80's, may be more likely to accept neck outside into IFU and do standard EVAR
 - Discussion stimulated by direct threat to FEVAR funding
 - Need for level 1 evidence
 - Retrospective study being set up by BSET
 - National initiative for prospective study
 - Assume that there will be a clear group of patients that the consensus is that these patients need FEVAR
 - Then define grey area – not agreed at consensus – area needing further study
 - Put this evidence to the DOH to fund further studies
 - HH has expertise in Cohort studies
 - ? feasibility of RCT
 - If cohort study – issue of identifying comparison group

1510 The problem of comparator groups – John Brennan

Discussion:

- Paper from Torbay re CPEX and outcome/long term survival
- Used on ITU – helps in making decision process re if they have a complication should they have long term ventilation
- Data shows if they have a bad CPEX result – pre-op intervention does not improve it
- Range of CPEX data – we know helps prediction results from open repair
- Not a lot of data re CPEX and aneurysm surgery
- Improve trial
- RCT – small numbers - ? possible to recruit enough patients for power calculation
- Should FEVAR be confined to specialist centres
 - What makes a specialist FEVAR centre
 - Volume of surgery

- Mortality rates
- Established FEVAR centres at present in UK and must persuade the DOH to continue funding of these centres
- Need for better evidence
- RCT – may never produce the answer in the real world – based on Georges paper – would need huge numbers to fulfil power calculation
- RCT may need to be worldwide to recruit enough numbers – due to cost would mean only countries with socialised medicine would be interested
- Feasibility of valid studies without RCT – where do we identify a comparative group
- Possibility of identifying within the NVD a cohort of similar anatomical open patients
- % of cases needing supra-renal clamp
- Go to PCT with a well-defined group of patients who we feel would definitely benefit from FEVAR
- 15% mortality if clamp above renal – in recent hospital audit of consensus group member
- NVD –last report 120 requiring supra-renal clamp – need to get the mortality of these
- Need to prospectively collect data on supra-renal clamping – help us to determine a comparison group
- As a group – need to put in a proposal to the vascular society for a prospective audit of supra-renal clamps – problem is that these will be a fit group of people and so this will skew the mortality rate
- What is the mort risk associated today with open and FEVAR
- Given other available options – probably find that the mort rate for open AAA has come down because now only operating on fit patients
- Identify group that don't get a repair
- NCEPOD – data of supra-renal clamps
- Current renal injury study

1545 The BSET prospective study on FEVAR - Rao Vallabhaneni

- Collaborative project
- Broad remit – to include everything other than standard infra-renal
- First stage – fenestrated grafts
- Collects pragmatic results
- All data is shared – all collaborators will have equal access
- First stage is retrospective data collection regarding FEVAR
- Positive response from all centres
- Small dataset to encourage compliance and allow risk stratification – used vPOSSUM as
this is the simplest to fill in a retrospective study

- Data capture by online electronic system
- Data analysis and presentation – available to all collaborators
- Due to start in the next few weeks
- Stage 2 – concurrent non randomised control
- Same centres
- Use anatomical criteria
- Calculated that need to recruit minimum of 98 supra-renal – i.e. can do a fenestrated but did not get a fenestrated procedure
- Stage 3 – concurrent, prospective, non-randomised, prospective data collection
- Will need patient consent for their data to be “warehoused”
- Should include best medical treatment group

Discussion

- Anatomical parameters not included
- Need to define 30 day mortality, major complications and 30 day target vessel patency
- Need to start simply – need to persuade DOH that this is a great technique for a certain group of patients
- Consensus is very important process to run alongside the prospective study
- Aneurysm morphology to be tackled over next stages of study
- Data set kept simple to overcome research storage issue
- Retrospective going back from Sept 2010
- Should also be inputting current data from now in a retrospective manner
- Will see software bugs and will need some time to iron out the glitches
- Should start including more complex data and also aneurysm morphology in the prospective data
- The retrospective audit should be presented as soon as possible to complete the audit cycle
- We now have a numbers of centres who are pushing this technology
- Approx. 300 cases/year in the UK
- If consensus exercise produces?30% of cases that it is very obvious that FEVAR is beneficial, how are we going to proceed with the remain grey area?
- Prospective study
- Certain PCT have not paid for FEVAR – need for research funding

Next Steps

- Chapters will be based on clinical attributes as discussed – assume none of these have a hostile abdomen

- Separate chapter for hostile abdomen
- To discuss with HH re taking out aneurysms of <5.5cm and EVAR within IFU recommendations
- Next meeting Tues 19th October
- Need to broaden panel

Appendix F

Guidance notes for aneurysm survey

Guidance notes for aneurysm survey

- Assume that all aneurysms are anatomically suitable for FEVAR

- Assume that all access vessels are adequate.

- Co-morbidities/risk
 - This is a subjective scale that you the assessor need to divide into 4 categories of low / mild / moderate / high risk patients for open surgical repair (as you do normally by whatever means you use in your clinic)

- Sizing of the aneurysm should be as if you have sized in your hospital and has been done using the technique that you feel most reliable

- Possible management options are:
 - Open Surgery
 - EVAR
 - FEVAR
 - Conservative Management

- We have not included aneurysms less than 5.5cm or type A morphology.
 - The consensus opinion is that aneurysms of less than 5.5cm should be managed conservatively except in exceptional circumstances.
 - The consensus opinion is that type A morphology does not need a fenestrated graft.

Categories

A) Age in years: less than 65
 65-74
 75-84
 more than or equal to 85

B) Aneurysm size in cm: <5.5
 5.5-6.0
 6.1-7.9
 >8cm

C) Co-morbidities/risk of surgery (after pre-op assessment and optimisation):

- a) **Low risk** (no significant PMH, <5% mortality risk of surgery)
- b) **Mild Risk** (some mild co-morbidities or reduced exercise tolerance or 5-10% mortality risk of open surgery)
- c) **Moderate Risk** (Some significant co-morbidities etc or > 10% open mortality risk)
- d) **High Risk** (house bound etc unfit for open)

D) AAA Morphology

Type A aneurysm - AAA with long infra-renal neck that is suitable for EVAR by manufacturers guidelines of the graft of your choice

Type B aneurysm - AAA that lies outside manufactures IFU but in your opinion EVAR is feasible (may be conical, thrombus lined, short neck angulated etc). Technically suitable for standard open repair involving an infra-renal clamp

Type C aneurysm - Standard EVAR not feasible but infra-renal clamp possible, abutting but below renals or suitable for a fenestrated graft

Type D aneurysm - AAA where, if open, suprarenal clamp necessary or double fenestrated EVAR

Type E aneurysm – Supra-renal/ Type IV AAA or AAA that requires supra-coeliac clamp/medial visceral rotation +/- reconstruction of renal/visceral arteries or 4 fenestrations / branches

Appendix G

Results Round 1

Aneurysm Survey Results

Please [click on the tab export to excel this](#), will export all the labels and values into an excel

A) Age less than 65 years

A male aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. He is categorised as low risk for surgery.	Response Percent	Response Total
Standard EVAR ■	4.8%	1
Open aneurysm repair ■	90.5%	19
Fenestrated EVAR ■	4.8%	1
Conservative management	0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		

A female aged less than 65 years presents with a 5.5-6.0 cm type C aneurysm. She is a low risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair ■	90.5%	19
Fenestrated EVAR ■	9.5%	2
Conservative management	0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		

A male aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. He is a low risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair ■	66.7%	14
Fenestrated EVAR ■	28.6%	6
Conservative management ■	4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		

A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		33.3%	7
Fenestrated EVAR		38.1%	8
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		23.8%	5
Open aneurysm repair		61.9%	13
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		28.6%	6
Open aneurysm repair		61.9%	13
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A female aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		60%	12
Fenestrated EVAR		40%	8
Conservative management		0%	0
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			

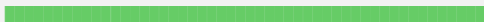


A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			33.3%	7
Fenestrated EVAR			42.9%	9
Conservative management			23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				



A male aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. He is a moderate risk category patient.			Response Percent	Response Total
Standard EVAR			52.4%	11
Open aneurysm repair			33.3%	7
Fenestrated EVAR			14.3%	3
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				


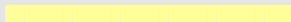
A female aged less than 65 years presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			23.8%	5
Fenestrated EVAR			76.2%	16
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				

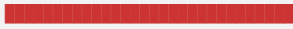
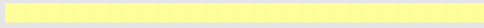
A female aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			9.5%	2
Fenestrated EVAR			90.5%	19
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				


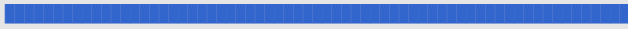

A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		14.3%	3
Fenestrated EVAR		61.9%	13
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A male aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

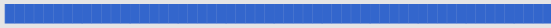

A female aged less than 65 years presents with a 5.5-6.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


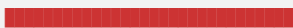
A female aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		61.9%	13
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

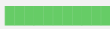


A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		38.1%	8
Conservative management		61.9%	13
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


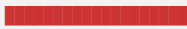
A male aged less than 65 years presents with a 6.1-7.9 cm type B aneurysm. He is categorised as low risk for surgery		Response Percent	Response Total
Standard EVAR		9.5%	2
Open aneurysm repair		81%	17
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A female aged less than 65 years presents with a 6.1-7.9 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		85.7%	18
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		71.4%	15
Fenestrated EVAR		28.6%	6
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		61.9%	13
Fenestrated EVAR		38.1%	8
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a 6.1-7.9 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		14.3%	3
Open aneurysm repair		71.4%	15
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a 6.1-7.9 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		76.2%	16
Fenestrated EVAR		23.8%	5
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A female aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		42.9%	9
Fenestrated EVAR		57.1%	12
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		38.1%	8
Fenestrated EVAR		57.1%	12
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A male aged less than 65 years presents with a 6.1-7.9 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		19%	4
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A female aged less than 65 years presents with a 6.1-7.9 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		23.8%	5
Fenestrated EVAR		76.2%	16
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


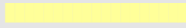
A female aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. She is categorised moderate risk of surgery		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		14.3%	3
Fenestrated EVAR		85.7%	18
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		85.7%	18
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A male aged less than 65 years presents with a 6.1-7.9 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		71.4%	15
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

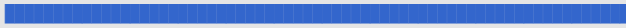
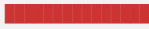
A female aged less than 65 years presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		85.7%	18
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a >8.0 cm type B aneurysm. He is categorised as low risk for surgery		Response Percent	Response Total
Standard EVAR		14.3%	3
Open aneurysm repair		85.7%	18
Fenestrated EVAR		0%	0
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a >8.0 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		90.5%	19
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a >8.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		81%	17
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a >8.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		61.9%	13
Fenestrated EVAR		38.1%	8
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A female aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		33.3%	7
Open aneurysm repair		52.4%	11
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a >8.0 cm type C aneurysm. He is categorised as mild risk for surgery		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		81%	17
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



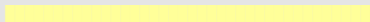
A male aged less than 65 years presents with a >8.0 cm type D aneurysm. He is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		71.4%	15
Fenestrated EVAR		28.6%	6
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			28.6%	6
Fenestrated EVAR			47.6%	10
Conservative management			23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				



A male aged less than 65 years presents with a >8.0 cm type B aneurysm. He is a moderate risk category patient.			Response Percent	Response Total
Standard EVAR			42.9%	9
Open aneurysm repair			28.6%	6
Fenestrated EVAR			28.6%	6
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				



A female aged less than 65 years presents with a >8.0 cm type C aneurysm. She is categorised moderate risk for surgery			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			28.6%	6
Fenestrated EVAR			71.4%	15
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				


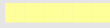
A female aged less than 65 years presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			19%	4
Fenestrated EVAR			81%	17
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				

A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		42.9%	9
Conservative management		47.6%	10
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


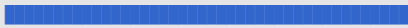

A male aged less than 65 years presents with a >8.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		0%	0
Fenestrated EVAR		23.8%	5
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A female aged less than 65 years presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

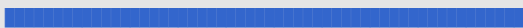


A female aged less than 65 years presents with a >8.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A male aged less than 65 years presents with a >8.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		85.7%	18
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

B Age 66-74 years

A man (age range 66-74 years) presents with a 5.5-6.0 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		38.1%	8
Open aneurysm repair		52.4%	11
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. She is a low risk category patient		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		76.2%	16
Fenestrated EVAR		23.8%	5
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		66.7%	14
Fenestrated EVAR		28.6%	6
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

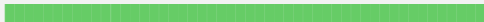



A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		47.6%	10
Fenestrated EVAR		52.4%	11
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A lady (age range 66-74 years) presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		42.9%	9
Open aneurysm repair		42.9%	9
Fenestrated EVAR		9.5%	2
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A man (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		52.4%	11
Fenestrated EVAR		42.9%	9
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

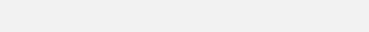
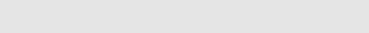


A man (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. He is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		52.4%	11
Fenestrated EVAR		38.1%	8
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

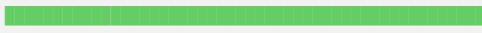
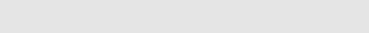


A man (age range 66-74 years) presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		57.1%	12
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

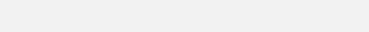
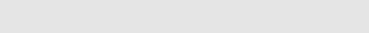


A man (age range 66-74 years) presents with a 5.5-6.0 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		4.8%	1
Fenestrated EVAR		28.6%	6
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

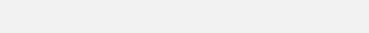
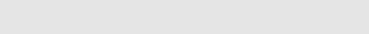
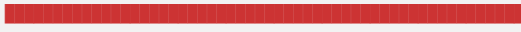
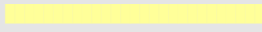
A lady (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		81%	17
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

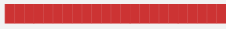

A lady (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		85.7%	18
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 66-74 years) presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		47.6%	10
Conservative management		52.4%	11
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


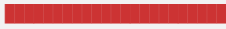
A man (age range 66-74 years) presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		0%	0
Fenestrated EVAR		9.5%	2
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

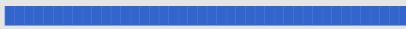

A lady (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		71.4%	15
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		66.7%	14
Conservative management		33.3%	7
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a 5.5-6.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		28.6%	6
Conservative management		71.4%	15
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a 6.1-7.9 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		23.8%	5
Open aneurysm repair		66.7%	14
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a 6.1-7.9 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		71.4%	15
Fenestrated EVAR		28.6%	6
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


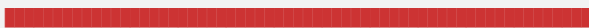
A man (age range 66-74 years) presents with a 6.1-7.9 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		52.4%	11
Fenestrated EVAR		47.6%	10
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

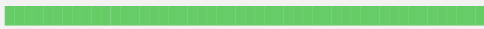


A man (age range 66-74 years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		33.3%	7
Fenestrated EVAR		66.7%	14
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A man (age range 66-74 years) presents with a 6.1-7.9 cm type B aneurysm. He is categorised mild risk for surgery		Response Percent	Response Total
Standard EVAR		33.3%	7
Open aneurysm repair		47.6%	10
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


A man (age range 66-74 years) presents with a 6.1-7.9 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		61.9%	13
Fenestrated EVAR		38.1%	8
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (age range 66-74 years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		33.3%	7
Fenestrated EVAR		66.7%	14
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 66-74 years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		23.8%	5
Fenestrated EVAR		76.2%	16
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


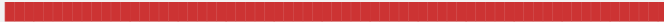

A man (age range 66-74 years) presents with a 6.1-7.9 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		4.8%	1
Fenestrated EVAR		33.3%	7
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (age range 66-74 years) presents with a 6.1-7.9 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		95.2%	20
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


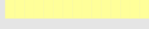
A lady (age range 66-74 years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		100%	21
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 66-74 years) presents with a 6.1-7.9 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		95.2%	20
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A male aged less than 65 years presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		57.1%	12
Open aneurysm repair		0%	0
Fenestrated EVAR		14.3%	3
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (age range 66-74 years) presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		4.8%	1
Open aneurysm repair		0%	0
Fenestrated EVAR		85.7%	18
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a 6.1-7.9 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		81%	17
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		23.8%	5
Open aneurysm repair		66.7%	14
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a >8.0 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		76.2%	16
Fenestrated EVAR		23.8%	5
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		66.7%	14
Fenestrated EVAR		33.3%	7
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		42.9%	9
Fenestrated EVAR		57.1%	12
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a >8.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		28.6%	6
Open aneurysm repair		52.4%	11
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		66.7%	14
Fenestrated EVAR		33.3%	7
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a >8.0 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		47.6%	10
Fenestrated EVAR		52.4%	11
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		38.1%	8
Fenestrated EVAR		61.9%	13
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 66-74 years) presents with a >8.0 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		57.1%	12
Open aneurysm repair		14.3%	3
Fenestrated EVAR		28.6%	6
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a >8.0 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		19%	4
Fenestrated EVAR		81%	17
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 66-74 years) presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		95.2%	20
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


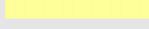
A man (age range 66-74 years) presents with a >8.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		90.5%	19
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

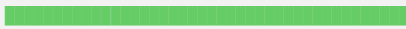



A man (age range 66-74 years) presents with a >8.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		76.2%	16
Open aneurysm repair		0%	0
Fenestrated EVAR		14.3%	3
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

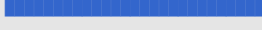


A lady (age range 66-74 years) presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A lady (age range 66-74 years) presents with a >8.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

C) Age 75-84 years

A man (age range 66-74 years) presents with a >8.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		81%	17
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a 5.5-6.0 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		52.4%	11
Open aneurysm repair		38.1%	8
Fenestrated EVAR		4.8%	1
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		33.3%	7
Fenestrated EVAR		47.6%	10
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


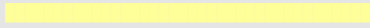
A man (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		14.3%	3
Fenestrated EVAR		57.1%	12
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




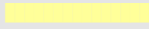
A man (age range 75-84years) presents with a 5.5-6.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		14.3%	3
Fenestrated EVAR		38.1%	8
Conservative management		47.6%	10
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



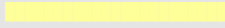
A lady (age range 75-84years) presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		14.3%	3
Fenestrated EVAR		9.5%	2
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


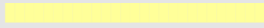
A man (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		19%	4
Fenestrated EVAR		61.9%	13
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

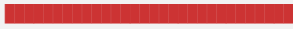
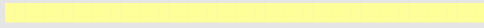
A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised mild risk for surgery		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		66.7%	14
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 75-84years) presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.		
	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	52.4%	11
Conservative management 	47.6%	10
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		

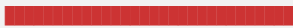
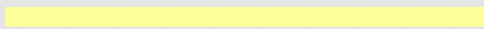
A man (age range 75-84years) presents with a 5.5-6.0 cm type B aneurysm. He is a moderate risk category patient.		
	Response Percent	Response Total
Standard EVAR 	66.7%	14
Open aneurysm repair 	4.8%	1
Fenestrated EVAR 	9.5%	2
Conservative management 	19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		


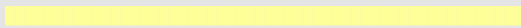
A lady (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery		
	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair 	4.8%	1
Fenestrated EVAR 	66.7%	14
Conservative management 	28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		


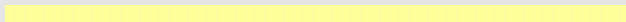
A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.		
	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	66.7%	14
Conservative management 	33.3%	7
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		




A man (age range 75-84years) presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		38.1%	8
Conservative management		61.9%	13
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A man (age range 75-84years) presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		42.9%	9
Open aneurysm repair		0%	0
Fenestrated EVAR		4.8%	1
Conservative management		52.4%	11
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		38.1%	8
Conservative management		61.9%	13
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		33.3%	7
Conservative management		66.7%	14
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a 5.5-6.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		81%	17
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a 6.1-7.9 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		57.1%	12
Open aneurysm repair		33.3%	7
Fenestrated EVAR		9.5%	2
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 75-84years) presents with a 6.1-7.9 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		47.6%	10
Fenestrated EVAR		52.4%	11
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 75-84years) presents with a 6.1-7.9 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		33.3%	7
Fenestrated EVAR		66.7%	14
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 75-84years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		23.8%	5
Fenestrated EVAR		71.4%	15
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (age range 75-84years) presents with a 6.1-7.9 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		19%	4
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


A man (age range 75-84years) presents with a 6.1-7.9 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		4.8%	1
Open aneurysm repair		23.8%	5
Fenestrated EVAR		71.4%	15
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

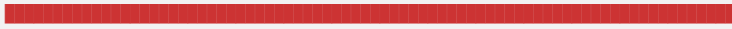

A lady (age range 75-84years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		90.5%	19
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


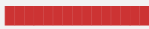
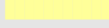
A man (age range 75-84years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		85.7%	18
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


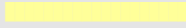
A man (age range 75-84years) presents with a 6.1-7.9 cm type B aneurysm. He is a moderate risk category patient..		Response Percent	Response Total
Standard EVAR		76.2%	16
Open aneurysm repair		4.8%	1
Fenestrated EVAR		19%	4
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


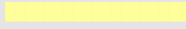
A lady (age range 75-84years) presents with a 6.1-7.9 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		95.2%	20
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

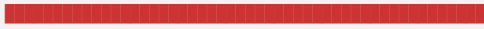

A lady (age range 75-84years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		100%	21
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

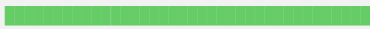


A man (age range 75-84years) presents with a 6.1-7.9 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		95%	19
Conservative management		5%	1
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			




A man (age range 75-84years) presents with a 6.1-7.9 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

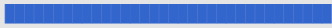
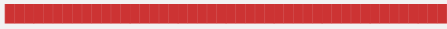
A lady (age range 75-84years) presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 75-84years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a 6.1-7.9 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		61.9%	13
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a >8.0 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		47.6%	10
Open aneurysm repair		38.1%	8
Fenestrated EVAR		14.3%	3
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (age range 75-84years) presents with a >8.0 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		4.8%	1
Open aneurysm repair		47.6%	10
Fenestrated EVAR		47.6%	10
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 75-84years) presents with a >8.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		42.9%	9
Fenestrated EVAR		57.1%	12
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			




A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is categorised low risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			28.6%	6
Fenestrated EVAR			66.7%	14
Conservative management			4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				



A lady (age range 75-84years) presents with a >8.0 cm type B aneurysm. She is categorised mild risk for surgery.			Response Percent	Response Total
Standard EVAR			66.7%	14
Open aneurysm repair			14.3%	3
Fenestrated EVAR			19%	4
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				


A man (age range 75-84years) presents with a >8.0 cm type C aneurysm. He is categorised as mild risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			33.3%	7
Fenestrated EVAR			66.7%	14
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				



A lady (age range 75-84years) presents with a >8.0 cm type D aneurysm. She is categorised mild risk for surgery.			Response Percent	Response Total
Standard EVAR			0%	0
Open aneurysm repair			14.3%	3
Fenestrated EVAR			85.7%	18
Conservative management			0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.				


