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To Evaluate and Compare the Possible Analgesic Properties of Sevoflurane with Desflurane in Patients Undergoing Laparoscopic Cholecystectomies under Volatile Induction and Maintenance Anaesthesia (VIMA)

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Abstract: ***Introduction: Sevoflurane, desflurane have been used in labour analgesia. Need more evidence to prove their analgesic properties, when used in VIMA. So, a randomized study single blinded comparative study was carried out. Method: 50 patients of either gender were randomly, equally allocated to 2 groups to be anaesthetized with sevoflurane or desflurane. Monitoring-routine multi parametric monitoring, depth of anaesthesia monitoring using Conox, qCON/qNOX kept between 40-60. Pain was scored using, VAS, before induction (T_0), after extubation (T_1), as shifted to Post Anaesthesia Care Unit (PACU) (T_2), on demand of rescue analgesia/2 hours in PACU, whichever came first (T_3). Rescue analgesia was administered before shifting to ward. Results: Demographically both the groups were similar. Haemodynamic parameters remained stable, suggesting, potentiation of fentanyl analgesia with appropriate depth of anaesthesia. VAS scores were consistently lower (1-3), at all time points. Recovery although far superior in desflurane group was also adequate even in sevoflurane group. In face of low VAS, rescue analgesia, had to be given pre-emptively before shifting to ward. Conclusion: Both IAAs have significant intraoperative and postoperative analgesic efficacy. Desflurane has rapid onset of analgesia, starting from time of induction. Amongst themselves the efficacy is similar.***

Keywords: Volatile Induction Maintenance Anaesthesia (VIMA), Sevoflurane, Desflurane, Laparoscopic Cholecystectomy, VAS

1. Introduction

It is generally considered that, except ether, trichloroethylene and methoxyflurane, majority of the inhalational anaesthetic agents (IAAs), especially the modern halogenated ethers, do not exhibit analgesic properties. Trichloroethylene, Methoxyflurane, isoflurane, sevoflurane and most recently desflurane have been used as obstetric analgesics for conduct of painless labour. [1] In addition, there have been some reports recently, which suggest, that the IAAs, especially, sevoflurane and desflurane may exhibit some analgesic properties. [2-4] Most recently, sevoflurane has been used for analgesia during uterine contractions in labor in conjunction with Entonox, as what the authors called 'Sevonox' and was found to be more beneficial than Entonox administrationalone. [1, 5]

These reports suggest that contrary to the general belief, there may be some anti-nociceptive properties exhibited by these agents. As the perception of pain is a complex phenomenon, there may be variety of mechanisms involved.

Laparoscopic cholecystectomy is one of the most frequently performed minimal access surgeries in our country and it bears a significant economic and financial share of the hospitals. [6] It is routinely performed as a day care procedure in Western world. With the advent of newer and better anaesthesia techniques, an early home discharge can be achieved for these patients in our settings as well, thus reducing monetary burden on the state. [7]

Further confirmation and additional work and building up of some evidence, needs to be carried out to come up with some concrete conclusion. With this background information, we conducted a prospective randomized study, in the patients undergoing the planned laparoscopic cholecystectomies.

Aim:
To evaluate, if the inhalational anaesthetic agents, sevoflurane and desflurane exhibit any analgesic properties

in the patients undergoing laparoscopic cholecystectomies under volatile induction maintenance anaesthesia (VIMA).

Objectives:

1) To compare the analgesic properties of sevoflurane and desflurane during VIMA
2) To compare the analgesic properties of sevoflurane and desflurane in theimmediate post-operative period following VIMA

Null hypothesis

Sevoflurane and desflurane do not have any analgesic property when used during VIMA or in the immediate post-operative period.

The study was conducted in accordance with the Ethical Principles for Medical Research Involving Human Subjects (Helsinki Declaration-2013).

2. Methods

Trial Design: Parallel group prospective randomized single blinded trial

Method of generating random sequence: Computer generated randomisation

Method of Concealment: On-site computer system

Blinding: Participant Blinded
Ethics: After obtaining approval from the Institutional Research committee (IRC), Ethics committee of the university and written informed consent from each patient, parallel group randomised single-blinded trial was conducted, in a Tertiary Care Post Graduate Teaching Institute in Northern India, for a period of 18 months.

