

A Cost Effectiveness Analysis Between Intraoperative Non Invasive And Invasive Hemodynamic Monitoring For Supratentorial Tumour Surgery: A Randomized Controlled Trial

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Abstract

Background: Invasive arterial pressure monitoring and central venous pressure monitoring is the mainstay of intraoperative haemodynamic monitoring for assessment during intracranial surgery. However, with the availability of advanced noninvasive monitoring techniques in the present era for such operative procedures, the use of invasive techniques seems to be unnecessary. Hence, a prospective, randomized study has been carried out to see the cost effectiveness of intraoperative invasive versus non-invasive haemodynamic monitoring in patients undergoing craniotomy for supratentorial tumor surgery.

Materials: and methods: Eighty-two adult patients (16 – 60 years of age; ASA I and II) were prospectively randomized into Non-invasive (NI) and Invasive (I) groups.

Results: In the present study, higher cost consumption was observed in the invasive group ($p < 0.001$). However, the increased cost of consumption in the invasive group did not translate into greater effectiveness when the two groups were compared as regards haemodynamic fluctuations ($>20\%$ of baseline), blood transfusion, vasoactive agents used, Glasgow Outcome Score(GOS) at discharge, return to pre-operative level and length of ICU/hospital stay. The duration of surgery ($p=0.033$) and anaesthesia ($p=0.045$) was found to be longer in the invasive group.

Conclusion: Invasive haemodynamic monitoring is not cost effective for craniotomy for supratentorial surgery, and can be done with noninvasive haemodynamic monitoring alone; but in large vascular tumors, invasive hemodynamic monitoring may be considered.

Keywords: Supratentorial tumor, craniotomy, invasive haemodynamic monitoring, non invasive haemodynamic monitoring, cost effectiveness

I. Introduction

Continued clinical research led to advancements in diagnostic methods, monitoring and development of newer drugs which ultimately resulted in safer and better medical practice as well better peri-operative anesthetic care;¹⁻³ but, this has also increased the treatment cost substantially. On the other hand, with the entry of insurance companies in the health sector, their legal consultants are questioning the modalities of treatment and their costs.⁴ Eddy pointed out that over the last few decades health care costs has been increasing at a rate of 11.5% a year, and if the current trend continues, it will grow to 32% of the gross domestic product (GDP) by the year 2030 in USA.

Intra-arterial blood pressure monitoring and central venous pressure monitoring is the mainstay of intra-operative haemodynamic monitoring during neurosurgery. Their use is considered to be a valuable aid in neuroanaesthetic practice. But, considering the generally benign intra-operative course of supratentorial tumors, their use might not be cost effective. Time taken in establishing these monitoring methods add to the operating time which apart from increasing consumption of anaesthetic drugs, may also result in denial or delay of operating slots to other patients and thus prolonging their stay and cost. Treatment costs cannot be considered exclusively as the cost of drugs and monitoring facilities. It also includes costs incurred due to complications of treatment modalities or monitoring techniques requiring additional observation, investigations and treatments which in turn demand increased intensive care unit or hospital stays. Thus judicious use of monitoring lines can lead to reduction of perioperative anaesthetic cost, avoidance of their complications, more efficient use of operating theatre timings and reducing intensive care/ hospital stay.

Cost analysis studies in neuroanaesthetic practice have been few^{5,6} and invasive and non-invasive monitoring has not been compared. Hence we planned to perform a cost effective analysis on intra-operative non-invasive versus invasive haemodynamic monitoring for supratentorial tumor surgery.

II. Materials And Methods

This randomized controlled study was carried out at a tertiary care hospital during the period of 2 years. Following Ethics Committee approval 82 adult patients (16-60 yrs of age, American Society of Anaesthesiologist I and II) scheduled for elective craniotomy for supratentorial tumor surgery were prospectively randomized, using computer generated randomization chart, in two groups: Non-invasive or NI (n = 39) and Invasive or I (n = 43).

