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Original Research Article

Comparison of surgical pleth index guided analgesia with conventional analgesia during laparoscopic surgeries-a randomised controlled trial

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ABSTRACT

Background and Aims: The Surgical Pleth Index (SPI) is a multivariate index derived noninvasively from finger plethysmographic signal. It has been demonstrated to correlate with surgical stress intensity. So, we examined these beneficial effects of SPI guided anaesthesia to determine the amount of intraoperative fentanyl consumption and haemodynamic stability in laparoscopic surgeries under general anaesthesia.
Methodology: After obtaining institutional ethical clearance and patient informed consent, A total of 100 Patients (20-65yrs) posted for laparoscopic surgeries under general anaesthesia were randomly allocated to the SPI and conventional analgesia group (50 patients each). In SPI group, SPI value >50; In conventional group, rise in heart rate(HR), mean arterial pressure (MAP) 20% above baseline were the criteria for fentanyl administration. Fentanyl 0.5 μg/kg is administered in each group for an event persisting for 5 min. Intraoperative fentanyl consumption, hemodynamic stability and postoperative pain for 1 hour were observed. Comparison analysis was performed for total intraoperative fentanyl consumption using t-test. Correlation analysis performed using the Pearson test and p- value <0.05 was considered significant.
Results: Total intraoperative fentanyl consumption was lower in SPI group than in the conventional group (108.30±21.84 μg vs 125.70±24.87 μg; p=0.0003) and it was statistically significant with good haemodynamic stability. Postoperative pain scores were comparable in both the groups. The postoperative fentanyl consumption in SPI group was 14.4 ± 1.7 μg and in conventional group was 19.4± 7.0 μg.
Conclusion: Compared with conventional analgesia, SPI guided analgesia resulted in lower intraoperative fentanyl consumption and more stable haemodynamics.

1. Introduction

One of the objectives of modern anaesthesia is to ensure adequate depth of anaesthesia. Both inadequate and excessive depth of anaesthesia due to inappropriate anaesthetic drug dosage may compromise patients outcome. Hence it is imperative for an anaesthesiologist to individualise anaesthetic drug dosage during general anaesthesia to reduce the incidence of under and over dosage.[1]

Significant haemodynamic changes occur in patients undergoing abdominal laparoscopic surgeries. Traditionally clinical signs such as tachycardia, hypertension, sweating and tearing were used to assess adequacy of analgesia. But these parameters have proved to be unreliable. Since then the search for an ideal variable has continued.[2,3] While several tools like bispectral index (BIS) and spectral entropy (SE) have been demonstrated to reflect the depth of hypnosis well,[4,5] the recently developed surgical pleth index (SPI) monitors guide proper analgesic administration during anaesthesia. This multivariate index which uses pulse photoplethysmographic amplitude (PPGA) and heart rate data from pulse oximetry measurements has demonstrated to correlate with surgical stress intensity.[6,7] Studies have shown beneficial effects of SPI guided analgesia in opioids consumption, haemodynamic stability and incidence of unwanted events in the setting of Total intravenous

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anaesthesia(TIVA).[2,8,9] Various opioids have been used during surgery to prevent haemodynamic response to nociceptive stimulus.[10]

Therefore, we examined the beneficial effects of SPI guided anaesthesia on the amount of intraoperative fentanyl consumption, hemodynamic stability and postoperative pain in laparoscopic surgeries under general anaesthesia.

Primary objective of our study was to determine the amount of intraoperative fentanyl consumption and secondary objectives were to determine the effect of SPI guided analgesia on postoperative pain and hemodynamic stability.

2. Methodology

We conducted this study from December 2016 to May 2018. It is a prospective randomised, double blinded clinical study which we carried out after approval by our institutional ethical committee. A total of 100 patients of American Institute of Anaesthesiologists (ASA) physical status of gradeI and II, aged 20-65 years undergoing elective laparoscopic surgeries were included in the study after obtaining written informed consent. Patients with lung, liver and renal disease, body mass index of 30 or more, hypersensitivity to any of the drugs to be used, pregnancy, history of cardiac arrhythmias and presence of neuromuscular diseases were excluded from the study. Total 100 patients were randomly allocated to the SPI guided analgesia group (SPI group) or the conventional group(control group), 50 in each group using computer generated randomization table. Random numbers from computer generated table were obtained and kept in a opaque sealed envelope which were opened by an independent anaesthesiologist who was not involved in the study. Thus the patient and the investigator assessing the total fentanyl consumption in each group were blinded to the study.

