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To Compare Efficacy of Sevoflurane and Desflurane Employed as Volatile Induction Maintenance Anaesthesia (VIMA) using Conox® in Patients Undergoing Laparoscopic Cholecystectomy

Gurleen Kaur[1], Mridul Madhav Panditrao[2], Minnu M Panditrao[1], Nikhil Jaura[3]

Dr. Gurleen Kaur Final Year JR (MD Anaesthesiology)
Dr. Mridul Madhav Panditrao Professor
Dr. Minnu M. Panditrao Professor & Head
Dr. Nikhil Jaura Senior Resident
[1]Department of Anaesthesiology & Intensive Care, Adesh Institute of Medical Sciences and Research, Bathinda
[2] Department of Anaesthesiology, Bharati Vidyapeeth Deemed University Medical College, Pune (Formerly Professor & Head, Department of Anaesthesiology & Intensive Care, Adesh Institute of Medical Sciences and Research, Bathinda)
[3]Department of General Surgery, Adesh Institute of Medical Sciences and Research, Bathinda

ABSTRACT:
Introduction:
Volatile induction maintenance anaesthesia (VIMA) can be considered as one of the pinnacles of achieving balanced general anaesthesia. Employing volatile agents like sevoflurane and now desflurane,under precise depth of anaesthesia monitoring, it is possible to tailor the peri-operative management precisely.
Methods:
A prospective study was carried out to compare the efficacy of sevoflurane and desflurane using volatile induction and maintenance anaesthesia (VIMA) in patients undergoing laparoscopic surgical procedures. 80 ASA Grade I & II patients undergoing elective laparoscopic surgery were included in the study. Outcomes were assessed based upon - induction time, time taken for intubation, intraoperative hemodynamic parameters, depth of anaesthesia monitoring using Conox device, time for spontaneous eye opening, extubation time and the recovery of the patients.*
Results:
Sevoflurane and desflurane both provided rapid induction and maintenance of anaesthesia with stable intraoperative hemodynamics and smooth recovery and no post operative residual effects or complications. Desflurane appeared to have quicker induction as well as rapid recovery as compared to sevoflurane.
Conclusion:
Sevoflurane as well as desflurane, employed for VIMA, with precise depth of anaesthesia monitoring,are equally effective in achieving optimum intra/postoperative conditions in patients undergoing the laparoscopic cholecystectomies.

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I. Introduction:

The origin of general anaesthesia (GA) was based with the volatile anaesthetic agents like, diethyl/divinyl ether, chloroform,trichloroethylene to mention a few. They were fraught with major challenges.[1] With the advent of the modern volatile agents (starting with halothane in 1956) a new era of rapid and safe inhalational induction began. With the introduction of halogenated ethers like, methoxyflurane, enflurane, isoflurane, sevoflurane and now desflurane, the entire outlook of inhalational anaesthetic agents has undergone complete transformation. In patients with a known difficult airway who present for elective surgery, inhalational agents like sevoflurane, are one of the major options available.[2] Modern volatile/inhalational agents are easier to titrate to the patient's depth of anaesthesia, blood pressure, pulse, minute ventilation and movements. The disadvantages associated with the use of intravenous agents like awareness during general anaesthesia, hemodynamic consequences of propofol, opioid induced hyperalgesia and neurotoxicity can also be avoided with the judicious use of inhalational agents.[3]

Volatile induction and maintenance anaesthesia (VIMA) involves the induction with the sole inhalational agent to produce the unconsciousness (induction). After achieving the muscle relaxation with a suitable neuromuscular junction blocking agent and control of the airway with an appropriate modality, the maintenance is continued with the gas mixture, which includes the volatile anaesthetic agent, which had been used for induction. [4,5] The rest of the procedure is similar to any modality of balanced general anaesthesia (balanced GA). It is a safe and precise technique without the negative effects of the intravenous induction agents and seamless continuation of the steps of induction to maintenance. There are minimal deleterious effects on the respiratory, cardiovascular, cerebral as well as on immunological system, for all the sectors of the age [4].

As the things stand at present, Sevoflurane has been in use in clinical practice for more than 2 decades and as already mentioned, has become a byword for conduct of safe general anaesthesia even in difficult circumstances.[5]

Desflurane has been marketed globally for more than a decade, but it has become available freely in our country only in last few years. It is being claimed as a "third generation inhaled anaesthetic agent". [6] Itwas our endeavor to compare, the well accepted/established and "gold standard", sevoflurane [7] with the claimed 'third generation' inhaled anaesthetic agent, desflurane, without any encumbrance of the ubiquitous intravenous induction agents and their disadvantages.[3] So we have decided to use "volatile induction maintenance anaesthesia (VIMA)".