Written informed consent was taken during the preoperative visit where the patients' general physical condition, haemodynamic parameters and neurological status-Glasgow Coma Score⁷(GCS) of the patients were also recorded. Details about the tumor regarding its location, size, and presence or absence of cerebral edema, mass effect, midline shift and hydrocephalus were also recorded. Steroids, anti-epileptic agents and other drugs for other co-morbid conditions were continued according to the standard protocol. No sedative premedication was given. Injection glycopyrrolate 0.2 mg was given intramuscularly in all patients 45 minutes to 1 hour prior to induction of anaesthesia. After adequate fasting period, patients were shifted to the operating theatre.

In the operation theatre, non-invasive monitoring (5 lead electrocardiography, pulse oximetry and automated blood pressure) was commenced in all the patients and baseline heart rate (HR) and mean arterial pressure (MAP) were recorded using Datex Ohmeda S/5 anesthesia monitor(GE Health care, Finland). In the 43 cases of group 'I', the radial artery was also cannulated after subcutaneous infiltration with 0.5 to 1 ml of 1% lignocaine. Intravenous access was achieved with 16 G - cannula. Before induction of anaesthesia, isoflurane vapourizer was filled afresh (100ml).

After recording patients' sensorium, anaesthesia was induced with fentanyl 2 µg/kg and thiopentone 5-6 mg/kg. Muscle relaxation was achieved with vecuronium 0.1mg/kg followed by positive pressure ventilation with a mixture of oxygen and nitrous oxide (50:50) for 3 min before laryngoscopy and tracheal intubation. Anaesthesia was maintained with 60% nitrous oxide in oxygen and isoflurane (0.5 to 1.5%) with a fresh gas flow of 2.5 litres /min (O₂ I L + N₂O 1.5 L). Intermittent positive pressure ventilation was adjusted to keep end tidal carbon dioxide (EtCO₂) between 28 to 30 mmHg. Fentanyl and vecuronium were repeated as deemed necessary by the attending anaesthesiologist. Normothermia was maintained in both the groups of patients (via a nasopharyngeal probe). Central venous access was achieved with 7 Fr. double lumen CVP catheter (VYGON) using Seldinger technique in the 'I' group. To avoid bias, only one investigator was putting the invasive lines. Site of insertion, number of attempts at putting invasive lines and complications of insertion were recorded and failure to insert invasive lines in three attempts at two different sites was a criterion for exclusion of the case.

Haemodynamic fluctuation more the 20% of the baseline value, use of vasoactive agents, total blood loss and blood transfusions were also recorded and isoflurane was cut off at dural closure. The duration of surgery (skin incision to closure) and duration of anaesthesia (induction to shifting of the patient out of the operation theatre) were also recorded.

At the end of surgery, after reversal of the neuromuscular blockade, decision to extubate the patient was taken by the attending anaesthesiologist on the basis of recovery from anaesthesia. Patients' level of consciousness, need for mechanical ventilation and immediate postoperative complications like shivering, restlessness, headache, nausea and vomiting were recorded. Intra-arterial lines were removed at the end of the procedure and after 6 hours for those planned for elective ventilation. Then, peripheral pulsations were compared after manual pressure for about 5 to 10 minutes. After extubation, isoflurane vapourizer was emptied completely and the amount of isoflurane consumed was noted. Along with this the number of vecuronium ampoules used, amount of IV fluids used were also noted to calculate the variable component of cost which varied with the duration of anaesthesia.

Patients were shifted to the intensive care unit postoperatively. Attention was paid to detect any complication of invasive monitoring like haemo / pneumothorax, local haematoma, spasm of the vessels cannulated for invasive monitoring etc. Other complication like fever, vomiting, seizures or complications due to surgery itself like development of dysphasia, aphasia, hemiparesis, hemiplegia and quadriplegia were also noted. The need for re-exploration and the number of postoperative chest X-rays and CT scan head were also recorded.

