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Original Research

Comparative Evaluation Of Dexmedetomidine And Lidocaine In Postoperative Analgesia In Open Cholecystectomy: A Double Blind Study

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ABSTRACT

Background: Postoperative pain causes increased morbidity and longer hospital stay and is most common complaint after open cholecystectomy. Perioperative infusion of dexmedetomidine and lidocaine decrease perioperative requirements for analgesics. The aim of the study is to compare the effects of intraoperative infusion of lidocaine and dexmedetomidine on postoperative analgesia after open cholecystectomy.

Materials and Methods: Double blind , randomized controlled study on eighty patients of both sex between 20-60 years, posted for elective open cholecystectomy were randomly assigned to two groups (n=40 each). The patients in group D received intravenous bolus of dexmedetomidine 1µg/kg followed by continuous infusion of 0.4µg/kg/h. The patients in group L received intravenous bolus of lidocaine 1.5mg/kg followed by continuous infusion of 2mg/kg/h. Bolus doses were given 10 minutes before induction of anaesthesia , followed by infusions which were stopped after last skin suture.Hemodynamic changes monitored changes and sedation score were evaluated in perioperative period. Visual analogue scale (VAS) score, total postoperative analgesic consumption were evaluated till 24 hours after surgery. Statistical analysis was analyzed using SPSS software version 15.0, Chi-square test was used for qualitative data. ANOVA and unpaired t test were used for continuous variables. P value of <0.05 was considered as significant.

Result: Dexmedetomidine had better postoperative analgesia, less VAS score (<4), and total postoperative analgesic consumption when compared to lidocaine (p<0.05). Conclusion: Both dexmedetomidine and lidocaine were effective for controlling postoperative pain, hemodynamic stabilization, but dexmedetomidine had a better analgesic profile.

Hence, Dexmedetomidine administered at bolus dose of 1µg/kg followed by infusion of 0.4µg/kg/h serve as an anaesthetic adjuvant of choice in patients undergoing elective open cholecystectomy.

Keywords: dexmedetomidine, lidocaine , postoperative analgesia , open cholecystectomy

INTRODUCTION

Inadequate analgesia in post operative period can lead to various negative consequences, such as increased morbidity, impaired quality of life, slower recovery, more healthcare associated expenses, extended use of opioids and chronicity of pain.[1]

Opioids are commonly used for pain control in post operative patients. But high doses of opioids have many side effects such as postoperative nausea and vomiting (PONV), respiratory depression, sedation, constipation and ileus, pruritis, urinary retention, allodynia and hyperalgesia, which can overshadow the benefits of analgesia, particularly after abdominal surgeries.[2]

Search for newer adjuvants and opioid sparing drugs is still going on. So, present study is conducted on newer drugs such as dexmedetomidine and lidocaine.

Dexmedetomidine is a highly selective alpha-2 receptor agonist. It has an opioid-sparing effect, antihyperalgesic action, also augments the effect of analgesic drugs without increasing the side effects.[3] In central nervous system, it acts by activating α-2 receptors situated in locus ceruleus. Spinal effects are through action on dorsal horn of spinal cord.[1]

Lidocaine acts through voltage-gated sodium channels. Intravenous lidocaine increases ACh (acetylcholine) concentration at spinal level via activation of muscarinic and nicotinic receptors, thus, increases the pain threshold. intra- venous administration, the anti-hyperalgesic effect is due to the blockade of NMDA receptor which is mediated indirectly by inhibiting protein kinase C

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pathway.Systemic lidocaine also has anti-inflammatory properties leading to decline in pro-inflammatory cytokines, as peri-operative pain is caused by inflammation, downregulation of these mediators helps to reduce the pain.[4]

Hence, present study was designed to evaluate the effects of intravenous infusion of Dexmedetomidine versus Lidocaine for postoperative analgesia in open cholecystectomy.