Inclusion Criteria
Age 18-65 years, both genders, ASA Grading, I, II, weight between 50-90 kgs, undergoing laparoscopic cholecystectomy under general anaesthesia.

Exclusion Criteria
< 18 and >65 years, non-consenting as well as pregnant patients, patients with uncontrolled co-existing systemic or metabolic diseases, history of alcohol or substance abuse, known sensitivity to sevoflurane, desflurane or any other halogenated anaesthetic agent, underwent recent GA within 7 days.

Methodology

During the conduct of VIMA, the haemodynamic responses and any autonomic responses suggestive of persistent noxious stimuli or their absence were planned to be continuously monitored and outcomes were to be assessed based upon the pain experienced by the patient as measured with help of Visual Analogue Scale [8] at T_0-before the induction of anaesthesia, T_1-immediately after extubation, T_2-after shifting to the post-operative recovery room, T_3-when the patient demands the rescue analgesia or 2 hours post-operatively whichever comes first. Inj. Ketorolac 30 mg diluted in 100 ml. of Normal saline to be given over the period of 10-15 minutes intravenously used as rescue analgesia.

Randomization was done with the help of computer-generated random number table and the patients were allotted to either of the two parallel groups-

GROUP S-Sevoflurane 25 patients
GROUP D-Desflurane 25 patients

In operation theatre, standard monitors-Pulse oximetry for saturation (SpO_2), Noninvasive blood pressure monitoring (NIBP), Electrocardiogram (ECG) was connected and baseline pulse rate, mean arterial pressure, oxygen saturation were recorded. Conox® device was attached to the patient to determine/ monitor the depth of anaesthesia. Conox^R is a non-invasive depth of anaesthesia monitor to be used by healthcare professionals in surgery rooms or ICU environments during anaesthesia and sedation procedures. It is a tool that helps to assess the patient's state of consciousness and the probability of response to noxious stimuli under the hypnotic and analgesic effects [9]. Pre operative values of qCON and qNOX were noted. Patients wereasked about presence of any pain experienced using visual analogue scale (VAS). Patients were premedicated with Inj. Midazolam 0.05mg/kg, Inj. Glycopyrrolate0.004mg/kgi. v and Inj. Fentanyl 2µg/kg i. v, Preoxygenation was done with 100% oxygen for 3 minutes. [10]Induction with Sevoflurane / Desflurane was given in decremental doses that is initially the induction was started with 6% of either desflurane or sevoflurane and then the dose was decreased gradually depending upon the response of the patient, along with muscle relaxant Inj. Rocuronium 0.6mg/kg i. v. Intubation with Endotracheal tube (E. T. T), cuffed, sized 7-7.5 mm for women and 8-8.5 mm for men was done. Group S was maintained with sevoflurane and Group D with desflurane in 33% oxygen and 67% nitrous oxide. Sevoflurane/Desflurane was be titrated to maintain the values of qCON between 40-60 ensuring adequate depth of anaesthesia and qNOX between 40-60. Intraoperatively variations between the heart rate, ECG changes, SPO_2, systolic, diastolic and mean arterial pressures any other abnormalities of the rhythm were assessed. At the end of the surgery after the discontinuation of the volatile agent, residual neuromuscular blockade reversed with Inj. Neostigmine 40ug/kg and Inj. Glycopyrrolate 10ug/kg i. v. Extubation done smoothly. Patients were verbally asked about the intensity of the pain using VAS. Patient was shifted out to the recovery and again the pain score was assessed again. The patient was monitored for 2 hours, Modified Aldrete score for the ward worthiness and permission to transfer to the ward was applied and transferred to the ward.

3. Results

All raw data was subsequently entered into a Microsoft Excel spreadsheet and was analysed using appropriate statistical methods using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA Data was expressed in mean ± SD (Standard Deviation), and $p<0.05$ was considered

statistically significant. Data was summarised by routine descriptive statistics, namely Mean and Standard deviation for numerical variables that are normally distributed, Median and Interquartile range for Skewed numerical variables and counts and percentages for categorical variables. Numerical variables were compared between the groups by Students' independent parallel t test, when normally distributed and by Mann-Whitney U test when skewed.