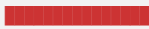
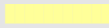
A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		85.7%	18
Conservative management		4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


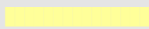
A man (age range 75-84years) presents with a >8.0 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		9.5%	2
Fenestrated EVAR		23.8%	5
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


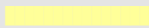
A lady (age range 75-84years) presents with a >8.0 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		90.5%	19
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

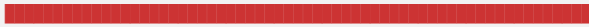

A lady (age range 75-84years) presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		100%	21
Conservative management		0%	0
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		90.5%	19
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



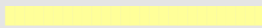
A man (age range 75-84years) presents with a >8.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



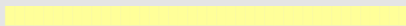
A lady (age range 75-84years) presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		81%	17
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


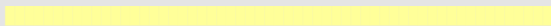
A lady (age range 75-84years) presents with a >8.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		81%	17
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

D) Age > or = 85 years

A man (85 years or over) presents with a 5.5-6.0 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		61.9%	13
Open aneurysm repair		4.8%	1
Fenestrated EVAR		0%	0
Conservative management		33.3%	7
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (85 years or over) presents with a 5.5-6.0 cm type C aneurysm. She is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		42.9%	9
Conservative management		52.4%	11
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


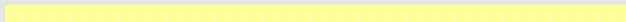
A man (85 years or over) presents with a 5.5-6.0 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		28.6%	6
Conservative management		71.4%	15
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



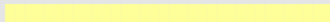
A man (85 years or over) presents with a 5.5-6.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		23.8%	5
Conservative management		76.2%	16
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (85 years or over) presents with a 5.5-6.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		0%	0
Fenestrated EVAR		0%	0
Conservative management		33.3%	7
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


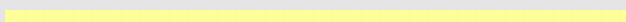
A man (85 years or over) presents with a 5.5-6.0 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		42.9%	9
Conservative management		57.1%	12
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


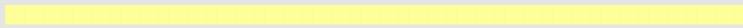
A lady (85 years or over) presents with a 5.5-6.0 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		33.3%	7
Conservative management		66.7%	14
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

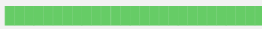
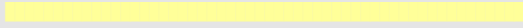
A man (85 years or over) presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		81%	17
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


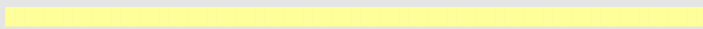
A man (85 years or over) presents with a 5.5-6.0 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		52.4%	11
Open aneurysm repair		0%	0
Fenestrated EVAR		4.8%	1
Conservative management		42.9%	9
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


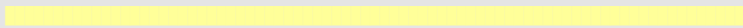
A lady (85 years or over) presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		28.6%	6
Conservative management		71.4%	15
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


A lady (85 years or over) presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		19%	4
Conservative management		81%	17
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

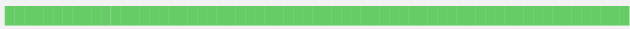

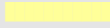
A man (85 years or over) presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	4.8%	1
Conservative management 	95.2%	20
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



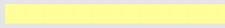
A man (85 years or over) presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.	Response Percent	Response Total
Standard EVAR 	33.3%	7
Open aneurysm repair	0%	0
Fenestrated EVAR	0%	0
Conservative management 	66.7%	14
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



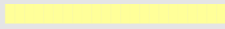
A lady (85 years or over) presents with a 5.5-6.0 cm type C aneurysm. She is categorised high risk for surgery.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	9.5%	2
Conservative management 	90.5%	19
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



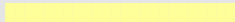
A lady (85 years or over) presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	4.8%	1
Conservative management 	95.2%	20
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



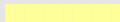
A man (85 years or over) presents with a 5.5-6.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		0%	0
Conservative management		100%	21
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



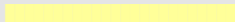
A man (85 years or over) presents with a 6.1-7.9 cm type B aneurysm. He is categorised as low risk for surgery.		Response Percent	Response Total
Standard EVAR		81%	17
Open aneurysm repair		4.8%	1
Fenestrated EVAR		0%	0
Conservative management		14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (85 years or over) presents with a 6.1-7.9 cm type C aneurysm. She is a low risk category patient		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		9.5%	2
Fenestrated EVAR		61.9%	13
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

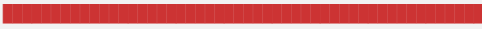
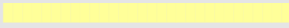
A man (85 years or over) presents with a 6.1-7.9 cm type D aneurysm. He is a low risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		66.7%	14
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


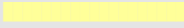
A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		5%	1
Open aneurysm repair		0%	0
Fenestrated EVAR		65%	13
Conservative management		30%	6
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			


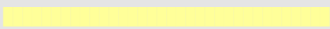
A lady (85 years or over) presents with a 6.1-7.9 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		80%	16
Open aneurysm repair		5%	1
Fenestrated EVAR		0%	0
Conservative management		15%	3
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			


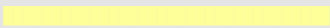
A man (85 years or over) presents with a 6.1-7.9 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		5%	1
Fenestrated EVAR		65%	13
Conservative management		30%	6
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			


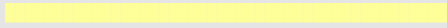
A lady (85 years or over) presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		71.4%	15
Conservative management		28.6%	6
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


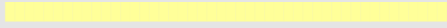
A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		61.9%	13
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


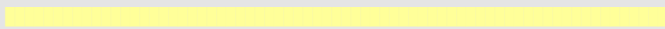
A man (85 years or over) presents with a 6.1-7.9 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		76.2%	16
Open aneurysm repair		0%	0
Fenestrated EVAR		0%	0
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


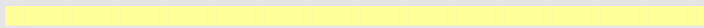
A lady (85 years or over) presents with a 6.1-7.9 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		57.1%	12
Conservative management		42.9%	9
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


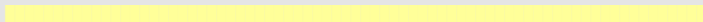
A lady (85 years or over) presents with a 6.1-7.9 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		57.1%	12
Conservative management		42.9%	9
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			





A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is a moderate risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	42.9%	9
Conservative management 	57.1%	12
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		





A man (85 years or over) presents with a 6.1-7.9 cm type B aneurysm. He is a high risk category patient.	Response Percent	Response Total
Standard EVAR 	42.9%	9
Open aneurysm repair	0%	0
Fenestrated EVAR	0%	0
Conservative management 	57.1%	12
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



A lady (85 years or over) presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	14.3%	3
Conservative management 	85.7%	18
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		

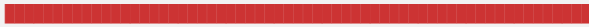
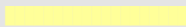
A lady (85 years or over) presents with a 6.1-7.9 cm type D aneurysm. She is categorised high risk of surgery.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	9.5%	2
Conservative management 	90.5%	19
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		




A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is a high risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	9.5%	2
Conservative management 	90.5%	19
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



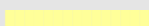
A man (85 years or over) presents with a >8.0 cm type B aneurysm. He is categorised as low risk for surgery.	Response Percent	Response Total
Standard EVAR 	85.7%	18
Open aneurysm repair 	4.8%	1
Fenestrated EVAR 	4.8%	1
Conservative management 	4.8%	1
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



A lady (85 years or over) presents with a >8.0 cm type C aneurysm. She is a low risk category patient.	Response Percent	Response Total
Standard EVAR 	4.8%	1
Open aneurysm repair 	4.8%	1
Fenestrated EVAR 	76.2%	16
Conservative management 	14.3%	3
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		



A man (85 years or over) presents with a >8.0 cm type D aneurysm. He is a low risk category patient.	Response Percent	Response Total
Standard EVAR	0%	0
Open aneurysm repair	0%	0
Fenestrated EVAR 	76.2%	16
Conservative management 	23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.		




A man (85 years or over) presents with a >8.0 cm type E aneurysm. He is categorised low risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A lady (85 years or over) presents with a >8.0 cm type B aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		85.7%	18
Open aneurysm repair		4.8%	1
Fenestrated EVAR		0%	0
Conservative management		9.5%	2
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			



A man (85 years or over) presents with a >8.0 cm type C aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		4.8%	1
Fenestrated EVAR		76.2%	16
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

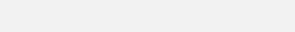
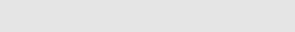
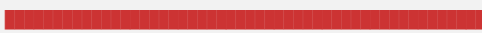
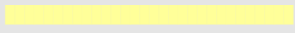
A lady (85 years or over) presents with a >8.0 cm type D aneurysm. She is categorised mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


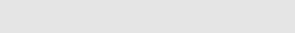


A man (85 years or over) presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		76.2%	16
Conservative management		23.8%	5
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

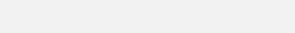
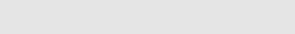


A man (85 years or over) presents with a >8.0 cm type B aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		66.7%	14
Open aneurysm repair		0%	0
Fenestrated EVAR		14.3%	3
Conservative management		19%	4
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

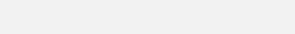
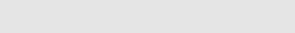


A lady (85 years or over) presents with a >8.0 cm type C aneurysm. She is categorised moderate risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		66.7%	14
Conservative management		33.3%	7
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			


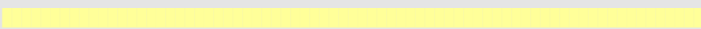
A lady (85 years or over) presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		61.9%	13
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (85 years or over) presents with a >8.0 cm type E aneurysm. He is a moderate risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		61.9%	13
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A man (85 years or over) presents with a >8.0 cm type B aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		52.4%	11
Open aneurysm repair		0%	0
Fenestrated EVAR		9.5%	2
Conservative management		38.1%	8
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

A lady (85 years or over) presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		28.6%	6
Conservative management		71.4%	15
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

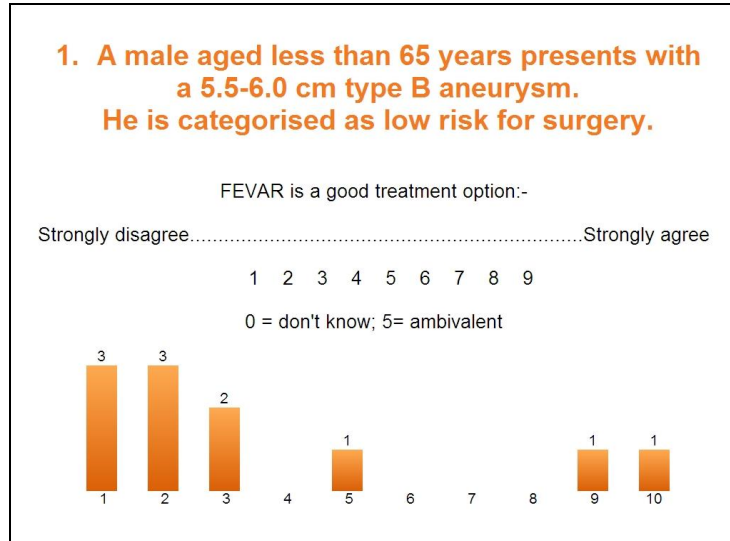
A lady (85 years or over) presents with a >8.0 cm type D aneurysm. She is categorised high risk of surgery.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		15%	3
Conservative management		85%	17
Total # of respondents 21. Statistics based on 20 respondents; 0 filtered; 1 skipped.			

A man (85 years or over) presents with a >8.0 cm type E aneurysm. He is a high risk category patient.		Response Percent	Response Total
Standard EVAR		0%	0
Open aneurysm repair		0%	0
Fenestrated EVAR		9.5%	2
Conservative management		90.5%	19
Total # of respondents 21. Statistics based on 21 respondents; 0 filtered; 0 skipped.			

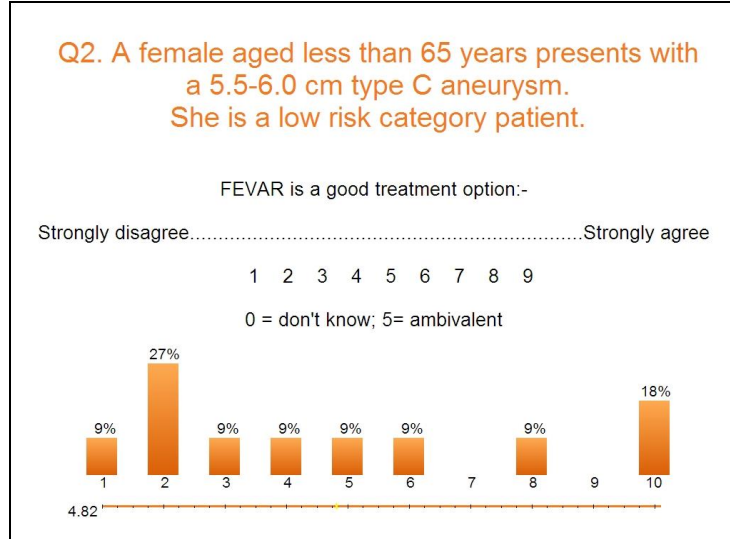
Appendix H

Results Round 2

Slide 1



Slide 2



Slide 3

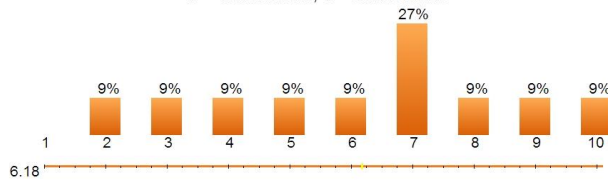
Q3. A male aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. He is a low risk category patient.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

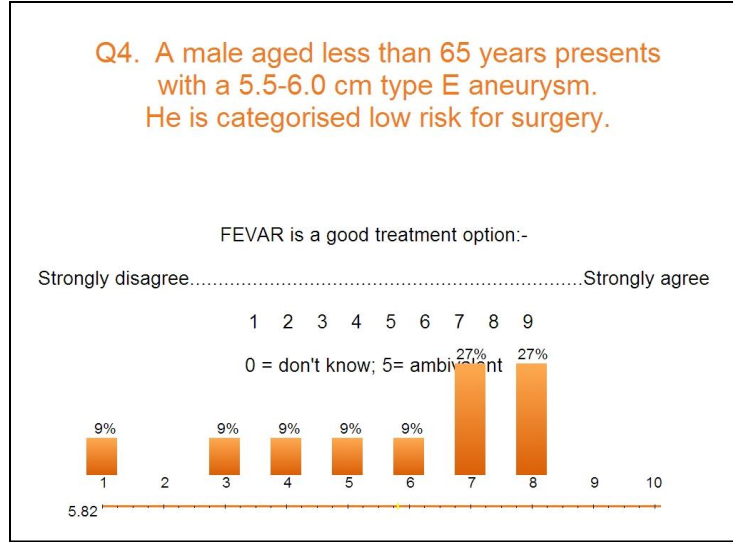
1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent

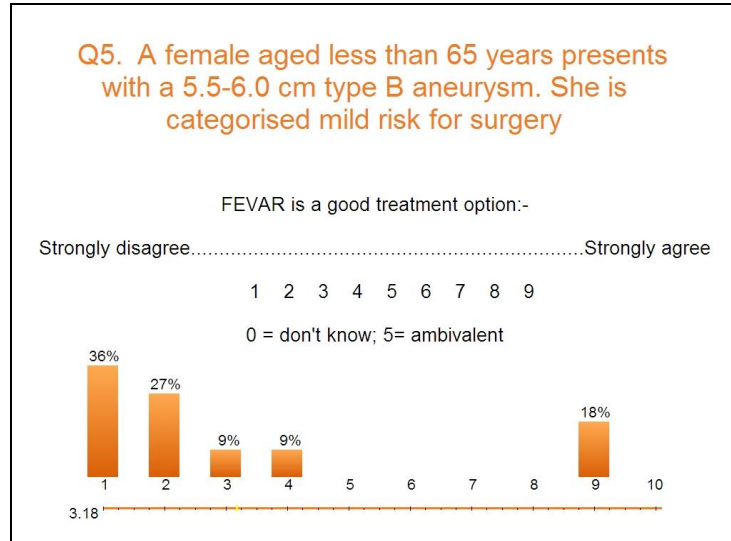


Slide 4

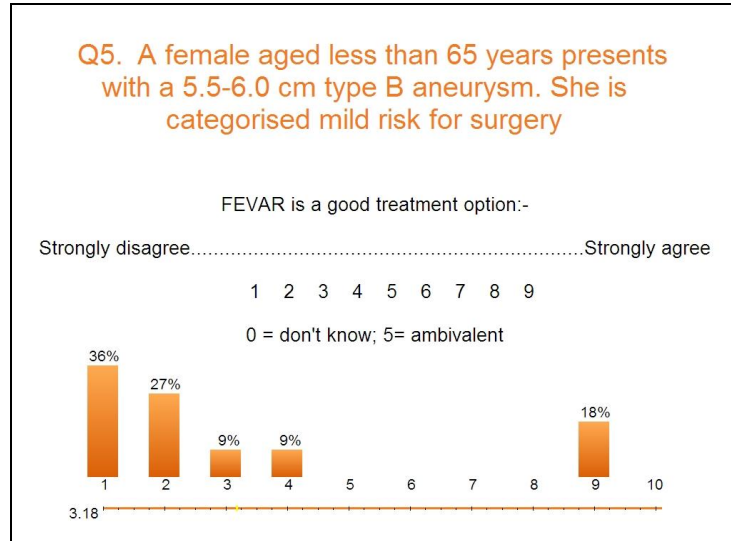
Q4. A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is categorised low risk for surgery.



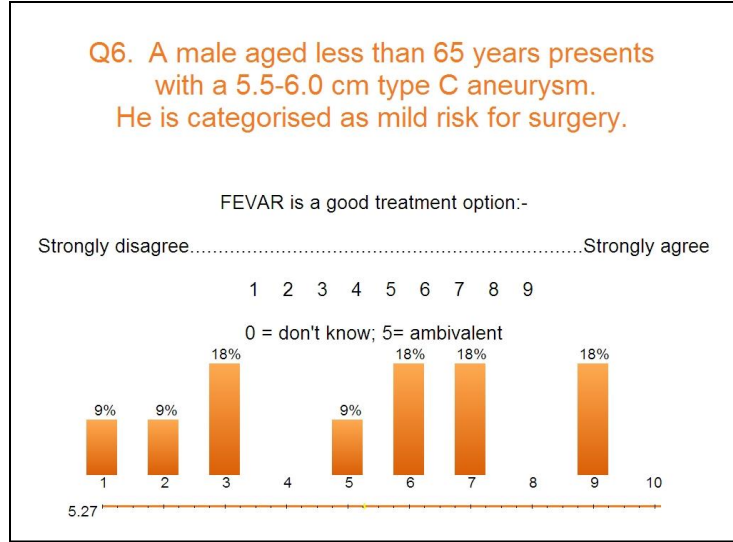
Slide 5



Slide 6



Slide 7



Slide 8

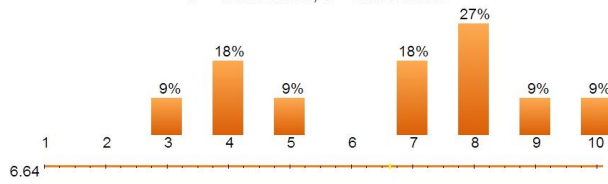
Q7. A female aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

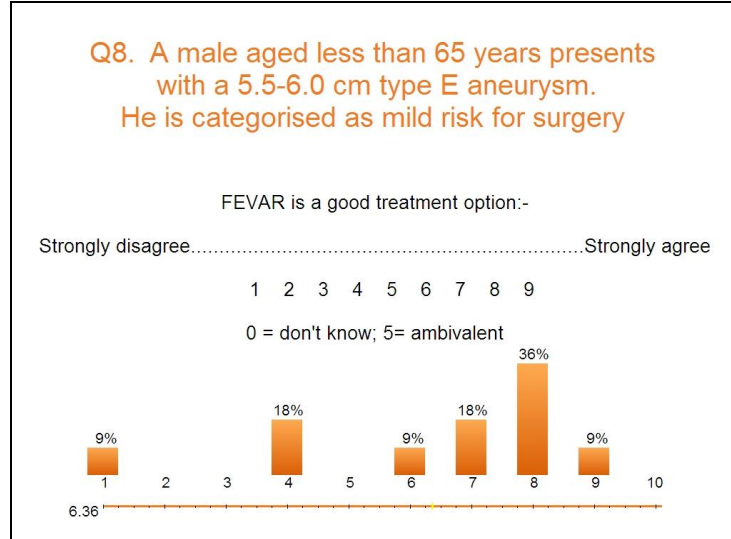
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

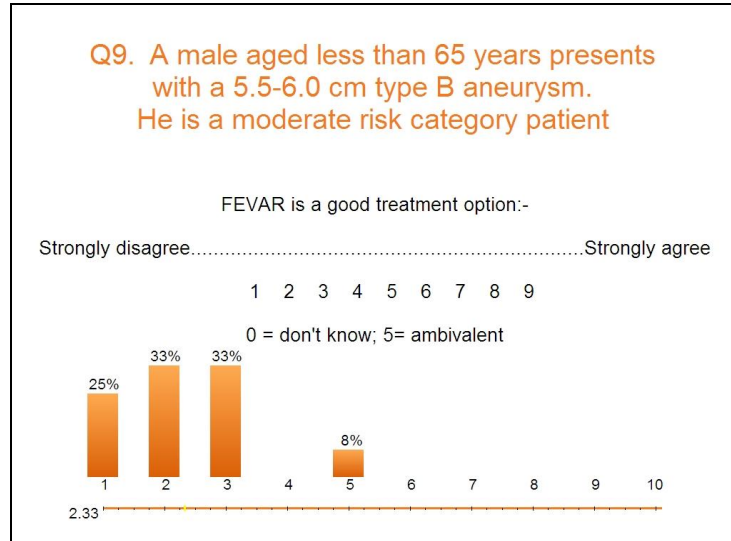
0 = don't know; 5= ambivalent



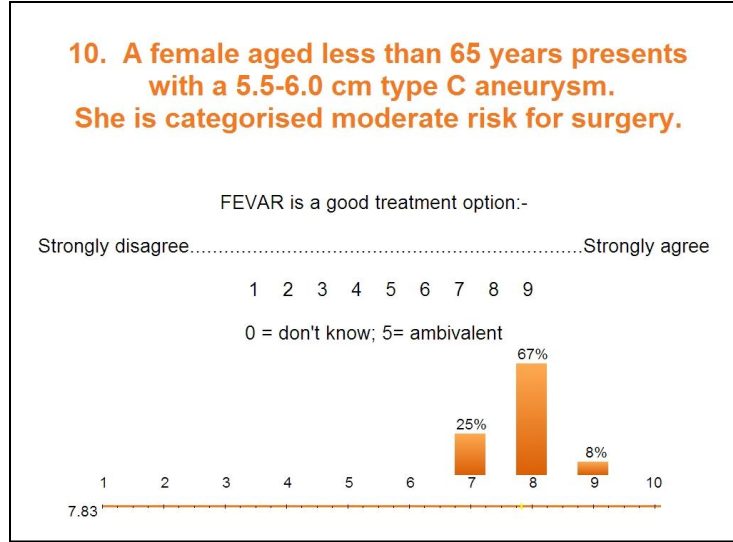
Slide 9



Slide 10



Slide 11



Slide 12

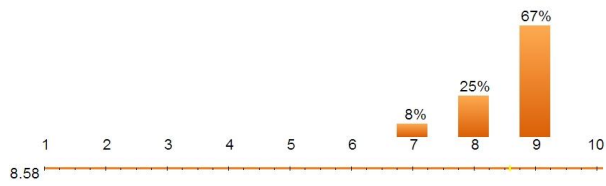
11. A female aged less than 65 years presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 13

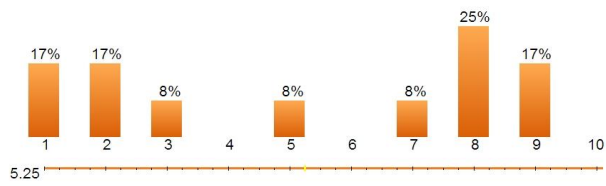
12. A male aged less than 65 years presents with a 5.5-6.0 cm type E aneurysm. He is a moderate risk category patient.

FEVAR is a good treatment option:-

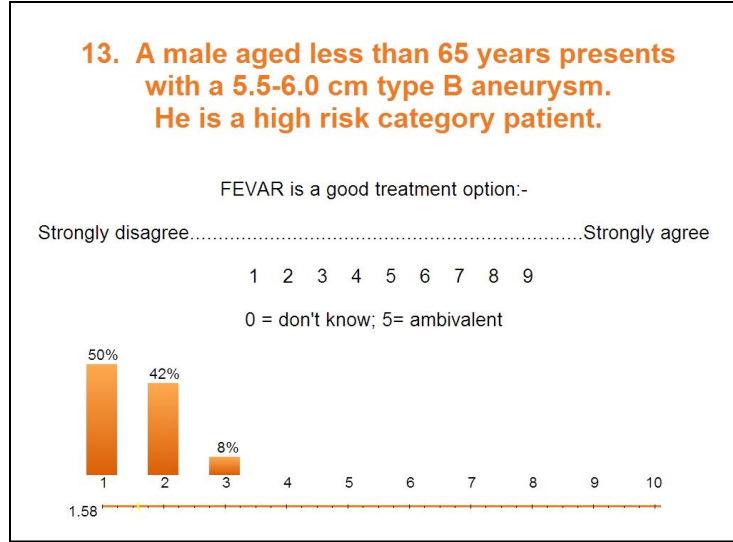
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

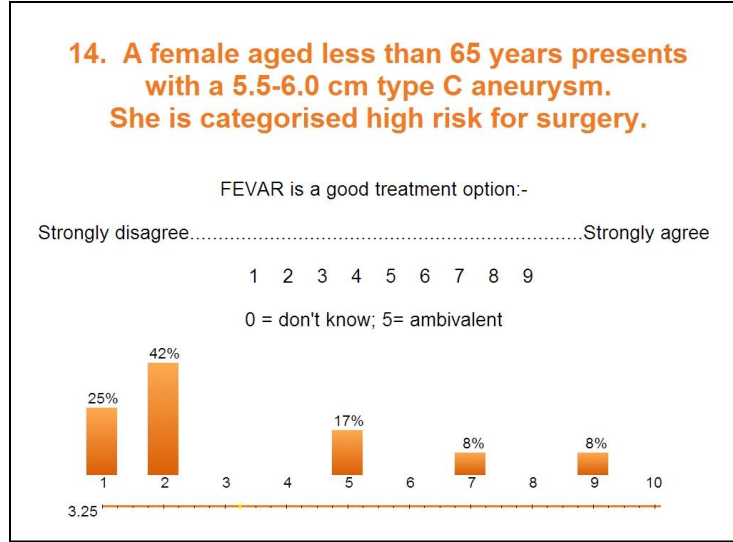
0 = don't know; 5= ambivalent



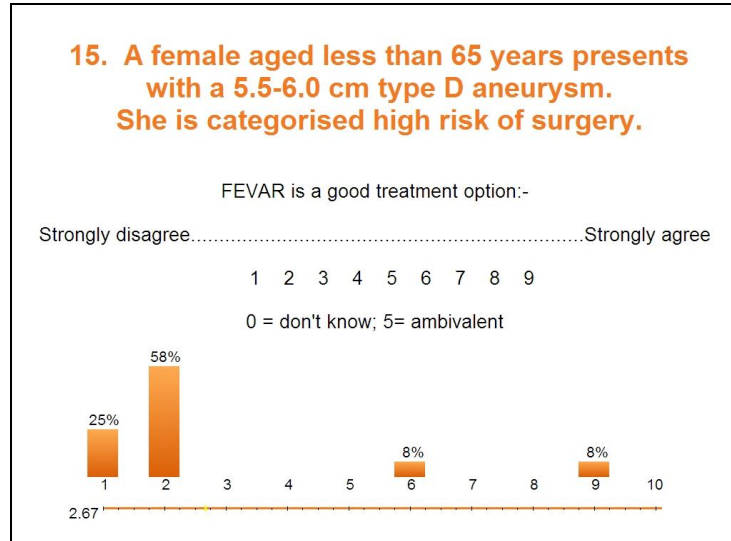
Slide 14



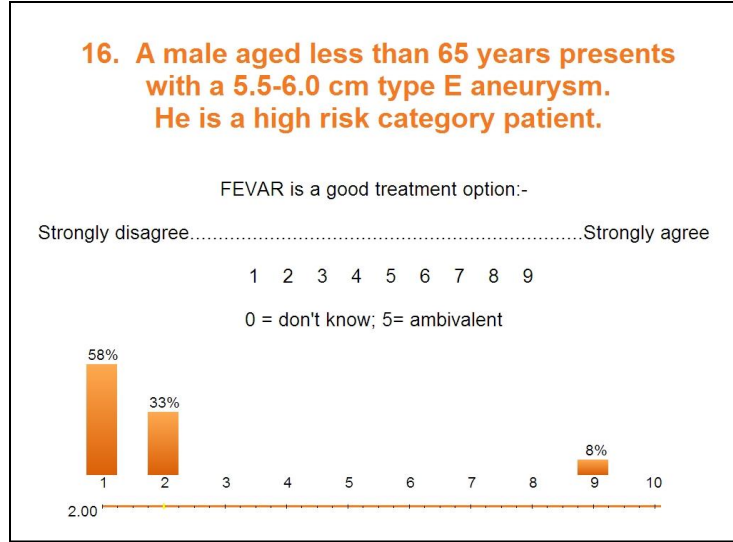
Slide 15



Slide 16



Slide 17



Slide 18

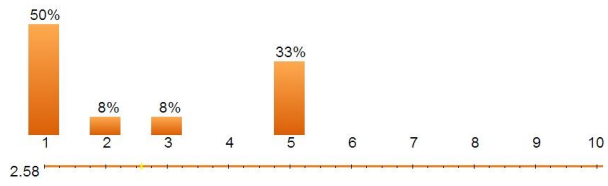
17. A male aged less than 65 years presents with a 6.1-7.9 cm type B aneurysm. He is categorised as low risk for surgery.