Cost calculation

As with any economic analysis it is important to specify which costs are included or excluded from the study⁸. We have restricted our cost analysis to the cost of invasive monitoring with anaesthetic drugs and intravenous fluids used during routine anesthetic practice. We have not included cost of non-invasive

monitoring like electrocardiography end-tidal carbon dioxide, pulse oximetry and temperature monitoring which are used commonly in both the groups.

We have neither included the cost of professional fees e.g. cost of invasive catheter insertion nor the cost of tests like arterial blood gas analysis, culture and sensitivity of the catheter tip after removal.

Since we cannot calculate cost of complications which include intangible costs, we have used a utility score⁹ to enable us to calculate QALYs¹⁰ (quality adjusted life years) for the short interval of hospital stay (average 12 days for our study). The latter is important when we take social perspective into account to include intangible costs. There are many ways to generate a utility score, which usually range from 1 (normal health) to 0 (death). For example, one year of life in good health might be equivalent to 0.5 years of life with hemiparesis. For our study, the utility score used is:

- 1- Baseline or preoperative level
- 0.9-Increased cost due to treatable complication
- 0.5 -Loss to society (loss of Job/ become dependent)

QALYs is calculated from the formula:

$$QALY = \sum_{j=1}^n Q_j \cdot t_j$$

Where **n** = number of sub interval(s) in the time horizon

Q_j = patient's utility during the jth interval

t_j = duration of the jth interval as fraction of one year.

For our study, cost effectiveness is expressed in terms of Glasgow Outcome Score (GOS)¹¹ gained or QALYs gained. Cost calculation was done based on the rate supplied in the institute during the study period.

III. Statistical Analysis

Assuming a mean difference in consumption of Rs.1000/- between the non invasive and invasive group and a standard deviation of Rs.2000/- (because of the skewed consumption due to differences in the length of stay in ICU or hospital, and difference in the amount of variable consumption due to difference in the duration of anaesthesia.), the sample size required for our study was 25 patients in each group for an α value of 5% and β value of 0.2 (i.e. 1- β or power of 80% and Z value of 1.645 for one-tailed Alpha). Because of this assumption we require a sensitivity analysis which we did with univariate analysis of variance weighted by the utility score using SPSS 16 (Students Package for social sciences V 16, Chicago Inc.). Cost effectiveness is expressed in terms of per GOS gained or per QALYs gained. For comparing effectiveness between the non-invasive and invasive group we used logistic regression analysis. One way ANOVA was used to see the tumor characteristics between the non-invasive and invasive group. Independent sample T test was used to see the mean GOS, utility score and mean cost consumption.

IV. Results

The patients in the two groups were comparable as regards the demographic profiles as well as the ASA status and GCS as shown in Table 1. The two groups are comparable. There is no significant difference in the lesion characteristics as regards diagnosis, size, presence or absence of midline shift, mass effect, cerebral edema and hydrocephalus as assessed by one-way ANOVA (Table 2).

Cost consumption due to invasive monitoring in this study is found to be significantly higher in the "I" group ($P < 0.001$). Three patients in the non-invasive group were later put invasive lines for ethical reasons. They were not excluded from the study and the extra cost incurred was added to the cost of variable consumption of the particular case. However, p-value remained the same ($p < 0.001$) when univariate analysis of variance was done to see if there was change in the level of significance of invasive monitoring because of interaction with other factors such as tumor diagnosis and size of the tumor (Table 3). However, the increased cost of consumption in the invasive group is not translated into greater effectiveness when the two groups were analysed by logistic regression analysis as regards haemodynamic fluctuation more than 20% of baseline, need for intra-operative blood transfusion and use of vasoactive agents, intra-operative and post operative complications, GOS at discharge, return to pre-operative level, length of stay in ICU and hospital (Table 4). The duration of surgery ($p = 0.033$) and anaesthesia ($p = 0.045$) were slightly longer in the invasive group. Post operative complications were mainly related to the tumor or surgical procedure itself. We did not encounter complication due to the invasive monitoring. In this study the GOS ranged from 3 to 5 as none of the patients deteriorated below 3 at the time of discharge. There was no significant difference in the mean GOS between the two groups (Table 5).

