International Journal of Surgery 12 (2014) 231–236

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

Original research

Multimodal intraoperative monitoring: An observational case series in high risk patients undergoing major peripheral vascular surgery

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ARTICLE INFO

Article history:
Received 28 November 2013
Accepted 25 December 2013
Available online 8 January 2014

Keywords:
Multimodal intraoperative monitoring
Haemodynamic monitoring
Depth of anaesthesia monitoring
Cerebral oximetry

ABSTRACT

Recent guidelines from the National Institute of Health and Care Excellence (NICE) and the UK National Health Service (NHS) have stipulated that intraoperative flow monitoring should be used in high-risk patients undergoing major surgery to improve outcomes and reduce costs. Depth of anaesthesia monitoring is also recommended for patients where excessive anaesthetic depth is poorly tolerated, along with cerebral oximetry in patients with proximal femoral fractures. The aims of this descriptive case series were to evaluate the impact of a multimodal intraoperative strategy and its effect on mortality and amputation rate for patients with critical leg ischaemia.

In an observational case series, 120 elderly patients undergoing major infra-inguinal bypass between 2007 and 2012 were included in this retrospective analysis of prospectively collected data. Nominal cardiac output (nCO, LiDCO*rapid*, LiDCO Ltd, UK), bispectral index to monitor depth of anaesthesia (BIS, Covidien, USA) and cerebral oxygenation, rSO_2 (Invos, Covidien, USA) readings were obtained before induction of general anaesthesia and throughout surgery.

30 day, 1-year mortality and amputation rates were analysed. Demographics and physiological parameters including correlation with V-POSSUM, age, gender and other co-morbidities were statistically analysed.

Thirty-day mortality rate was 0.8% ($n = 1$). V-POSSUM scoring indicated a predicted mortality of 9%. Amputation rate was less than 2% at one year. Only 8% of patients (10 of 120) were admitted to a high dependency unit (HDU) postoperatively.

30-day mortality in our case series was lower than predicted by V-POSSUM scoring. Use of multimodal intraoperative monitoring with the specific aim of limiting build-up of oxygen debt should be subjected to a randomised controlled study to assess the reproducibility of these results.

1. Introduction

High-risk surgical procedures represent about 12.5% of surgery carried out in the UK but contribute to 84% of deaths.[1] Elderly patients constitute an increasingly large proportion of the high-risk surgical group and undergo surgery four times more often than younger patients.[2] The 30-day mortality is higher in the elderly and has recently been quoted as 5%–10%.[3] A recent study from the USA in a similar group of high-risk vascular surgical patients to those reported here had an overall 30-day mortality of 5.1%.[4] The mortality in similar patients in the UK is probably higher.[5] This general high surgical morbidity and mortality in the UK has led to recent guidance from the NHS and NICE which has mandated the use of flow monitoring (initially evaluating the Oesophageal Doppler[6] (ODM) and subsequently including all flow monitors[7]) in high-risk patients in an attempt to improve patient outcomes and thereby produce *net* savings estimated at £400m per annum.[7] Following NICE evaluation,[8] further guidance from the NHS has also suggested the use of depth of anaesthesia monitoring in patients at risk of the adverse effects of excessively deep anaesthesia including the elderly and those with poor cardiovascular function.[9] In 2012 the Association of Anaesthetists of Great Britain and Ireland have added cerebral oximetry, alongside flow and depth of anaesthesia, to the list of additional monitors for use in another group of very high risk patients, those with proximal femoral fractures.[10] Recent studies using the ODM[11] *on its own* have failed to substantiate evidence from previous trials of benefit or superiority to regimes aiming at simply minimising fluid input.[12] This suggests that a more complex strategy may be needed to improve outcome in

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http://dx.doi.org/10.1016/j.ijsu.2013.12.016

this high-risk group of patients e.g. adding depth of anaesthesia to minimise cardiovascular depression and cerebral oxygenation to assess the adequacy of tissue perfusion.[13]