The process of monitoring depth of GA and administration of anaesthetic during surgery is a closed-loop control system where the human is liable for reasoning and action. The anaesthesiologist plays the roles of controller and actuator by electing the quantity of anaesthetic and when to administer it. On the opposite hand, the activity of monitoring is performed automatically by commercially available DGA monitors.Conox^{R} is a non-invasive depth of anaesthesia monitor to be employed by healthcare professionals in surgery rooms or ICU environments during anaesthesia and sedation procedures.

AIM:

To compare the efficacy of sevoflurane and desflurane using volatile induction and maintenance anaesthesia (VIMA) in patients undergoing laparoscopic surgical procedures

OBEJECTIVES:

1. To compare the induction time in the two groups
2. To monitor the depth of anaesthesia using qCON and qNOX and correlating them with the amount of inhalational agent used
3. To compare the intraoperative hemodynamic conditions
4. To evaluate the recovery between the two groups
5. To monitor and treat the side effects/complications during this period if any.

NULL HYPOTHESIS:

When administered to the patients undergoing the surgical procedure of laparoscopic cholecystectomy:

1. Sevoflurane and desflurane, may not be effective for VIMA.
2. There is no difference when they are compared with each other, in terms of efficacy for VIMA.

II. Material And Methods:

Setting and Place:The present study was a hospital based study, conducted in the Main Operating Theatre complex (Department of Anaesthesiology & Intensive Care), of a tertiary care university hospitalin Northern India

Study design: A Prospective, randomized, single blinded study.

Time frame: Study was carried for a period of 18 months after getting approval from the Institutional Research committee (/AIMSR/MC/Estt/12/2K20/1893), and Ethics Committee of University (AU/EC/FM/2021).

Population/ Participants: Patients for the study were of ASA Grade I & II undergoing elective laparoscopic surgery under general anaesthesia and applying inclusion and exclusion criteria after obtaining their informed written consent.

Sample size: Sample size was calculated using sample size calculator method [8] with confidence level 95% and margin of error 5%. Sample size was found to be 70 (35 per group). In addition, for any cases which might be excluded after the start of the procedure 10% additional number of cases were added to the sample size. So the final sample size was 80 (40 per group).

Methods: All patients planned to undergo the laparoscopic cholecystectomieswere screened for inclusion and exclusion criteria and enrolled in the study. Patients were counselled and informed written consent was taken. Pre-anaesthetic checkup/clinical examination was carried out.

Inclusion Criteria:

1. Age 18-65 years
2. Both genders
3. ASA Grading, I, II
4. Weight between 50 – 90 kgs.
5. Laparoscopic cholecystectomy under general anaesthesia

Exclusion critera:

1. Age < 18 and >65 years, non-consenting as well as pregnant patients
2. Patients with uncontrolled co-existing systemic or metabolic diseases. However their controlled counterparts (considered as ASA II) were considered
3. History of alcohol or substance abuse
4. Known sensitivity to sevoflurane, desflurane or any other halogenated anaesthetic agents
5. Underwent recent GA within 7 days
6. Potential susceptibility to malignant hyperthermia

A pilot study was carried out while the Clinical Trials Registry – India (CTRI) number was awaited. Till that time, the enrollment of the patients was withheld. Thereafter, after having obtained the CTRI registration number the study was conducted in 80 patients.

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

Group S- Sevoflurane 40 Patients

Group D - Desflurane 40 patients

To ensure the selection was completely unbiased, the patients were allocated into either of the two groups by "Chit in the box" system wherein a person uninvolved with the study was asked to pick up a chit from a box containing 80 chits (40 each for both sevoflurane and desflurane) and patients were randomly assigned at a 1:1 ratio to receive sevoflurane or desflurane.

In operation theatre, standard monitors which included the pulse-oximetry for saturation (SpO_2), noninvasive blood pressure monitoring (NIBP), electrocardiogram (ECG) were connected and baseline pulse rate, systolic, diastolic and mean arterial pressure, oxygen saturation were recorded.Conox device was attached to the patient to determine the depth of anaesthesia. Pre-operative values of qCON and qNOX were noted.

