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To study role of hemodynamic guidance and intraoperative Fetanyl requirements in mastectomy

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Background and objectives: The purpose of this study is to compare the intraoperative Fentanyl dose given to the study group with that given to the control group within the designated study population. In order to differentiate between the two groups with respect to the amount of Fentanyl that was supplied intraoperatively. Quantification of postoperative pain experienced by both the experimental and control groups. Research and control group rescue analgesic needs estimation in the postoperative care unit. In order to document the perioperative complications experienced by both the experimental and control groups. Estimating the time needed for extubation in both the study group and the control group.

Material and Methods: A study was conducted in the Department of Anesthesiology, Konaseema Institute of Medical Sciences & Research, Amalapuram, Andhra Pradesh, from January 2011 to December 2011. The study was prospective comparative randomized and involved obtaining informed consent from patients. The study included females aged 18-60 years who underwent mastectomy surgery under general anesthesia.

Results: The study conducted a statistical analysis to assess the impact of intraoperative fentanyl dosage based on hemodynamic and superficial percutaneous index (SPI) parameters. The study aimed to assess the correlation between various dosages of fentanyl and the following parameters: age, body mass index (BMI), cardiovascular health, spectral entropy, intraoperative and postoperative events and symptoms, as well as mean extubation time during mastectomy.

Conclusion: The study concludes that mastectomy performed under general anesthesia yields superior hemodynamic stability in the SPI guided group, leading to a reduced need for intraoperative fentanyl. Additionally, the study found that there was a positive analgesic effect and a reduced likelihood of postoperative nausea and vomiting compared to the trial conducted using conventional hemodynamic guidance.

Keyword: BMI, extubation time, hemodynamic parameter, mastectomy.

INTRODUCTION

Anaesthesia plays a crucial role in providing patients with relief from pain during surgical procedures. Various types of anesthesia are employed, including general anesthesia and regional/local anesthesia. General anesthesia refers to the state of unconsciousness and reduced sensitivity to pain caused by drugs [1, 2]. The definition of balanced anesthesia is the use of lower doses of several drugs to enhance their desired effects and reduce their adverse side effects.

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Hypnosis and immobility are induced with general anesthetics and muscle relaxants, respectively. Spectral entropy is a method used to analyze EEG signals [2, 3]. The monitors are utilized to quantify and examine the anomalies existing in the EEG signals, subsequently presenting two numerical values that serve as indicators of the level of anesthesia. The assessment of sedation and anesthesia often involves the utilization of two spectral entropy indicators, namely State Entropy (SE) and Response Entropy (RE) [3, 4, 5]. Research has shown that the entropy of the signal drops while a patient falls asleep and increases again upon awakening. Analgesia refers to the state of experiencing painlessness in response to stimuli that would typically elicit pain [5, 6]. During surgery, providing sufficient pain relief with a combination of pain-relieving and pain-relieving medications can help prevent certain side effects, such as excessive or insufficient dosage and the resulting negative reactions. Moreover, it is associated with improved post-operative outcomes in terms of wound healing, mobility, and patient contentment. At present, there is a lack of established benchmarks for assessing the equilibrium between nociception and antinociception in the context of anesthesia [6, 7, 8].

The anaesthesiologist's expertise remains the basis for the administration of analgesics. The importance of post-operative pain control in post-anesthesia treatment is equivalent to that of intraoperative pain control. Postoperative pain is assessed using a range of scales. The assessment of post-operative pain following a six-surgery procedure involves the utilization of various instruments, including the Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), Verbal Rating Scale (VRS), and McGill Pain Questionnaire. NSAIDS were the most commonly prescribed drugs for post-operative pain, with opioid analgesics being the second most commonly used [8, 9].

Methodology

A study was conducted in the Department of Anesthesiology, Konaseema Institute of Medical Sciences & Research, Amalapuram, Andhra Pradesh, from January 2011 to December 2011. The study was prospective comparative randomized and involved obtaining informed consent from patients. The study included females aged 18-60 years who underwent mastectomy surgery under general anesthesia.

Inclusion criteria

- 18 – 65 years
- ASA grade I and II
- Females
- Scheduled for elective mastectomy

Exclusion criteria

- Patient Refusal
- Known allergy to Fentanyl drug
- Hypertension & those on beta blockers
- Previous Sympathectomy, Vagotomy

.

Results

The study involved 15 to 30 participants to be in each group i.e., Study group and control group. Population only included all female participants aged between 18-65 year undergoing mastectomy surgery for breast cancer.