Many scoring systems that predict patients' morbidity and mortality have been developed over the years. The most commonly used one in vascular surgery is the Vascular-Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (V-POSSUM) which is a risk-adjusted scoring system and potentially useful in predicting 30-day mortality in high-risk patients undergoing vascular surgery.[14]

Multimodal monitoring has been the subject of recent reviews.[13,15] In brief, the LiDCO*rapid* (LiDCO Ltd, UK)[16] was used for haemodynamic monitoring and an attempt was made to maintain nominal cardiac output (nCO) and oxygen delivery (nDO_2) throughout surgery to within 10% of the pre-induction value in these elective patients to minimise build-up of oxygen debt, a major predictor of morbidity and mortality.[17] Depth of anaesthesia or more correctly *degree of cortical suppression* was assessed by BIS (Covidien, USA) and the value during anaesthesia maintained at the recommended range of 40–60.[18] This strategy has recently been shown to reduce the incidence of delirium and cognitive dysfunction in elderly patients,[19,20] significant predictors of poor outcome.[21] Cerebral oxygen saturation (rSO_2) can be monitored by the use of near infrared technology (NIRS), a technology which has been available clinically for around 15 years.[22] Cerebral oximetry (Invos, Covidien, USA) provides an index of brain (and overall tissue) oxygenation.[23] A baseline value of rSO_2, prior to induction of anaesthesia, is essential to provide an index from which to measure cumulative desaturation.[24]The normal rSO_2 in a fit patient may be around 60–70%, however, values as low as 35% are seen in elderly patients presenting for cardiac surgery and is probably associated with poor outcome.[25]

There is still considerable debate about the cost/benefit that such a combined monitoring strategy would involve or indeed whether it would be possible to maintain flow, depth of anaesthesia[26] and cerebral oxygenation in the recommended range in very high risk elderly patients. Multimodal monitoring using flow, depth of anaesthesia and cerebral oxygen monitoring with a defined strategy for intraoperative management has been utilised for the last 5 years in our unit for high risk patients undergoing complex major infra-inguinal bypass surgery for critical leg ischaemia (CLI).

To our knowledge the impact of intraoperative multimodal monitoring with a pre-emptive strategy of reducing build-up of oxygen debt on reducing morbidity and mortality of vascular patients has not been reported.

The aim of this study was to evaluate this strategy and the possible effect on outcome in terms of mortality and major amputation rate.

2. Methods

This is a retrospective analysis of prospectively collected data of a case series of 120 patients with critical lower limb ischaemia (CLI) who underwent complex major infra-inguinal bypass between October 2007 and January 2012. Local ethical committee approval was sought but was not deemed necessary as the procedures carried out were normal practice in this unit. Consecutive patients who were treated by the same surgical and anaesthetic teams were included in the study.

Data were collected from electronic hospital and anaesthesia records. 1-year follow-ups were conducted by telephone interviews. The 30-day and 1-year mortality rates were calculated. The analysed variables were age, gender, anaemia, diabetes mellitus (DM), ischaemic heart disease/myocardial infarction (IHD/MI), chronic obstructive pulmonary disease (COPD), cerebrovascular disease (CVD), and renal dysfunction/failure (RF). Anaemia was defined as haemoglobin levels lower than 130 g l^{-1} in men and lower than 115 g l^{-1} in women and RF was defined as estimated glomerular filtration rate (eGFR) of less than 60 ml min^{-1}. This value was chosen as a recent meta analysis has shown an eGFR of less than 60 to be a strong predictor of all cause mortality in vascular surgery.[27] This data also included the type of bypass according to the anatomical position of the distal anastomosis. Femoro-popliteal bypass was defined as having the distal anastomosis to the popliteal artery and femoro-distal bypass was defined as having the distal anastomosis to the crural or pedal arteries.