Patients were premedicated with Inj. Midazolam 0.05mg/kg, Inj. Glycopyrrolate 0.004mg/kg i.v and Inj. Fentanyl 2µg/kg IV.

Preoxygenation was done with 100% oxygen for 3 minutes.[9]

Induction: Sevoflurane/Desflurane were given in decremental doses, that is initially the induction 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.

Induction time was noted (time from the onset of giving inhalational agent till the loss of eyelash reflex).

Values of qCON and qNOX were noted as follows –

1. C_1 - At the loss of eye lash reflex
2. C_2- At the time of intubation
3. Thereafter every 10 mins

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 the mixture of 33% oxygen and 67% nitrous oxide.

Sevoflurane/Desflurane were titrated to maintain the values of qCON between 40 – 60 ensuring adequate depth of anaesthesia and qNOX between 40 – 60

Ventilation was controlled to maintain the end tidal CO_2 between 32–36 mmHg with tidal volume of 6 – 8 ml/kg and respiratory rate of 10 – 12/min. The respiratory rate had to be increased especially after CO_2 pneumoperitoneum.

Intraoperatively variations between the heart rate, ECG changes, SPO_2, systolic, diastolic and mean arterial pressures were assessed.

Nitrous oxide and the volatile agent were continued till the last skin suture.

After the discontinuation of the volatile agent, residual neuromuscular blockade was reversed with Inj. Neostigmine 40ug/kg and Inj. Glycopyrrolate 10ug/kg i.v

Here again the values of qCON and qNOX were noted

Extubation was done and the patient was shifted out

In the recovery room all the parameters were re-assessed, and the patient was assessed using Modified Aldrete Score and shifted to the ward.

Outcome Measures:
Outcomes were assessed based upon –

- T_1 - time from the onset of volatile agent inhalation to the loss of eyelash reflex (inductiontime)
- T_2 - time taken for intubation
- T_3 - time for spontaneous eye opening
- T_4 – extubation time
- Intraoperative parameters such as heart rate, oxygen saturation (SpO_2)
- Blood pressure measurements -systolic, diastolic and mean arterial pressure
- Depth of anaesthesia monitoring using Conox* device in which two main indices qCON (patient's level of consciousness) and qNOX (patient's response to noxious stimuli) were kept at predetermined level, which correlated to the patients level of consciousness and patients response to noxious stimuli respectively
- The recovery of the patients (Modified Aldrete Score)

Statistical analysis:

For statistical analysis data was entered into a Microsoft excel spreadsheet and then analysed by SPSS and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. One-way analysis of variance (one-way ANOVA) was a technique used to compare means of three or more samples for numerical data (using the F distribution). A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

The Mann–Whitney U test is a nonparametric test of the null hypothesis that it is equally likely that a randomly selected value from one sample is less than or greater than a randomly selected value from a second sample.

Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. Correlation was calculated by Pearson correlation analysis. Multivariate analysis was performed by logistic regression method for calculation of risk factors. The Kaplan–Meier estimator (Kaplan-Meier survival analysis) was a non-parametricstatistic used to estimate the survival function from time data.
P-value ≤ 0.05 was considered for statistically significant.

III. Results:

As per the results of the pilot study induction time was shorter in patients receiving desflurane (p=<0.0001). There was no difference in the hemodynamics of the two groups and they remained stable throughout. Since qCON was kept at a predetermined value of 40-60 so no difference was observed between the two groups. However, to achieve the desired level of depth of anaesthesia the amount of desflurane used was more as compared to sevoflurane (p=<0.0001). Further, desflurane provided quicker onset of analgesia as indicated by low qNOX value starting from the induction itself. The time to eye opening and extubation time was also found to be shorter in desflurane group (p<0.0001).
The results of the main study conducted are as follows –

Table 1 : Distribution of mean INDUCTION TIME T 1 (Sec)

		Number	Mean	SD	p-value
INDUCTION TIME T 1 (Sec)	DESFLURANE	40	43.85	8.562	0.001
	SEVOFLURANE	40	75.02	14.724	

Table 2 : Distribution of mean INTUBATION TIME T 2 (Sec)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
INTUBATION TIME T 2 (Sec)	DESFLURANE	40	39.5500	9.5995	1.0000	54.0000	40.0000	0.5907
	SEVOFLURANE	40	38.1150	13.7964	1.0000	56.0000	40.0000	