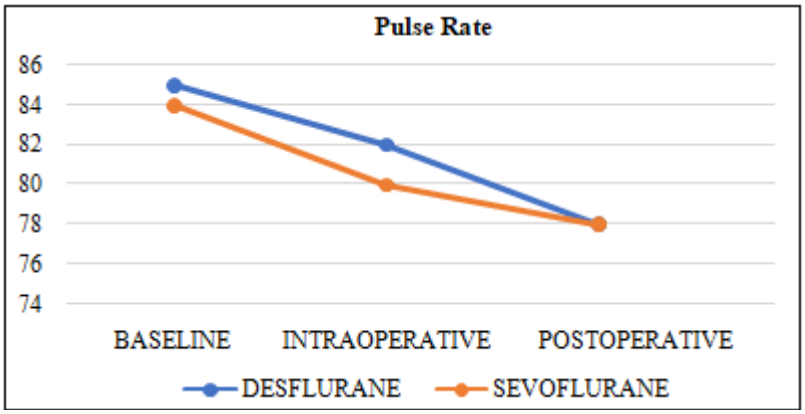
- The demographic profile of all the patients and the total duration of surgery was comparable in both the groups with no statistically significant difference (Table 1):

	Group S	Group D	P value
Age (years)	32.57+/-8.	36.57+/-8.4	0.069
Weight (kg)	55.8+/-8.44	60.06+/-11.07	0.101
Sex-Female Male	77.5 22.5	67.5 32.5	0.316
Duration of surgery (min)	67.5+/-18.7	74+/-17.14	0.167

- Changes in Pulse rate

Pulse Rate	Group D	Group S	P value
Baseline	85.8± 9.3	84.3± 9.9	0.490
Intraoperative	82.7+/-7.2	80.1+/-8.1	0.270
Postoperative	79.0± 8.6	78.7± 7.3	0.835

The comparison between the baseline and mean intraoperative and postoperative pulse rate showed minimal change, suggesting minimal hemodynamic variations intraoperatively as well as postoperatively.



Comparison of pulse rate within the desflurane group at different time points showed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus intraoperative	3.575	0.8803 to 6.270	**	0.0057
Baseline versus Postoperative	6.725	4.030 to 9.420	****	<0.0001
Intraoperative versus Postoperative	3.150	0.4553 to 5.845	*	0.0174

The difference in the mean pulse rate at different time intervals was highly significant indicating some residual effects of desflurane in the postoperative period. Comparison was done using Repeated Measures Anova with Post Hoc Tukey's test.

Comparison of pulse rate within the sevoflurane group at different time points showed the following results-

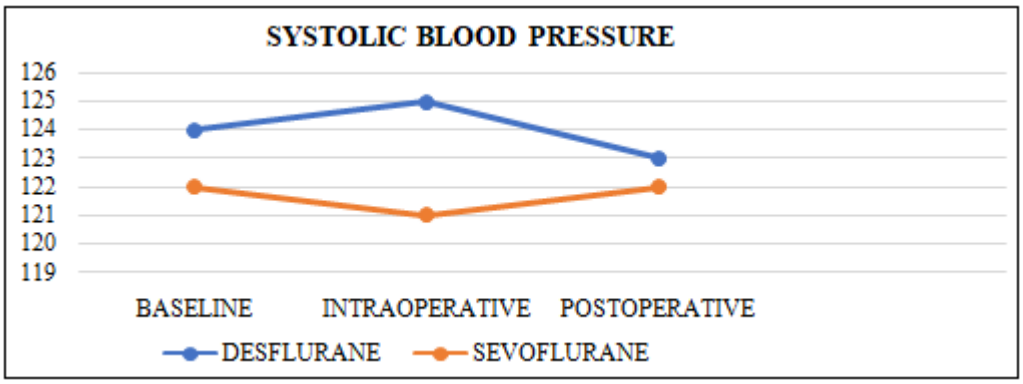
	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	4.050	1.355 to 6.270	**	0.0014
Baseline versus Postoperative	5.600	2.905 to 8.295	****	<0.0001
Intraoperative versus Postoperative	1.550	- 1.145 to 4.245	Not significant (ns)	0.3639

The difference between the mean pulse rate was highly significant in the baseline versus intraoperative and postoperative periods but when compared postoperatively the difference was not significant indicating stable haemodynamics with sevoflurane.

