EDITORS’ INTRODUCTION

Trans-Atlantic Debate: Debate whether Abdominal Aortic Aneurysm Surgery should be Centralised at Higher Volume Centers

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Over the last number of years volume-outcome relationships in vascular surgery have become increasingly relevant. At the individual surgeon level, increased experience has been linked with improved patient outcomes following volume-outcome and learning curve analyses. At the hospital level, further analyses have generally shown a similar relationship linking the busier hospitals with improved outcomes. However, is this relationship sufficient and robust enough to support important health care delivery decisions regarding centralisation of care? In England such information has helped to shape the vascular surgery reorganization process in London. The following is a discussion of the advantages and disadvantages of the practical utilization of such information.

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Part One: All Major Arterial Interventions Should Now be Performed in High Volume Centres — Abdominal Aortic Aneurysms

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Introduction

“...increased hospital and surgeon experience leads to improved outcomes following various vascular surgery procedures including EVAR”

Thomas L Forbes et al. 1996

It seems almost inconceivable that, in the modern healthcare climate, vascular professionals continue to debate whether complex surgical interventions with high morbidity and mortality, should be performed in centres of proven excellence with an adequate caseload, or whether they should remain in a greater number of more local, low volume providers with little proof of safety. The evidence for centralisation appears robust and incontrovertible, and yet there are still influential figures that suggest aneurysm services are best provided in small volume units, with sparse surgical cover and mortality rates that are often unacceptable high. There may be a multiplicity of motives for clinicians who argue for the historic “status quo”, but it is obvious that arguments in favour of small volume providers cannot be based on achieving the best outcome for patients.

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This article will present, briefly, an overview of the current evidence that supports the premise that fewer patients will die immediately after elective aneurysm surgery, if the surgery is performed in a unit with a high case volume and record of safety.

The Volume-outcome Relationship for Elective Aneurysm Repair

There is a strong evidence base that suggests that mortality from elective aneurysm surgery is significantly less in centres with a high caseload than in units that perform a lower number of procedures. A meta-analysis of the existing literature reviewed studies containing 421,299 elective aneurysm repairs and reported a weighted odds ratio of 0.66 in favour of higher volume centres dichotomised at 43 cases per year. This result echoes meta-analyses of most complex surgical interventions and should be regarded as definitive and highly informative.

However, although robust, meta-analyses can be criticised due to publication bias, heterogeneity and the predominance of data from certain countries. Additional information may be gathered by analysing national administrative data. A typical "volume-outcome" curve is illustrated in Fig. 1 for elective aneurysm repair in the UK between 2001 and 2005. These data demonstrated that the mean mortality for an elective repair was 7.4%, and that 80% of all aneurysm repairs were carried out in units performing less than 33 cases annually. Importantly, the mortality rate in the units with lowest caseload was 8.5% as compared to the 5.9% reported by units with a higher workload. Even more worrying are the many small volume centres where the elective mortality may often exceed 20% (region A in Fig. 1).

Individual hospital performance from administrative datasets can be assessed by safety plots. In a safety analysis of UK data 30 of 410 hospitals performing elective aneurysm surgery had a mortality rate significantly above the national average. All of these units with high mortality rates were at the low end of the volume spectrum. Additionally, to statistically demonstrate a record of safe surgery (below the national average), an annual volume of at least 39 elective cases was required with a mean mortality of 7.4%. If the national mean mortality were to be lower (as might be expected with EVAR), then a greater number of cases would be needed in order to prove safety.

The blunt message, virtually unopposed in a vast literature base from many different sources, is that elective and ruptured aneurysm repair is performed with lower mortality rates in units with a large caseload, that services are currently inappropriately organised in a mass of small volume centres and that units with low volumes cannot demonstrate evidence of safety.

In other specialities, such data have been sufficient to prompt a reorganisation of services with centralisation of complex interventions. However vascular surgery has been curiously reluctant to recognise the importance of the volume-outcome relationship, with an attendant excess mortality under current service configurations, and centralise aneurysm services. A number of theoretical objections to centralisation have been raised and these will be addressed below.