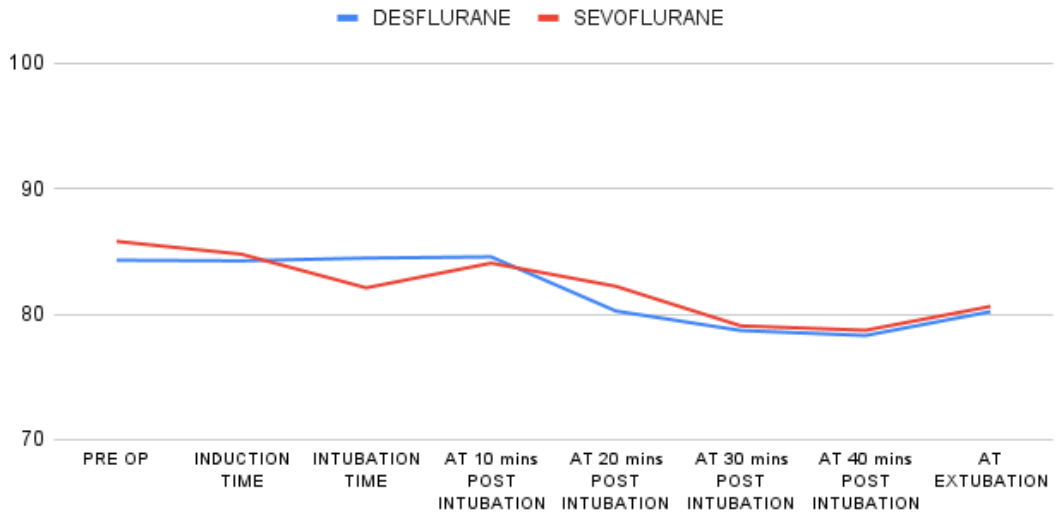

Figure 1 : Distribution of mean Pulse Rate at different time intervals

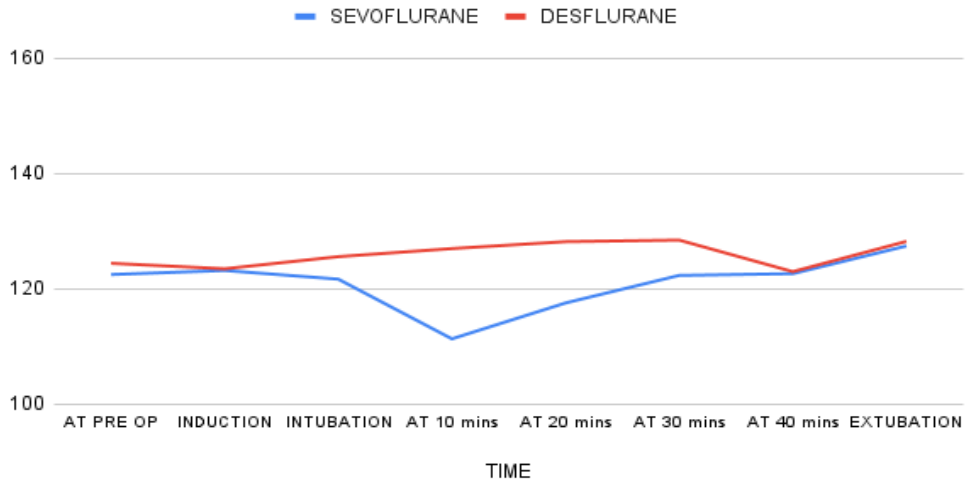

Figure 2 : Distribution of mean SBP at different time interval

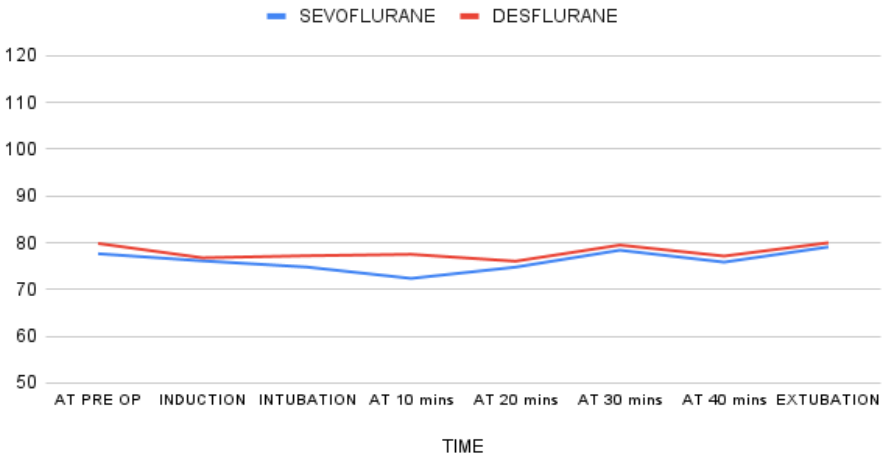

Figure 3 : Distribution of mean DBP at different time interval

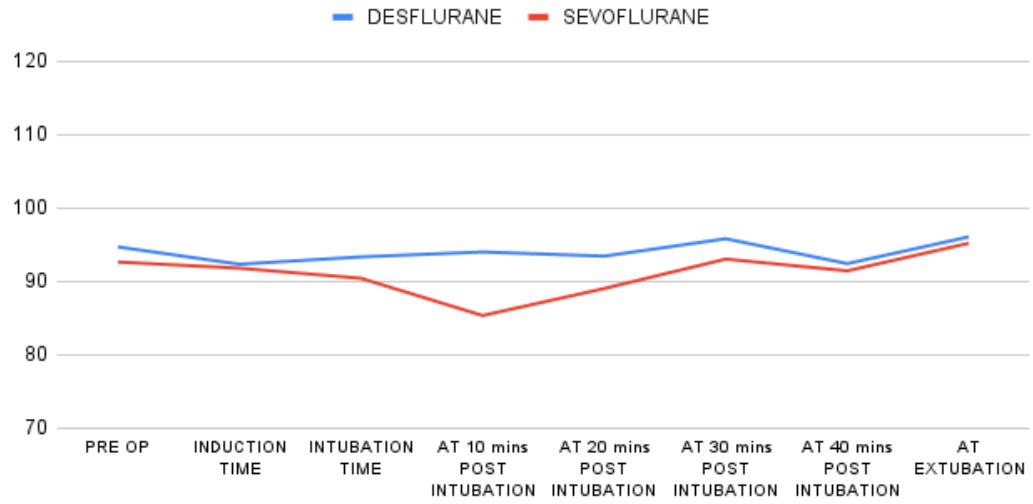

Figure 4 : Distribution of mean MAP at different time interval

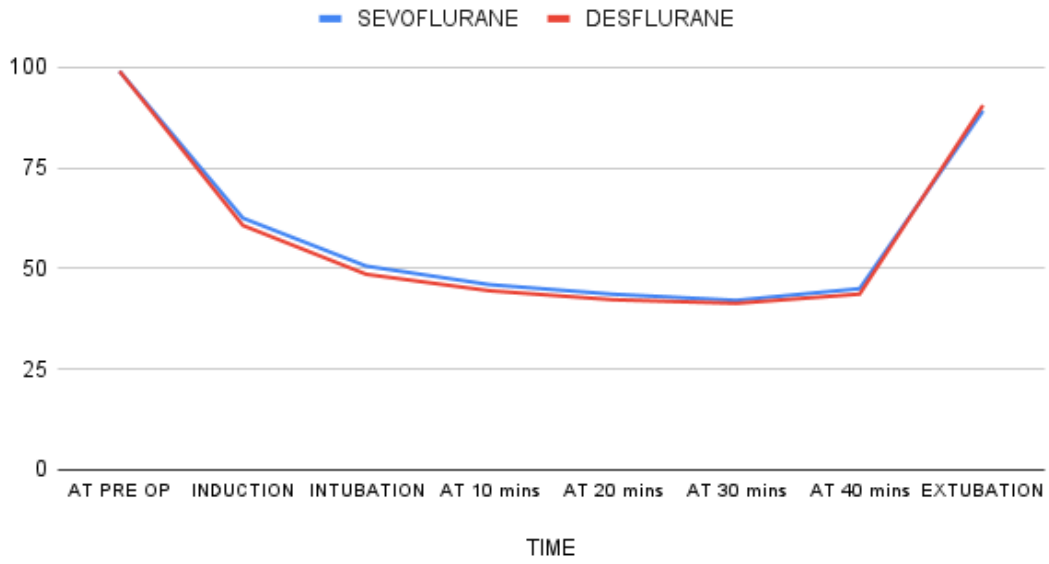

Figure 5 : Distribution of mean qCON at different time intervals

Table 3 : Distribution of mean qNOX at different time interval

		Number	Mean	SD	Minimum	Maximum	Median	p-value
qNOX C 1	DESFLURANE	40	39.9250	7.760	29.000	54.0000	39.500	<0.0001
	SEVOFLURANE	40	58.5750	7.941	44.000	74.0000	59.000	
qNOX C 2	DESFLURANE	40	38.2500	6.327	28.000	54.0000	38.500	<0.0001
	SEVOFLURANE	40	53.3750	5.395	42.000	64.0000	54.000	
qNOX 10	DESFLURANE	40	36.6750	6.203	28.000	50.0000	36.000	<0.0001
	SEVOFLURANE	40	50.5250	5.913	36.000	64.0000	50.000	
qNOX 20	DESFLURANE	40	36.8000	5.970	28.000	54.0000	35.000	<0.0001
	SEVOFLURANE	40	46.2250	5.618	32.000	54.0000	48.000	
qNOX 30	DESFLURANE	40	38.5750	6.931	28.000	57.0000	39.000	0.0002
	SEVOFLURANE	40	44.3000	6.276	26.000	54.0000	44.000	
qNOX 40	DESFLURANE	40	42.4000	7.499	28.000	62.0000	42.500	0.3589