METHODS

Ethical approval from Institutional Ethics Committee (IEC) was taken. This prospective randomized double-blind study conducted in Guru Nanak Dev Hospital attached to Government Medical College, Amritsar. Assuming that use of dexmedetomidine and lidocaine reduce post operative analgesic requirements in patients undergoing general surgery, the sample size of 80 patients was calculted to achieve power of study more than 80% and p-value of 0.05, with mean Visual Analogue Scale (VAS) score and haemodynamic changes over 24 hours being the primary outcome variable. Double blind randomised study was conducted on 80 patients (40 in each group) with age 20-60 years, American Society of Anaesthesiologists (ASA) grade I and II undergoing open cholecystectomy under general anaesthesia. Written informed consent from patients in their vernacular language was taken. Written informed consent from patients in their vernacular language was taken. Patients with history of allergy to study drugs, chronic use of analgesic or any other chronic drug therapy, alcohol abuse, obesity (BMI >35), decreased autonomic control (Diabetes, Chronic Hypertension, Severe cardiac disease, beta-blocker therapy or Calcium channel blocker therapy), renal insufficiency were excluded from the study.

During the pre-operative visit, patient were familiarized with use of Visual Analogue Scale (VAS), where 0 corresponds to no pain and 10 corresponds to worst pain possible.

Patients were randomly allocated to Group L (Lidocaine) or Group D (Dexmedetomidine) by computer-generated random number tables and group assignments were sealed in sequentially numbered opaque envelopes, which were opened immediately before surgery. Patients were blinded to their group allocation.

On arrival of patient in operation theatre standard non-invasive monitoring was established and Intravenous access was established . Continuous monitoring of heart rate, blood pressure, SpO2, EtCO2 was done. All patients received 35mcg/kg of intravenous midazolam. Five minutes later all patients in both groups received the study drugs. Group L patients received intravenous lidocaine 1.5mg/kg body weight followed by infusion of 2mg/kg/hr. Group D patients received 1µg/kg dexmedetomidine, followed by infusion of 0.4 µg/kg/hr. In both groups bolus dose was prepared in volume of 20ml and infused over 10 min. Drug for hourly infusion was prepared in a volume of 50ml and infused over 1hour. All the study medications were given by independent investigator. All the observations were recorded by another investigator who was blinded to the study.

General Anaesthesia was induced with injection fentanyl 1mcg/kg and propofol 1-2mg/kg, vecuronium 0.12mg/kg body weight was administered for neuromuscular blockade and the airway was secured by appropriate size cuffed endotracheal tube. Maintenance of anaesthesia in both groups was done by 60:40 N2O:O2, Isoflurane and intermittent vecuronium. The patient's lungs were ventilated mechanically to maintain normocarbia. 15 minutes before end of surgery all patients received injection ketorolac 30mg and injection ondansetron 0.1mg/kg body weight. Infusion of study drug was discontinued before skin stitches. Neuromuscular blockade was reversed with inj. Myopyrolate (neostigmine + glycopyrrolate). Patients was shifted to PACU (Post Anaesthesia Care Unit) after extubation.

Immediately on arrival to PACU (Post Anaesthesia Care Unit) sedation was assessed by Ramsay's sedation scale.All patients were kept in PACU for 24 hours and pain was assessed at 15 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours post operatively. When the VAS score was more than 3 or the patient requested for analgesics, intravenous diclofenac 1.5 mg/kg (In 100ml Normal Saline) was administered. Any patient who complained of pain in less than 8 hours, after injection diclofenac was given, 50 mg of intravenous tramadol (In 100ml Normal Saline) was given. If patient complained of pain more than 8 hours after diclofenac, injection diclofenac was repeated. Total post operative analgesic consumption in 24 hours was noted.

Any incidence of post operative nausea vomiting was recorded and if required ondansetron 0.1 mg/kg was given intravenously.

The data from the present study was systematically collected, compiled and statistically analysed to draw relevant conclusion. Continuous data was presented as mean with standard deviation. Categorical data was expressed as percentages. Numerical variables were normally distributed and were compared using Chi Square test for non-parametric data and student 't' test for parametric data .Data was recorded in a Microsoft excel spread sheet and analysed using Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago. The results were analysed and compared to previous studies to draw relevant conclusions.

RESULTS

There was no significant difference between various demographic data like age, weight, height, BMI and duration of surgery among two study groups-group D and group L.