FEVAR is a good treatment option:-

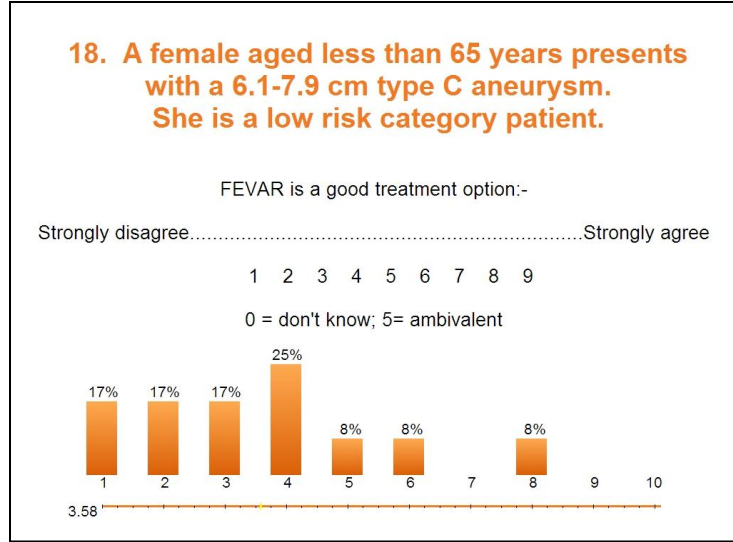
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

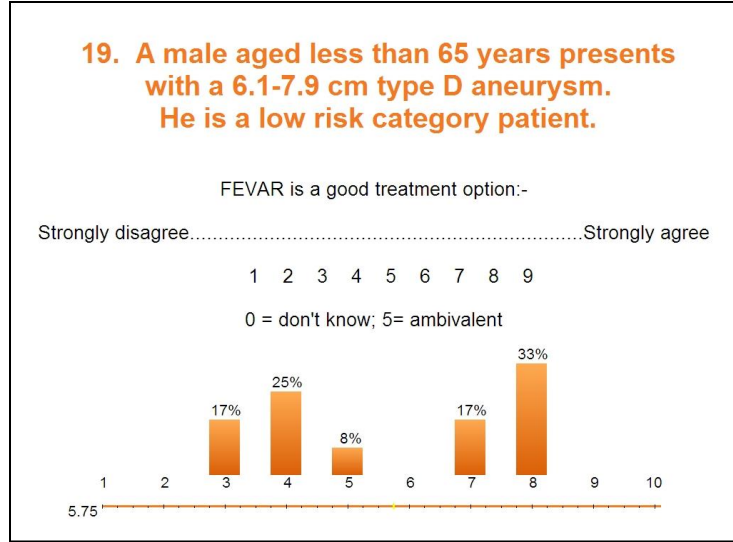
0 = don't know; 5= ambivalent



Slide 19



Slide 20



Slide 21

20. A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent

Slide 22

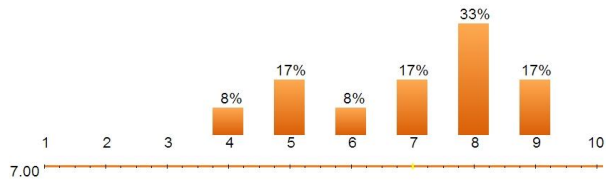
20. A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.

FEVAR is a good treatment option:-

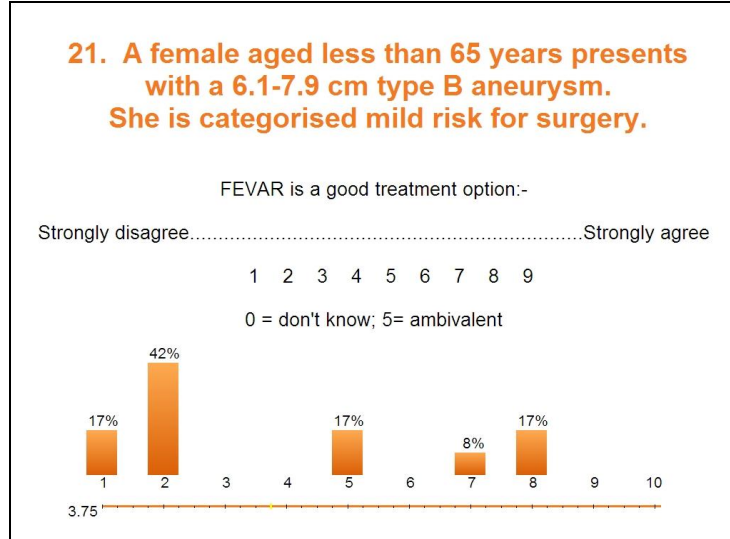
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

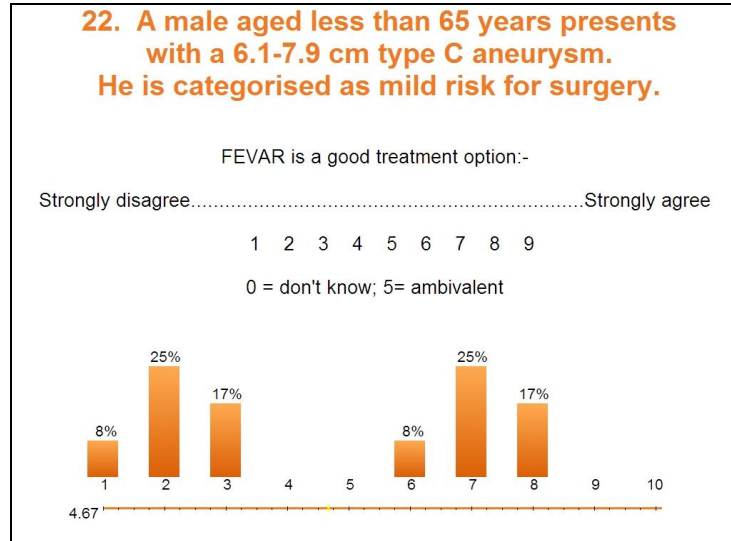
0 = don't know; 5= ambivalent



Slide 23



Slide 24



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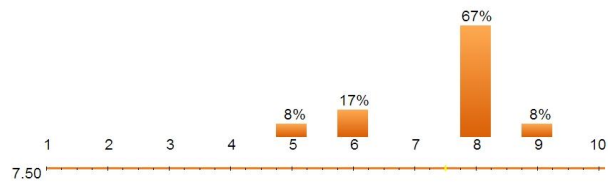
23. A female aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 26

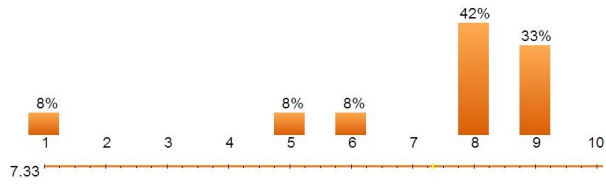
24. A male aged less than 65 years presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

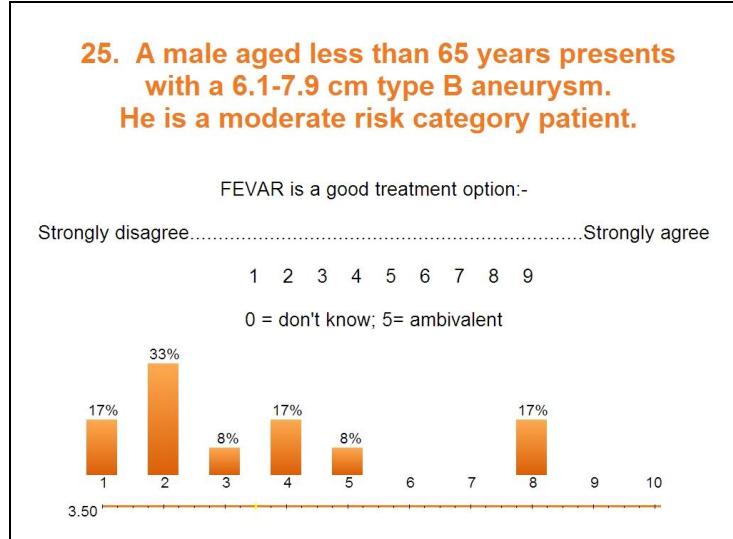
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 27



Slide 28

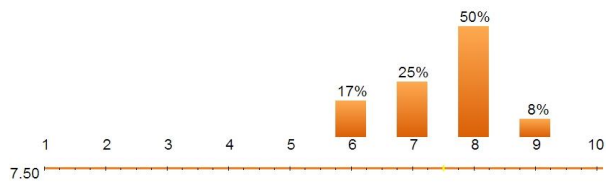
26. A female aged less than 65 years presents with a 6.1-7.9 cm type C aneurysm. She is categorised moderate risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 29

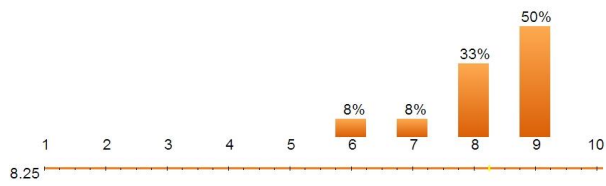
27. A female aged less than 65 years presents with a 6.1-7.9 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

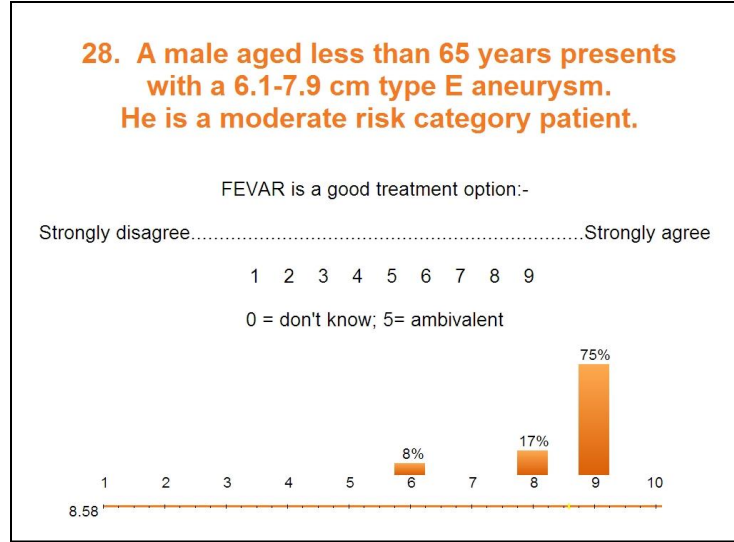
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

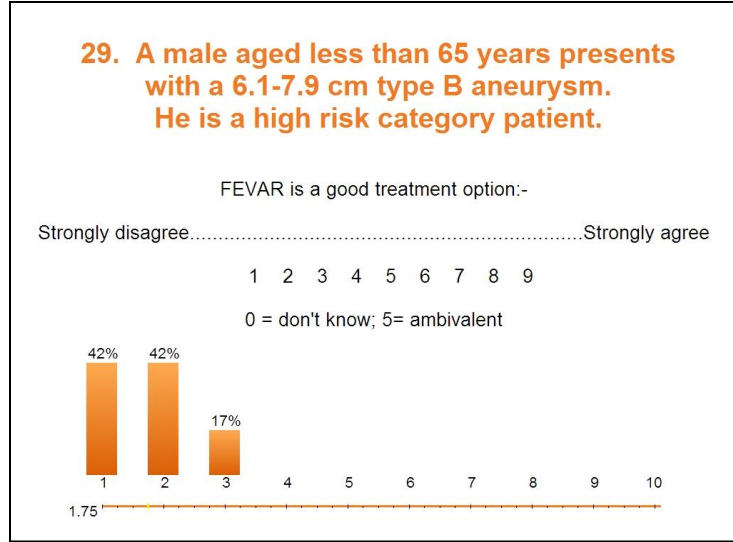
0 = don't know; 5= ambivalent



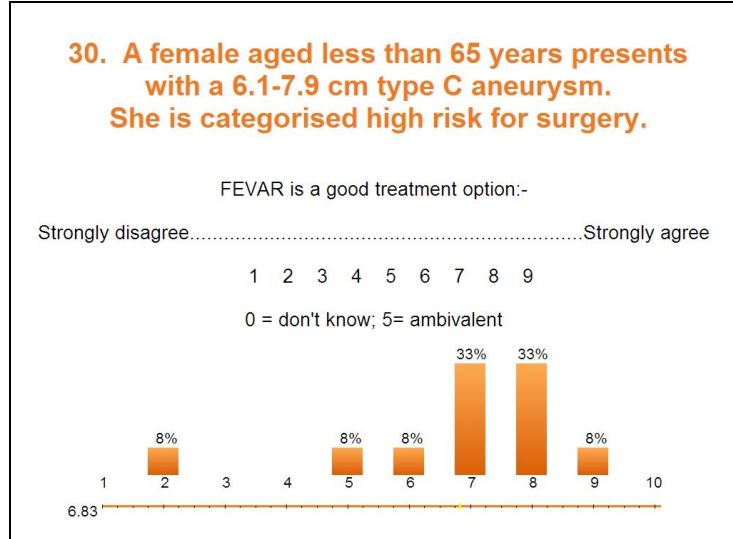
Slide 30



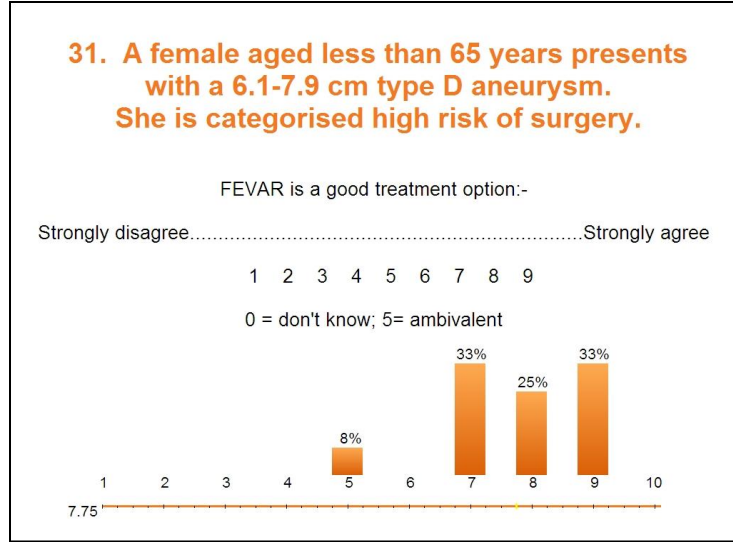
Slide 31



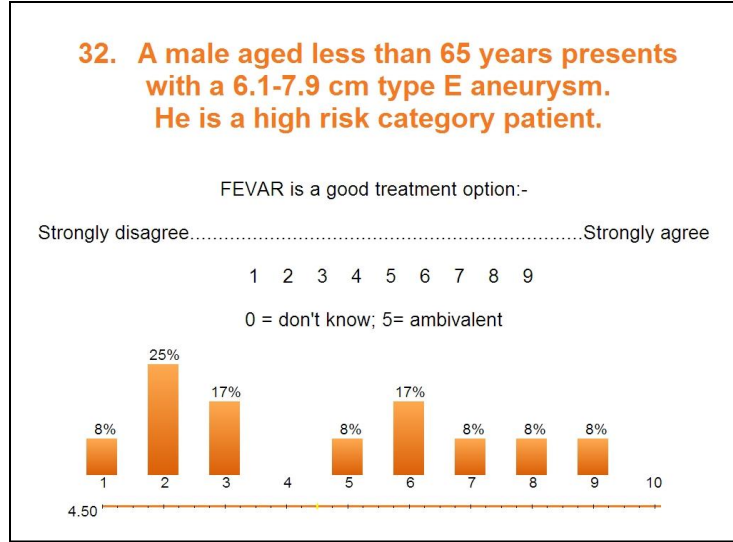
Slide 32



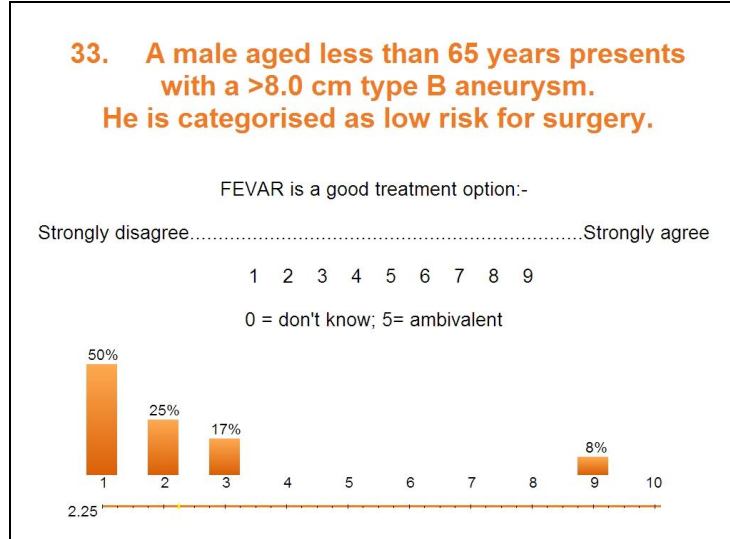
Slide 33



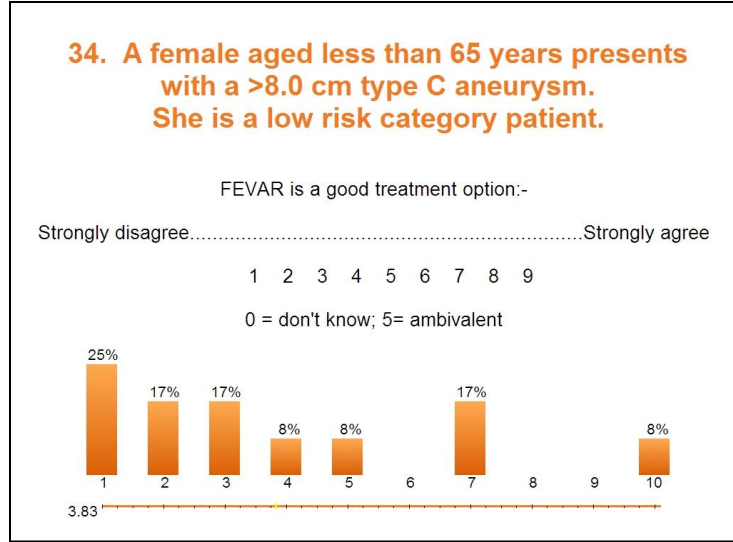
Slide 34



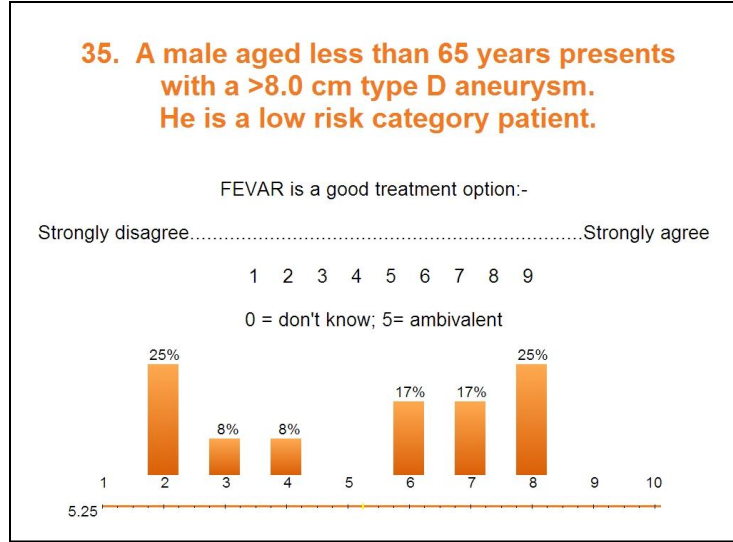
Slide 35



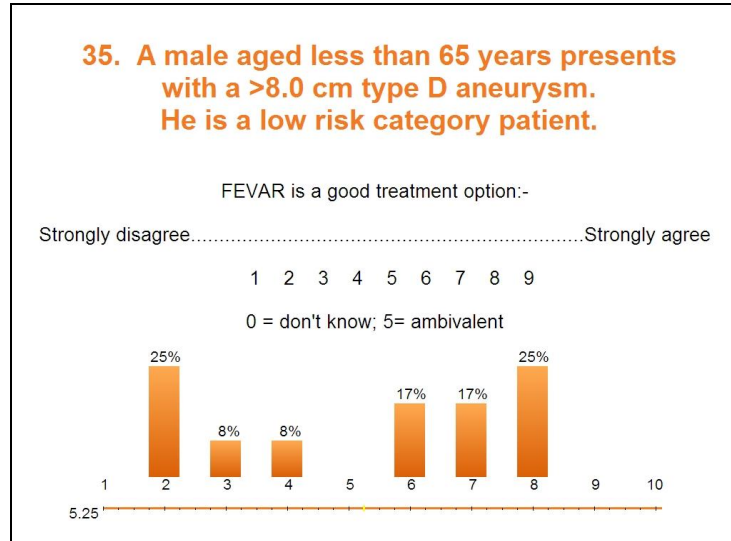
Slide 36



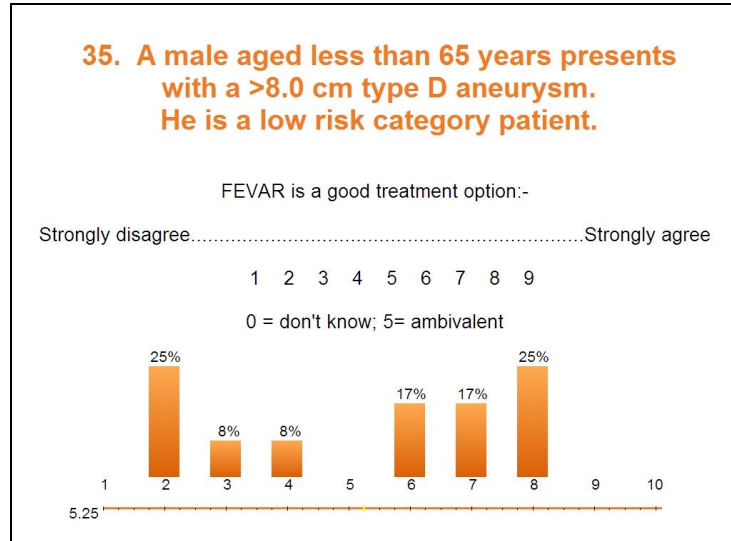
Slide 37



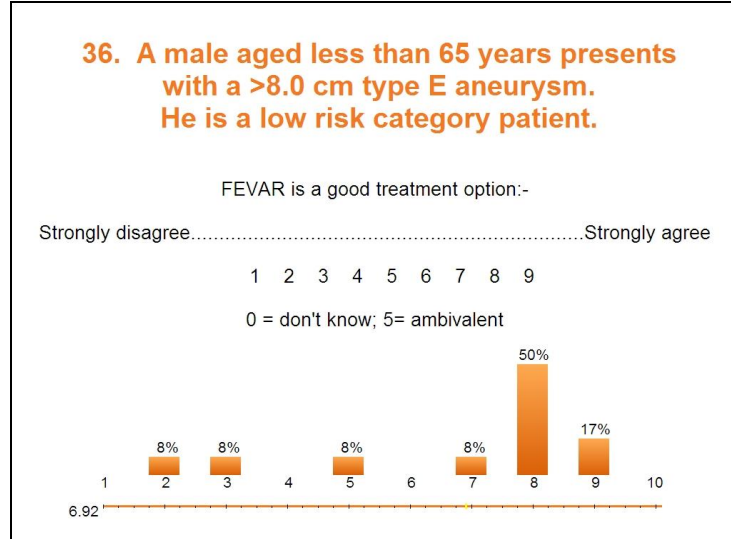
Slide 38



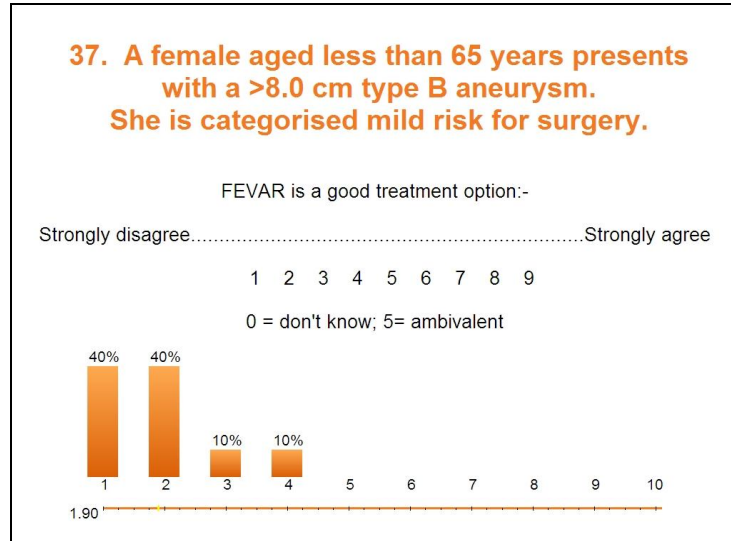
Slide 39



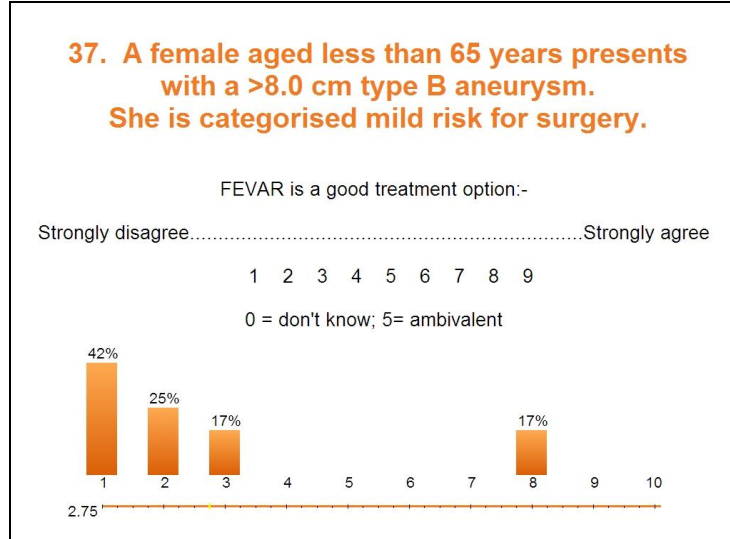
Slide 40



Slide 41



Slide 42



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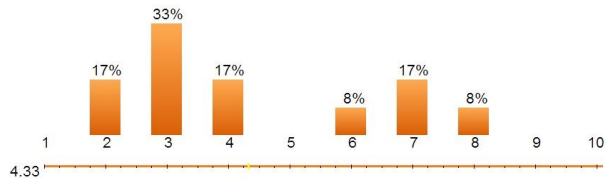
38. A male aged less than 65 years presents with a >8.0 cm type C aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