Before induction in conventional group, the patients were monitored for vital parameters like Non-invasive Blood pressure (NIBP), electrocardiography(ECG), pulse oximetry, end-tidal carbon dioxide(EtCO2), while in SPI group along with the above parameters SPI and state entropy(SE) were also monitored by Avance® Carestation; GE Healthcare, Finland. Induction and maintenance of anaesthesia was carried out by independent anaesthesiologist who was not involved in the study. Baseline MAP and HR were recorded by him. Intravenous(IV) propofol 2mg/kg and IV fentanyl 1μg/kg were given for induction following which 0.1mg/kg vecuronium was given after confirming bag and mask ventilation. Patients were ventilated with oxygen 6L/min and isoflurane 2-3 vol% for 3 minutes before intubating with appropriate size endotracheal tube. Anaesthesia was maintained with isoflurane 1-2vol% in 50% nitrous oxide and oxygen mixture (both at 1.5 L/min) to achieve state entropy between 40 and 60.

Fentanyl was administered so as to maintain SPI value $<$ 50 in SPI group and an increase in heart rate(HR) and Mean arterial pressure(MAP) above 20% from the baseline in conventional group as defined by Chen et alcriteria.[1] Fentanyl 0.5μg/kg IV was administered when an event (SPI $>$ 50, increase in HR and MAP$>$20% of baseline) persisted for 3 min and the same dose was repeated if the event persisted for $>$ 5 min. MAP and HR were recorded every 5 min and In SPI guided group the SPI value was also documented at the same interval.

After the completion of surgery patient was reversed with injection IV glycopyrrolate 0.008 mg/kg and injection neostigmine 0.05 mg/kg. After adequate spontaneous ventilation patient was extubated. Pain was scored by the investigator blinded to the patient's assignment in the recovery room. The pain score was determined using the Numerical Rating Score (NRS) which comprises 0-10 scale (0-no pain to 10-worst imaginable pain). Fentanyl 0.25 μg/kg was administered to the patient whose NRS is 4, and the assessment of the patient was done for one hour for every 15 min. Adverse events, like nausea, vomiting and respiratory depression (oxygen saturation $<$95%) were recorded. In patients who experienced respiratory depression, oxygen mask was used to administer oxygen. IV ondansetron 0.15 mg/kg was used to treat nausea and vomiting.

Total sample size of 100 was calculated using open epi software version 2.3.1. At 95% confidence level, 80% power of study according to study conducted by Chen X et al mean$\pm$SD remifentanil consumption by SPI group was 9.5$\pm$3.8μg/kg/h, mean$\pm$SD remifentanil consumption by conventional group was 12.3$\pm$5.28μg/kg/h, hence sample size calculated was 45 in each group. So in our study total 100 patients were considered to compensate for dropouts, 50 in SPI group and 50 in conventional group using computer generated table. The power of the present study was calculated for intraoperative fentanyl consumption, it was found to be 96.06% (which is $>$80%). Hence it justifies the sample size of 50 in each group. The exercising of power calculation was done since the sample size calculation was based on the article Chen X et al[1],where remifentanil was used.

Continuous data was expressed as mean standard deviation [SD]; categorical data was expressed as number of occurrences (percentages). Comparison analysis was performed using the t-test for continuous variables and chi-square or Fischer exact tests, as appropriate, for non-continuous variables. Correlation analysis was performed using the Pearson test. P value $<$0.05 was considered significant. Statistical analyses were conducted using SPSS version 22.

3. Results

A total of 100 patients were enrolled in the study 50 in each group. Demographic data concerning patients age, sex, weight, height and duration of surgery between the two groups were comparable (Table 1).

In our study baseline HR values were comparable in both the groups. Intraoperatively values were higher in conventional group than in SPI group ($p<0.05$). Differences were statistically significant (Figure 1). And also baseline MAP values were comparable in both the groups. Intraoperative MAP values were higher in conventional group than in SPI group ($p<0.05$). These differences were statistically significant (Figure 2).