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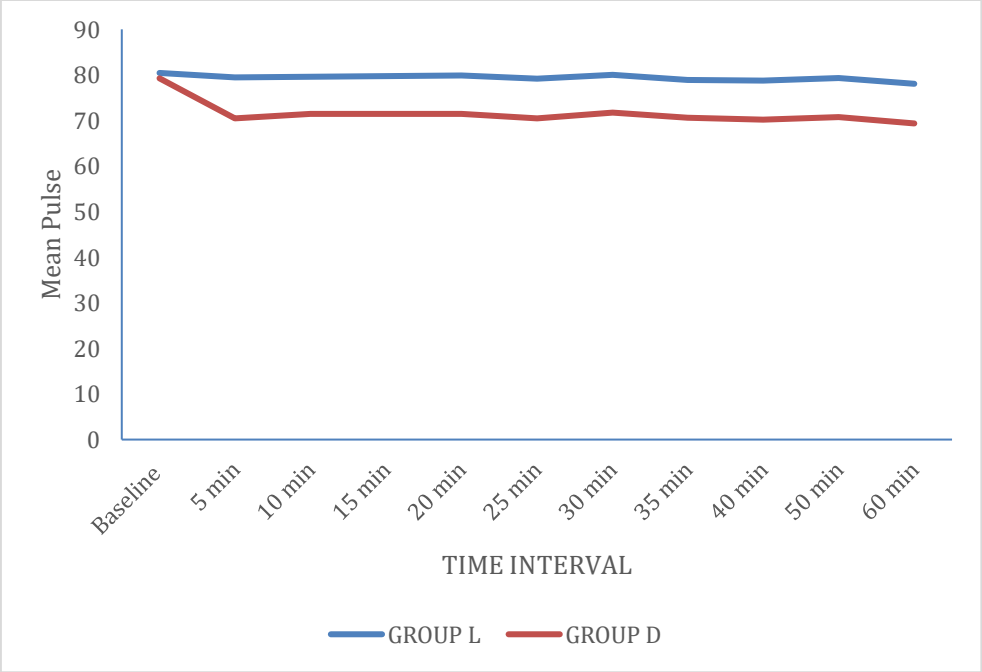
Hemodynamic effects:
The two groups were comparable in baseline HR(Heart rate) and MAP (mean arterial pressure). In group D, baseline HR was 79.25±4.55 bpm. After bolus dose, it decreased to 70.4±6.83. When the mean Heart Rate (HR) at different time points was compared in two groups, significant decrease was found 10 minutes after giving bolus dose in group D when compared to group L (P<0.05). After that mean HR showed insignificant change in group D and remained between 69.60 to 72.39 bpm for entire intraoperative period. In group L, mean HR showed insignificant change and remained between 76.56 to 77.33 bpm after bolus dose and infusion intraoperative. [Table 1].

Table 1: Intraoperative Heart Rate (Beats Per Minute)

Time interval	Group L		Group D		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	80.430	6.760	79.250	4.550	-2.950	0.130
5 min	79.480	5.160	70.400	6.830	0.540	0.000
10 min	79.600	3.870	71.380	5.950	1.400	0.000
15 min	79.780	5.210	71.430	5.100	1.710	0.000
20 min	79.830	5.320	71.450	5.150	2.750	0.000
25 min	79.150	4.500	70.530	4.880	2.810	0.000
30 min	79.950	5.000	71.680	4.800	1.670	0.000
35 min	78.930	4.450	70.580	5.480	3.160	0.000
40 min	78.700	4.430	70.180	4.820	4.000	0.000
50 min	79.300	4.140	70.700	4.510	3.970	0.000
60 min	78.050	4.140	69.350	5.620	5.240	0.000



Baseline mean arterial pressure in group D was 83.3±2.04 mmHg and after giving bolus dose mean arterial pressure decreased to 75.78±1.89 after 10minutes, whereas for group L baseline mean arterial pressure was 82.65±2.74 mmHg, 10 minutes after giving bolus dose, mean arterial pressure decreased to 80.65±1.92 mmHg. On comparing mean arterial pressure between group D and group L at different time intervals, significant fall in mean arterial pressure was observed in group D as compared to group L (p<0.05) [Table 2].

TABLE 2: INTRAOPERATIVE MEAN ARTERIAL PRESSURE (MAP) (in mmHg)

Time interval	Group L		Group D		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	82.650	2.740	83.300	2.040	-1.030	0.120
5 min	80.250	2.190	75.180	2.870	7.380	0.000
10 min	80.650	1.920	75.780	1.990	9.150	0.000