	SEVOFLURANE	40	43.7750	5.704	34.000	56.0000	42.000	
qNOX At Extubation	DESFLURANE	40	64.7750	8.062	50.000	79.0000	65.500	0.5111
	SEVOFLURANE	40	65.9250	7.508	50.000	78.0000	65.500	

Table 4 :Assessment of unconsciousness level with % of sevoflurane and desflurane used

% inhalational Agent (Mean)	SEVOFLURANE	qCON (Mean & Std Deviation)	DESFLURANE	qCON (Mean & Std Deviation)	p-value
INDUCTION TIME	6	62.52 ± 4.70	6	60.70 ± 6.14	-
INTUBATION TIME	4	50.60 ± 5.08	4	48.57± 4.95	-
AT 10 mins POST INTUBATION	2	46.00 ± 4.87	2.25	44.47 ± 6.66	0.0006
AT 20 mins POST INTUBATION	1.6	43.62 ± 5.10	2.16	42.25 ± 5.45	0.0001
AT 30 mins POST INTUBATION	1.462	42.10 ± 3.52	1.99	41.35 ± 3.99	0.0001
AT 40 mins POST INTUBATION	1.38	45.00 ± 5.07	1.72	43.65 ± 4.39	0.0001

Table 5 : Distribution of mean SPONTANEOUS EYE OPENING TIME T3 (Min) and mean EXTUBATION TIME T4 (Mins)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
SPONTANEOUS EYE OPENING TIME T3 (Min)	DESFLURANE	40	7.825	.8439	6.000	9.0000	8.000	<0.0001
	SEVOFLURANE	40	10.625	.9251	9.000	12.0000	11.000	
EXTUBATION TIME T4 (Min)	DESFLURANE	40	8.875	.9111	7.000	10.0000	9.000	<0.0001
	SEVOFLURANE	40	11.675	.8286	10.000	13.0000	12.000	

IV. Discussion:

In this study, 80 ASA grade I, II patients who underwent laparoscopic cholecystectomies under general anesthesia, were compared with respect of their induction time, intraoperative hemodynamics, depth of anaesthesia with the help of CONOX^{R}, device which takes into account two variables qCON and qNOX and recovery characteristics of sevoflurane with that of desflurane. VIMA did not precipitate any adverse events in any of the patients. Throughout the surgical procedure the value of qCON was maintained at 40-60 by titrating the amount of the inhalational agent and none of the patients experienced awareness during anaesthesia.

In our study, the two groups were standardized with respect to age, gender, weight, BMI and duration of surgery.

The time taken for induction of patients using VIMA was significantly shorter in desflurane (p=0.001) group (Table 1). Several studies have demonstrated similar results. Study by Wrigley SR[10] et al demonstrated similar results in their study comparing desflurane with propofol for induction in patients undergoing day care surgeries (p=0.001). Leong WM[11] et al also demonstrated similar results showing faster acceptance of LMA in desflurane group along with better jaw opening as compared to propofol (p=0.027).The time taken for intubation was comparable between the two groups (Table 2) .