- Changes in Systolic blood pressure

SBP	Group D	Group S	P value
Baseline	124.4± 8.7	122.6± 8.9	0.366
Intraoperative	125.6± 9.1	121.7± 11.7	0.102
Postoperative	123.0± 9.3	122.6± 8.2	0.859

Baseline, intraoperative and postoperative systolic blood pressure was comparable between the desflurane and sevoflurane groups. There was no statistically significant difference.



Comparison of systolic blood pressure within the desflurane group at different time pointsshowed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	- 1.150	- 5.920 to 3.620	ns	0.8276
Baseline versus Postoperative	1.450	- 3.022 to 5.922	ns	0.7113
Intraoperative versus Postoperative	2.600	- 2.333 to 7.533	ns	0.4125

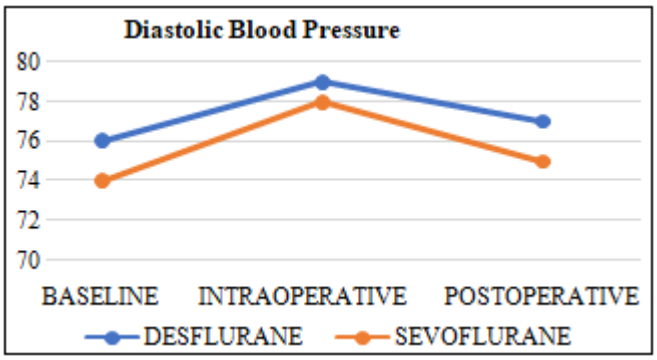
Comparison of systolic blood pressure within the sevoflurane group at different time points showed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	-2.950	-7.193 to 1.293	ns	0.2203
Baseline versus Postoperative	-0.3500	-5.729 to 5.029	ns	0.9862
Intraoperative versus Postoperative	2.600	-2.333 to 7.533	ns	0.4125

- Changes in Diastolic blood pressure

DBP	Group D	Group S	P value
Baseline	76.0± 7.2	74.7± 8.3	0.458
Intraoperative	79.5± 6.3	78.4± 6.9	0.462
Postoperative	77.1± 5.1	75.8± 5.6	0.288

Baseline, intraoperative and postoperative diastolic blood pressure were comparable between the desflurane and sevoflurane groups. There was no statistically significant difference.



Comparison of diastolic blood pressure within the desflurane group at different time points showed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	- 3.425	- 7.161 to 0.310	ns	0.0780
Baseline versus Postoperative	- 1.075	- 4.609 to 2.459	ns	0.7408
Intraoperative versus Postoperative	2.350	- 1.089 to 5.789	ns	0.2315

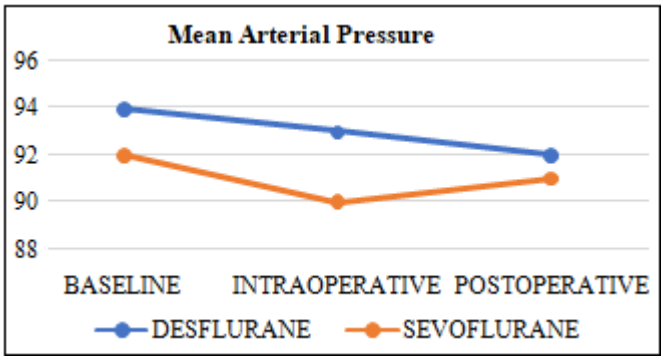
Comparison of diastolic blood pressure within the sevoflurane group at different time points showed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	- 3.625	- 7.540 to 0.289	ns	0.0743
Baseline versus Postoperative	- 1.075	- 5.308 to 3.158	ns	0.8108
Intraoperative versus Postoperative	2.550	- 0.545 to 5.645	ns	0.1239

- Changes Mean Arterial Pressure

MAP	Group D	Group S	P value
Baseline	94.7± 7.8	92.6± 7.0	0.219
Intraoperative	93.3± 6.9	90.4± 9.2	0.114
Postoperative	92.4± 4.3	91.4± 4.3	0.316

The baseline, intraoperative and postoperative means arterial pressure in both desflurane and sevoflurane groups were comparable with no statistically significant difference.