2.1. Intraoperative management

In addition to routine monitoring, baseline BIS and rSO_2 readings were obtained in the majority of patients pre-induction of anaesthesia. A radial artery line was inserted under local anaesthesia and connected to a LiDCO*rapid*, a pulse power analysis cardiac output monitor.[16] This enabled pre-induction nominal ("calibrated" using a nomogram utilising age, weight and height) cardiac output (nCO), stroke volume (nSV) and nominal oxygen delivery (nDO_2) data to be obtained continuously.

Anaesthesia was induced using target-controlled intravenous anaesthesia (TCI) using remifentanil (administered until a 2–3 ng ml^{-1}) predicted effect site concentration, Ceff, was achieved and 2% propofol administered to maintain depth of anaesthesia in the range of BIS values between 40 and 60 (see Table 3). Haemodynamic variables, as above, were continuously monitored via LIDCO*rapid*, enabling appropriate use of vasopressor drugs or fluids[28] to maintain the baseline nDO_2 within 10% of the pre-induction value, minimising the build-up of significant oxygen debt. rSO_2 was maintained to within 10% of baseline as previously described.[20] All patients received antibiotic prophylaxis and core body temperature in the 36 to 37 °C range was maintained with forced air and under patient warming.

nCO and other haemodynamic parameters were collected at 5 s intervals in the LiDCO*rapid*, BIS and rSO_2 readings were obtained from the respective monitors at 30 s intervals.

Statistical analysis was performed on age, gender, diabetes, renal impairment or failure (RF), ischaemic heart disease and myocardial infarction (IHD/MI), chronic obstructive pulmonary disease (COPD) and cerebrovascular disease (CVD). Correlation was considered significant when the p value was <0.05.

Assessment of the ability of this strategy to maintain nDO_2 was assessed by analysing:

1. The ratio of average nCO obtained during surgery from the LiDCO*rapid* and the pre-induction value. From this a prediction could be made of likely oxygen debt during surgery.
2. The average value of BIS obtained during the procedure. An attempt was made to keep this in the 40 to 60 range.[18]
3. Variation in the amount of propofol needed in mg kg^{-1} h^{-1} to maintain BIS in the normal range.
4. The ratio of average rSO_2 obtained during the procedure and its relation to the starting value. Maintenance of intraoperative rSO_2 at similar (or higher) value to pre-induction would suggest that build-up of oxygen debt was minimal

2.2. Statistical methods

Univariate and multivariate analysis were performed on age, gender, diabetes mellitus (DM), renal impairment (RF), anaemia, ischaemic heart disease and history of myocardial infarction (IHD/), chronic obstructive pulmonary disease (COPD) and cerebrovascular disease (CVD). Correlation was considered significant when the p value was <0.05.

Receiver Operator Characteristic (ROC) analysis was applied to rSO_2 and its correlation with age, gender and the above selected co-morbidities. using Medcalc® (Belgium).

3. Results

Data from 120 patients (median age; 72 years, range 45–95, 97 were male) were analysed. Patient characteristics are summarised in Table 1. Most of the bypasses were distal ($n = 79$, 66%) followed by femoro-popliteal ($n = 29$, 24%). Duration of surgery ranged between 2.8 and 7.45 h (median of 4.4 h). Intraoperative details and perioperative management are summarised in Table 3.

The within 30-day mortality rate was 0.8% ($n = 1$) and 1-year mortality was 12% ($n = 14$). V-Possum scoring predicted a 30-day mortality rate of 9%. Most of deaths were not documented to be related to a specific cause (8 patients). Two deaths occurred as a result of cardiac complications, and 2 secondary to severe sepsis and cancer. Acute renal failure and multi-organ failure were each responsible for one death. There was no difference in mortality in terms of bypass type, 10 distal bypass and 4 femoro-popliteal out of 79 (12.5%) and 29 (14%) respectively, died within 1 year (p value: 1.0). Similarly, the length of surgery did not correlate to the mortality rate (6 deaths <4 h), and (8 deaths >4 h) (p value 0.563).