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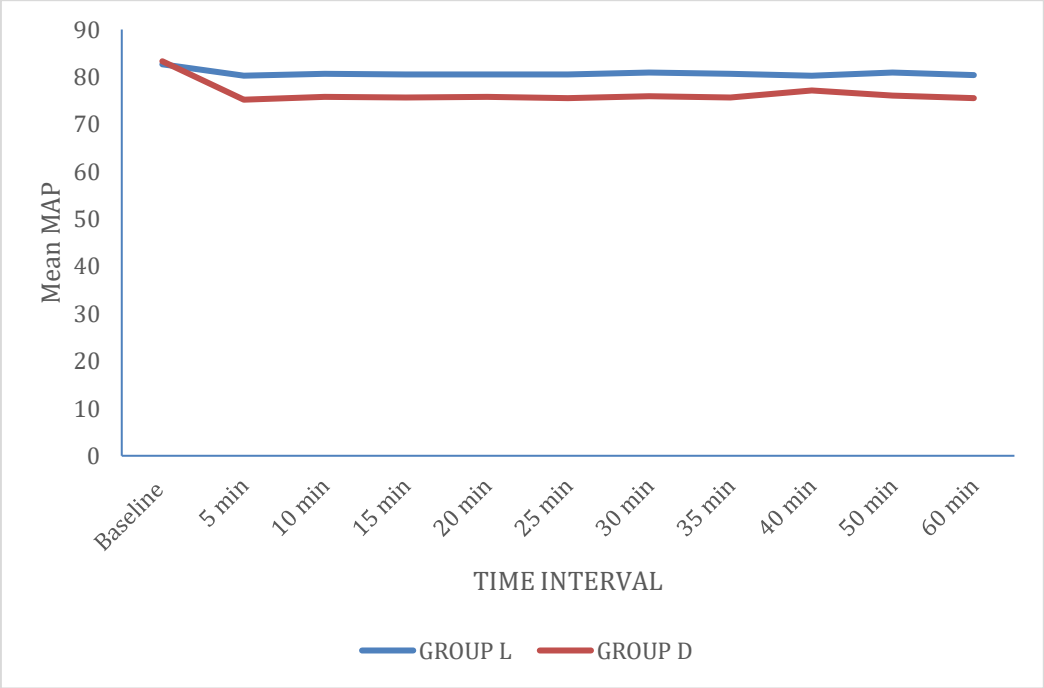
15 min	80.450	1.580	75.600	2.440	8.930	0.000
20 min	80.530	1.620	75.730	2.250	10.020	0.000
25 min	80.530	1.930	75.480	3.040	7.380	0.000
30 min	80.850	1.780	75.980	2.210	9.070	0.000
35 min	80.650	1.810	75.580	2.670	7.760	0.000
40 min	80.300	1.960	77.150	2.290	5.460	0.000
50 min	80.880	2.000	76.050	1.960	9.260	0.000
60 min	80.430	2.110	75.500	2.230	9.500	0.000



The difference in mean HR and mean MBP were statistically insignificant in postoperative period in all three groups (P>0.05).

(VAS) score:

VAS score was used post operatively to evaluate the level of analgesia in patients at various points in time. Comparing the mean VAS score between the two groups, the mean VAS score was less in group D (<4) when compared to group L at all points of time. In group L, it was >4 at 12 hours postoperative. (P<0.05) [Table 3].

Table 3: Visual Analogue Score (Vas)

Time interval	Group L		Group D		t-value	p-value
	Mean	SD	Mean	SD		
15 min	3.050	0.680	2.080	0.270	7.660	0.000
30 min	3.280	0.450	2.250	0.440	9.060	0.000
1 hr	2.950	0.390	2.600	0.670	2.610	0.000
2 hrs	3.100	0.300	2.480	0.600	4.860	0.000
4 hrs	3.030	0.160	2.780	0.700	1.940	0.010
8 hrs	3.480	0.550	3.230	0.800	1.360	0.050
12 hrs	4.150	0.700	3.250	0.710	4.290	0.000
24 hrs	3.480	0.550	3.350	0.580	-1.029	0.306