Table 1: Age wise distribution of the study participants

Age Group	< 45 years	≥ 45 years	Total Number (%)
SG	3 (20)	12 (80)	15
CG	1 (6.67)	14 (93.33)	15
Total	4 (13.33)	15 (86.67)	30 (100)

P = 0.2 (not significant)

Table 2: Distribution of the study population based on BMI classification

BMI Classification for Asians (kg/m^2)	Study Group n (%)	Control Group n (%)	Total n (%)
Underweight (<18.5)	1 (100)	0 (0)	1 (100)
Normal (18.5 – 22.9)	5 (45)	6 (55)	11 (100)
Overweight (23-24.9)	2 (50)	2 (50)	4 (100)
Obese (≥ 25)	7 (50)	7 (50)	14 (100)
Total	15 (50)	15 (50)	30 (100)

P = 0.7 (not significant); n = frequency

Table 3: Table showing the distribution of study participants according to ASA grading in study and control group

Parameter	Study Participants		Total (%)
	Study Group (n)	Control Group (n)	
ASA 1	7	8	15 (50)
ASA II	8	7	15 (50)
Total (%)	15 (50)	15 (50)	30 (100)

P = 0.7 (not significant) n= frequency

Table 4: Table showing the Mean arterial pressure values at different time intervals intra-operatively

Time of readings	Mean MAP Mean (SD) mmHg		P value (t test)
	Study Group	Control Group	
Baseline Readings	94.35 (9.82)	92.04 (3.55)	0.3
1 min after intubation	94.68 (12.37)	101.82 (11.69)	0.1
5 min after intubation	90.02 (10.57)	96.75 (8.11)	0.06
1 min after Incision	101.02 (11.51)	107.6 (9.24)	0.09
5 min after incision	91.33 (9.43)	97.78 (9.55)	0.07
10 min after incision	87.06 (8.52)	92.04 (6.9)	0.08
20 min after incision	91.73 (13.5)	100.04 (10.94)	0.07
30 min after incision	91.08 (8.54)	98.53 (13.07)	0.07
60 min after incision	89.26 (7.52)	90.53 (6.48)	0.62
End of surgery	90.53 (9.18)	87.28 (4.71)	0.2
At extubation	94.62 (10.57)	94.26 (5.82)	0.9

$p<0.05$ - significant

Table 5: Table showing the Heart rate values at different time intervals intra-operatively

Time interval	Mean HR (SD)		P Value
	SG beats/min	CG beats/min	
Baseline Readings	81.2 (14.31)	78.8 (10.93)	0.6
1 min after intubation	85.73 (12.84)	86.93 (13.38)	0.8
5 min after intubation	77.8 (9.03)	84.33 (8.59)	0.052
1 min after Incision	84.2 (9.44)	93.73 (17.01)	0.06
5 min after incision	78.13 (9.16)	85.46 (13.87)	0.1
10 min after incision	76.13 (8.08)	82.6 (11.76)	0.08
20 min after incision	79.8 (8.45)	88.13 (15.62)	0.08
30 min after incision	78.2 (11)	85.73 (12.09)	0.08
60 min after incision	72.2 (3.09)	78.67(12.96)	0.07
End of surgery	75.47 (10.06)	77 (10.81)	0.6
At extubation	85 (14.04)	79.6 (14)	0.3

$p<0.05$ - significant

Table 6: Table showing the Mean values of Spectral entropy indicators

Time of readings	State Entropy (mean±SD)			Response Entropy (mean±SD)		
	Study Group	Control group	P value	Study Group	Control group	P value
Baseline Readings	86.73±5.64	84.53±12.59	0.54	92.13±7.15	87.93±12.33	0.2
1 min after intubation	49.93±11.8	50.40±10.07	0.9	54.40±8.97	54.80±7.63	0.8
5 min after intubation	49.13±9.12	51.40±9.39	0.51	52.93±7.93	57.13±10.11	0.2
1 min after Incision	49.47±10.74	52.67±7.09	0.3	51.93±11.66	58.07±9.65	0.1
5 min after incision	50.13±9.69	51.87±8.33	0.6	53.53±9.8	57.40±7.13	0.2
10 min after incision	54.27±7.56	50.13±3.48	0.06	56.67±9.33	51.73±3.17	0.06
20 min after incision	51.67±8.4	53.00±6.71	0.6	54.60±8.72	56.60±6.95	0.4
30 min after incision	50.33±7.51	50.67±7.65	0.9	54.27±8.72	56.07±5.43	0.5
60 min after incision	55.93±3.75	51.93±4.59	0.01	57.20±3.93	55.53±5.46	0.3
End of surgery	61.73±7.52	57.00±5.76	0.06	63.27±8.36	60.47±6.16	0.3
At extubation	86.47±4.05	86.80±5.27	0.8	92.07±3.35	91.67±3.96	0.7