Only age and CVD were significant predictors of 1-year mortality with p values = 0.013 and 0.018, and odd ratios of 1.87 and 4.061 respectively (Table 2).

3.1. *Effectiveness of intraoperative monitoring strategy*

3.1.1. *Nominal cardiac output and oxygen delivery*

The overall ratio of nCO during the procedure compared with that of the pre-induction value was 87% (based on complete data in 109 patients, IQR 75–97).

3.1.2. *BIS*

Average BIS during anaesthesia maintenance was 45 (range 34–55).

3.1.3. *rSO_2*

The mean starting rSO_2 in 100 patients was 54 (range; 31–80). The ROC for 1 year mortality showed that starting rSO_2 had some value in predicting one year survival as the area under the curve (AUC) was 0.61 (95% confidence interval of 0.533–0.744) ($p < 0.05$). No one year mortality occurred in patients who had a starting rSO_2 of greater than 62. The ratio of rSO_2 during anaesthesia maintenance to the pre-induction baseline was 112% (range 87–163). Low starting rSO_2 had a statistically significant correlation with anaemia and diabetes mellitus (Fig. 1) AOC: 0.75 and AUC: 0.7; $p = 0.0001$ and 0.0002 respectively. No statistical correlation was seen between starting rSO_2 and previous IHD/MI, pre-induction nCO, RF or CVD. Similarly, there was no correlation between the starting rSO_2 and age ($p = 0.17$).

3.1.4. *Outcome*

The major amputation rate at 1 year was 2% with 0% at one year in diabetics having distal bypass.

Nine patients (8%) had a central line inserted pre-induction due to lack of peripheral venous access. Postoperatively 110 (92%)

Table 1
Patient demographics, investigations and co-morbidities. For abbreviations see text.

Parameter	Value/No.	Range or %
Age (years, mean and range)	72	45–95
Male	97	81%
Female	23	19%
Weight (kg, mean and range)	78	37–125
Diabetes mellitus	80	67%
Ischaemic heart disease/infarction	37	31%
Hypertension	56	47%
Cerebrovascular disease	28	23%
Renal impairment	45	37%
Anaemia	38	32%
Chronic obstructive pulmonary disease	10	8%
ASA (mean and range)	3	2–4
V-POSSUM predicted 30 day mortality (range for all patients)	9%	1–45
Actual 30 day mortality	0.80%	
Hb ($g \cdot l^{-1}$, mean and range)	118	(79–170)
Estimated. creatinine clearance (eCC) ml min^{-1} (mean and range)	63	(8–190)

Table 2
Multivariate analysis of risk factors for 1 year mortality. For abbreviations, see text.

Parameter	p Value	Odd ratio/(95% CI)
Age	0.013	1.087/(1.018–1.161)
Gender	0.757	0.804/(0.201–3.215)
DM	0.471	1.537/(0.477–4.954)
IHD/MI	0.193	0.249/(0.031–2.018)
CVD	0.018	4.061/(1.269–12.991)
RF	0.056	3.176/(0.973–10.370)
Anaemia	0.294	0.486/(0.126–1.870)
COPD	0.925	0.901/(0.102–7.935)

Table 3
Operative details and postoperative location.