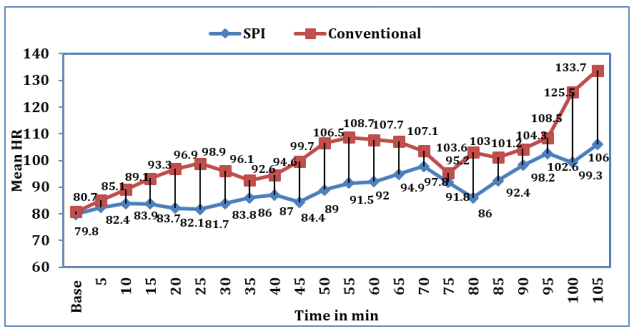

Fig. 1: Comparison of baseline and intraoperative HR changes in both groups

*HR- Heart Rate †SPI-Surgical Pleth Index *min-Minutes

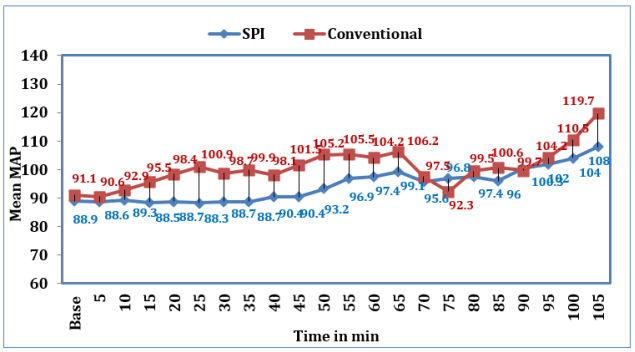

Fig. 2: Comparison of baseline and intraoperative MAP changes in both the groups

*MAP-Mean Arterial Pressure †SPI-Surgical Pleth Index *min-Minutes

In our study total intraoperative fentanyl consumption was lower in SPI group than in the conventional group ($108.30\pm21.84\mu g$ vs $125.70\pm24.87\mu g$; p=0.0003) and it was statistically significant (Figure 4). The intraoperative values of SPI are shown in Figure 3. Postoperative pain scores were comparable in both the groups (Table 2). The postoperative fentanyl consumption in SPI group was $14\pm1.7\mu g$ and in conventional group was $19.4 \pm 7.0\ \mu g$ (Figure 4).

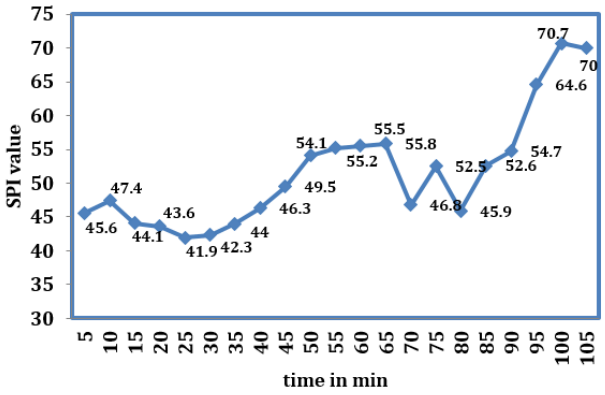

Fig. 3: Intraoperative SPI values in SPI group

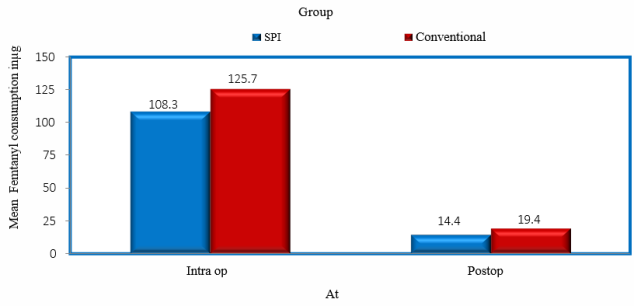

Fig. 4: Total intraoperative and postoperative fentanyl consumption in both the groups

4. Discussion

In our study we found that total intraoperative fentanyl consumption in SPI group was less when compared to conventional method. The newly developed SPI monitors seems to be a promising tool which reflects the real time intraoperative stress level or nociception during general anaesthesia. The SPI value when maintained between 20 and 50 has shown the effectiveness in managing nociception-antinociception balance during general anaesthesia for ENT surgery and gynaecological laparoscopic surgeries.[11–13]

Huiku et al, report methodology was used in calculating the SPI. SPI values range from 0 to 100, with higher scores indicating higher stress levels, and calculated as follows. The heart beat interval (HBI) and PPGA were determined first from photoplethysmography through pulse oximetry. Of these, PPGA was measured as the distance from the pulse baseline to pulse maximum in the plethysmographic signal.[6]

Table 1: Comparison of two groups with respect to demographic data, procedure and duration of surgery