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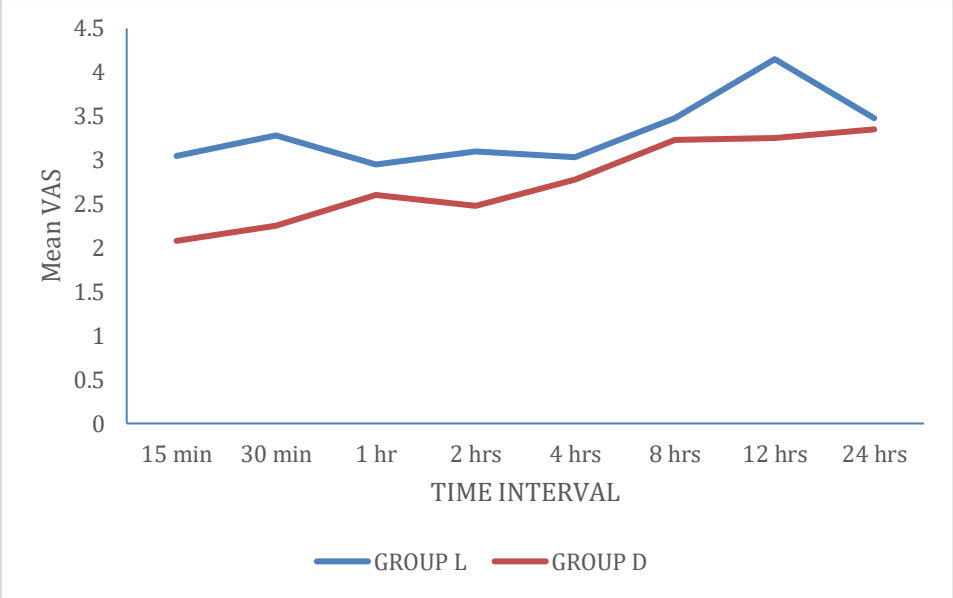
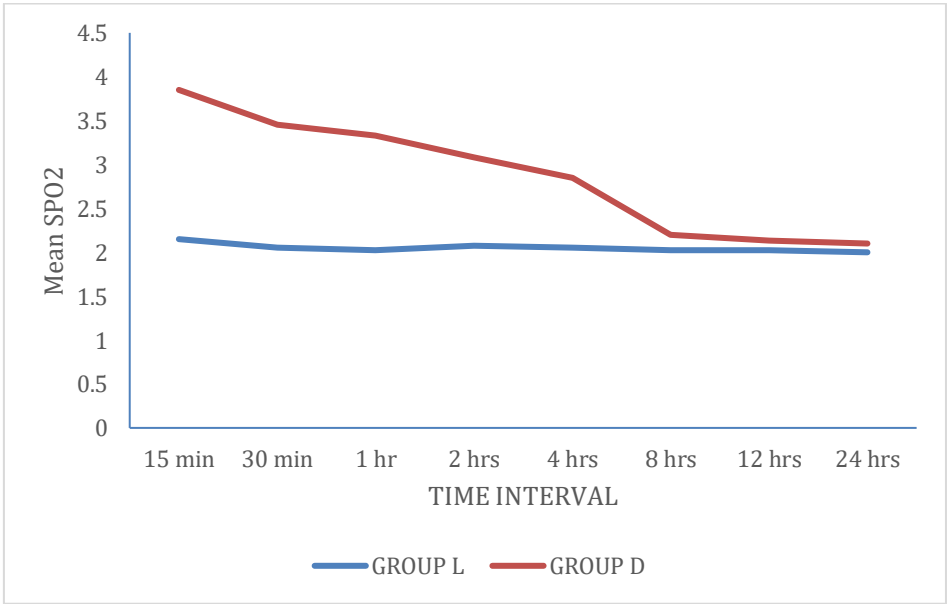


Requirement Of Additional Postoperative Analgesia

Mean postoperative rescue analgesia was higher in group L (mean 2.95 doses i.e. diclofenac 221.25 mg) as compared to group D (mean 1.25 doses i.e. diclofenac 93.75 mg). However, total doses required post operatively for rescue analgesia was less in group D as compared to group L, on comparing both groups, difference was highly significant (p-value=0.001).

Ramsay Sedation Score

Time interval	Group L		Group D		t-value	p-value
	Mean	SD	Mean	SD		
15 min	2.15	0.70	3.85	0.36	13.659	0.001
30 min	2.05	0.630	3.45	0.50	11.009	0.001
1 hr	2.025	0.474	3.33	0.47	12.465	0.001
2 hrs	2.075	0.418	3.08	0.47	10.242	0.001
4 hrs	2.05	0.387	2.85	0.36	9.660	0.001
8 hrs	2.025	0.352	2.20	0.41	2.112	0.030
12 hrs	2.025	0.352	2.13	0.33	1.446	0.151
24 hrs	2.0	0.312	2.10	0.30	1.443	0.146



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Ramsay sedation score was observed in both groups (group D and group L) in post anaesthesia care unit (PACU) immediately after arrival till 24 hours postoperatively. The patients in group D were more sedated at 15 minutes, 30 minutes, 1 hour, 2 hours, 4hours and the difference was found to be statistically significant ($p<0.05$).