Parameter	Value (mean)	Range or %
Operation duration (h)	4.4	2.8–7.45
Monitoring and iv access (nos)		
Radial arterial line	120	100%
Central line	9	6%
Cerebral oximeter (Invos, rSO_2)	100	83%
BIS	120	100%
Surgical procedure		
Femoro-distal bypass	79	66%
other femoral bypass	41	38%
Anaesthesia		
Propofol (mg kg h^{-1})	4.4	2.1–8.2
Remifentanil (µg kg min^{-1})	0.07	0.04–0.14
Controlled ventilation	120	100%
Intubation: laryngeal mask airway (nos)	96	80%
Intubation: endotracheal tube (nos)	24	20%
Cisatracurium (neuromuscular blocker)	120	100%
BIS levels (mean and range)	45	34–55
Fluid input		
Crystalloid Hartmann's (ml)	567	100–1800
Crystalloid Glucose (0.4%) NaCl (0.18%) (ml)	898	100–2000
Colloid (ml)	880	100–3000
Fluid in ml kg^{-1} h^{-1} (excluding blood)	4.9	1.2–12.3
Blood (ml)	224	0–2700
Fluid output		
Urine output (ml.)	904	50–2400
Blood (ml.)	430	0–3000
Inotrope/vasoactive drug use		
Phenylephrine mg. (63 patients)	4.3	1–13
Ephedrine mg (73 patients)	13	3–55
Intraoperative haemodynamics		
Mean nCO lpm, as % of pre-induction value	87	43–130
Mean rSO_2 as % of pre-induction value (100 pts)	112	87–163
Postoperative location (no of pts)		
High dependency unit	10	8%
General ward following recovery ward	110	92%

Abbreviations: rSO_2 regional oxygen saturation % (Invos, Covidien, USA); BIS (bispectral index, Covidien, USA); nCO nominal cardiac output (LiDCO*rapid*, LiDCO PLC, UK).

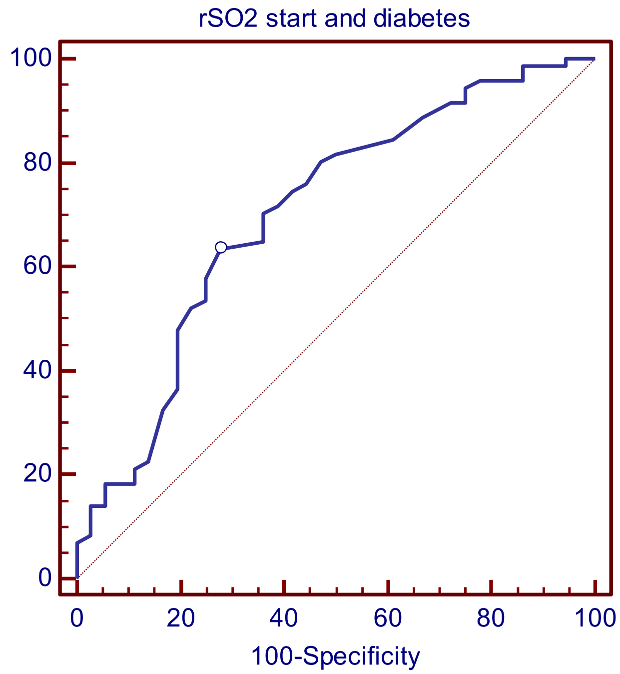

Fig. 1. Low starting rSO_2 had a statistically significant correlation with the presence of diabetes mellitus. AUC: 0.7; $p = 0.0002$.

patients returned to the general/vascular ward whilst 10 patients (8%) were admitted electively to the high dependency unit (HDU). (See Table 3).

4. Discussion

The economic and personal cost of morbidity and mortality from high risk surgery has led to the recommendation for advanced perioperative monitoring in an attempt to reduce these costs and complications, especially the use of flow and depth of anaesthesia monitoring during surgery.[6,7] Although recent meta-analyses had suggested a reduction in mortality with the addition of flow monitoring as a pre-emptive strategy,[29,30] this was not confirmed in a recent Cochrane review.[31] Maintaining pre-induction levels of nCO and nDO_2 during elective, high risk surgery, by using the patient as their own control, may be a better strategy than trying to achieve unrealistic and arbitrary population based targets such as a DO_2 of 600 ml m^{-2} This oxygen delivery target would require a CO of around 10 l min^{-1} in a patient with a Hb of 80 g l^{-1}. Perhaps achievable in a 30 year old but not easily obtainable and potentially dangerous in an 80 year old! In addition, a high dependency unit (HDU) with invasive monitoring, significant fluid input and the addition of inotropes would be needed.

