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Original Research Article

Comparative Clinical Study of Dexmedetomidine and Fentanyl for Attenuation of Haemodynamic Response to Laryngoscopy, Tracheal Intubation and Intra-Operative Pneumoperitoneum in Patients Undergoing Laparoscopic Cholecystectomy

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Abstract

Background: The pressor response during laryngoscopy, intubation and pneumoperitoneum (PNP) which is part of a huge spectrum of stress responses, results from the increase in sympathetic and sympatho-adrenal activity. Laparoscopic cholecystectomy is favoured by many because of less postoperative pain compared with the open approach; nevertheless, pain is still a frequent complaint.

Objective: To know the effect of Dexmedetomidine v/s Fentanyl for attenuation of hemodynamic response in laparoscopic cholecystectomy.

Methods: Our study was prospective, randomized, double-blind comparative clinical study done to evaluate the efficacy of dexmdetomidine and fentanyl in attenuation of pressor responses to laryngoscopy, intubation and PNP in laparoscopic cholecystectomy (LC). Total number of 80 patients belongs to 18-55years of American Society of Anesthesiologists Class I/II of both sex for Laparoscopic cholecystectomy (LC), were included. The patients were made into two groups of 40 patients each. Group D received dexmedetomidine and Group F Fentanyl with loading 1µg/kg over 10 min followed by maintenance 0.2 µg/kg/h throughout the PNP.

Result: Significantly attenuated hemodynamic stress response was observed in group D interms of HR, SBP, DBP, MAP. There was significantly less sedation, longer time of request of first rescue analgesia and postoperative analgesic requirements in group D when compared with group F. No significant side effects were noted in both groups.

Conclusion: Dexmedetomidine is superior to fentanyl for the attenuation of hemodynamic response to laryngoscopy, tracheal intubation and intra-operative pneumoperitoneum in patients undergoing laparoscopic cholecystectomy also reduces the requirement of rescue analgesics post operatively.

Keywords: Dexmedetomidine, fentanyl, laparoscopic cholecystectomy, pneumoperitoneum, pressor response.

Introduction

Laparoscopic surgeries have become a routine for the surgical practice because of its magnification, dexterity, lesser cosmetic effect, decreased post-operative pain and hospital stay along with less morbidity and mortality[1]. The gold standard for gall bladder diseases is Laparoscopic cholecystectomy.

Anaesthetic manoeuvres such as induction, laryngoscopy, tracheal intubation and extubating involve sympathetic stimulation and autonomic reflex activity during general anaesthesia [3]. In laparoscopic cholecystectomy, reverse Trendelenburg position, creation of pneumoperitoneum. Systemic absorption of CO2 because systemic pathophysiological changes occurs of the body leads to increase in nor epinephrine, epinephrine and plasma renin activity[4]. All these factors together contribute to increase in heart rate (HR), mean arterial pressure (MAP), and increased systemic and pulmonary vascular resistance[5]. The hemodynamic changes predispose the myocardium in vulnerable patients to ischemic changes. Hence, the basic needs, continuously felt in anesthesia for the practice of drug availability that electively suppresses all hazardous responses to noxious stimuli with maximum safety-ness [6]. Various agents such as opioid analgesic, benzodiazepines, beta blockers, calcium channel blockers and vasodilators have been used to suppress the unwanted hemodynamic responses.[3]. Alpha two agonists possess various properties of hypnotic, sedative, anxiolytic, sympatholytic and analgesic properties and not producing significant respiratory depression. Opioids are being used for blunting the hemodynamic response during intubation also suppress surgical stress responses, but they usually present with nausea, vomiting, and respiratory depression[7]. Hence nowadays opioid free analgesia is recommended to avoid opioid carrying all above adverse effects and addiction which is considered as hazardous to human community.

Hence this study was to know the effect of Dexmedetomidine v/s Fentanyl for attenuation of haemodynamic response in laparoscopic cholecystectomy.

Materials and Methods: This study was conducted on 80 subjects aged between 18-55 years ASA I and II undergoing elective laparoscopic cholecystectomy under General Anaesthesia at Mysore Medical College and Research Institute, Mysore, during November 2019 to June 2021.

Inclusion criteria:

Adult patients of either sex, aged between 18-55 years belonging to ASA class 1 and 2 without any severe co-morbid diseases scheduled for elective laparoscopic cholecystectomy.

Exclusion criteria:

- Age group less than 18years and more than 55years.
- Patients belonging to ASA class III, IV, V.
- Patients posted for emergency surgeries.
- Patients having any absolute contraindications for general anaesthesia.
- Patients with severe co-morbid diseases like diabetes, hypertension, cardiovascular diseases and any other are excluded from the study.
- Patients with known history of allergy to study drugs.

Methods of collection of data: Data was collected in all 80 patients of ASA grade I and grade II patients posted for elective laparoscopic cholecystectomy under general anaesthesia without any co-morbid diseases and are grouped randomly into 2

groups. This is designed as prospective randomized double-blinded and comparative study.