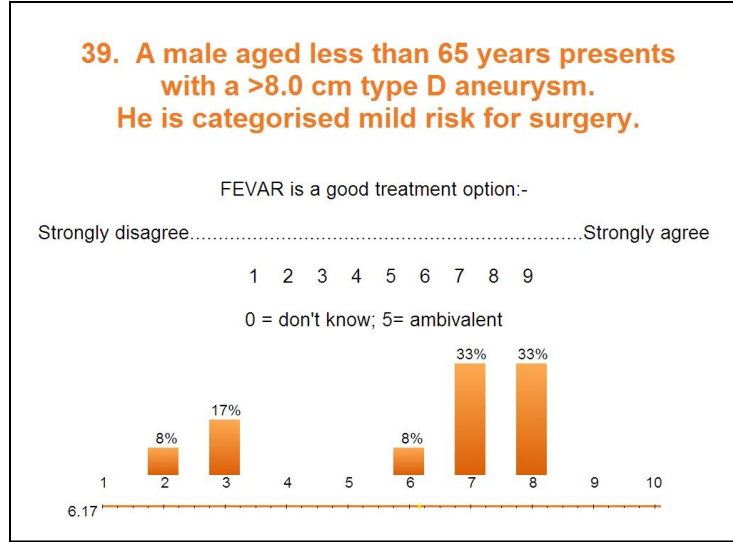
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 44



Slide 45

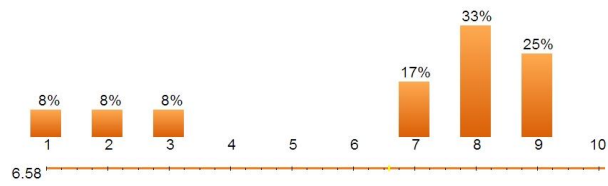
40. A male aged less than 65 years presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

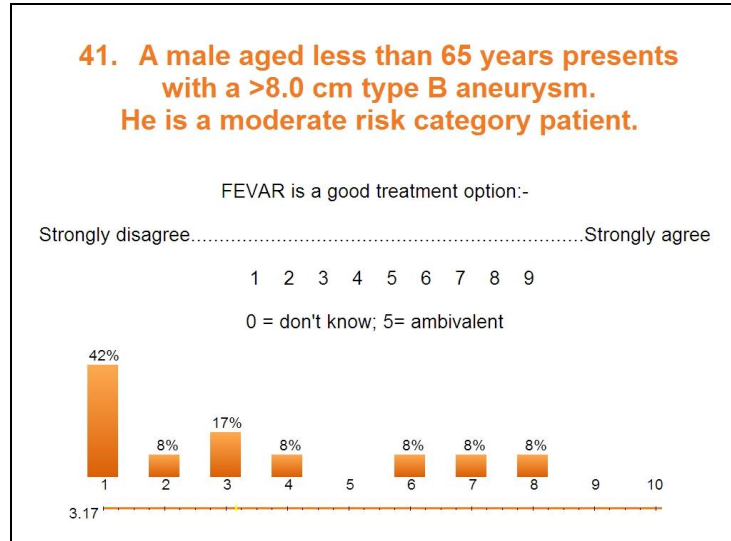
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

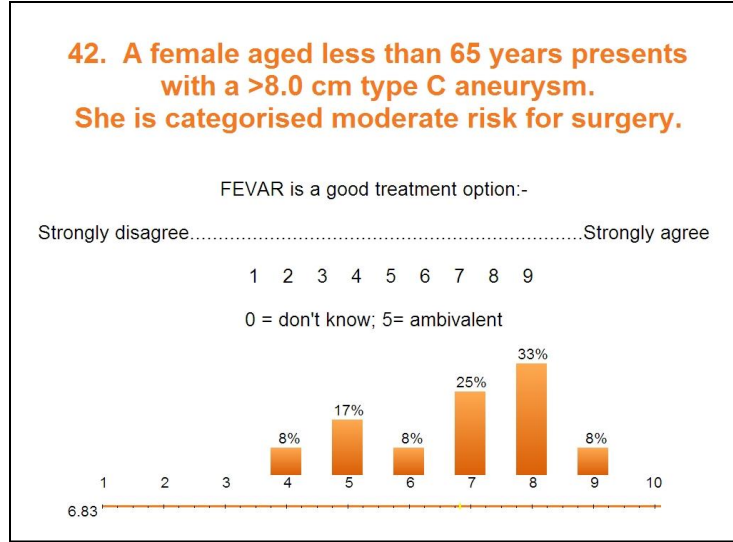
0 = don't know; 5= ambivalent



Slide 46



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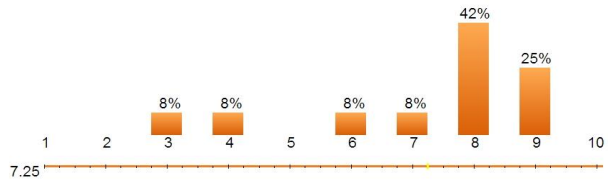
43. A female aged less than 65 years presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

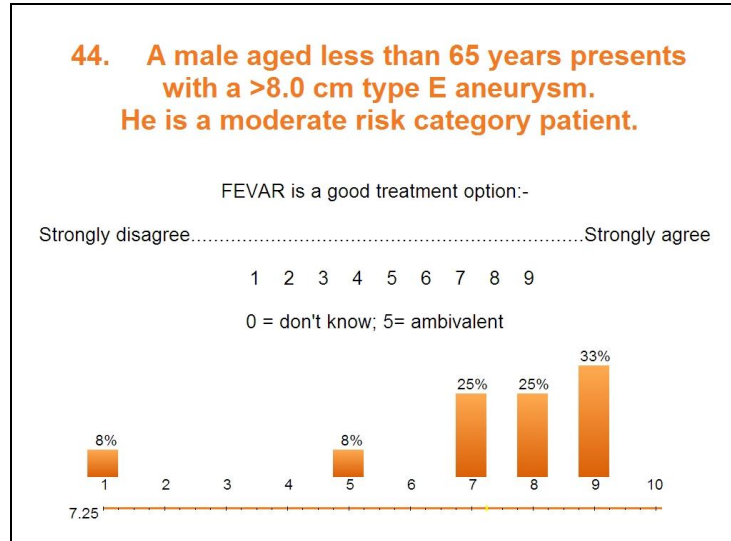
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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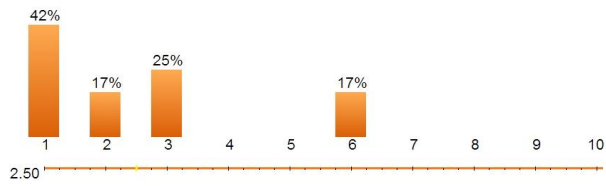
45. A male aged less than 65 years presents with a >8.0 cm type B aneurysm. He is a high risk category patient.

FEVAR is a good treatment option:-

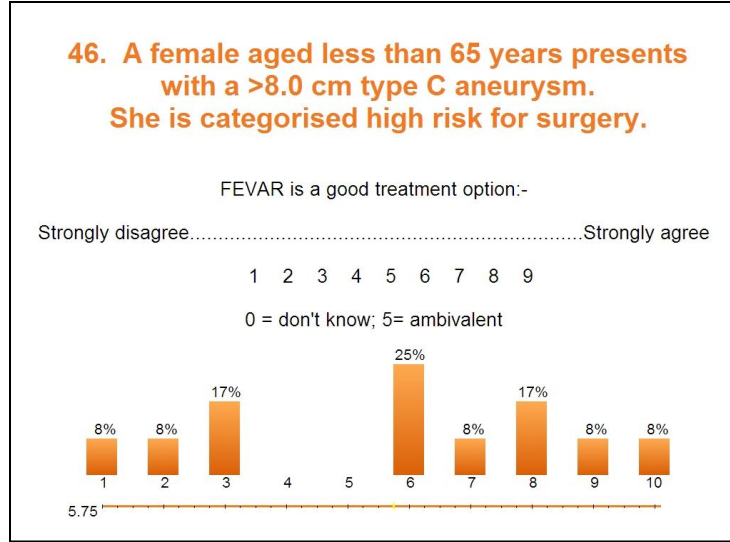
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

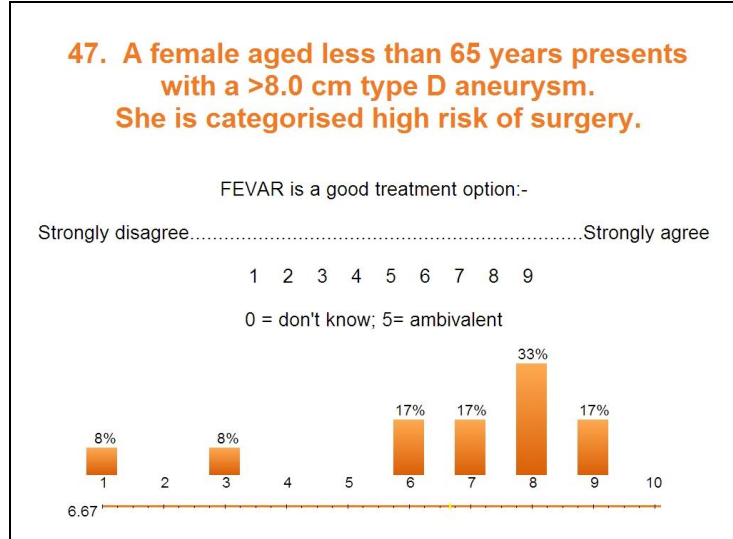
0 = don't know; 5= ambivalent



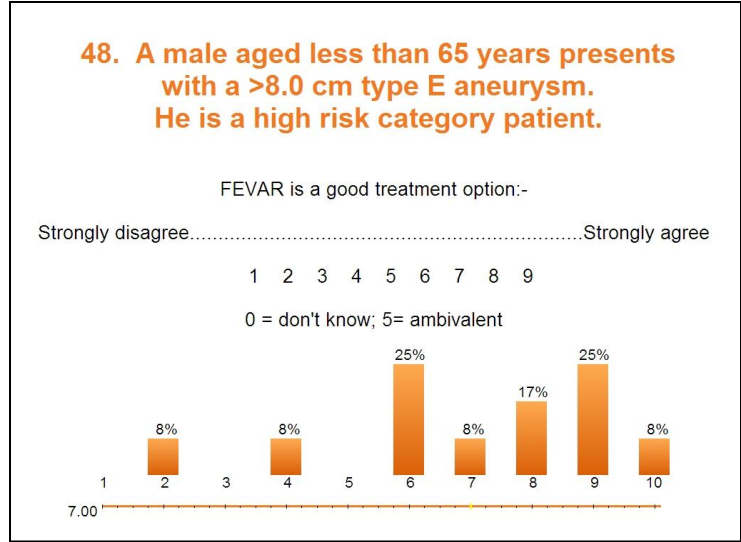
Slide 51



Slide 52



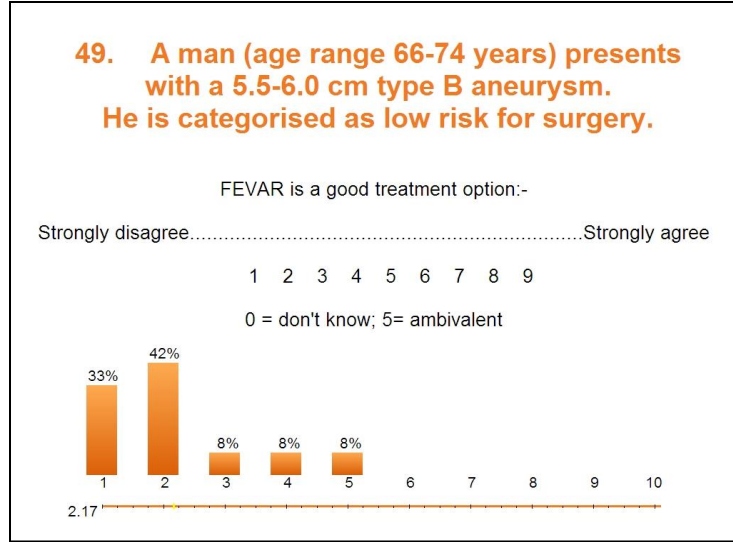
Slide 53



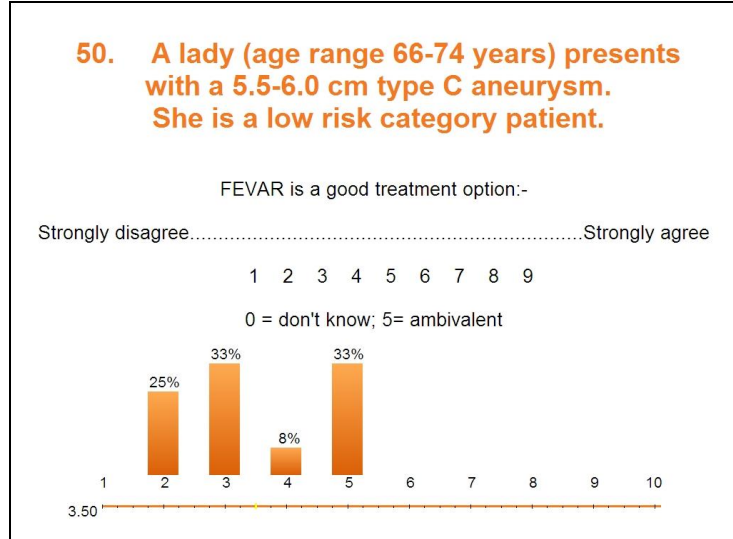
Slide 54

B Age 66-74 years

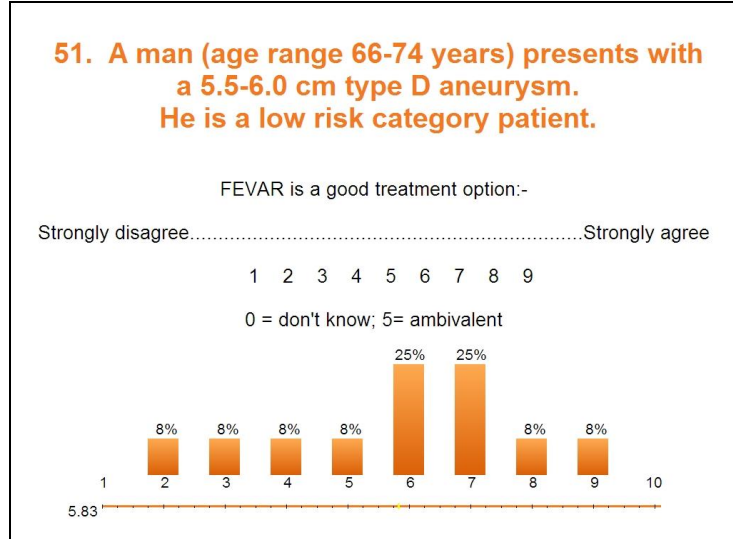
Slide 55



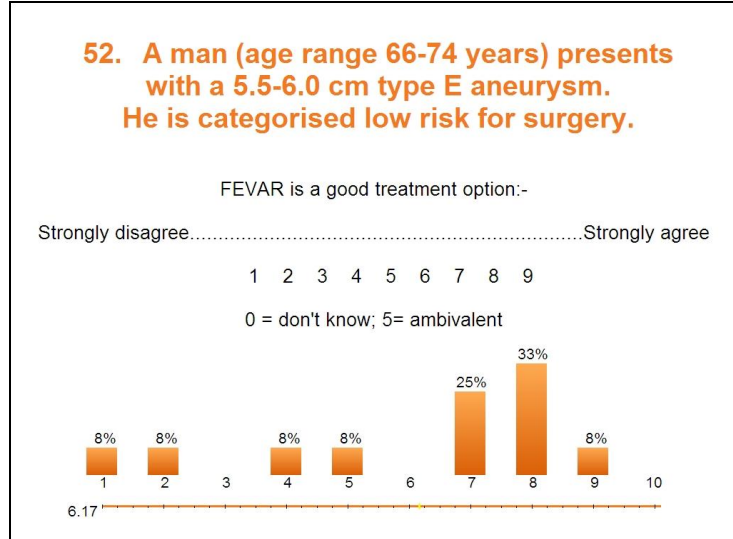
Slide 56



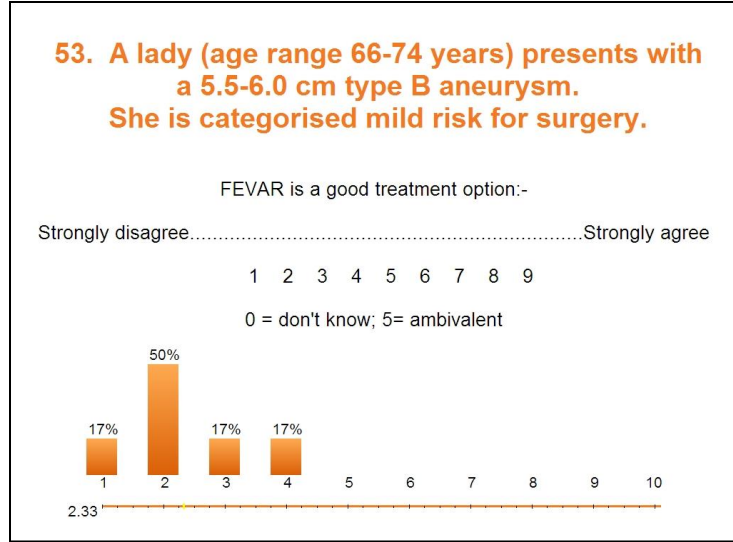
Slide 57



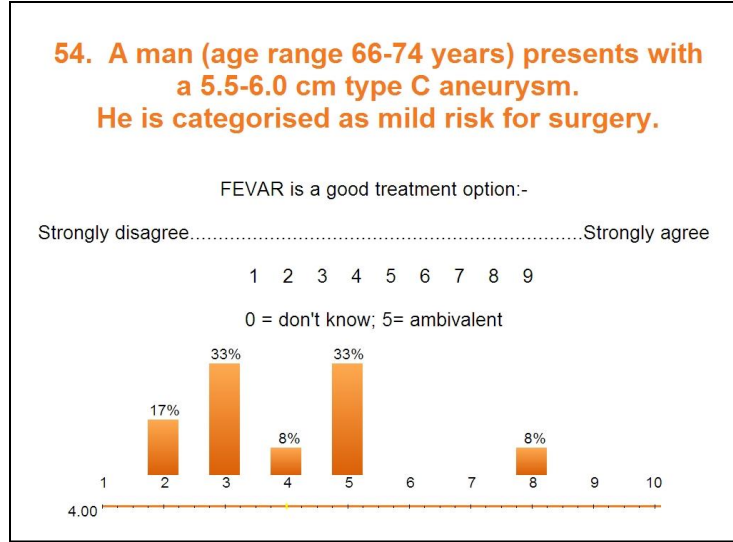
Slide 58



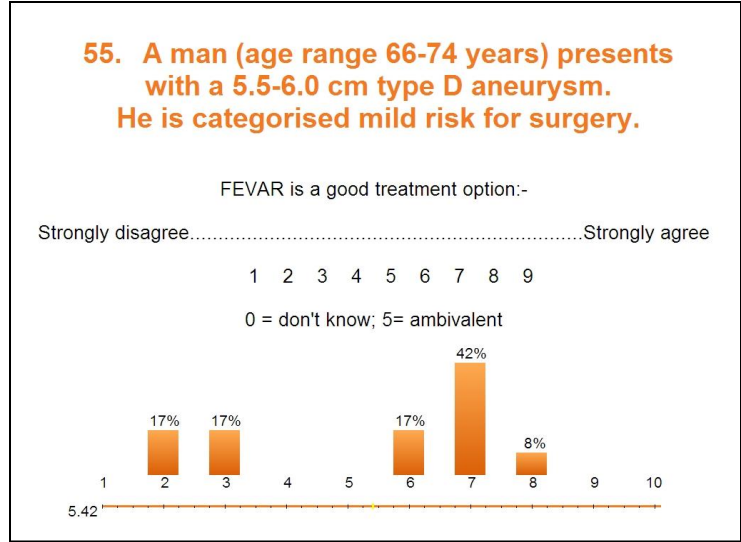
Slide 59



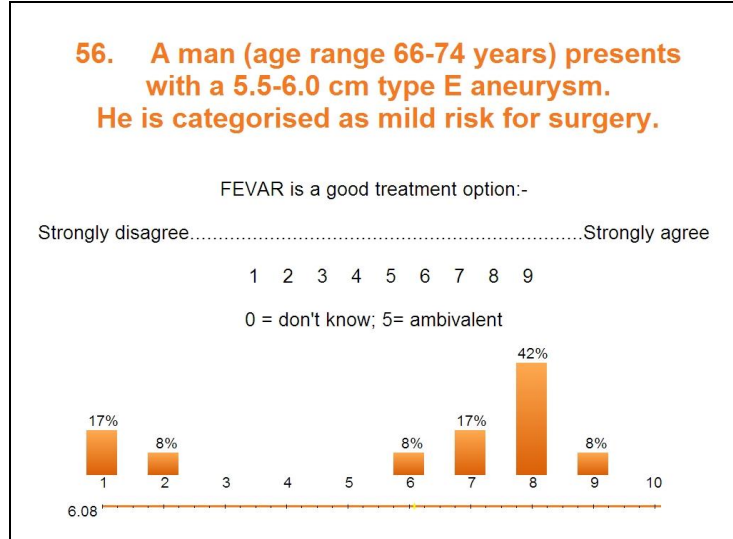
Slide 60



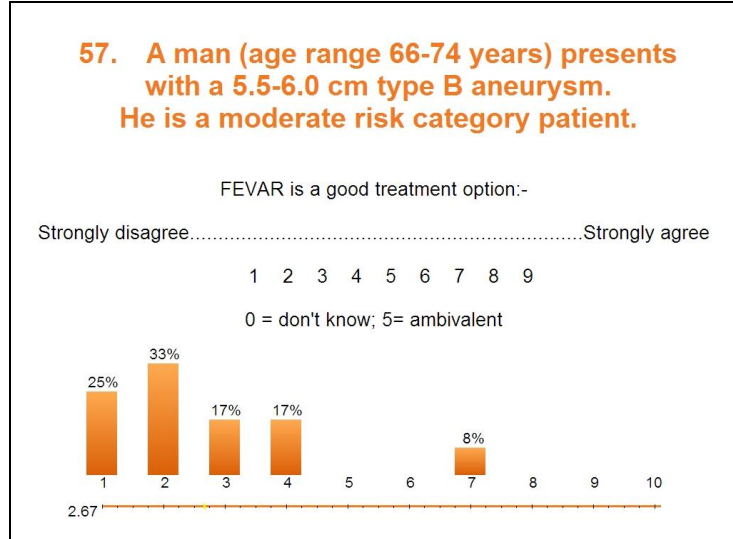
Slide 61



Slide 62



Slide 63



Slide 64

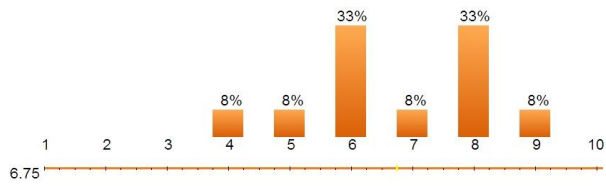
58. A lady (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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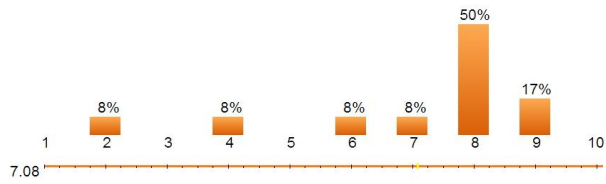
59. A lady (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

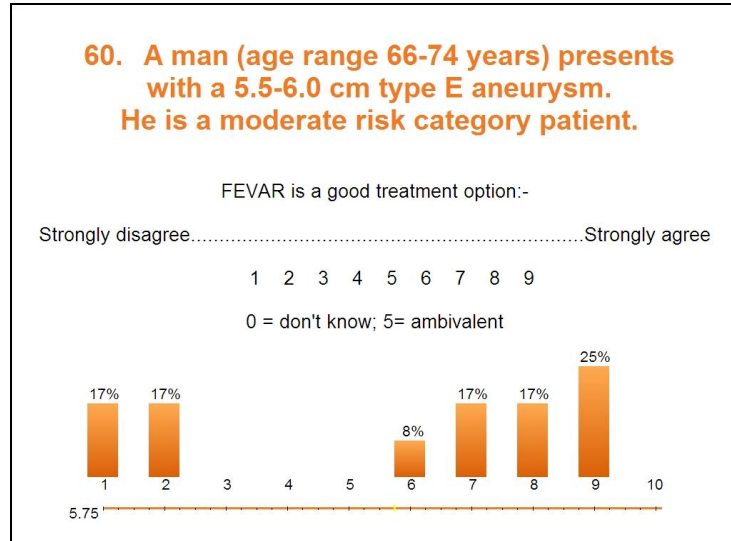
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 66



Slide 67

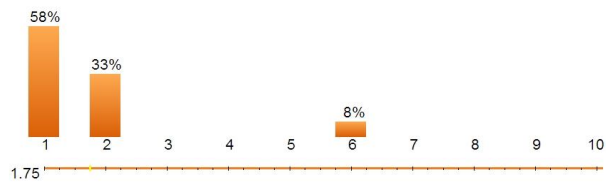
61. A man (age range 66-74 years) presents with a 5.5-6.0 cm type B aneurysm. He is a high risk category patient.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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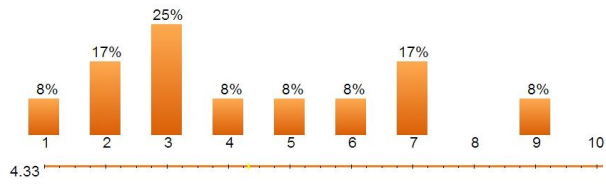
62. A lady (age range 66-74 years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised high risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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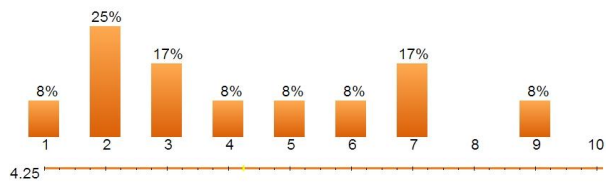
63. A lady (age range 66-74 years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery.