Studies have also suggested that patients undergoing high-risk surgery benefit from preoperative[32] or postoperative[33] optimisation to improve outcomes. Such strategies are resource intensive and may not be needed as long as DO_2 is maintained intraoperatively. From the physiological point of view, this makes sense as the heart is the servant of the circulation and not the other way round. Attempting to increase DO_2 by driving the heart to unsustainable levels of CO using a stroke volume optimisation/maximisation strategy will not necessarily mean that cells and tissues are better oxygenated and may be deleterious in the elderly.[34]

The role of 'combined' advanced intraoperative monitoring to reduce oxygen debt and improve outcomes in the elderly patient has been emphasised,[13,15] alongside the urgent need for large prospective randomised controlled trials in the perioperative period.[35] Multimodal monitoring in the high risk elderly patient has also been stressed in recently published guidelines for managing proximal femoral fractures in the UK and includes using depth of anaesthesia, flow monitoring together with cerebral oximetry.[10] The rationale for this combined approach has been the subject of a recent review.[15]

What is the current level of evidence that a *combination* of these monitoring technologies might be beneficial[15]? This has emerged from studies looking at depth of anaesthesia, cerebral oxygenation and haemodynamics on outcome.

4.1. Depth of anaesthesia monitoring and morbidity and mortality

Although there is conflicting evidence that BIS consistently below 45 on its own is associated with poor outcome,[26,36,37] this is probably only the case when low BIS is combined with low MAP <75 mmHg and increased "anaesthetic sensitivity" (i.e. low minimal alveolar concentration- MAC of less than 0.7). This so-called 'triple low' was associated with an estimated four-fold increase in 30 day mortality.[38]The average BIS value was maintained here at 45 and the study found no evidence that BIS values are inherently lower in this group of high risk patients as suggested by other studies.[26] However, a 4-fold variation in propofol requirements (2.1–8.2 mg kg^{-1} h^{-1}) was needed to maintain BIS in the 40 to 60 range (Table 3).

4.2. Cerebral and tissue oxygenation

Reducing the build-up of oxygen debt and maintaining tissue oxygenation are key elements of this strategy. "Measuring and obtaining adequate tissue oxygenation may prevent postoperative complications and may thus be cost effective".[23]

4.3. Calculation of predicted oxygen debt

In the original Shoemaker study this was calculated as the difference between the oxygen consumption (VO_2) obtained pre-induction and the VO_2 obtained during the operative procedure (using a pulmonary artery catheter and thermo-dilution cardiac output).[17] He also assumed that the VO_2 during surgery would fall by about 15% to compensate for reduced oxygen requirement from the combined effects of anaesthesia and temperature change. So, if the VO_2 were 250 ml min^{-1} pre-induction then about 210 ml would be expected on average during the procedure and, if achieved, would not result in a build-up of oxygen debt. If VO_2 was less than this it would result in accumulation of oxygen debt. If the actual VO_2 were 110 ml during surgery then oxygen debt would be accumulating at the rate of 100 ml min^{-1} or 6 l h^{-1}. For a patient with a body surface area of 2 m^2 this would amount to 3 l m^2 h^{-1}. The threshold for the potential of non-survival in his series **at the end of surgery** was around 10 l m^2 overall, which could occur over a 3-h procedure and put the patient at risk. In general, intraoperative VO_2 was closely related to CO and DO_2 and in non-survivors it had to fall by at least 15–20% during surgery before significant oxygen debt accumulated. Thus, in this series, although VO_2 was not measured directly, maintaining intraoperative nDO_2 at about 80–90% of pre-induction level may be comparable. In addition, if rSO_2 was maintained at or above the pre-induction level it would suggest that this was an appropriate strategy.