Table 7: The Mean values of the difference of SE and RE in Study group and Control group

Time of readings	SE-RE		P value (t test)
	Study Group	Control Group	
Baseline Readings	-5.4 (3.98)	-3.40 (4.19)	0.1
1 min after intubation	-4.47 (4.56)	-4.40 (5.79)	0.9
5 min after intubation	-3.80 (5.4)	-5.73 (4.79)	0.3
1 min after Incision	-2.47 (4.42)	-5.40 (5.04)	0.1
5 min after incision	-3.40 (4.29)	-5.53 (4.44)	0.2
10 min after incision	-2.40 (4.78)	-1.60 (2.87)	0.5
20 min after incision	-2.93 (4.01)	-3.60 (4.45)	0.6
30 min after incision	-3.93 (6.02)	-5.40 (7.34)	0.5
60 min after incision	-1.27 (3.20)	-3.60 (3.40)	0.06
End of surgery	-1.53 (3.64)	-3.47 (6.29)	0.3
At extubation	-5.60 (3.40)	-4.87 (5.04)	0.6

Table 8: Table showing the mean dose of fentanyl drug in both study and control groups

Fentanyl requirement	Group (Mean±SD)		P value
	Study Group	Control group	
Loading dose (µg)	116.4±14.67	113.33±15.58	0.5
Intra operative dose (µg)	36.47±20.18	73.53±34.21	0.001
Total (µg)	152.8±33.14	186.87±45.79	0.02

p< 0.05 = significant

Table 9: The Mean No. of Fentanyl doses given intra-operatively in the study participants in Study group and Control group

No. of Fentanyl bolus	Study Group	Control Group	P value
Mean	1.2	2.53	**< 0.001**
Standard deviation	0.56	1.06	

p < 0.05 significant

Table 10: The requirement of fentanyl dose in study group and control group after giving the loading dose of fentanyl drug

Time interval	Mean Fentanyl administered (µg/kg)		P value
	SG	CG	
Baseline Readings	0	0	0
1 min after intubation	8 (2.06)	8 (2.06)	> 0.99
5 min after intubation	1.33 (0.34)	1.33 (0.34)	> 0.99
1 min after Incision	9.33 (2.4)	16 (4.13)	0.1
5 min after incision	2.67 (0.68)	5.33 (1.37)	0.09
10 min after incision	0	1.33 (0.34)	**0.001**
20 min after incision	0	10.67 (2.75)	**0.001**
30 min after incision	2.67 (0.68)	8 (2.06)	**0.02**
60 min after incision	0	0	0
End of surgery	0	0	0
At extubation	0	0	0

Table 11: Table showing the Mean Extubation time in the study participants

Extubation time	Study Group (Min)	Control Group (min)	P value
Mean	6.26	10.33	**< 0.001**
Standard Deviation	2.49	3.47	

p< 0.05 - significant

Table 12: The post-operative details of the study participants while in PACU

Parameter	Category	Frequency (Percentage)		Chi square value
		Study group	Control group	P value
Post operative Nausea	None (8)	7 (87.5)	1 (12.5)	9.05 **0.02**
	Mild (11)	6 (54.5)	5 (45.5)	
	Moderate (6)	1 (16.7)	5 (83.3)	
	Severe (5)	1 (20)	4 (80)	
Post operative Vomiting	Yes (10)	2 (20)	8 (80)	5.4 **0.02**
	No (20)	13 (65)	7 (35)	
Total (%)	30 (100)	15 (50)	15 (50)	

* p<0.05 was considered as significant

Table 13: Post operative requirement of Analgesic medication in the study participants

Analgesia in PACU	Study Group (mg)	Control Group (mg)	P value
Mean Rescue Ketorolac Requirement*	12	25	**< 0.001**
Standard Deviation	8.41	7.32	

* The analgesic used in the present study was Inj. ketorolac 15mg

Table 14: Post-operative requirement of Medication for PONV in the study and control group