FEVAR is a good treatment option:-

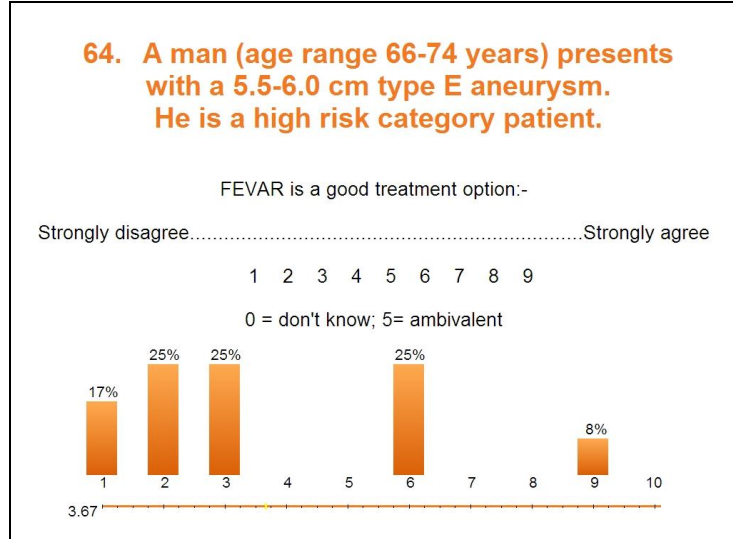
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

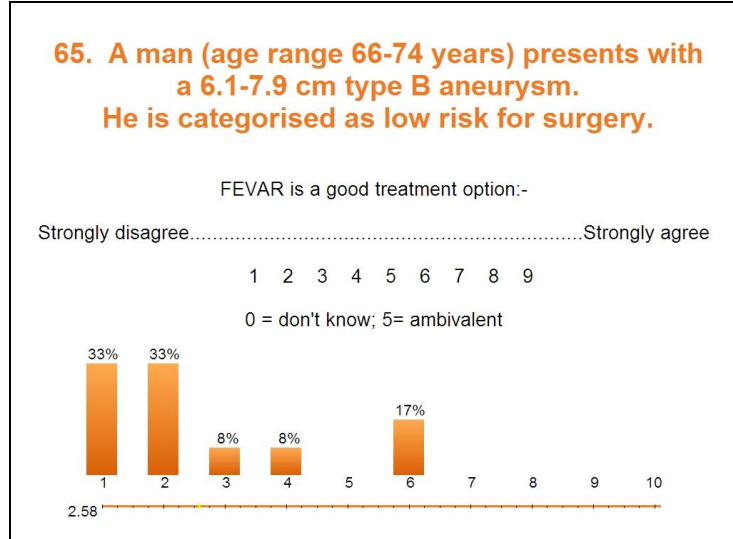
0 = don't know; 5= ambivalent



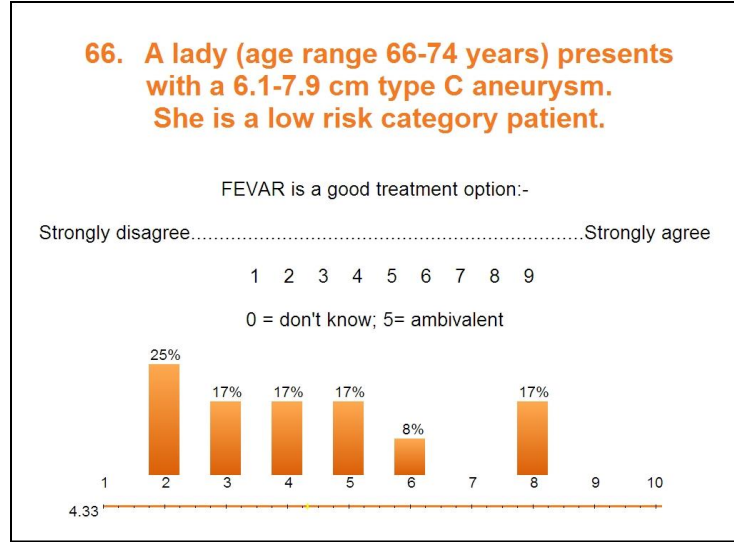
Slide 70



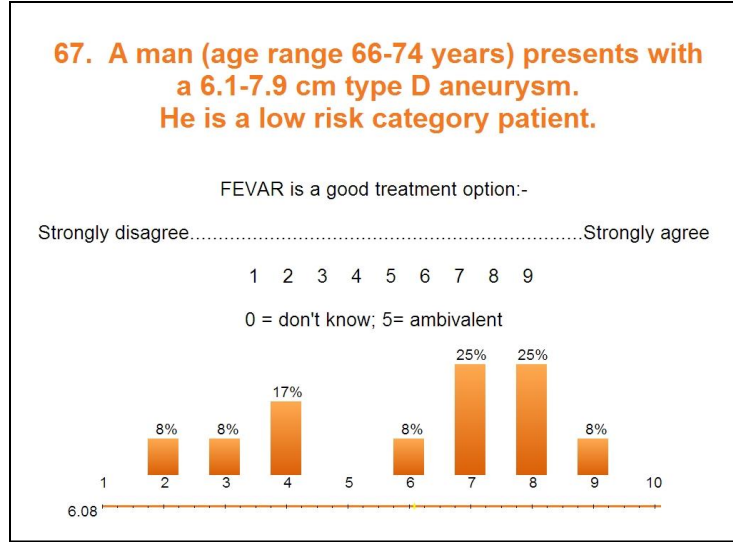
Slide 71



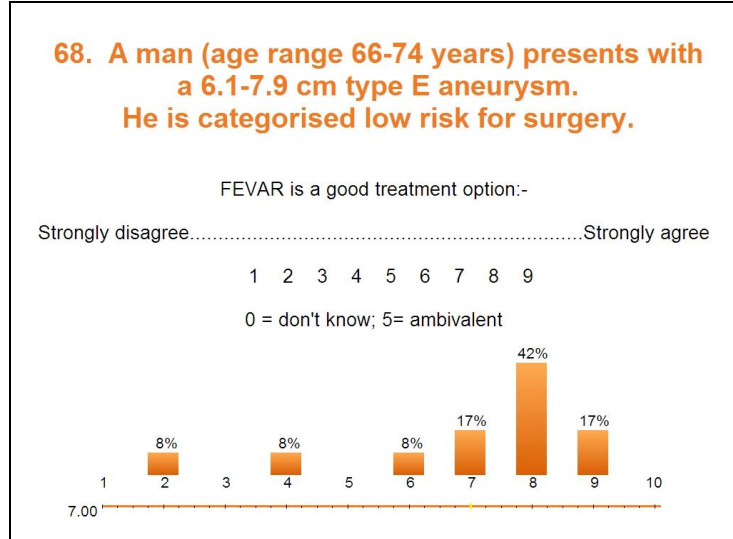
Slide 72



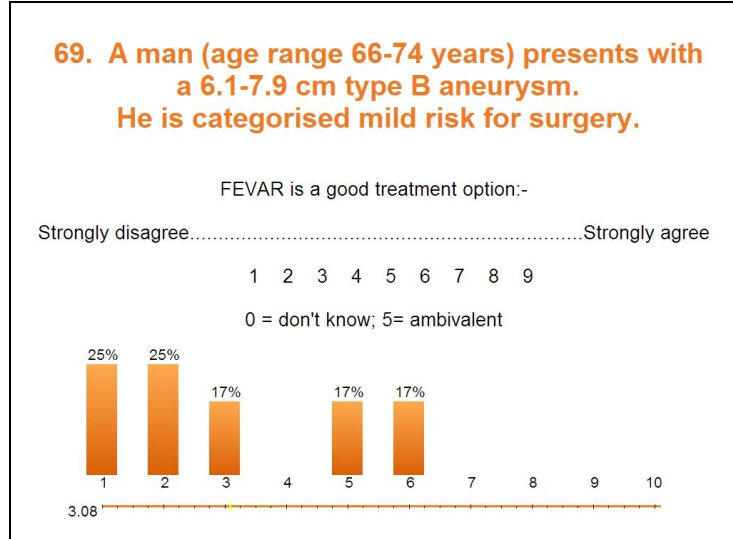
Slide 73



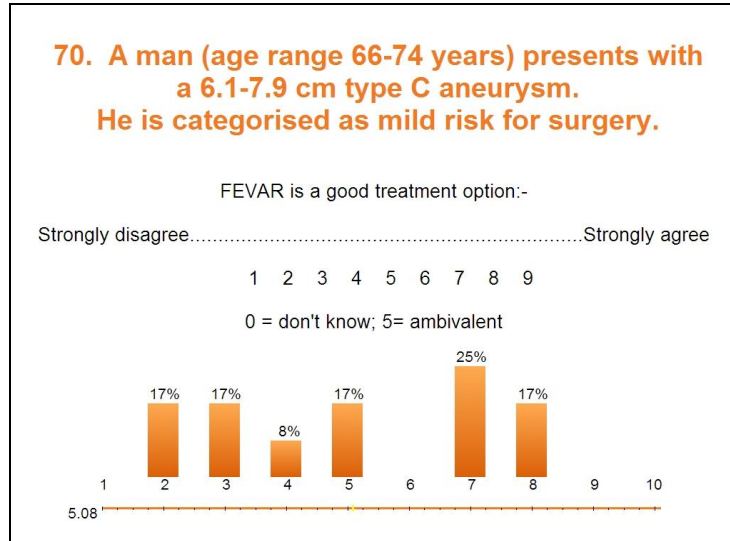
Slide 74



Slide 75



Slide 76



Slide 77

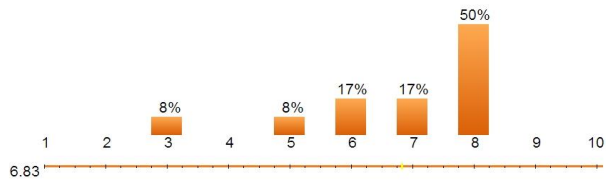
71. A lady (age range 66-74 years) presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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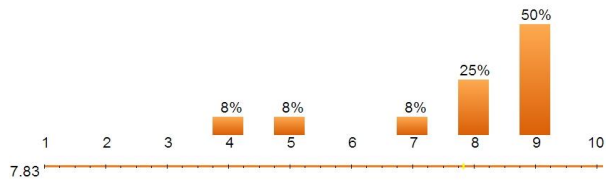
72. A man (age range 66-74 years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

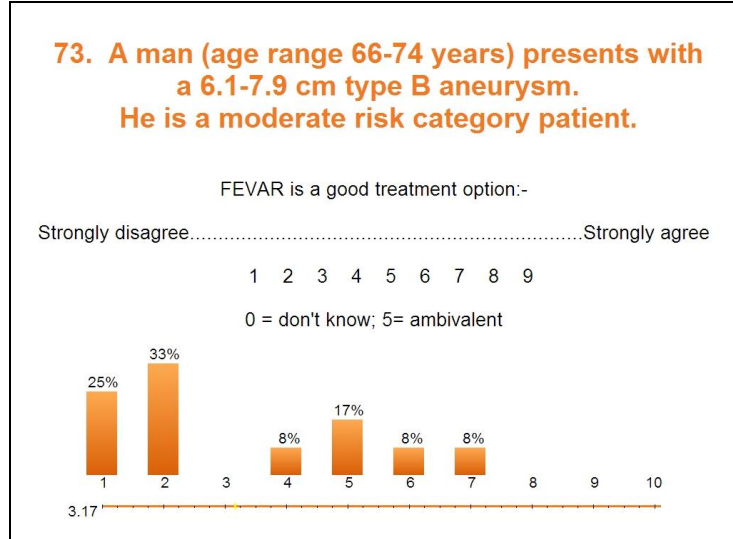
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

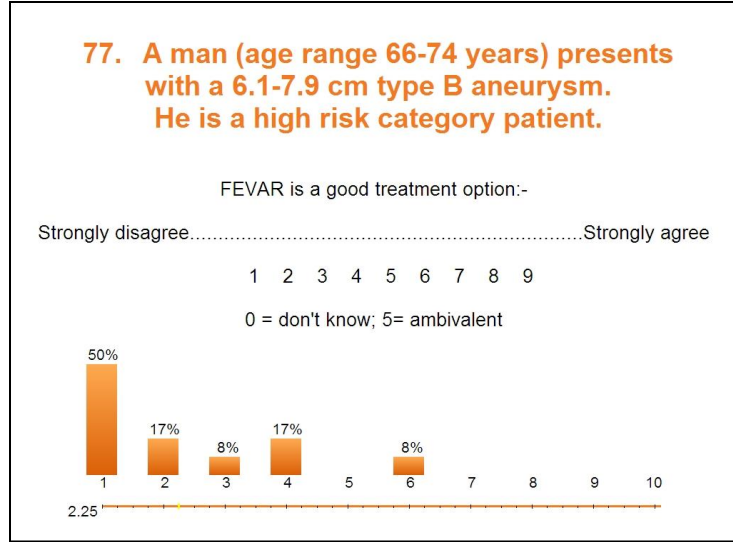
0 = don't know; 5= ambivalent



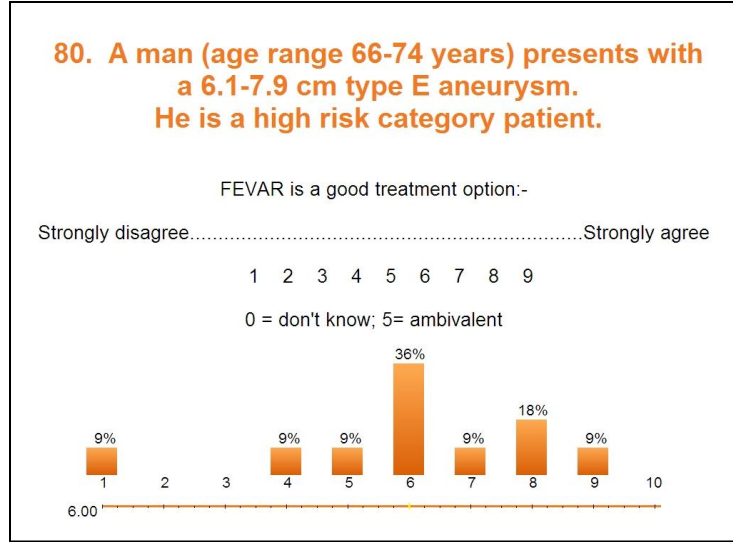
Slide 79



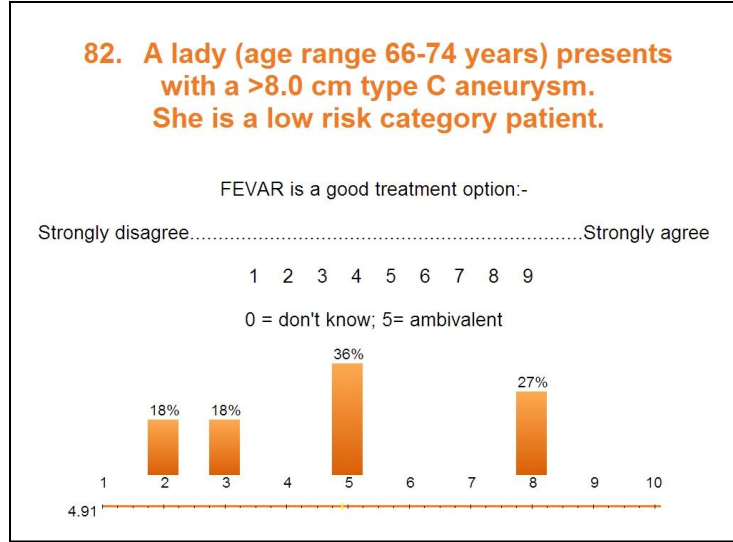
Slide 80



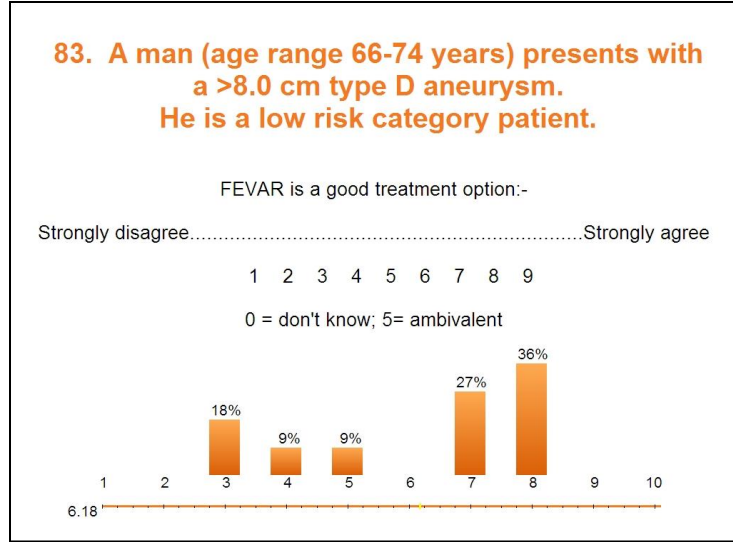
Slide 81



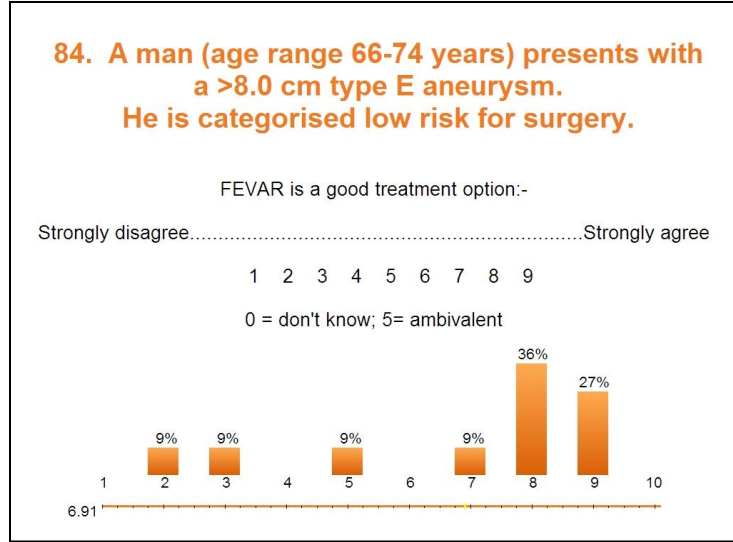
Slide 82



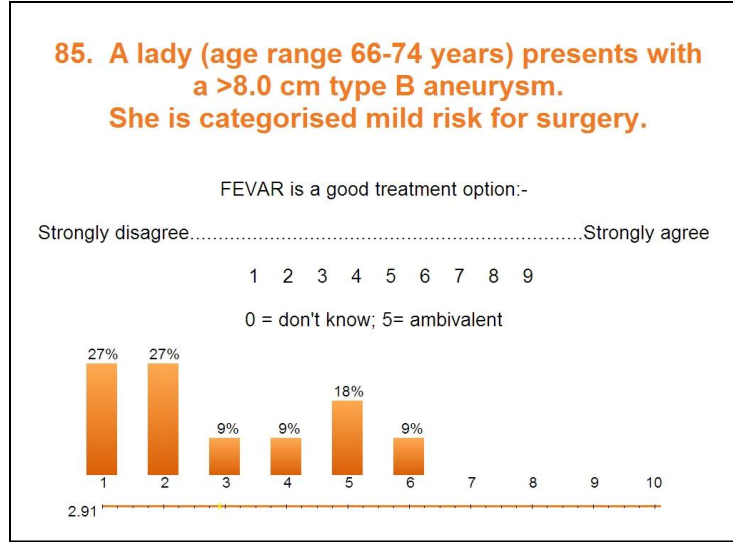
Slide 83



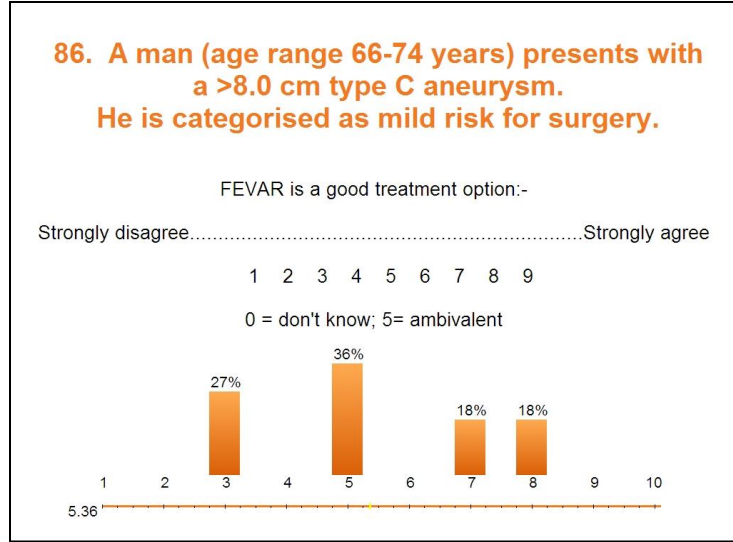
Slide 84



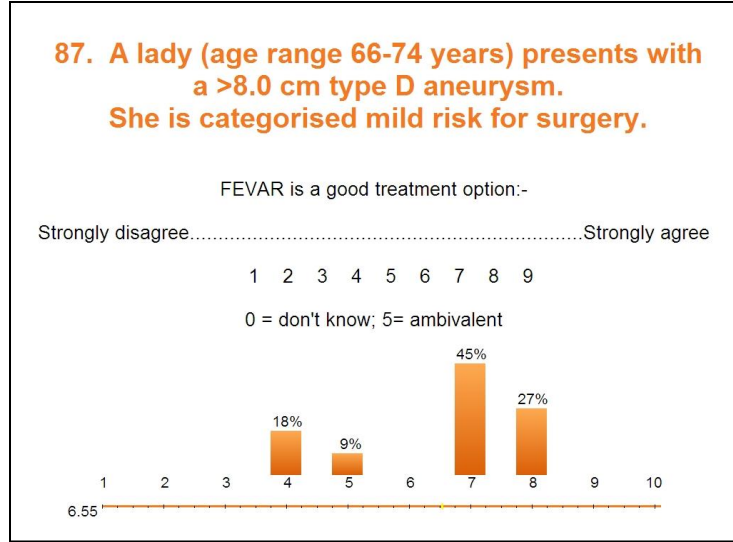
Slide 85



Slide 86



Slide 87



Slide 88

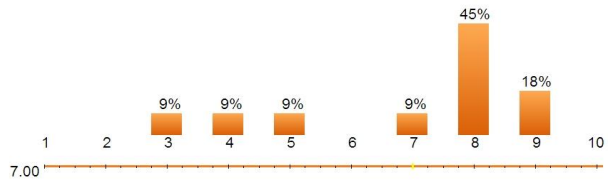
88. A man (age range 66-74 years) presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

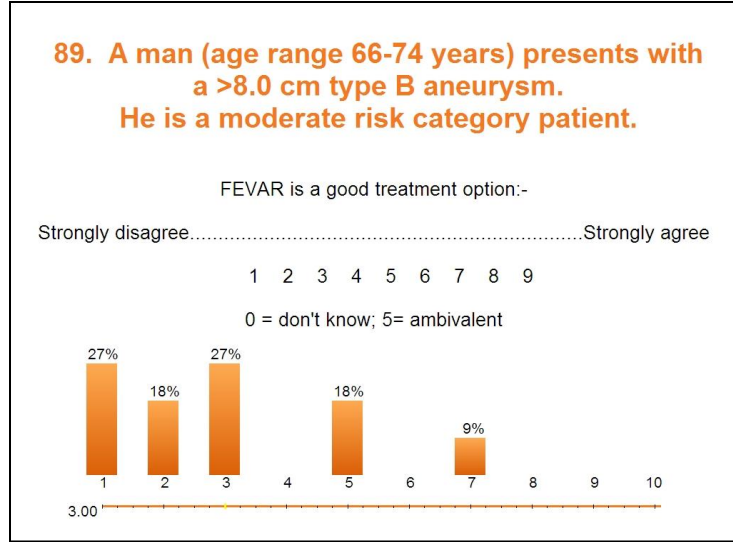
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

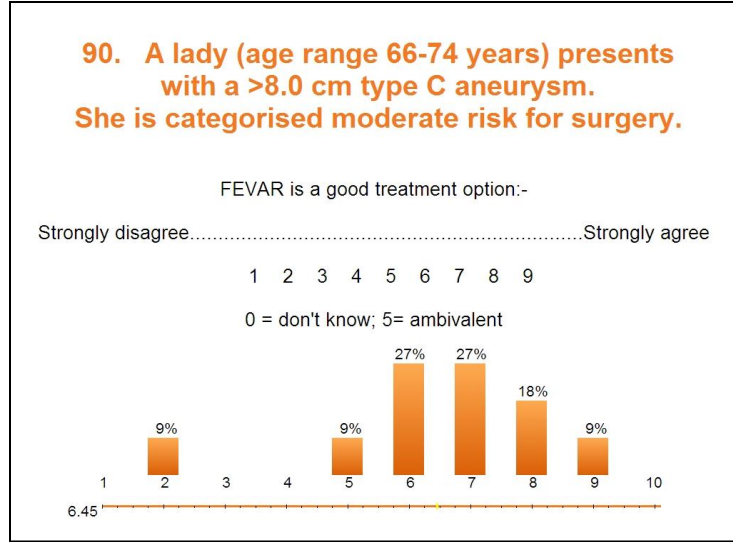
0 = don't know; 5= ambivalent



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91. A lady (age range 66-74 years) presents with a >8.0 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent

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93. A man (age range 66-74 years) presents with a >8.0 cm type B aneurysm. He is a high risk category patient.