Current intraoperative management has placed less emphasis on **preventing** the build-up of O_2 debt intraoperatively and more on playing 'catch up' by repaying presumed intraoperative oxygen debt in the immediate postoperative period. A pre-emptive haemodynamic strategy using LiDCO and BIS, demonstrates that intraoperative nCO and nDO_2 can be maintained at around 90% of pre-induction values even in high risk patients. Maintenance of cerebral rSO_2 suggests that tissue oxygenation was adequate. This strategy also reduced dramatically the requirement for post-operative high dependency management with only 8% of patients requiring admission to HDU.

4.4. *Is infra-inguinal bypass surgery high risk?*

Infra-inguinal bypass surgery carries a very high risk of post-operative morbidity and mortality. Recent studies showed that infra-inguinal bypass has a 10–21% risk of major amputation and 30-day and 1-year mortality rates of 5–8% and 18–20%[4,5] respectively. Indeed, after major amputation alone, the 30 day mortality may approach 10%.[39] Could multimodal monitoring reduce this high level of mortality and morbidity? Many of the patients presented here were refused surgery elsewhere because of this high morbidity and mortality and may be offered angioplasty instead as a "safer alternative". The long term impact of this strategy has been the subject of a recent trial which suggests that although angioplasty carries a lower short term risk it's beneficial effects are reduced after one year or so.[40]

4.5. *Outcome: does multimodal monitoring make a difference to outcome?*

What about the impact of the multimodal monitoring strategy on mortality? V-POSSUM scoring system, like any other prediction system, uses multiple variables to predict 30-days mortality after vascular surgery.[14] Our low within 30-day mortality rate (0.8%) compared with 9% predicted suggests that we can improve outcome in this group of elderly patients and this proposition should be addressed by a large, randomised controlled trial.[35]

As for morbidity, the major amputation rate was 2% with 0% at one year in diabetics. Within 30-day and 1-year mortality was 0.8% and 13.7% respectively. With morbidity and mortality this low, more patients could possibly be offered a definitive bypass rather than being subjected to preliminary angioplasty which might also prejudice the success of a future bypass if needed.[5]

There are limitations to this study. Although the patients were not randomised to receive multimodal monitoring and thus are subject to bias, this was a consecutive series of patients operated upon by the same surgical and anaesthetic team. No patients were excluded from analysis. In addition, many of the patients accepted for bypass operation had been refused surgery elsewhere due to the high-predicted mortality from the V-POSSUM score.

Multimodal monitoring is costly but net savings in the UK looking specifically at flow monitoring are estimated to be around £400 m per annum. The reduction in requirement for central venous catheterisation, postoperative admission to HDU and good patient outcomes with low morbidity and mortality suggests that multimodal monitoring should be cost effective. However, it is essential that propositions such as this be subjected to a large, randomised controlled trial before widespread implementation.[35]

5. Conclusion

Multimodal monitoring combining flow with depth of anaesthesia and cerebral oxygenation appeared to reduce morbidity and mortality as compared to other reported studies in this group of high-risk, elderly patients undergoing major infra-inguinal bypass surgery for critical leg ischaemia. Intraoperative maintenance of cardiac output, oxygen delivery and depth of anaesthesia to minimise oxygen debt may have contributed to the low morbidity and 30-day mortality and should be subjected to a randomised controlled trial.

Ethical approval

Ethical approval was not deemed necessary, as advised by the Research and development department.

Funding

David Green has received monitoring equipment on loan and some disposables from Edwards Laboratories, LiDCO PLC, Philips Respironics, Deltex Medical Group and Covidien Inc. He has also received traveling expenses from LiDCO PLC to speak at meetings and he has received honoraria and traveling expenses from Glaxo Smith Kline PLC and Covidien Inc. to speak at meetings. Heena Bidd's research resident post at King's College Hospital was partially funded with a £15k annual grant from LiDCO PLC.

Author contribution

David Green contributed to the study design, data collection, data analysis and in the writing.

Heena Bidd contributed to the data collection, writing and submission of the manuscript.

Hisham Rashid contributed to the study design of the paper.

Conflict of interest

No conflicts of interest.

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