Comparison of mean arterial blood pressure within the desflurane group at different time points showed the following results-

	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	-3.457	- 7.456 to 0.158	ns	0.0789
Baseline versus Postoperative	-1.076	- 5.200 to 3.278	ns	0.7432
Intraoperative versus Postoperative	2.556	- 0.454 to 5.600	ns	0.1432

Comparison of mean arterial blood pressure within the sevoflurane group at different time points showed the following results:

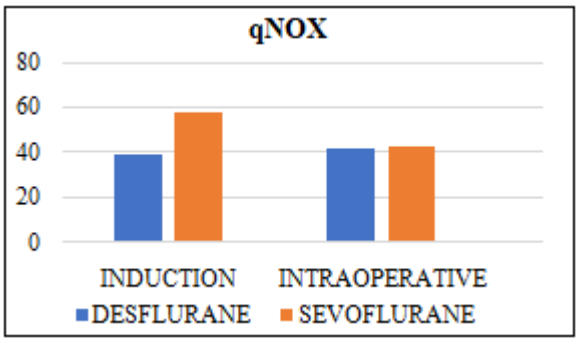
	Mean Diff	95% CI of diff	Level of significance	P value
Baseline versus Intraoperative	-3.560	-7.606 to 0.162	ns	0.0682
Baseline versus Postoperative	-1.202	-5.346 to 3.674	ns	0.7200
Intraoperative versus Postoperative	2.001	-0.489 to 5.420	ns	0.1822

The steadfast stability of all the haemodynamic parameters inclusive of SBP/DBP/MAP intra-operatively as well as postoperatively, confirmed by no statistically significant difference both, between the groups or intragroup in both the groups at various time points and at the similar depth of anaesthesia (q CON/q NOX), suggests, lack of noxious/nociceptive stimuli due to potentiation of opioid analgesia by IAAS.

- Values of qNOX

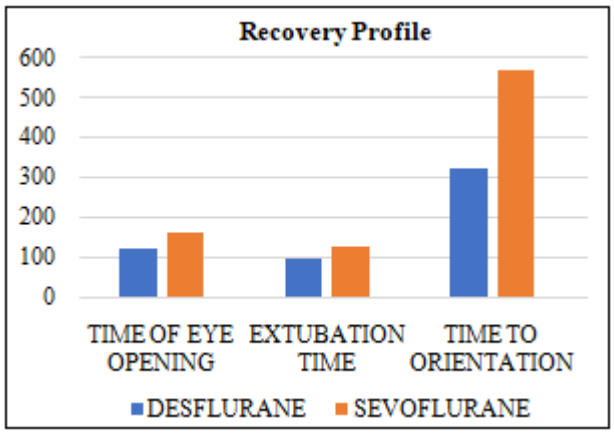
qNOX AT Induction		P value
Group D	39.92 +/-7.7	<0.0001
Group S	58.57 +/-7.9	
qNOX Intraoperative		
Group D	42.4 +/-7.4	0.358
Group S	43.7 +/-5.7	

At induction
Distribution of mean qNOX was statistically significant (p=<0.0001)
Intraoperatively
Distribution of mean qNOX was not statistically significant (p=0.3589)



- Early recovery parameters-The time from discontinuation of inhalational agent to removal of ETT, time to eye opening and time to orient were significantly faster and statistically significant in patients receiving desflurane as compared to patients receiving sevoflurane.

Time to achieve early recovery end points (s)	Group S	Group D	P value
Time of eye opening	160.23+/-61.2	120.59+/-61.42	0.004
Extubation time	126.48+/-64.94	94.07+/-42.19	0.001
Time of orientation	569.90+/-253.9	321.24+/-148.59	0.001