After obtaining clearance from ethical and scientific committee, randomization was done using shuffled closed opaque envelope technique, so that the anaesthesia giving and monitoring individuals both are blinded.

The study population was divided into 2 groups of 40 patients each.

- Group D [DEXMEDETOMIDINE GROUP] – Dexmedetomidine was started intravenously at a rate of 1mcg/kg, after induction continuous infusion started at the rate of 0.2mcg/kg/hr throughout the surgery.
- Group F [FENTANYL GROUP]- intravenous infusion Fentanyl is infused as loading dose at the rate of 1mcg/kg followed by induction and then continuous infusion at the rate of 0.2mcg/kg/hr throughout the surgery.

After getting hospital ethical and clinical committee approvals, Pre-anaesthetic evaluation (PAE) was done on the evening before surgery.

A routine pre-anaesthetic examination is conducted assessing:

1. General condition of the patient.
2. Airway assessment by Mallampati grading and rule 1-2-3.
3. Nutritional status and body weight of the patient.
4. A detailed examination of cardiovascular system.
5. A detailed examination of respiratory system.
6. A detailed written informed anaesthetic consent is obtained from all the subjects who are volunteering for the study.

All those subjects who are included in the study with their informed consent, are given tablet Pantoprazole 40 mg and tablet Alprazolam 0.5 mg orally at bed time the previous night before surgery as our institute protocol. After transferring the subjects into the Operation Theatre (OT) the following morning, an intravenous line is secured using 18G cannula on the non-dominant hand and infusion of ringer lactate was started. All subjects was connected to non-invasive monitoring pulse oximetry (SPO2), Non-invasive blood pressure (NIBP) and electrocardiogram (ECG) using multi-parameter monitor (EDAN iM80). The baseline systolic, diastolic blood pressure, mean arterial pressure and heart rate are recorded. The heart rate and rhythm are also monitored from a continuous display of ECG.

All the patients was premedicated with injection glycopyrrolate 0.01 mg/kg of body weight, injection ondansetron 4 mg, injection midazolam 0.1 mg/kg of body weight, injection dexamethasone 8 mg and was pre oxygenated for 3 minutes with 100% oxygen.

Induction was done using injection propofol 2 mg/kg and injection vecuronium 0.1 mg/kg. After ventilating the patient with 50% oxygen, 50% nitrous oxide and 0.6% isoflurane for 3 minutes, oral endotracheal intubation was done with appropriately sized cuffed endotracheal tube.

Immediate intubation response is noted. After five point auscultation, visual confirmation and with ETCO2, the endotracheal tube is fixed and is connected to the ventilator. Anaesthesia was maintained with 66% nitrous oxide, 33% oxygen and 0.6% isoflurane. Pneumoperitoneum is created by insufflation of CO2 into the peritoneum (at the rate of 2L/min). Intra-abdominal pressure was maintained at 12-14 mm of Hg.

All the following parameters are noted,

- Heart Rate (HR)
- Systolic Blood Pressure (SBP)
- Diastolic Blood Pressure (DBP)
- Mean Arterial Pressure (MAP)
- SPO2
- EtCO2

Haemodynamic monitoring like HR, SBP, DBP, MAP, ETCO2 and SPO_2 was done before induction, after induction, after intubation, 1min, 3min,5min,10min, after pneumoperitoneum (immediate, 15min, 30min,45min,60min), after extubation (immediate, 3min, 5min, 10min)noted.

The drug infusion was stopped after surgery. Residual neuromuscular blockade was reversed with 0.05 mg/kg of neostigimine and 0.01 mg/kg glycopyrrolate after the recovery assessment patient is extubated. Time to extubation and respond to commands and time to get oriented was noted. Sedation in both groups is noted using Ramsay Sedation Score. Time of request first analgesia. Monitoring done to see patient acceptance, any un toward adverse reactions, effect of study drug used.

Statistical analysis:

Data was analysed using SPSS 21.0 software. Descriptive parameters was represented as mean with SD or median. Continuous variables was compared using unpaired t test /Mann Whitney u test. Chi-square or t test was used to determine significant outcome difference. Categorical data was represented as frequency with percentage. For all tests a p value of <0.05 was considered as statistically significant.

Results

All the patients recruited for elective laparoscopic cholecystectomy surgery were in the age group of 30-60 years. The mean age in group D was 35.48±3.41 years and in group F was 32.88±2.68 years. (p=0.864).

In group D female patients were 24(60%) and male patients were 16(40%). In group F male patients were 12(30%) and female patients were 28(70%). Both groups were comparable with respect to sex of the patients which was not significant (p=0.348).

The mean BMI in group D was 22.13±2.1 kg/m^2 and in group F was 22.4±1.68 kg/m^2. (p=0.52).