Is the Magnitude of Absolute Difference in Mortality Sufficient to Justify Centralisation?

It might be argued that the 3–4% absolute mortality difference between the lowest volume and highest volume units does not justify centralisation of aneurysm services. It must, by necessity, be a matter of opinion how big a mortality difference is acceptable to an individual healthcare system, but we would argue that all patients should have access to high quality services, with a proven record of safety.

Irrespective of the absolute mortality differences in elective surgery, the mortality differences in the emergency setting are more dramatic. In a study of ruptured AAA in the UK between 2003 and 2008, the absolute mortality differences between hospitals in the lowest and highest volume quintiles reached a staggering 24%. The significance of this absolute difference would not appear to be in doubt.

Of course, relying on operative mortality only tells part of the story, as case mix and patients considered "unfit" for surgery must also be considered. In these areas there is evidence to suggest disparate practices, with no surgical intervention being offered to over 50% of emergency patients in lowest quintile units as compared to approximately 20% in the highest volume centres. Again, the absolute difference in these practices cannot be considered acceptable.

What about Low-volume Centres with No Mortality?

In any volume-outcome plot there are a number of relatively low-volume units that have an elective aneurysm mortality of 0% (region B in Fig. 1). It is tempting to speculate that these units should not be part of any centralisation due to their apparent good results. This zero mortality paradox was investigated by Dimick and Welch who studied hospitals that had reported a zero mortality between 1997 and 1999. When the outcomes for these
hospitals in 2000 were compared with the rest of the Medicare data, the “zero mortality” hospitals had a lower caseload (4 vs. 13) and higher mortality (6.3% vs. 5.8%). The finding of zero mortality in this study was therefore not reflective of superior results, just a function of low case volume. None of these hospitals would be able to demonstrate statistical evidence of safety.

**Are Volume-outcome Data Applicable to the Endovascular Era?**

The majority of data investigating the effect of caseload on elective aneurysm surgery have been derived by analysis of patients undergoing open repair. Clearly, the advent of endovascular surgery will change this relationship. Two recent studies have investigated the effect of endovascular repair on the volume-outcome relationship for elective aneurysm surgery. The studies demonstrated that:

- Hospital volume was significantly related to elective aneurysm mortality for open repair, endovascular repair and the combined (open + endovascular) group. There was a significant difference between endovascular mortality between the lowest and highest quintile providers (6.88 vs. 2.88%), and a 77% reduction in mortality was observed for every 100 endovascular repairs performed.
- Higher volume hospitals were more likely to adopt endovascular therapy (44% in high volume hospitals vs. 18% in low volume hospitals).
- Hospital volume was an independent predictor of mortality.
- Results were defined by the total aneurysm caseload rather than either endovascular or open cohorts alone i.e. hospitals with a large, predominantly endovascular, caseload also reported better than average results from open aneurysm repair.

The data from both studies suggested that, if anything, the relationship between hospital caseload and outcome becomes even more important if endovascular technology is incorporated into the analysis.

**Travel Times and Patient Preferences**

The most important aspect defining the provision of aneurysm (or any other) services must be the acceptability to patients. There is a clear trade off between the advantages associated with a high-volume centre and the difficulties caused by prolonged travel times for both patients and relatives. In a modelling exercise Holt et al. defined the increased travel times that would be associated with a centralised model of care for aneurysm surgery in the UK. If aneurysm surgery was performed in centres with a record of demonstrable safety and a relatively low volume threshold of 33 procedures per year, the number of hospital performing aneurysm repair fell from 242 to 48 and travel times increased by 28 min relative to the nearest hospital.