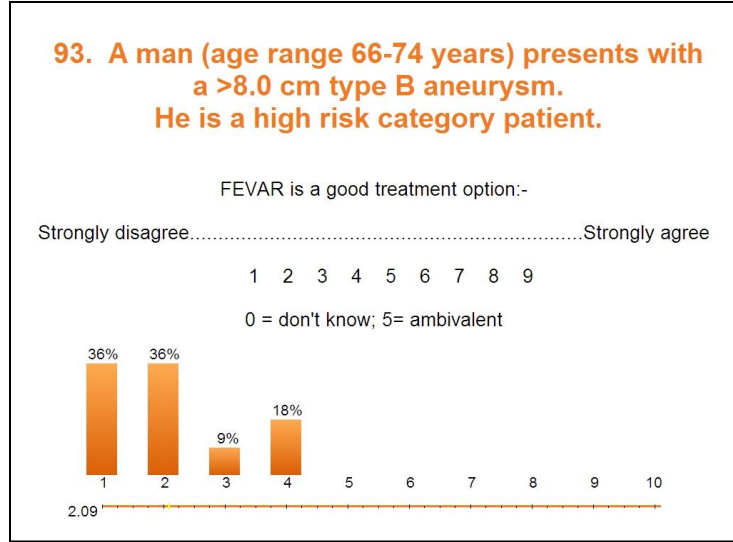
FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

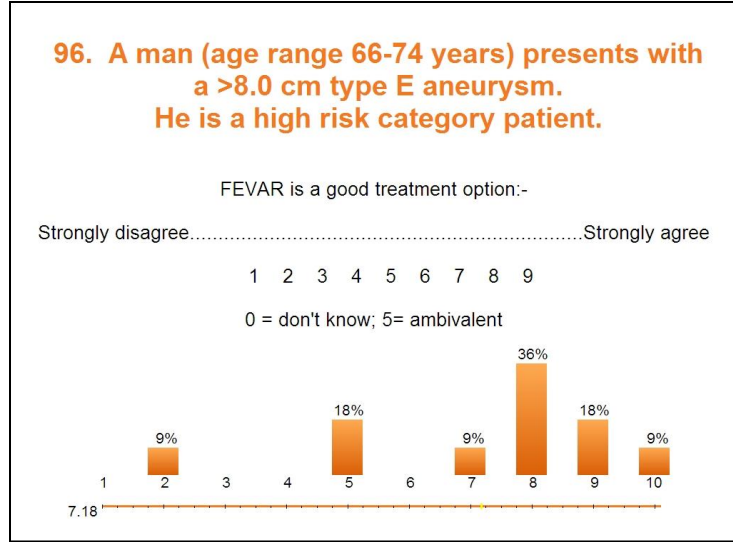
1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent

Slide 93



Slide 94



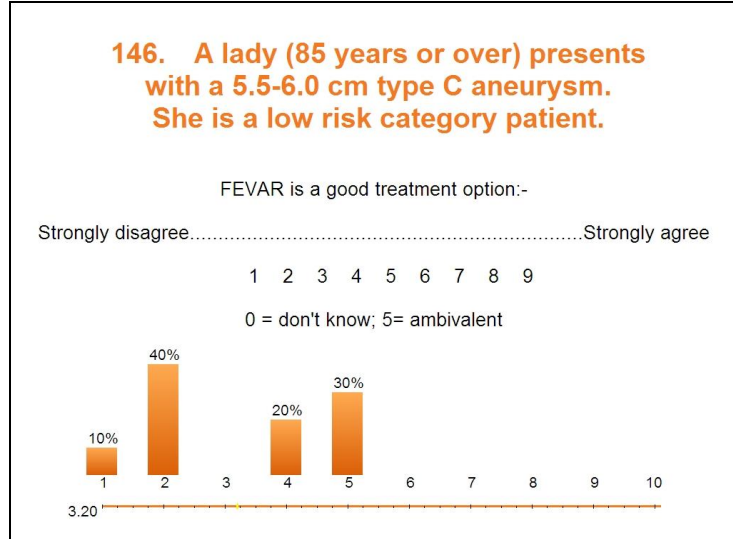
Slide 95

C) Age 75-84 years

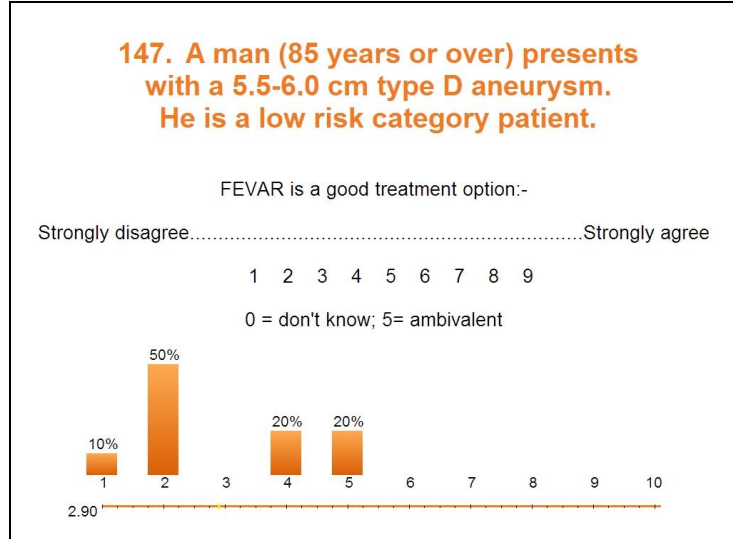
Slide 96

D) Age $>$ or $=$ 85 years

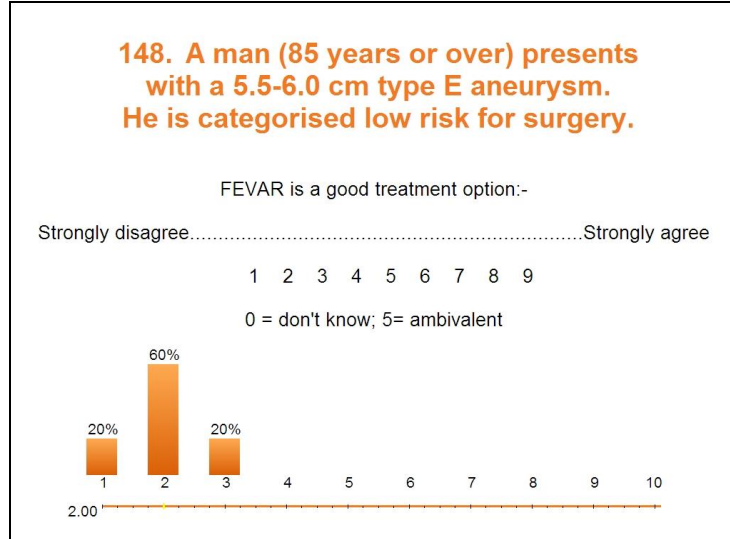
Slide 97



Slide 98



Slide 99



Slide 100

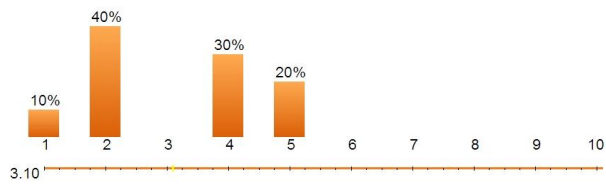
150. A man (85 years or over) presents with a 5.5-6.0 cm type C aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

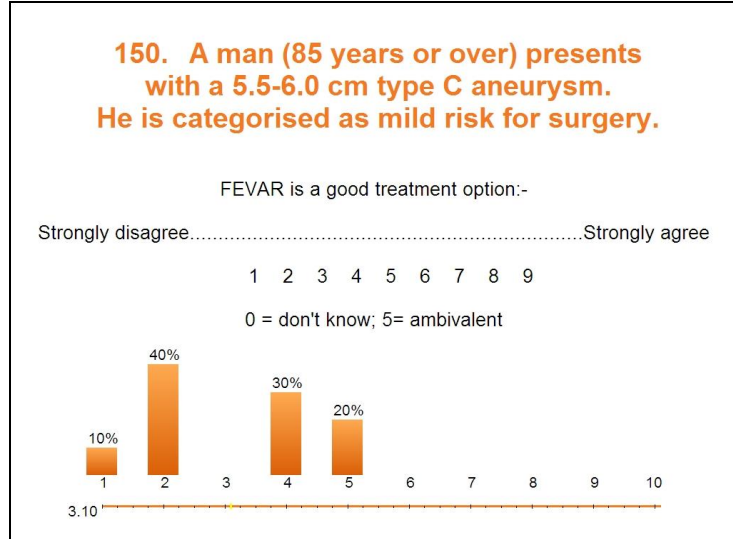
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

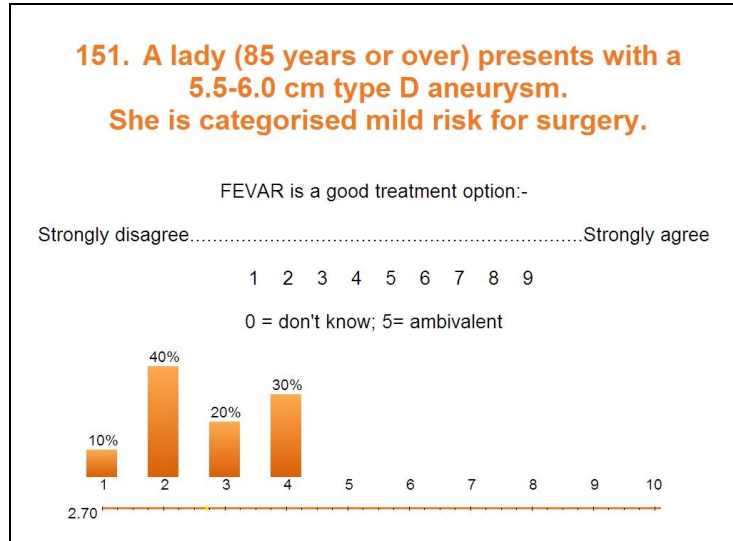
0 = don't know; 5= ambivalent



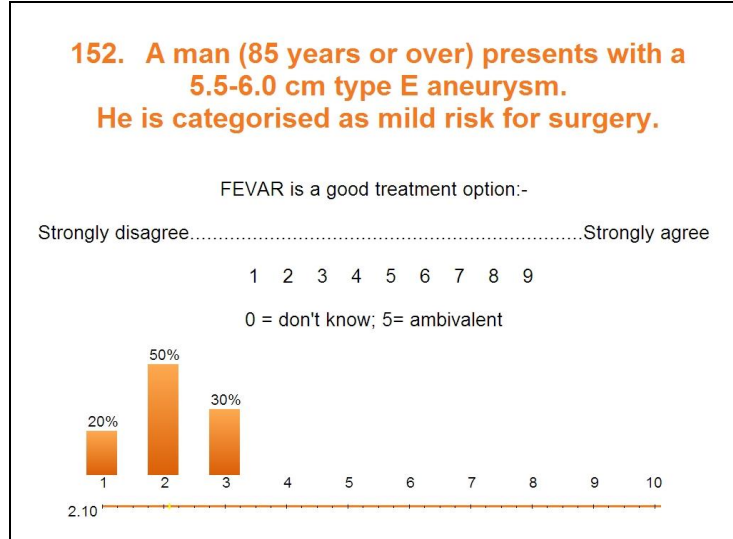
Slide 100



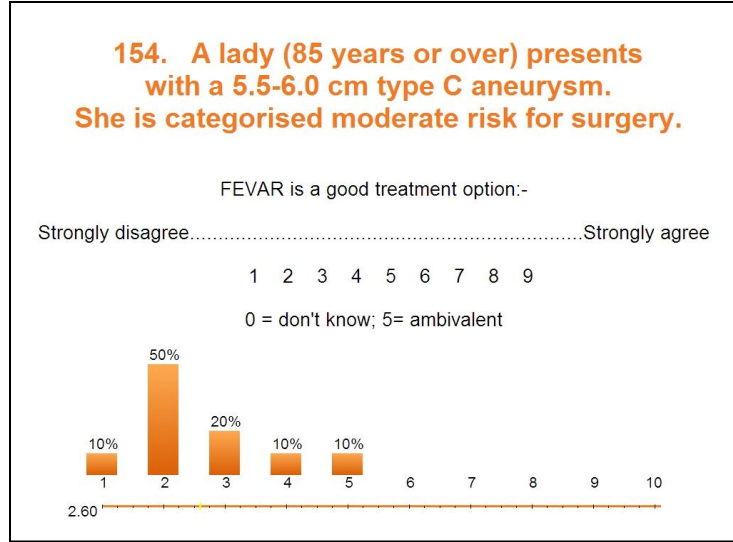
Slide 101



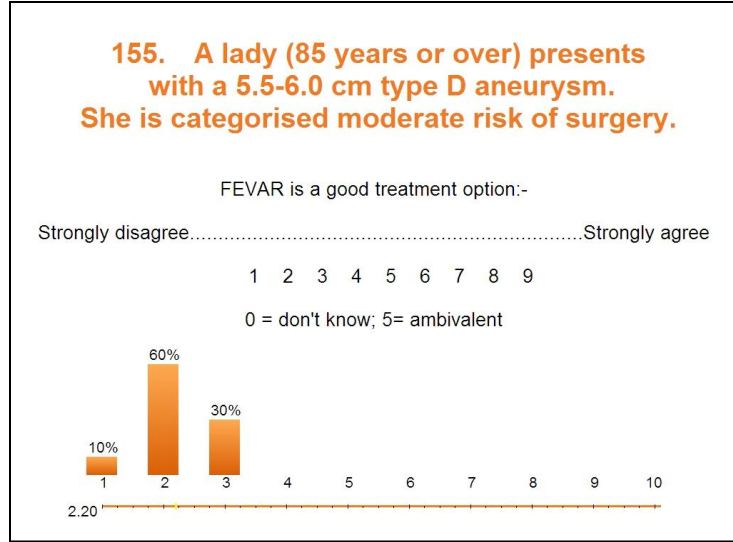
Slide 102



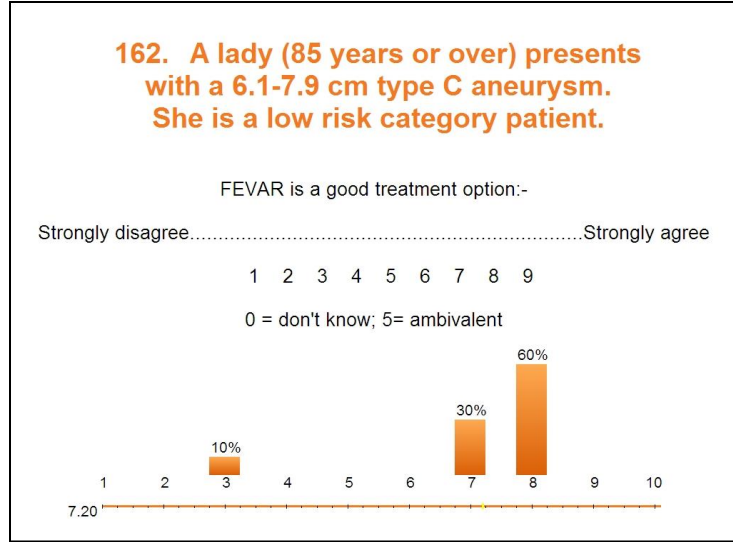
Slide 103



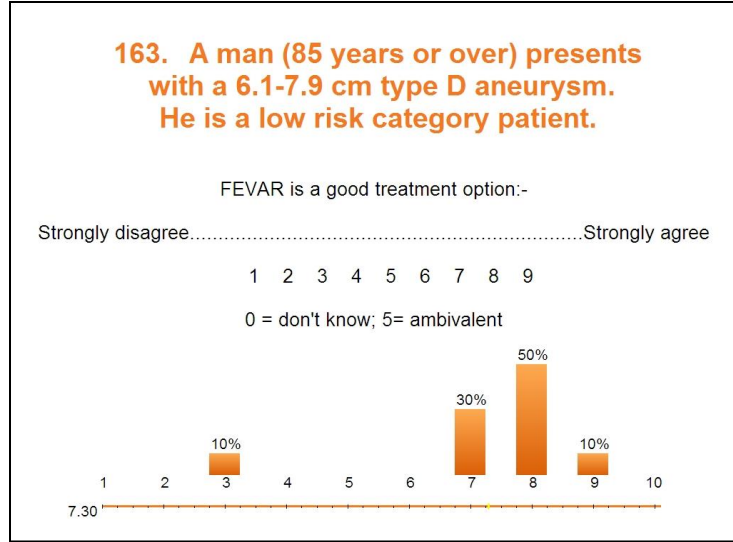
Slide 104



Slide 105



Slide 106



Slide 107

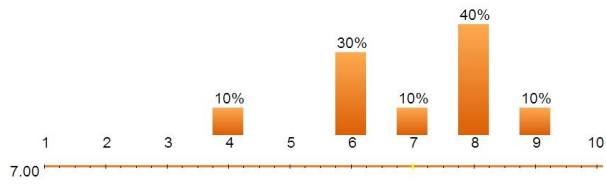
164. A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 108

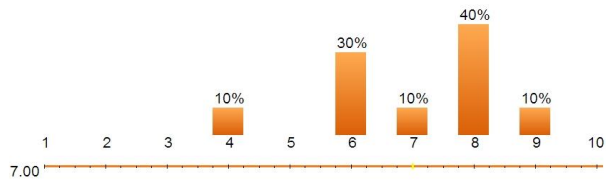
164. A man (85 years or over) presents with a 6.1-7.9 cm type E aneurysm. He is categorised low risk for surgery.

FEVAR is a good treatment option:-

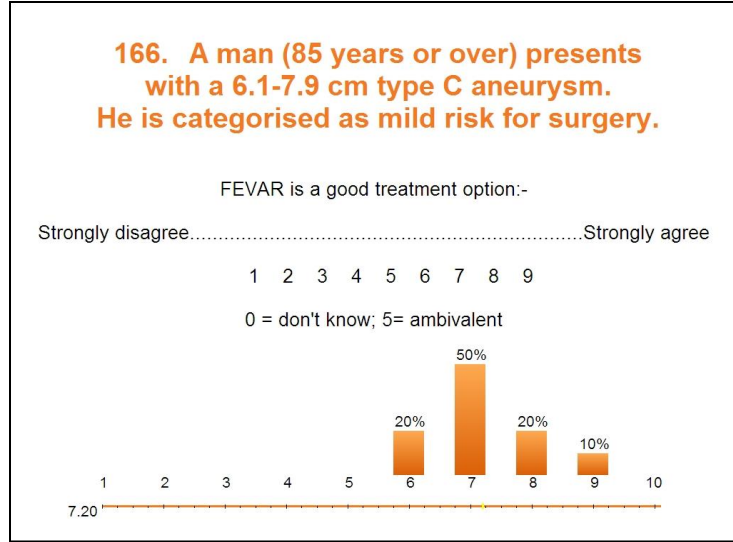
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 109



Slide 110

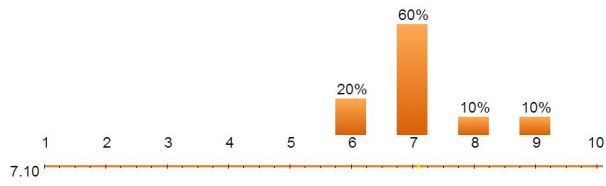
167. A lady (85 years or over) presents with a 6.1-7.9 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

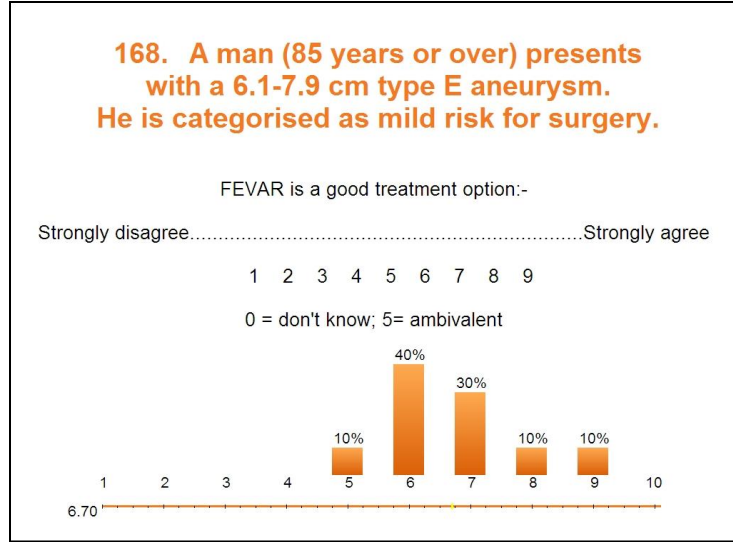
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

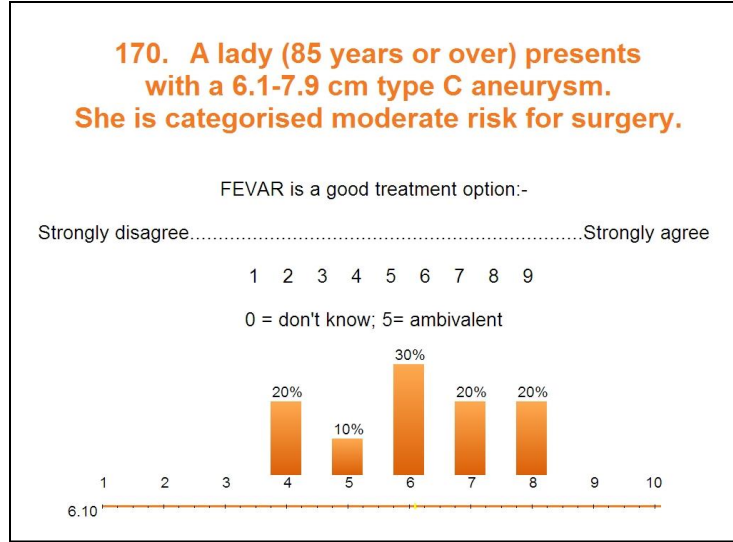
0 = don't know; 5= ambivalent



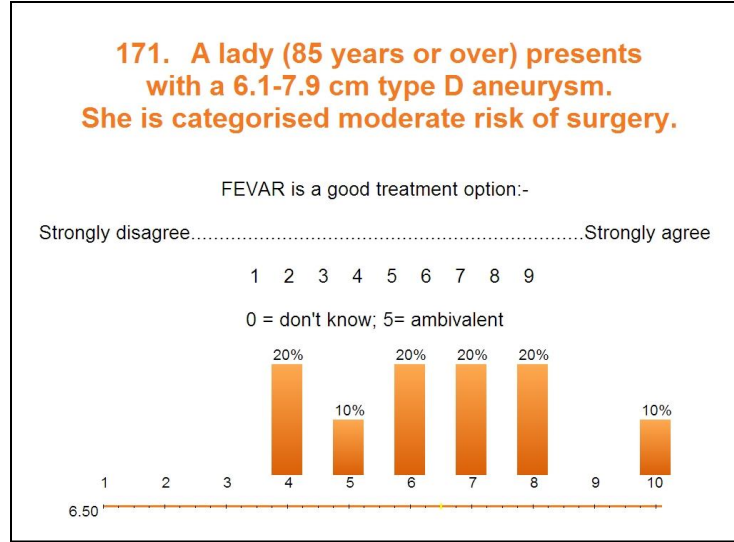
Slide 111



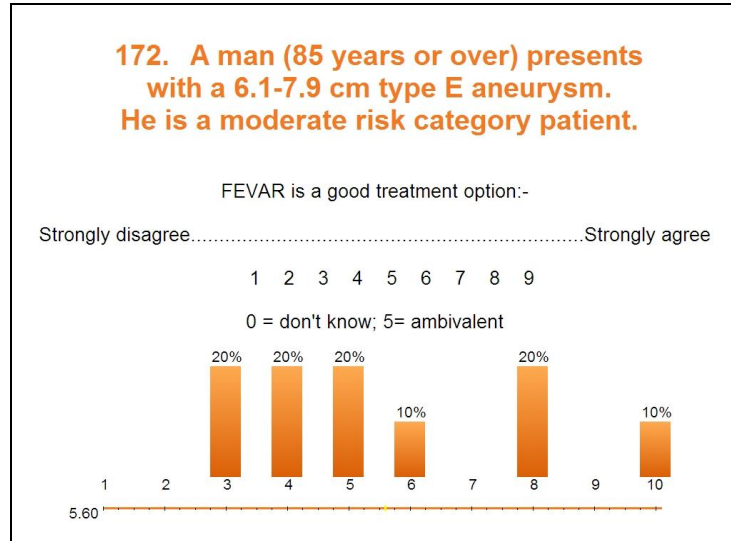
Slide 112



Slide 113



Slide 114



Slide 115

174. A lady (85 years or over) presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.

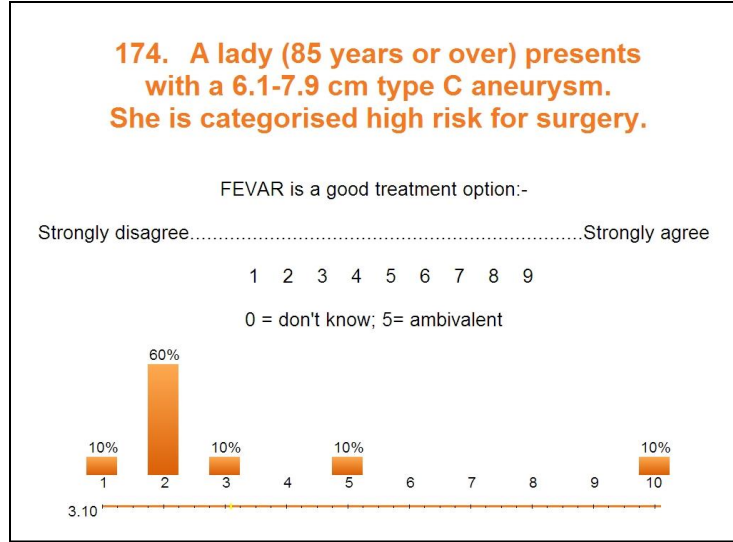
FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