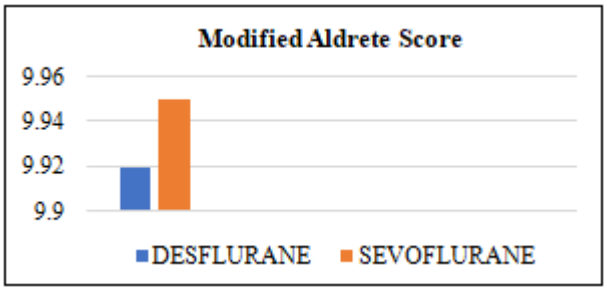
- Recovery characteristics as assessed by MODIFIED ALDRETE SCORE

Group	Mean+/-SD	P value
D	9.92+/-0.26	0.649
S	9.95+/-0.22	

In Desflurane, the mean Modified Aldrete Score (mean± S. D) of patients was 9.92±.26

In Sevoflurane, the mean Modified Aldrete Score (mean± S. D) of patients was 9.95±.22

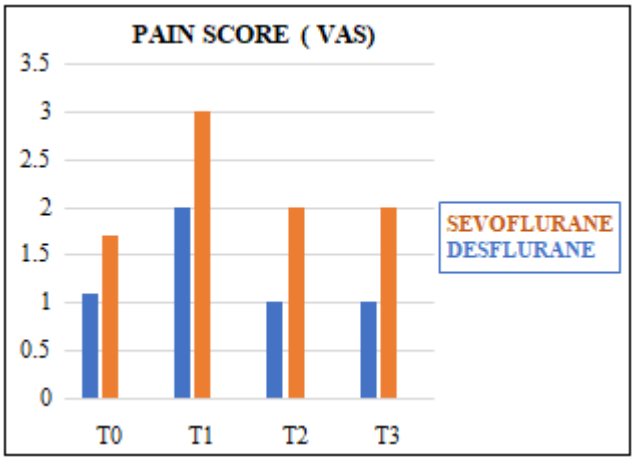
The difference between the distribution of mean Modified Aldrete Score was statistically non-significant, suggesting adequate recovery/ wardworthyness in both the groups (p=0.649)



- Pain assessment based on VAS

VAS	Group D	Group S	P value
T_0	1.1	1.7	0.28
T_1	2	3	0.72
T_2	1	2	0.68
T_3	1	2	0.87

The primary outcome was postoperative pain scores on the VAS from 0 to 2 hours after surgery. In all the patients in both the groups the values in immediate post-operative period, viz; On the table (T_1), immediately after shifting to PACU (T_2) and either after demand of rescue analgesia or 2 hours after shifting, whichever first (T_3), the VAS values were low, ranging between 1 to 3, almost as low as Pre-operative (T0), suggestive of persistence of analgesia, in the immediate post-operative period. Even at the end of two hours, when the patients were ready to be shifted to the ward the VAS score was significantly low for either of the two volatile agents (desflurane 1, sevoflurane 2), therefore electively Inj. Ketorolac 30 mg diluted in 100 ml Normal saline over 10-15 mins was given to the patients and patients were shifted to ward.



4. Discussion

Our contention was if we could assess any possible analgesic properties of both the IAAs during conduct of general anaesthesia and, in the immediate postoperative period, using VIMA, oxygen/nitrous oxide mixture along with a potent opioid and maintaining properly monitored adequate depth of anaesthesia.

As is evident, there was no significant difference in the participant's demographics as well as the duration of surgery in both the groups. (Table 1)

There was reduction in the qNOX value [11] while induction with desflurane as compared with sevoflurane suggestive of significant (p=<0.000) potency of desflurane as compared to sevoflurane which could translate to its analgesic property.

The intra-operative stability of haemodynamic parameters is again suggestive of potentiation of intra-operative analgesia of fentanyl by the IAAS. Intraoperative hemodynamic stability was easily achieved with both sevoflurane and desflurane, with MAP and HR maintained within ±20% of baseline values during the entire maintenance period. Further, the use of CONOX^R monitoring helped standardise the depth of anaesthesia and maintain the same in a consistent manner. Gergin *et al* studied the haemodynamics, emergence and recovery characteristics of sevoflurane with those of desflurane in nitrous oxide anaesthesia and concluded that the groups did not differ in these haemodynamic measures. [12]

The striking fact to be taken in to consideration is, that with help of q CON and q NOX, the deeper planes of anaesthesia/ analgesia were achieved, and at these depths, only parameter which can be indicative of any persistent nociception would be haemodynamic variations, like, tachycardia or bradycardia, hypertension and any arrhythmias. [11] Complete absence of any of these variations and maintained stability in the intra-operative period suggests potentiation of the fentanyl produced analgesia by the inhalational agents both sevoflurane and desflurane, confirming our contention.