DISCUSSION

Open cholecystectomy, on comparison with laparoscopic technique have bigger incisions, more postoperative pain, increased morbidity and longer hospital stay. Thus, by providing sufficient pain relief with effective analgesia, the difference between open and laparoscopic cholecystectomy can be narrowed ; leading to a shorter recovery period, reduction in post-operative morbidity, lesser cost of healthcare expenses, shorter hospital stay and quicker return to daily activities. Therefore, effective management of pain is important in postoperative period.

In this study in group D (Dexmedetomidine), mean HR and mean MBP remained decreased at all point of time compared to group L(Lidocaine). The observations made in our study coincides with the study conducted by Mohammed NS et al[5] (2020) that, at 10, 15, 30 and 60 min, the MBP and HR significantly decreased in group D (received inj. Dexmedetomidine) compared to group X, received inj. Lidocaine.

In this study we observed statistically significant differences in MAP changes between group Dexmedetomidine, Lidocaine and Normal saline ($P<0.05$). A study conducted by Ahmed I MA et al[6] (2020) also noted that, regarding MAP changes, statistically significant differences were observed between the three groups (magnesium sulfate, dexmedetomidine, and lignocaine) and control group all over the study ($P<0.05$). The differences in MAP changes between each of magnesium, dexmedetomidine, and lignocaine during the study were statistically significant ($P<0.05$).

In our study, we observed higher postoperative analgesic doses in group L (2.95±0.32), compared to group D in which postoperative analgesic doses were 1.25±0.21.The VAS score was significantly higher in group L compared to group D. VAS score was found higher in group L at 1 hour, 2 hour, 4 hour, 12-hour, 24 hour interval when compared to group D. On comparison of both the groups, it was found significant statistically. ($p<0.05$)

Similar study conducted by Nama V et al,[7](2023), concluded that mean VAS score was lower in group D when compared to group L at 1 hr, 2 hr, 4 hours, 12 hours and 24 hours and it was found statistically significant. ($p<0.05$)

Mohammed N S et al,[5] (2020) also noted that, there was significantly higher numeric rating scale in group X (received Lidocaine) compared to group D (received dexmedetomidine) postoperatively.

Like other studies in our study Dexmedetomidine bolus of 1 µg/kg and continuous intravenous infusion of 0.4µg/kg/hour reduces rise in heart rate and mean blood pressure associated with laryngoscopy and intubation, and extubation during open cholecystectomy. After bolus dose heart rate and mean blood pressure decreased and then remained sustained for entire intraoperative period. Dexmedetomidine decreases VAS score, provides postoperative analgesia, reduces total postoperative analgesic consumption. Lidocaine bolus of 1.5 mg/kg and continuous intravenous infusion of 2mg/kg/hour reduces rise in heart rate and mean blood pressure associated with laryngoscopy and intubation,and extubation during open cholecystectomy. After bolus dose and infusion, heart rate and mean blood pressure remained sustained for entire intraoperative period. Lidocaine also decreases VAS score, provides postoperative analgesia, and decreased total postoperative analgesic consumption.

The patients in Dexmedetomidine group show significant sedation for a short time, as compared to Lidocaine group, but length of PACU stay was shorter in Dexmedetomidine group.

The mean postoperative total doses of rescue analgesic were much higher in group Lidocaine (mean2.95 doses i.e. diclofenac 221.25 mg) when compared to group Dexmedetomidine (mean 1.25 doses i.e. diclofenac 93.75 mg).

Dexmedetomidine had better postoperative analgesia, less VAS score, decreased total postoperative analgesic consumption when compared to lidocaine. Hence, we conclude that Dexmedetomidine administered as bolusdose of 1 µg/kg followed by infusion of 0.4 µg/kg/hour serve as anaesthetic adjuvant of choice in patients undergoing open cholecystectomy.

CONCLUSION

Dexmedetomidine and lignocaine both drugs were effective as adjuvants to general anaesthesia in cases of open cholecystectomy for control of post operative pain. Dexmedetomidine (1µg/kg body weight intravenous followed by infusion of 0.4 µg/kg/hr) was better at reducing postoperative pain than lignocaine infusion (1.5 mg/kg body weight intravenous followed by infusion of 2mg/kg/hr).

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