The acceptability of increased travel times was assessed in a study of 262 patients. Patients were asked to complete a questionnaire that was calibrated against the time an individual was willing to travel to access specific attributes of an aneurysm service. Approximately 92% of individuals stated a willingness to travel for at least 1 h beyond their nearest hospital in order to access services with a lower perioperative mortality, lower non-fatal complication rates, a high annual caseload of aneurysm repairs, and routine availability of endovascular repair. This study demonstrated that patients’ preference to access safe, modern surgery in a high volume centre outweighed their concerns over travel. The significance of these data should not be underestimated when considering where aneurysm services should be delivered.

**Centralisation Implies Poor Surgeon Performance in Low-volume Units**

Undoubtedly, discussion of centralisation has been personalised by the feeling that stopping aneurysm surgery at an institution, implies that surgeons in these centres are performing poorly. Whilst there is a relationship between individual surgical caseload and outcome, it is the institutional experience which is the most important facet of delivering good quality care. The importance of the institutional component was recently emphasised by Ghaferi et al. who studied 84,730 inpatients undergoing vascular or general surgery. The study reported that complication rates after surgery were not different between high and low volume institutions but that mortality following major complications was much higher in the low-volume units (21.4% vs. 12.5%). This study gives credence to the impression that outcomes may be defined by the institutional facilities, protocols and familiarity with challenging management of complex interventions.

**Conclusions**

The brief review of evidence presented above mandates the centralisation of aneurysm services to high quality, high volume providers with a proven record of safety. There appear to be no convincing arguments for maintaining aneurysm repair in low volume hospitals. We have deliberately not discussed the financial implications of such centralisation but these are likely to be neutral at worst with increased travel times being balanced by increased quality and reduced hospital stay as units move towards national and international exemplars.

Perhaps the most pertinent unresolved question is how to define high and low-volume centres. The available literature utilises differing thresholds according to study design with many studies merely dividing caseload data into quartiles or quintiles to demonstrate the nature of the relationship. Exact volume thresholds will differ in various healthcare systems where there is disparate organisation of services. However, it is important to note that the volume-outcome relationship is continuous with improvements in outcome seen with increasing volume. Clearly, a pragmatic approach to defining an appropriate threshold
is mandated. We feel that aneurysm repair should not be undertaken in centres performing less than 50 cases per year, and ideally than annual caseload should approach 150.

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None.

References


Part Two: The Case Against Centralisation of Abdominal Aortic Aneurysm Surgery in Higher Volume Centers

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Introduction

At first glance this might not seem like much of a debate. Over the last decade or so, proponents of centralisation of abdominal aortic aneurysm (AAA) surgery have amassed volumes of literature in support of their position, with much of this literature originating from the esteemed St. George’s Vascular Institute.1–5 Their arguments are persuasive with their convincing evidence of a volume—outcome relationship with AAA surgery. This relationship is so intuitive to most surgeons, and so carefully demonstrated by the centralisation proponents, that it is become an almost indisputable motherhood type principle. That’s all well and good when the debate remains an academic one, but when such centralisation strategies are implemented a closer and more practically relevant analysis is necessary. On further scrutiny this volume—outcome relationship is not as clear cut and persuasive as it might be at first glance.

Biases on both sides of the argument are obvious and pervasive. Not surprisingly, centralisation supporters tend to work at higher volume centres with favourable outcomes while those resisting centralisation efforts often work at lower volume centres, often with favourable outcomes. Centralisation of AAA surgery has occurred in several international jurisdictions with either a planned and data driven approach,6 or an unplanned approach by exclusion.7 In either instance the practical challenges of a centralisation strategy have outlined the complexity of the situation, rather than the simplicity of a simple volume—outcome relationship. So, before blindly following our colleagues who would advocate centralisation of AAA surgery, let’s take a closer look at some of the intricacies, challenges, and possibly some negative effects that such a strategy would necessitate.

Volume—Outcome Relationship

When superficially examined this volume—outcome relationship with elective aneurysm surgery is simple, intuitive, and makes good common sense. We would hope that more experience results in better results, and it generally does.

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