Although multiple factors are at play intra-operatively in expression of these parameters, the continued low VAS scores in both the groups in immediate post-operative period up to 2 hours when still some amount of residual blood levels of inhalational agents are expected, may corroborate the continuation of analgesia by inhalational agents in immediate post-operative periods. In fact the persistence of low VAS score at even the time interval T3, which in our cases coincided with 2 hours period (mean VAS of 1 group D and 2 in group S) necessitated us to give rescue analgesia, pre-emptively before transferring the patients to the wards. It was noteworthy that the VAS scores were similar and there was no statistically significant difference between the groups in context with VAS. This may be considered as a similar efficacy of analgesic effect of both inhalational agents at all the time intervals.

There was no significant intergroup difference between both the groups with regards to VAS, may suggest that, the analgesic effect by both the inhalational agents may be same quality and level.

Ryu KH did a study to determine whether Desflurane reduces intraoperative remifentanil requirements more than sevoflurane using surgical pleth index-guided analgesia. Eighty-two subjects undergoing laparoscopic cholecystectomy were randomly allocated to two groups receiving either sevoflurane (*n*=40) or desflurane (*n*=42). Anaesthesia was maintained with the assigned inhaled anaesthetics and remifentanil. Remifentanil infusion was continuously adjusted to achieve a surgical pleth index of 20–50. Mean remifentanil infusion rate, which was the primary outcome of the study, was calculated as the total

infused remifentanil dose per kg body weight per minute of total operative time. During the steady state of age-corrected 1.0 MAC, mean SPI values throughout the entire study period were significantly higher in the sevoflurane group than in the desflurane group (38.1 ± 12.8 *vs*.30.7 ± 8.8, respectively, *P* = 0.005), and mean BIS values were significantly higher in the sevoflurane group than in the desflurane group (40.7 ± 5.8 *vs*.36.8 ± 6.2, respectively, *P* = 0.008). They concluded that equi-MAC of sevoflurane and desflurane did not produce similar surgical pleth index values. Therefore, sevoflurane and desflurane may have different analgesic properties at equipotent concentrations. [3]

Literature suggests that volatile anaesthetics may have analgesic properties. In rats desflurane attenuates the response to tibial nerve stimulation and the pressor response to electrical stimulation. [13] These actions indicate antinociceptive properties of this anaesthetic. Sevoflurane decreased the number of fos-like immunoreactive neurons in the dorsal horn of the spinal cord in rats that were subjected to the formalin test. [14] This effect was antagonized by administration of naloxone and naltrexone. The literature assessing postoperative pain does not address the possible impact of general anaesthetics on postoperative pain, except for a recent study by Cheng et al. [15] showing that propofol anaesthesia was associated with less postoperative pain than isoflurane anaesthesia. As pain assessment and analgesic requirements were recorded during the first 2 h postoperatively, our results apply rather to the impact of the subanaesthetic concentrations [4] of the anaesthetics on postoperative pain than to the concentrations we administered to maintain general anaesthesia.

Also, sevoflurane and desflurane provided similar intraoperative conditions during the maintenance period. Although recovery was more rapid after desflurane. The practical benefit of earlier emergence from anaesthesia can lead to more rapid discharge from the post anaesthesia care unit.

5. Conclusion

As per the results in our study, VIMA, with either sevoflurane or desflurane and oxygen/nitrous oxide mixture, might potentiate the intraoperative analgesic effects of fentanyl, however the two do not significantly differ in their efficacy to do so. Desflurane appears to have quicker onset of analgesic effect starting at the induction itself. The analgesic potentiation may be persisting even in the immediate postoperative period, indicated by low VAS scores and delay in the requirement of rescue analgesia.

6. Limitation

To further strengthen the result of our study VAS scoring could have been further extended over 4, 6, 12 and 24 hours post operatively and the number of times rescue analgesic required by the patients should have been noted down. Secondly, larger number of patients may be studied for more confirmation of the results.

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