Desflurane and sevoflurane both had equivalent hemodynamic effects when administered to patients undergoing laparoscopic cholecystectomy (Figures 1-4) . No statistically significant difference between the two treatment groups, according to our analysis, was detected. No rescue/additional doses of Fentanyl were required for maintaining hemodynamics in both groups. The study by Kaur A[12] revealed that sevoflurane and desflurane provided similar intraoperative conditions in patients undergoing bariatric surgery. These findings were similar with the study done by Magni et al[13]. The studies done by White et al[14] and Patel and Parmar[15] also showed comparable hemodynamic parameters between desflurane and sevoflurane. A study by Gupta et al[16] demonstrated that both the groups had stable and comparable haemodynamics at various stages of surgery. Similarly study done by OzdoganHK[17] revealed stable intraoperative hemodynamics with desflurane and sevoflurane in patients undergoing laparoscopic sleeve gastrectomy.

Our study showed that both desflurane and sevoflurane attained similar levels of qCON (p >0.05) during the peri-operative period while safely maintaining the hemodynamic parameters (Fig.5). There was nostatistical difference in the values of qCON between the two groups since the value of qCON was kept at a pre-determined level between 40-60 by titrating the amount of inhalational agentused. Clarke KW[18] in his article stated that desflurane and sevoflurane both have kinetics that result in rapid induction and easy maintenance of a stable level of anesthesia.

When the interpretation for the values of qNOX was done it was found that in both the groups, at all time-points the values were lower in desflurane as compared to sevoflurane ($p<0.05$). While the values of qCON were maintained 40-60 with the help of varying concentrations of the inhalational agent, qNOX values were purely patient's response to noxious stimuli. After the results it was evident that desflurane group had much lower values of qNOX ($p<0.0001$) suggesting more potent analgesia produced by desflurane as compared to sevoflurane, suggesting the potentiation of fentanyl analgesia by desflurane as compared to sevoflurane (Table 3). This appears to be a major finding which needs to be investigated further. In-spite of intense literature search, it was not possible to find out any studies mentioning this finding.

Our study showed that for maintenance of adequate depth of anaesthesia viz. qCON values of 40-60, a greater amount of desflurane was needed as compared to sevoflurane ($p<0.05$) (Table 4). Similar findings were seen in the studies by Taş BA et al[19] and Ghobrial HZ et al[20] where consumption was more for desflurane than sevoflurane for same similar maintenance of anesthesia.

The mean eye-opening time was found to be lesser in the desflurane group than in the sevoflurane group and the results were found to be statistically significant ($p <0.0001$) (Table 5). The study by ValasareddySK et al[21] showed the time for spontaneous eye opening on verbal commands was 5.17±1.48 minutes in desflurane group compared to sevoflurane group which was 8.96±1.58 minutes with mean difference of 3.79±0.1 minutes ($p=0.001$). These results were concurrent with our study. Singh PM et al[22] showed similar results.

The time to extubation was significantly shorter in desflurane group i.e.8.87 ± 0.91 as compared to sevoflurane 11.67 ± 0.83 ($p<0.0001$) (Table 5). Numerous studies viz;,Nathanson et al[23] and Magni et al[13] have demonstrated early recovery with desflurane as compared to sevoflurane. Cohen et al[24] observed desflurane providing early emergence and recovery as compared to sevoflurane in children undergoing adenoidectomy. In children undergoing minor surgery, it was observed that the eye opening on verbal commands and tracheal extubation were earlier in desflurane group. Dexter F et al[25] also showed lower extubation time with desflurane.

It was found that the modified Aldrete score was comparable between the two groups ($p=0.6492$), indicating equal ward worthiness amongst the two. Similar results were found in study done by Rortgen D et al[26] with similar modified Aldrete scores at 5, 15, 30 and 45 mins with p = 0.23, 0.46, 0.38. 0.67 respectively.

V. Conclusion:

As per the results in our study –

- Sevoflurane and desflurane provide rapid induction and maintenance of anaesthesia, stable intraoperative hemodynamics and smooth recovery with no postoperative residual effects or complications.
- Desflurane appears to have quicker induction as well as rapid recoveryas compared to sevoflurane.
- However intraoperative consumption of volatile anaesthetic agent was more with desflurane to maintain adequate depth of anaesthesia.
- VIMA with either sevoflurane or desflurane might potentiate the intraoperative analgesic effects of fentanyl as indicated by low qNOX values throughout the surgical procedure.
- Desflurane appears to have quicker onset of analgesic effect starting at the induction itself.

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