The result in table 3, only identifies the costs and has given some idea about cost minimization. Cost effectiveness analysis was done by expressing the cost consumed in terms of GOS or QALY for the short interval of average hospital stay of 12 days. The value of QALYs is very small as the assessment interval is very short when expressed as a fraction of one year.

After calculation, it was observed in this study that the invasive group will consume Rs.15,985.00 per GOS gained. When expressed in terms of QALYs the consumption will be very large because $QALY_{non-invasive} - QALY_{invasive}$ is nearly zero, and any constant divided by zero is equal to infinity implying that we cannot calculate the intangible cost because loss to society might be huge when the patients did not regain the pre-operative level.

V. Discussion

It is now generally agreed that in a resource-constrained, publicly-funded health care system we need to look at the cost-effectiveness of our endeavors in providing health care. Some investigators maintain the fact that intra-operative anaesthesia cost is less than 6% of the total hospital cost¹² and changes in anaesthesia care are unlikely to reduce the total hospital costs.¹³ However, we cannot deny the fact that additional costs due to longer operative procedure time, extensive monitoring, more drug use and prolonged postoperative intensive care observation following complications of invasive monitoring and longer intensive care unit / hospital stay may increase total hospital costs. If the current trend of increase in health care costs goes unchecked, it will occupy a big chunk of the gross domestic product, implying that we require 'rationing' of our health care costs.

Nearly 25 years ago, all the patients undergoing craniotomy in USA were monitored with an arterial line and majority had a central venous pressure monitor (CVP).¹⁴ The rationale was that an arterial line was needed for continuous monitoring of blood pressure and repeated blood-gas analysis while CVP facilitated treatment of air embolism. Both the invasive monitoring seemed to be reasonably justified in the years gone by. However, with the advances in technology like automated blood pressure recording, pulse oximetry and capnography an arterial cannula is not necessary in the majority of the patients.

Clinical practice patterns including work force modifications are now being examined with best outcome at the most reasonable cost, a concept termed "value base anaesthesia" care.¹⁵ Johnstone and Jozefczyk demonstrated that a single education programme informing anaesthesiologist of the cost of anaesthetic drugs at their tertiary care center in the United States was associated with a 23% reduction of monthly drug expenditure without affecting the quality of care.¹⁶ In one study, reducing the fresh gas flows from 8 L/min to 4 L/min was associated with a 55% decrease in the cost of isoflurane without altering the quality of care.¹⁷ Lubarsky et al (1997) also found that health care resources can be more appropriately utilized without affecting the clinical outcome.¹⁸

Although outcome with or without invasive monitoring in neuroanaesthesia practice have not been studied, invasive monitoring has been studied in cardiac surgical patients and no significant difference in outcome was found with more invasive monitoring techniques.^{19,20} In the present study we have found significantly higher cost consumption in the invasive group ($p < 0.001$) mainly due to invasive monitoring itself. The increased cost here is solely because of the cost of invasive catheter and accessory lines. We did not encounter any complication of the invasive monitoring itself although it had been reported in other studies.^{21,22} Scheer et al²¹ listed complications of arterial cannulation as temporary occlusion (19.7%), haematoma (14.4%), local infection (0.72%), bleeding (0.53%), sepsis (0.13%), permanent ischaemic damage (0.09%) and pseudoaneurysm (0.09%). Depending on the route used for central venous cannulation, various complications (viz catheter malposition, arrhythmias, arterial puncture, haemo / pneumothorax, mediastinal hematoma, venous thrombosis, sepsis, etc.) have been described with various incidences.