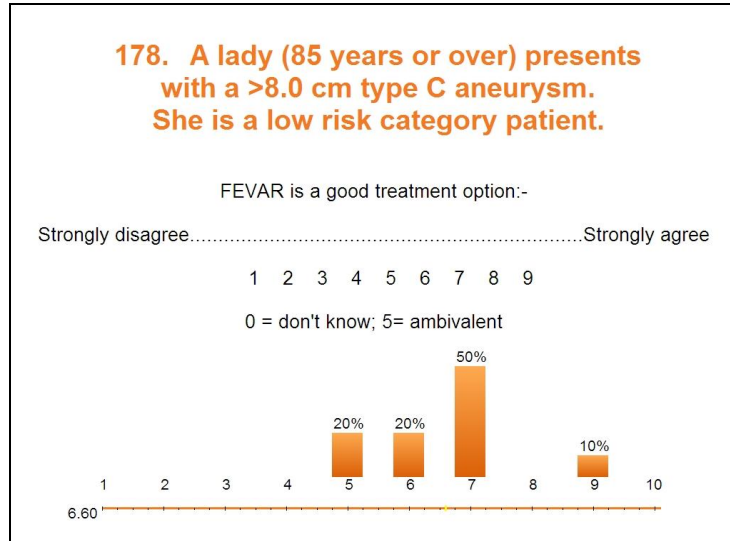
1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent

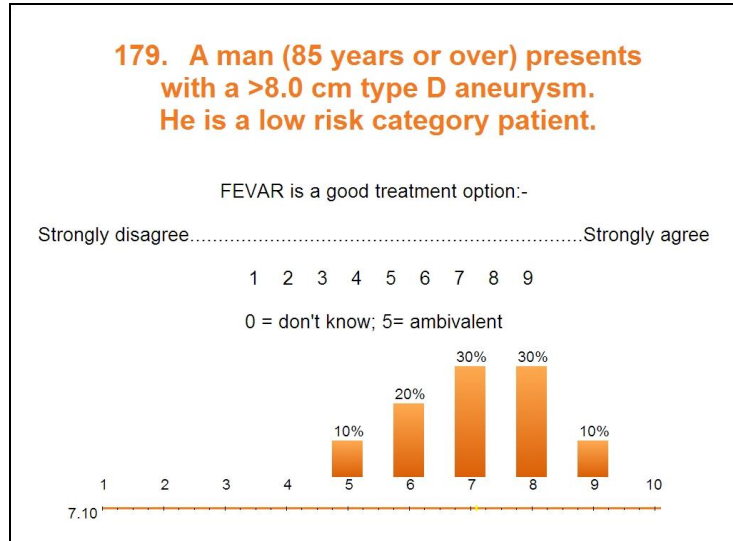
Slide 116



Slide 117



Slide 118



Slide 119

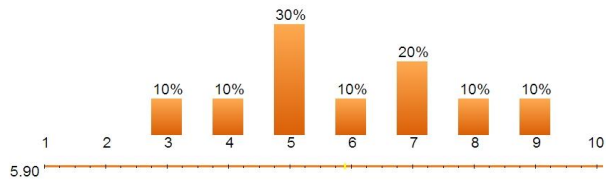
180. A man (85 years or over) presents with a >8.0 cm type E aneurysm. He is categorised low risk for surgery.

FEVAR is a good treatment option:-

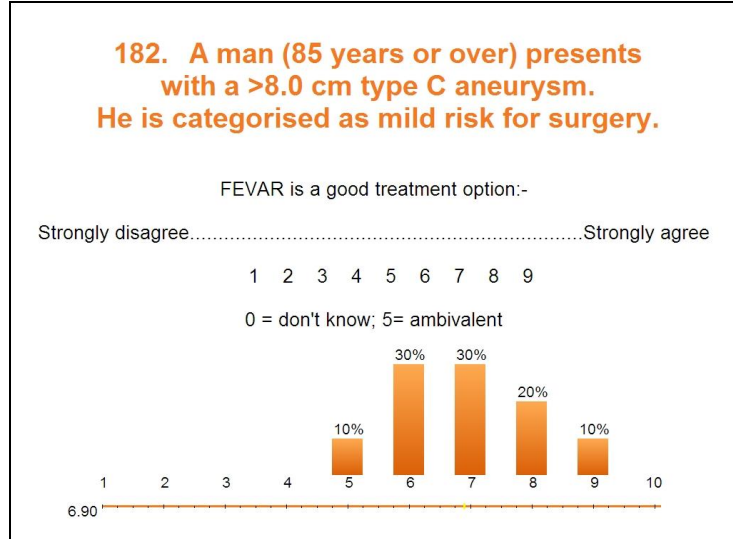
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 120



Slide 121

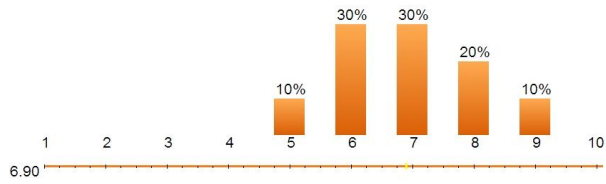
183. A lady (85 years or over) presents with a >8.0 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

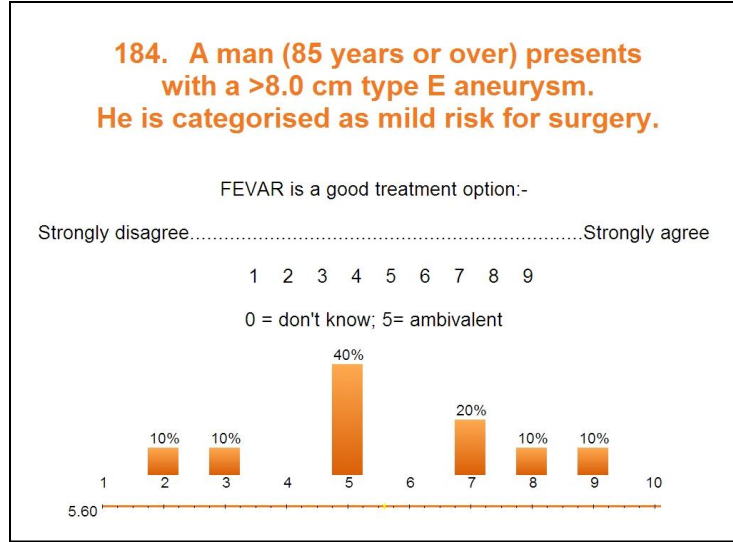
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 122



Slide 123

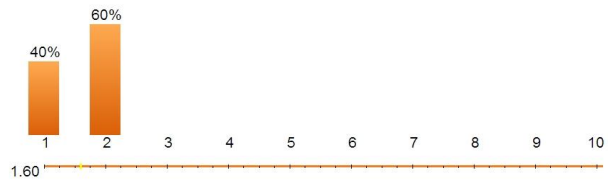
185. A man (85 years or over) presents with a >8.0 cm type B aneurysm. He is a moderate risk category patient.

FEVAR is a good treatment option:-

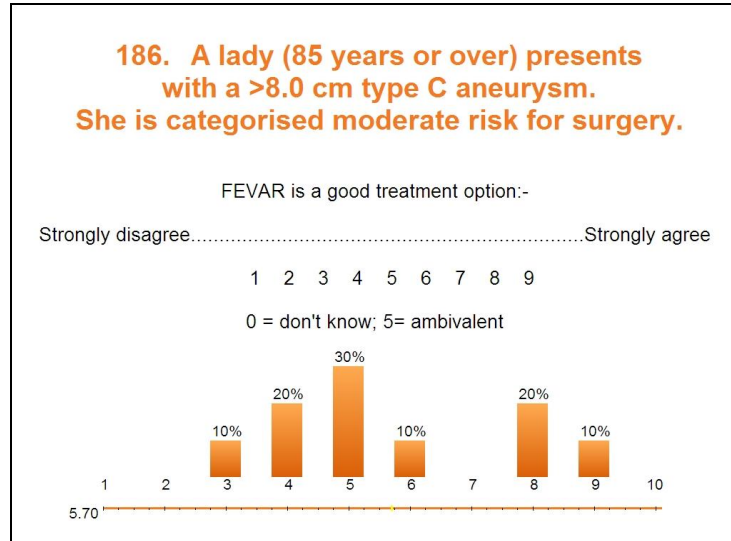
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

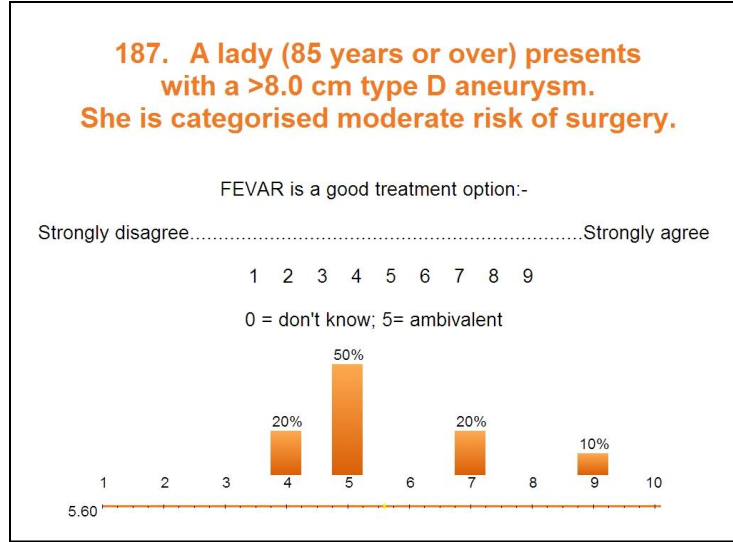
0 = don't know; 5= ambivalent



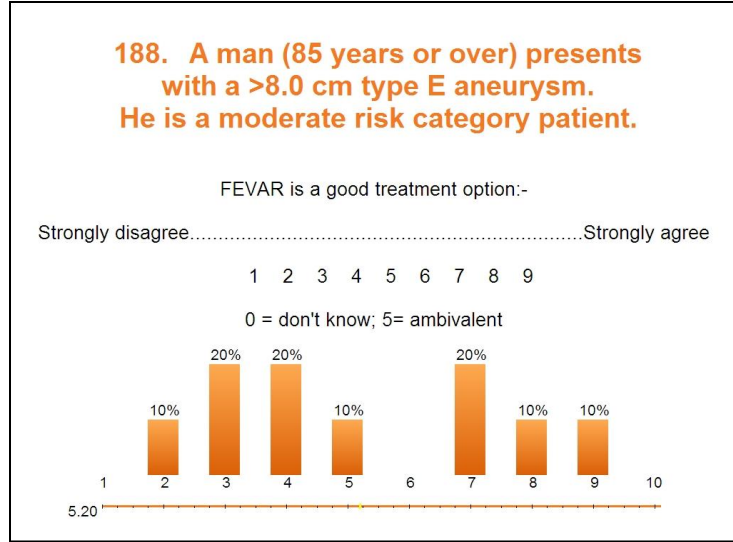
Slide 124



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Slide 126



Slide 127

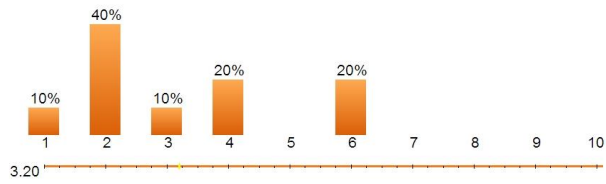
190. A lady (85 years or over) presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 128

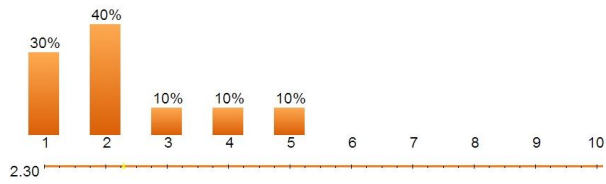
191. A lady (85 years or over) presents with a >8.0 cm type D aneurysm. She is categorised high risk of surgery.

FEVAR is a good treatment option:-

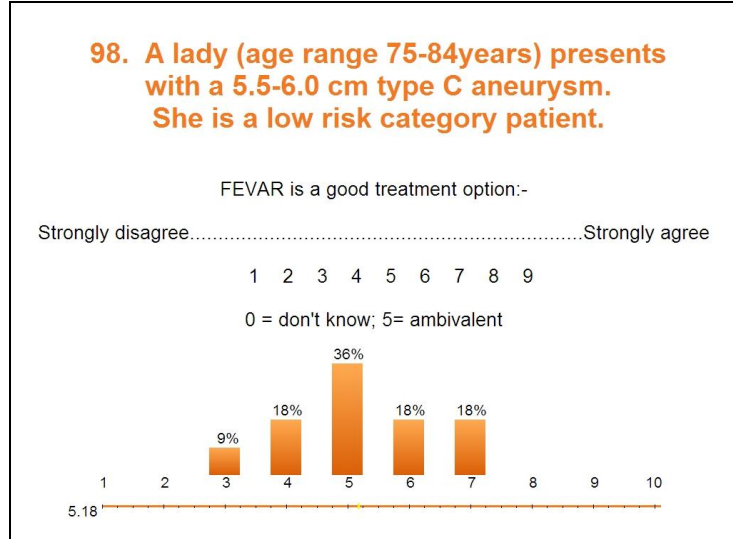
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

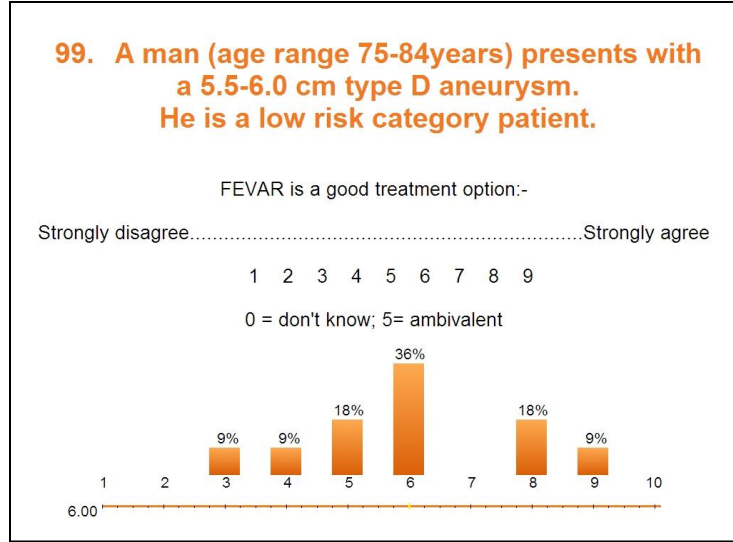
0 = don't know; 5= ambivalent



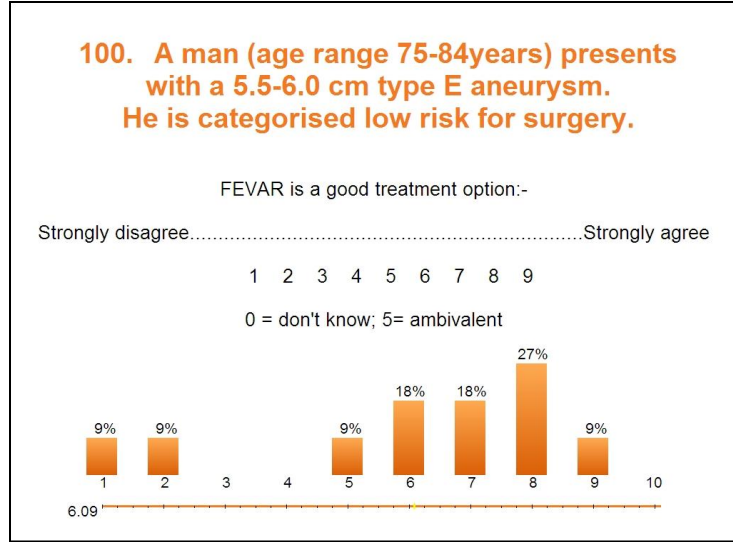
Slide 129



Slide 130



Slide 131



Slide 132

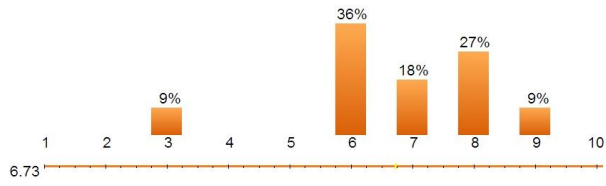
102. A man (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 133

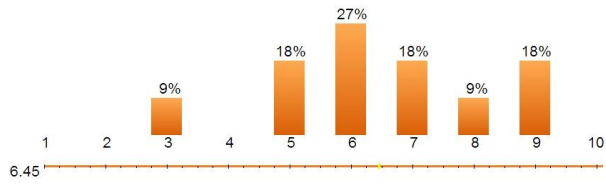
103. A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 134

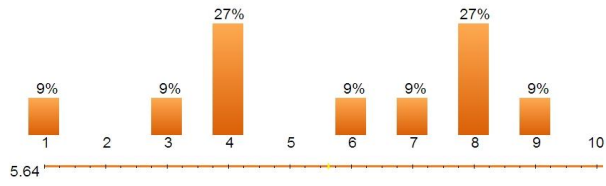
104. A man (age range 75-84years) presents with a 5.5-6.0 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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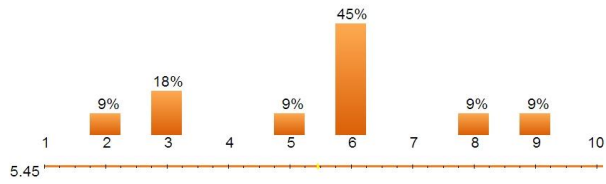
106. A lady (age range 75-84years) presents with a 5.5-6.0 cm type C aneurysm. She is categorised moderate risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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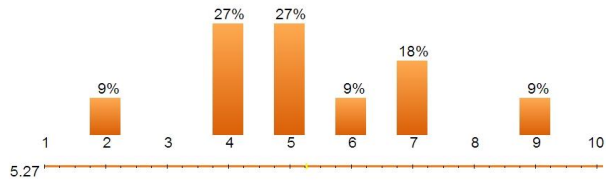
107. A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised moderate risk of surgery.

FEVAR is a good treatment option:-

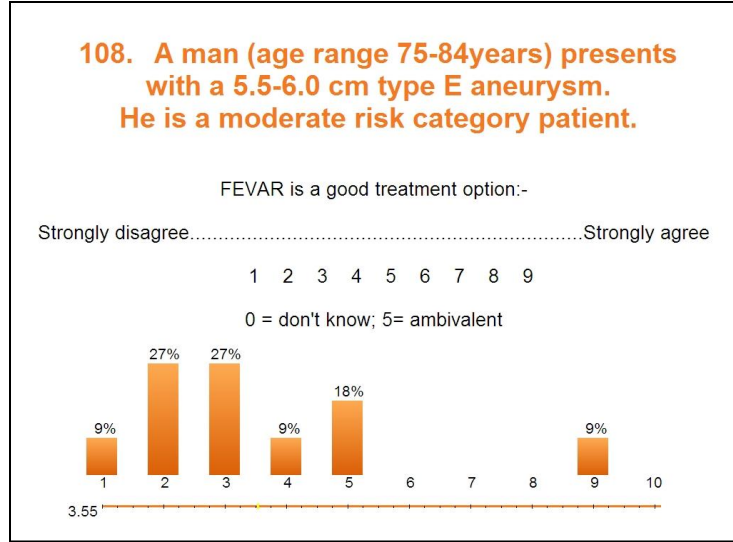
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

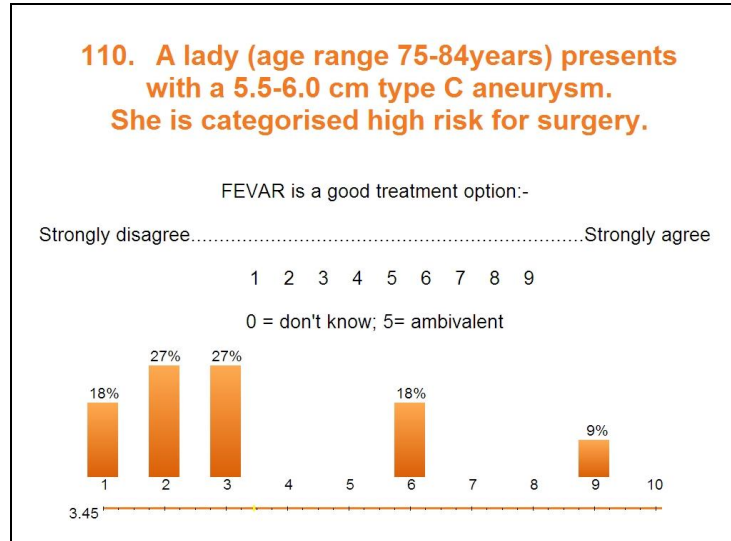
0 = don't know; 5= ambivalent



Slide 137



Slide 138



Slide 139

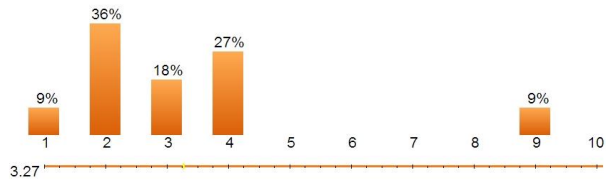
111. A lady (age range 75-84years) presents with a 5.5-6.0 cm type D aneurysm. She is categorised high risk of surgery.