Anti-emetic in PACU	Study Group	Control Group	P value
Mean Rescue Ondansetron Requirement	0.53	2.13	**0.01**
Standard Error	0.13	0.55	

$p < 0.05$ – significant

Discussions

The primary objective of the latest study is to conduct a comparative analysis of the intraoperative dosage administration of fentanyl between the study group and the control group within the study population [14, 15]. The department often employed propofol titrated with Fentanyl for the induction and intraoperative maintenance of anesthesia. In our study [15, 16], we observed that the baseline hemodynamic parameters were similar between the SPI led group and the Conventional monitoring group. The present investigation observed intraoperative hemodynamic alterations, such as an increase in parameters in response to painful stimuli during intubation and incision, in both groups. An elevation in SPI values is also noted in reaction to harmful stimuli and is incongruous with the associated hemodynamic alterations [17]. The measurement of Surgical Pleth Index (SPI) during General Anaesthesia provides a more accurate representation of sympathetic changes compared to hemodynamic changes. The SPI guided group had a lower mean fentanyl administration, while the SPI guided group demonstrated a greater mean postoperative analgesic demand. This difference can be attributed to the existence of blood vessel distensibility and an increased baseline heart rate in children [17, 18]. The experimental group required a reduced dosage of fentanyl in comparison to the control group. In our investigation, it was shown that the SPI directed group had a considerably lower mean amount of fluid infusion and blood loss. The improved hemodynamic stability observed in the SPI guided group can be attributed to the fact that the titrations of analgesics and anesthetics are based on changes in SPI values rather than hemodynamic changes [18].

The observed shorter average duration of surgery in the study group in the current investigation can be attributed to either random chance or improved hemodynamic stability, as seen by fewer surgical events and reduced blood loss in the group guided by the SPI. In the present investigation, it was shown that the average duration of extubation was notably shorter in the group guided by SPI compared to the traditional group. This finding may be attributed to the sedative effect of a greater dose of fentanyl in the control group [18, 19]. Furthermore, it was shown that there was a rise in SPI values when subjected to painful stimuli such as intubation or incision. This alteration was found to be incongruous with the observed changes in 63 hemodynamic measures. The average postoperative pain scores, as assessed using the NRS scale, in the post PACU setting, as well as the average rescue analgesic requirement for approximately one hour, are lower in our study group compared to the control group. This can be attributed to the reduced intraoperative stress experienced by the SPI guided group, which has a positive impact on postoperative recovery. The Control group exhibited a considerably higher incidence of postoperative nausea and vomiting, as well as a greater need for rescue Ondansetron, compared to the study group. This can be attributed to the administration of a higher amount of fentanyl during the operation. The increase in blood pressure and heart rate observed during surgical procedures is commonly attributed to the elevated levels of surgical stress, as indicated by a significant proportion

of cases undergoing surgery [19]. Indeed, the observed hemodynamic abnormalities can be attributed to the delayed manifestation of sympathetic activation in reaction to harmful stimuli [19, 20]. The modulation of the autonomic nervous system (ANS) may serve as a more reliable indicator of nociceptive stress during surgery. This can be assessed through the measurement of heart rate variability and pulse plethysmography, often known as SPI [20]. Therefore, the utilization of SPI 64 guidance is expected to yield superior analgesic and hypnotic drug titrations during General Anaesthesia compared to the usual monitoring approach. The investigation of SPI guiding in the monitoring of general anesthesia holds significant importance within the realm of Anaesthesia research.

Conclusion

In our experiment, which involved 30 patients undergoing mastectomy under general anesthesia, we found that the patients in the SPI advised group had a decreased average intraoperative fentanyl demand. In addition, the group led by the SPI had a reduced incidence of hemodynamic events, IV fluids, intraoperative blood losses, and extended surgical durations. The administration of a lower dose of fentanyl allowed for early extubation, while the requirement for ondansetron was decreased as a result of less nausea and vomiting. The utilization of SPI guidance resulted in enhanced postoperative analgesia, leading to a reduction in the need for rescue analgesics, as seen by the lower NRS values. Hence, it can be inferred that mastectomy conducted under general anesthesia with the utilization of SPI guidance yields superior hemodynamic stability, reduced reliance on intraoperative fentanyl, enhanced postoperative analgesia, and a decreased occurrence of postoperative nausea and vomiting compared to the utilization of conventional hemodynamic guidance.

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Conflict of Interest

None

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