But when the non-invasive and invasive groups are compared (using logistic regression analysis) as regards haemodynamic fluctuations more than 20% from baseline, need for intra-operative blood transfusion, use of vasoactive agents, Glasgow Outcome Score at discharge, return to pre-operative level, duration of surgery and anaesthesia, and length of stay in intensive care unit and hospital – we found both the groups to be equally effective. This is not to conclude that invasive monitoring is not necessary even though the duration of surgery ($P=0.033$) and anaesthesia ($P=0.045$) are slightly longer in the invasive group. Since the difference between the two QALYs is nearly zero and constant divided by zero is equal to infinity, it follows that intangible cost will be very large for both the groups. Indeed, we cannot quantify the magnitude of loss to society when one becomes handicapped, loses job, loses productivity, develop mental agony and become dependent on others. This is also reflected by the mean utility scores of 0.897 and 0.926. Normally utility scores range from 1 (perfect health) to 0 (death). We have taken score 1 as baseline or pre-operative level and in both the groups, it did not reach the pre-operative level.

Todd et al⁵ examined three anesthetic regimens for neurosurgery in 121 adult patients for supratentorial intracranial mass lesions and found no difference in short term outcome for patients randomized to receive any of the anesthetic regimens. The drug cost for the three regimens were however different.

Guy et al⁶ compared fentanyl (2 µg/kg bolus + 0.03 µg/kg/min infusion) with remifentanyl (1 µg/kg bolus + 0.2 µg/kg/min) in 63 adults undergoing supratentorial craniotomy and found that naloxone use was less but emergence hypertension and post-surgical pain were greater in the remifentanyl group-thereby implying that costlier alternatives are not necessarily better in all aspects.

VI. Limitations

Questions may arise regarding the use of high flows during cost-effective analysis as one limitation of our study. However it should not be a source of bias as high flows are used in both the groups. There was unavoidable spillage of isoflurane during filling or emptying for measurement of the amount of isoflurane consumed. We have measured the outcome in the form of Glasgow Outcome Score at discharge. We have not considered the change in clinical behaviour because of pathological diagnosis of tumor. Glioblastoma multiforme will have quite a turbulent clinical course compared with pilocystic astrocytoma even though both are gliomas. Since our assessment period is limited from admission to discharge, that consideration should not be a source of bias. Consumption on common items could not be strictly fixed. We used more intravenous cannulas, IV sets and extension lines in the non-invasive group when we anticipated significant blood loss. For uniformity, cost of hospital stay is taken at the rate of the general ward even for patients in the private ward to avoid marked variations due to unequal changes. Our sample size will be small if we assume large standard deviations when the real cost of stay in private ward is taken into consideration. Duration of anesthesia was from induction to shifting of the patient out of the operation theatre. Some authors use duration of anaesthesia from induction to closure of the inhalational agents.²³

VII. Conclusion

It may be concluded that supratentorial craniotomy can be done without invasive monitoring and the use of invasive monitoring is not cost effective; however, individual merit of the case needs to be considered.

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Conflict of interest: Nil

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Table 1: Demographic Profile. Value in mean \pm SD except for sex ASA grading and GCS

Variables	Non-invasive (NI) (n =39)	Invasive (I) (n =43)
Age in Yrs.	38.92 \pm 13.72	36.51 \pm 12.34
Sex (M: F)	26 : 13	28 : 15
Weight in Kg.	58.00 \pm 11.45	58.46 \pm 10.55
ASA (1 : 2)	34 : 5	36 : 7
GCS	15	15

Values expressed as number, Mean \pm S.D; GCS – Glasgow Coma Score.

Table 2: Tumor Characteristic as assessed on-way ANOVA

Characteristics	Non-invasive Group (n=39)	Invasive Group (n=43)	p-value
Diagnosis :			
Glioma	24	25	0.755
Meningioma	13	17	
Suprasellar epidermoid	0	1	
Intraventricular Neurocytoma	2	0	
Size :			
\leq 3.5 cm (maximum diameter)	8	5	0.516
3.6- 6 cm	26	33	
$>$ 6 cm	5	5	
Midline Shift ($>$ 5 mm) :			
No	19	18	0.539
Yes	20	25	
Mass Effect :			
No	19	18	0.700
Yes	20	25	
Cerebral Edema :			
No	14	11	0.317
Yes	25	32	
Hydrocephalus :			
No	36	42	0.265
Yes	3	1	