FEVAR is a good treatment option:-

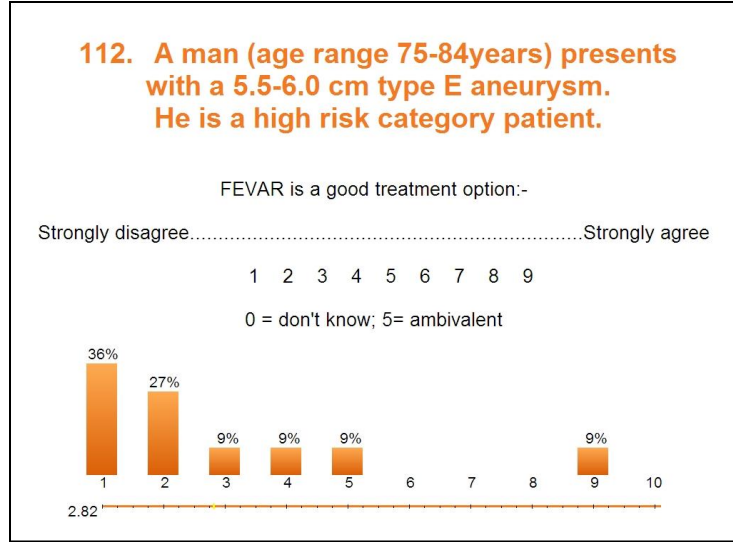
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

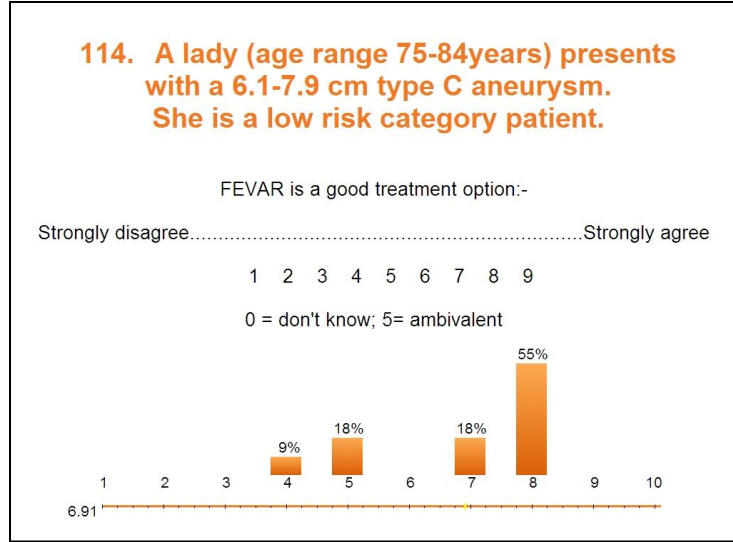
0 = don't know; 5= ambivalent



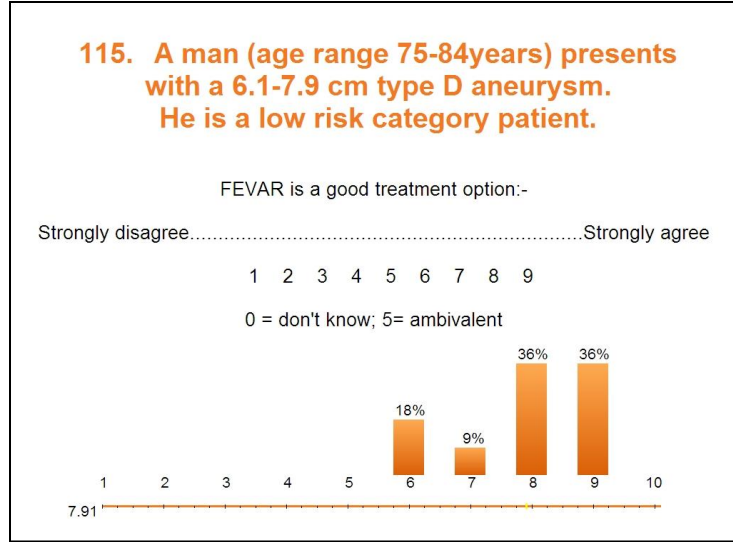
Slide 140



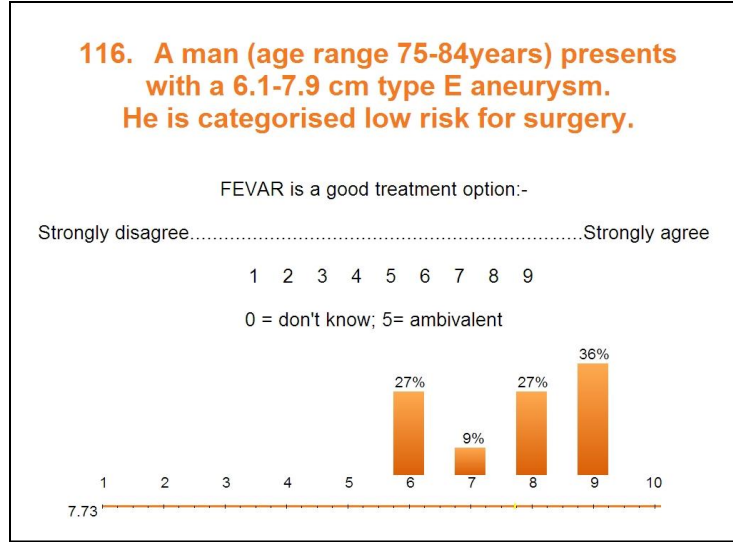
Slide 141



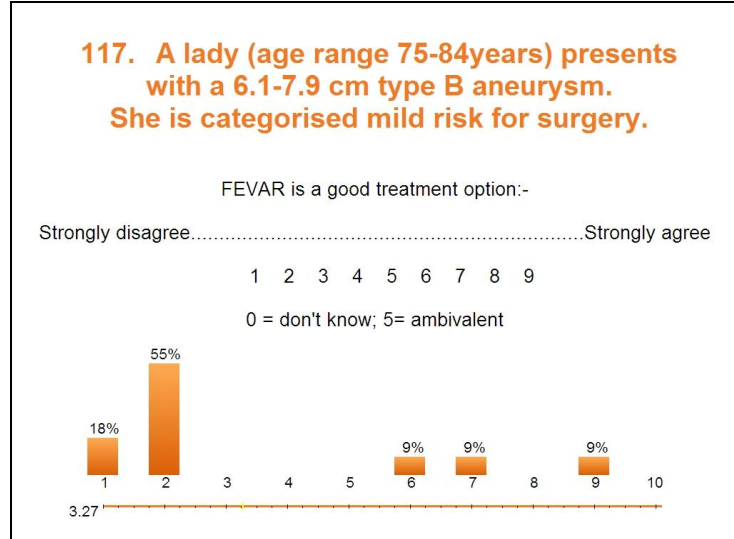
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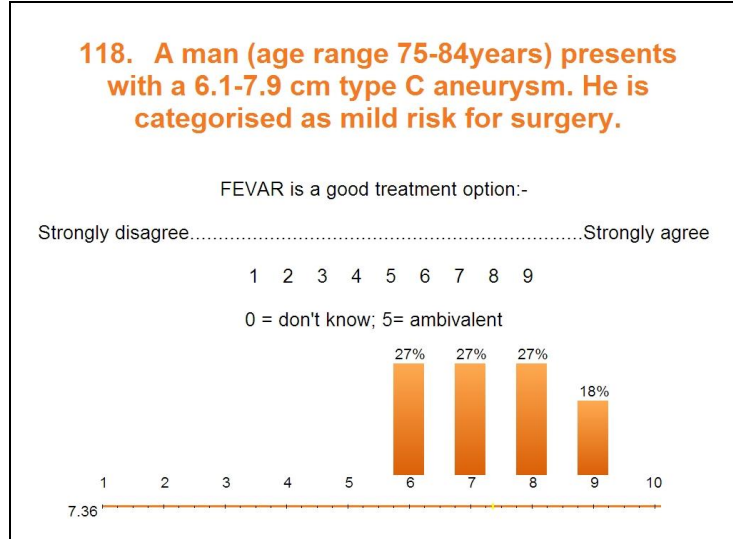
Slide 143



Slide 144



Slide 145



Slide 146

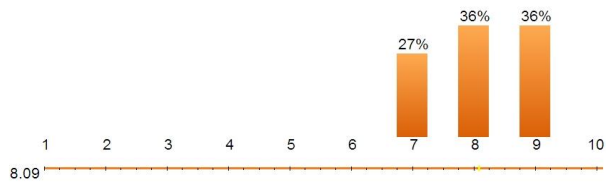
120. A man (age range 75-84years) presents with a 6.1-7.9 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

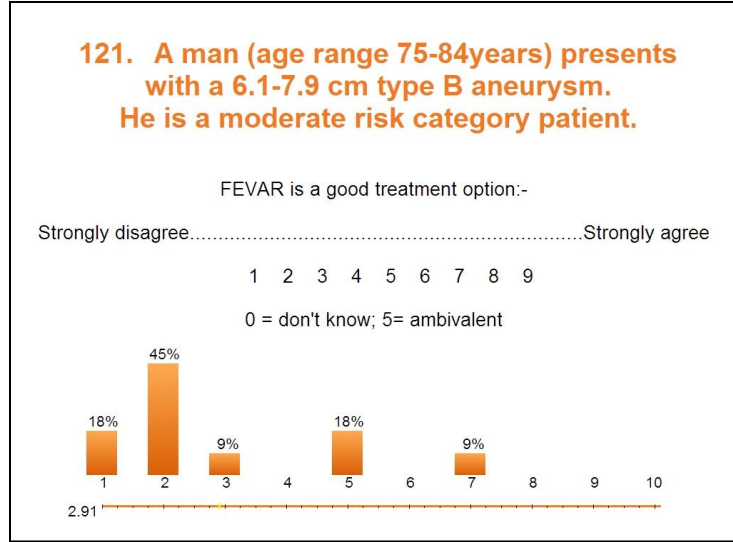
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

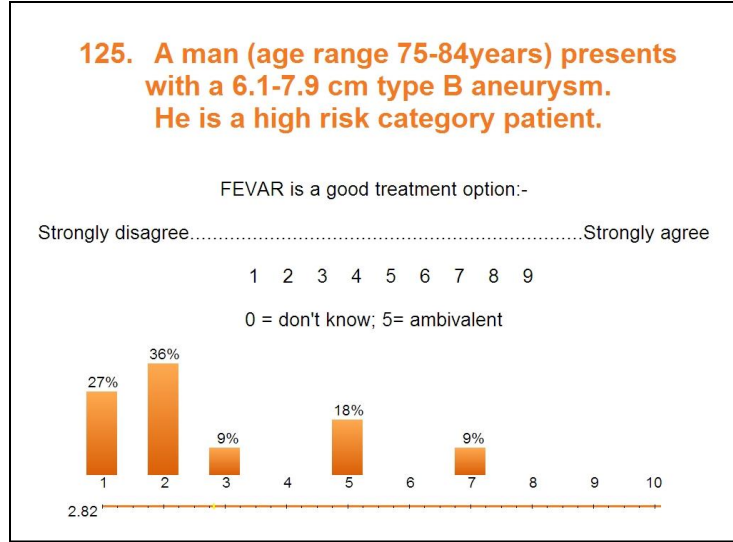
0 = don't know; 5= ambivalent



Slide 147



Slide 148



Slide 149

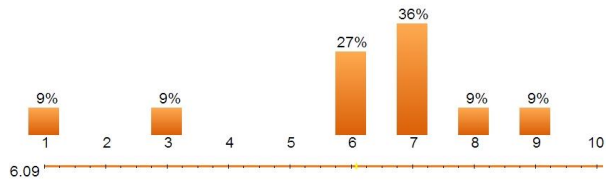
126. A lady (age range 75-84years) presents with a 6.1-7.9 cm type C aneurysm. She is categorised high risk for surgery.

FEVAR is a good treatment option:-

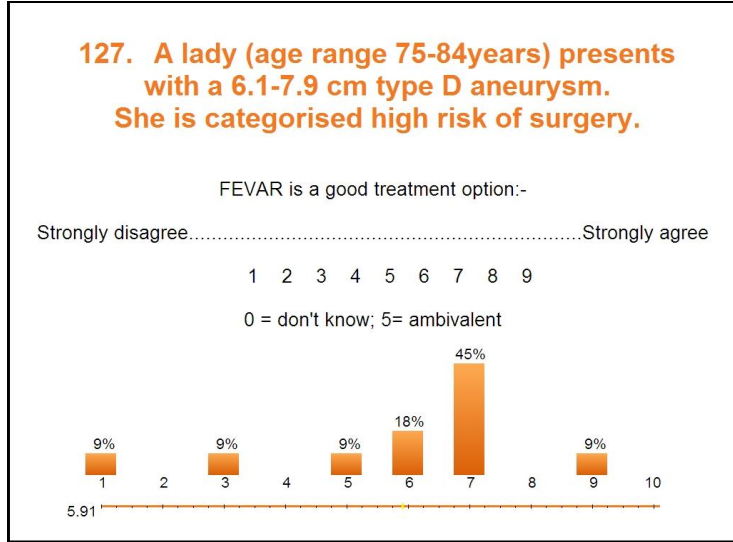
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

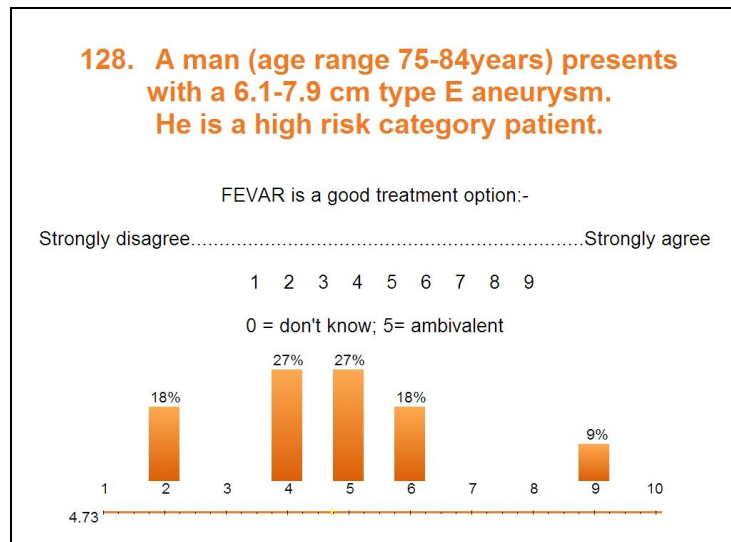
0 = don't know; 5= ambivalent



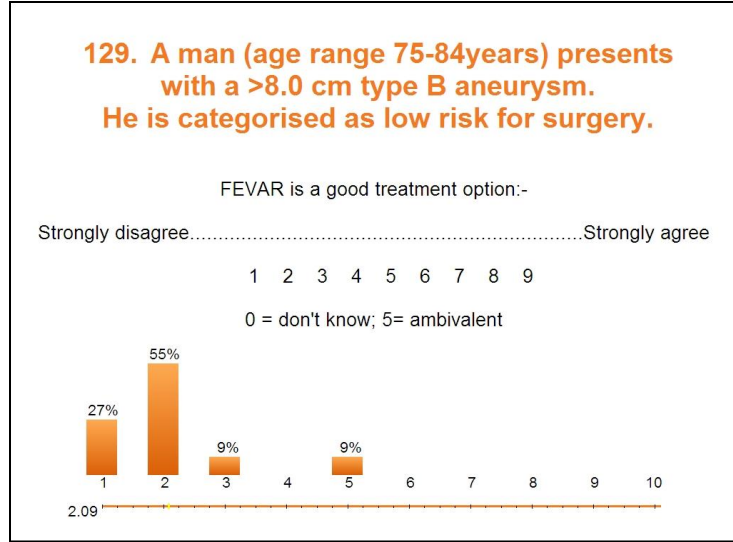
Slide 150



Slide 151



Slide 152



Slide 153

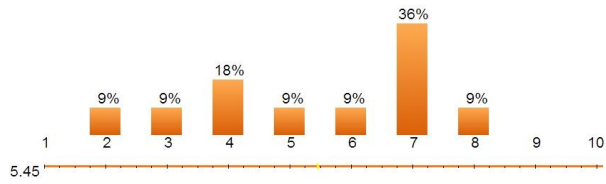
130. A lady (age range 75-84years) presents with a >8.0 cm type C aneurysm. She is a low risk category patient.

FEVAR is a good treatment option:-

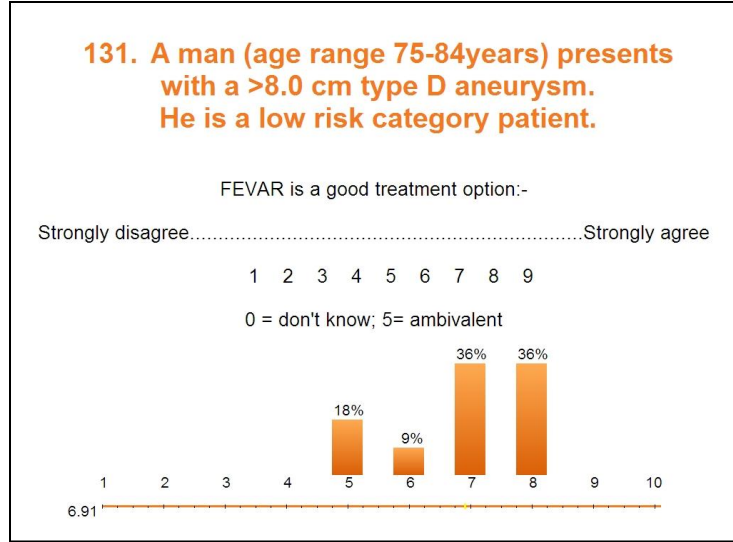
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

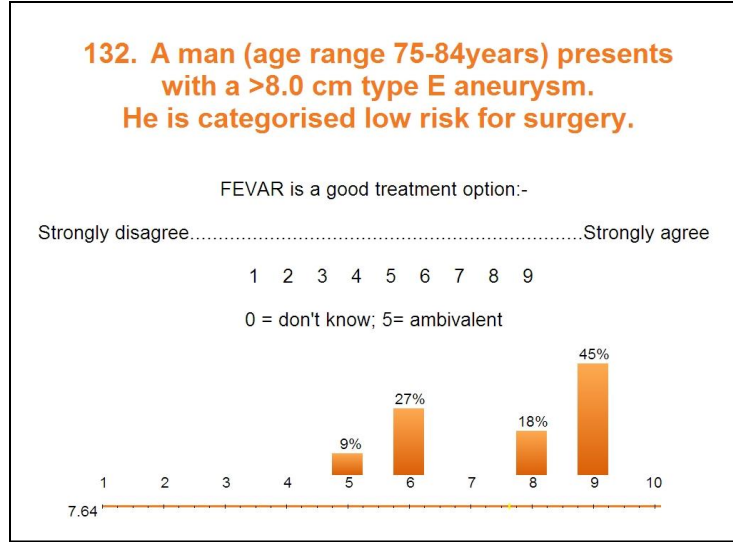
0 = don't know; 5= ambivalent



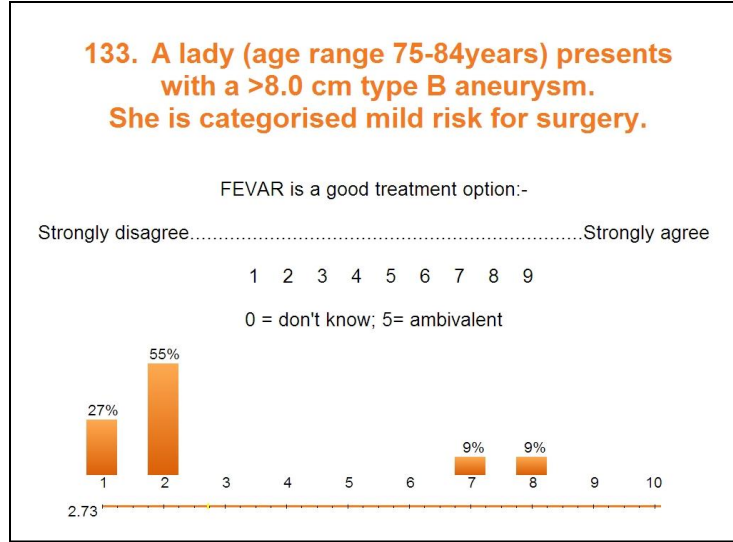
Slide 154



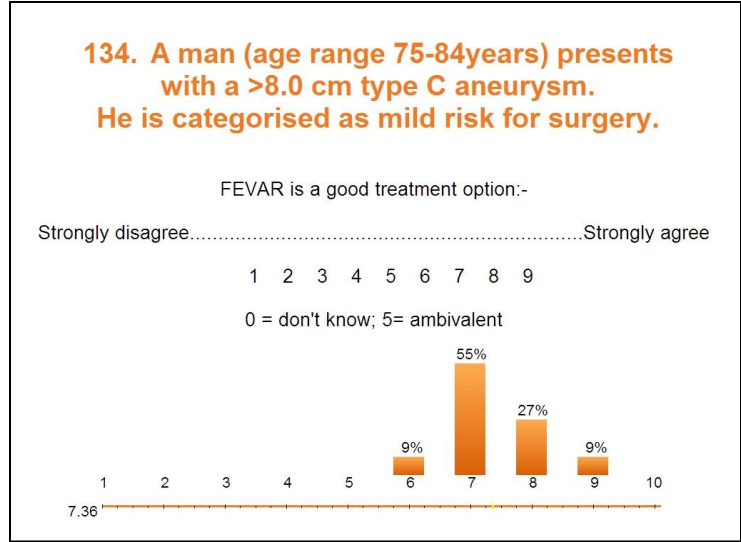
Slide 155



Slide 156



Slide 157



Slide 158

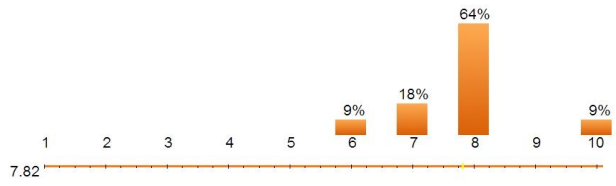
135. A lady (age range 75-84years) presents with a >8.0 cm type D aneurysm. She is categorised mild risk for surgery.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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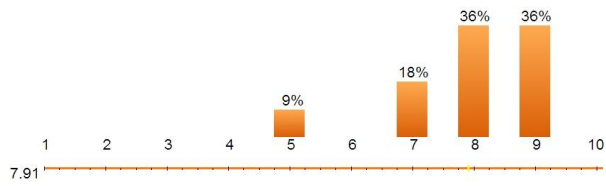
136. A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is categorised as mild risk for surgery.

FEVAR is a good treatment option:-

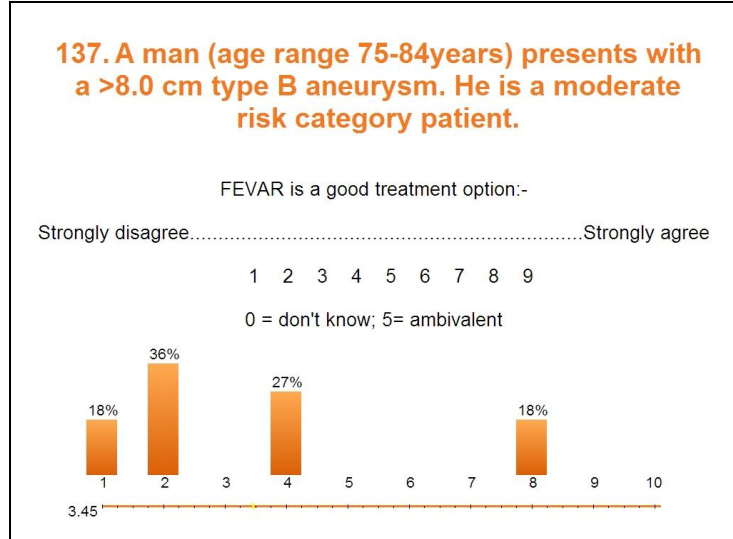
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 160



Slide 161

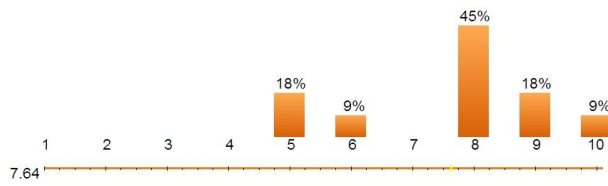
140. A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is a moderate risk category patient.

FEVAR is a good treatment option:-

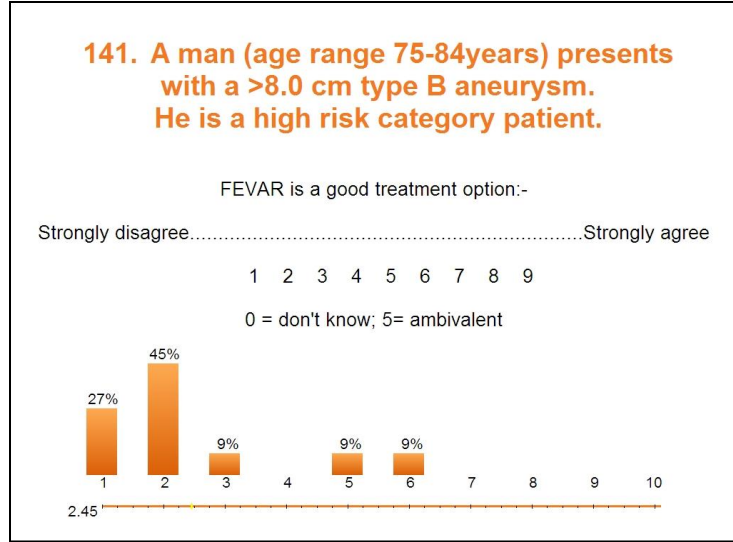
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



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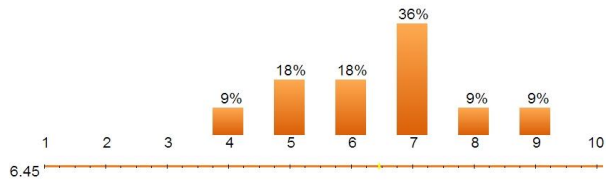
142. A lady (age range 75-84years) presents with a >8.0 cm type C aneurysm. She is categorised high risk for surgery.

FEVAR is a good treatment option:-

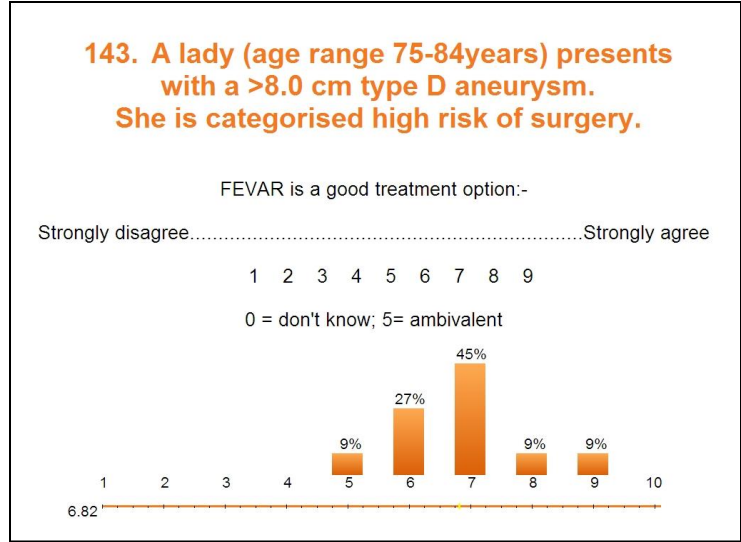
Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Slide 164



Slide 165

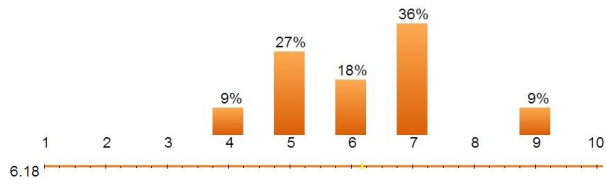
144. A man (age range 75-84years) presents with a >8.0 cm type E aneurysm. He is a high risk category patient.

FEVAR is a good treatment option:-

Strongly disagree.....Strongly agree

1 2 3 4 5 6 7 8 9

0 = don't know; 5= ambivalent



Appendix I

References

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg*. 1991;5(6):491-9.
2. Brown LC, Epstein D, Manca A, Beard JD, Powell JT, Greenhalgh RM. The UK Endovascular Aneurysm Repair (EVAR) trials: design, methodology and progress. *Eur J Vasc Endovasc Surg*. 2004;27(4):372-81.
3. Prinssen M, Buskens E, Blankensteijn JD. The Dutch Randomised Endovascular Aneurysm Management (DREAM) trial. Background, design and methods. *J Cardiovasc Surg (Torino)*. 2002;43(3):379-84.
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