Variables	SPI group	Conventional group	P value
Age in years(mean±SD)	32.7±12.0	32.9±12.2	0.934
Sex(male/female)	20/30	24/26	0.55
Weight in kgs (mean±SD)	57±6.8	58.1±5.6	0.397
Height in cm (mean±SD)	157.6±7.7	158.5±6.7	0.534
Duration of surgery(min) (mean±SD)	50.8±16.7	49.4±18.0	0.705

Table 2: Postoperative pain score for 1 hr in both the groups

Time (in min)	Group	N	NRS Mean± SD	P-Value
0	SPI group	50	3.10± 1.49	0.210
	Conventional group	50	4.22± 2.40	0.339
15	SPI group	50	2.48± 0.71	0.099
	Conventional group	50	2.64± 0.48	0.068
30	SPI group	50	2.16±0.42	0.059
	Conventional group	50	2.64±1.22	0.173
45	SPI group	50	1.96±0.40	0.056
	Conventional group	50	2.06± 0.47	0.066
60	SPI group	50	1.62±0.49	0.069
	Conventional group	50	1.70±0.61	0.086

* NRS-numerical rating scale for pain †SD-standard deviation

We found total intraoperative fentanyl consumption and haemodynamic changes reduced in SPI group than in conventional group. Ahonen J et al studied in 30 women undergoing gynaecological laparoscopic surgery who randomly received either esmolol or remifentanil for maintaining state entropy value at 50 and they concluded that SPI was higher in patients receiving esmolol than in patients receiving remifentanil and also SPI value reflects intraoperative surgical stress during general anaesthesia which is similar to our study.[13] The same results were observed by the study done by Huiku et al and Chen et al in which they used Propofol and Remifentanil as target controlled infusions(TCI). Propofol TCI was adjusted to maintain state entropy level between 35 to 60 where as we used isoflurane 1 to 2% to maintain state entropy between 20 to 60 and fentanyl for analgesia.[1,6]

A study by Bergmann et al, a total of 170 outpatients given total intravenous anaesthesia(TIVA) with propofol and remifentanil. In this study, patients were randomized to have the remifentanil dose either adjusted according to the SPI (SPI group) or to clinical parameters (control group). The dosage of propofol was adjusted according to state entropy in both groups and they concluded that, adjusting the remifentanil dosage according to SPI in outpatient anaesthesia reduced the consumption of both remifentanil and propofol and resulted in faster recovery.[8] Results were comparable with our study.

SPI is found to correlate with surgical stress intensity. In the setting of total intravenous anaesthesia (TIVA) many studies had shown the beneficial effects of SPI guided analgesia in terms of remifentanil consumption, hemodynamic stability and incidence of unwanted events.

Colombo R et al studied 42 adult patients undergoing laparoscopic abdominal surgeries and concluded that ANS modulation correlated with changes in SPI in the context of balanced anaesthesia.[12]

All the above mentioned studies were conducted on adults only, whereas Park JH et al studied 45 children undergoing elective adenotonsillectomy for fentanyl requirement and found that the intraoperative requirement of fentanyl was lower in SPI guided group whereas postoperative pain score and rescue fentanyl consumption was higher in SPI guided group. This is in contrast to our study conducted on adults where we found post-operative pain score were comparable in both groups. This difference in results was implicated due to the blood vessel distensibility and increased baseline heart rate in children.[14]

The beneficial effect of SPI guided analgesia is that it specifically identifies haemodynamic changes secondary to noxious stimulus distinguishing from those that occur secondary to other causes like pneumoperitoneum, hypercarbia and positioning of patient. And since it gives a real time objective assessment of the balance between analgesia and noxious stimulus, a SPI value <50 warrants us to look for other causes of hypertension and tachycardia.

Though we found the intraoperative fentanyl consumption was less in SPI group which was statistically significant but the difference in mean values of two groups is not clinically significant. There are several studies on SPI guided analgesia using different opioids which have conflicting results regarding intraoperative consumption and postoperative pain. Thus further research on SPI guided analgesia with different opioids is needed to confirm the results.

One of the limitations of our study is that the MAP and HR were measured every 5 minutes so the extremely transient episodes of hypertension and tachycardia might not have been detected in the conventional group. Use of isoflurane at concentration ranging from 1-2% is a confounding factor in our study as it affects haemodynamic parameters and hence fentanyl consumption.

5. Conclusion

In our study SPI guided analgesia resulted in lower intra-operative opioid consumption and stable haemodynamics as compared to conventional analgesia. However further studies on SPI guided analgesia using different opioids is needed to confirm efficacy and clinical significance of SPI guided analgesia.

6. Source of Funding

None.

7. Conflict of Interest

None.

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