Values expressed as Number of patients; $p < 0.05$ significant

Table 3. Evaluation of cost comparison in relation to tumor diagnosis and size as assessed by univariate analysis of variance weighted by the utility score

Parameter	Non-invasive Group (n=39)	Invasive Group (n=43)	p-value
Consumption of common items(Endotracheal tubes, IV lines, cannula etc.)	283.41 \pm 21.711	274.0 \pm 11.037	0.812
Variable consumption(IV fluid, muscle relaxant, Inhalation agents .)	850.59 \pm 490.398	814.67 \pm 411.559	0.427
Consumption of invasive monitoring	0	1188.16 \pm 24.515	< 0.001
Cost of hospital stay	455.72 \pm 222.175	453.34 \pm 202.659	0.646
Cost of post operative CT, CXR	394.871 \pm 232.774	369.77 \pm 156.654	0.664
Total consumption (Rs.)	1984.59 \pm 706.869	3103.54 \pm 82.133	< 0.001
Diagnosis :			
Glioma	24	25	0.289
Meningioma	13	17	
Epidermoid (Suprasellar)	-	1	
Neurocytoma	2	-	
Size in cm (maximum. diameter) :			
\leq 3.5	8	5	0.716
3.6 - 6	26	33	
$>$ 6	5	5	

Values expressed as number of patients and Mean \pm SD; < 0.05 significant

Table 4: Comparison between Non-invasive and invasive groups as assessed by logistic regression analysis

Parameters	Non-invasive Group (n=39)	Invasive Group (n=43)	p-value
<u>Haemodynamic fluctuations</u> (MAP </>20% of baseline): No Yes	23 16 (41.02%)	33 10 (23.25%)	0.400
Total Estimated Blood Loss (ml) <u>Intraoperative blood transfusion:</u> No Yes	539.74±535.84 33 06 (15.38%)	665.12±608.32 32 11 (25.58%)	0.327 0.074
<u>Vasoactive drug use</u> (Mephentermine or esmolol): No Yes	26 13 (33.33%)	37 06 (13.95%)	0.457
<u>Intraoperative complications:</u> Tense Brain Bradycardia Venous air embolism	03 (7.69%) 00 01	09 (20.93%) 01 00	0.585
<u>Postoperative complications:</u> Fever	00	02	0.770
Vomiting	02	01	
Seizure	03	03	
Pulmonary edema	01	00	
Re-exploration	01 (Extra Dural Hematoma)	01 (Residual Tumor)	
Diabetes insipidus	01(Neurocytoma)	01(Epidermoid)	
Aphasia (transient)	00	01	
Dysphasia (transient)	01	00	
Dysphasia (persistent)	01	01	
Hemiparesis (transient)	04	04	
Hemiparesis (persistent)	02	01	
Hemiplegia	00	01	
Quadriparesis	01	00	
Depression	01	00	
Homonymous hemianopia	00	01	
Duration of surgery (min)	276.28 ± 0.068	280.60±105.017	0.033
Duration of Anaesthesia (min)	346.13±00.987	360.47±105.958	0.045
Length of stay in ICU (days)	2.77 ± 2.265	2.86 ± 2.077	0.748
Length of stay in Hospital (days)	12.33 ± 6.293	12.26 ± 5.469	0.848
GOS at discharge (Mean)	04.46	04.53	0.973
Return to preoperative level: No Yes	08 (20.51%) 31	08 (18.60%) 35	0.912

Values expressed as Number, percentage in parentheses and Mean ± SD; p< 0.05 significant

Table 5: Data about cost calculations

Parameters	Non-invasive Group (n=39)	Invasive Group (n=43)	p-value
Treatment cost (Total mean consumption in Rupees)	1948.59	3103.54	<0.001
Utility Score	0.897 ± 0.17	0.926 ± 0.16	0.460
Glasgow Outcome Score	4.46 ± 0.720	4.53 ± 0.702	0.642
QALYs	0.0632	0.0642	-