In group D 10(25%) patients were belonging to ASA physical status I and 30(75%) patients to II. In group F 11(27.5%) patients were belonging to ASA physical status I and 29(72.5%) patients to II. (p=0.799). There was statistically significant difference in the mean heart rate between two groups at all-time intervals measured (p<0.05). Heart rate before induction in group D was 73(±5.15) and in group F was 76.45(±4.84). After intubation heart rate did not go above baseline in group D compared with group F(72.08(±3.98), 78.6(±4.57)). Mean heart rate after creation of pneumoperitoneum and after extubation in group D did not go above baseline compared to group F. And over all mean heart rate were less in group D compared to group F at all the time intervals. Table 1

Table 1: Mean Heart rate (bpm) at various time intervals

	Group D Mean ±SD	Group F Mean ±SD	p value
HR/baseline	81.6(±4.03)	80.68(±4.54)	0.35
HR/before induction	73(±5.15)	76.45(±4.84)	0.00
HR/after induction	68.23(±5.71)	74.28(±5.22)	0.00
HR/after intubation immediate	72.08(±3.98)	78.6(±4.57)	0.00
HR/1 min	72.1(±4.12)	78.88(±4.51)	0.00
HR/3 min	70.18(±4.01)	78.8(±4.46)	0.00
HR/5 min	69.18(±4.01)	78.63(±4.5)	0.00
HR/10 min	68.13(±4.07)	78.48(±4.54)	0.00
HR/pneumoperitoneum -0min	70.9(±4.16)	82.45(±4.57)	0.00
HR/pneumoperitoneum -15 min	72.48(±4.24)	83.45(±4.57)	0.00
HR/ pneumoperitoneum -30 min	70.6(±4.14)	83.5(±4.55)	0.00
HR/ pneumoperitoneum -45min	69.63(±4.07)	83.45(±4.57)	0.00

HR/ pneumoperitoneum -60min	68.75(±4.06)	83.45(±4.57)	0.00
HR/post extubation immediate	68.75(±4.06)	84.4(±4.53)	0.00
HR/post extubation 3min	68.55(±3.94)	85.18(±4.47)	0.00
HR/post extubation 5min	67.8(±4.02)	85.15(±4.52)	0.00
HR/post extubation 10min	67.63(±4.02)	85.1(±4.5)	0.00

The mean systolic blood pressure were comparable between two groups, and it was less in group D compared to group F at all the time intervals measured. ($p<0.05$).

The mean diastolic blood pressure were comparable between two groups, and it was less in group D compared to group F at all the time intervals measured. ($p<0.05$).

Table 2: Mean arterial pressure (mmHg) at various time intervals

	Group D (Mean ±SD)	**Group F (Mean ±SD)**	**p value**
MAP/baseline	93.45(±3.02)	93.43(±6.2)	0.98
MAP/before induction	84.85(±2.72)	88.7(±6.6)	0.00
MAP/after induction	79.55(±3.7)	85(±6.47)	0.00
MAP/after intubation	84.23(±2.62)	90.7(±5.88)	0.00
MAP/1 min	84.55(±2.66)	91.18(±5.72)	0.00
MAP/3 min	83.08(±2.61)	90.83(±5.76)	0.00
MAP/5 min	81.55(±2.6)	90.28(±5.95)	0.00
MAP/10min	80.58(±2.69)	89.35(±5.95)	0.00
MAP/pneumoperitoneum immediate	83.35(±2.76)	92.9(±5.85)	0.00
MAP/pneumoperitoneum 15min	84.55(±2.55)	95.35(±5.68)	0.00
MAP/pneumoperitoneum 30min	84.08(±2.61)	94.98(±5.71)	0.00
MAP/pneumoperitoneum 45min	83.43(±2.69)	94.15(±5.73)	0.00
MAP/pneumoperitoneum 60min	83.38(±2.79)	93.73(±8.16)	0.00
MAP/post extubation immediate	84.3(±2.88)	95.23(±5.92)	0.00
MAP/post extubation 3min	83.55(±2.76)	94.78(±5.91)	0.00
MAP/post extubation 5min	82.83(±2.58)	94.3(±5.85)	0.00
MAP/post extubation 10min	82.63(±2.67)	94.13(±5.87)	0.00

The mean arterial pressure between two groups were comparable and it was less in group D compared to group F at all the time intervals measured. ($p<0.05$).

In group D 25(65.5%) patients had RSS of 2, 15(37.5%) patients had RSS of 3. In group F 40(100%) patients had RSS of 2. ($p<0.05$).

Table 3: Ramsay sedation score at 2nd hour

	Group D No. of patients(%)	**Group F No. of patients(%)**	**p value**
2	25(62.5%)	40(100%)	0.000
3	15(37.5%)	0(0%)	
Total	40(100%)	40(100%)	

In group D mean time for first rescue analgesic request was 349.5(±26.5) minutes and in group F it was 153.48(±18.56)minutes. Inj. diclofenac sodium 75mg IM given for postop analgesia. There was statistically significant difference in the mean time for first rescue analgesic request between two groups. Fig 1

Comparison of intraoperative complications between two groups

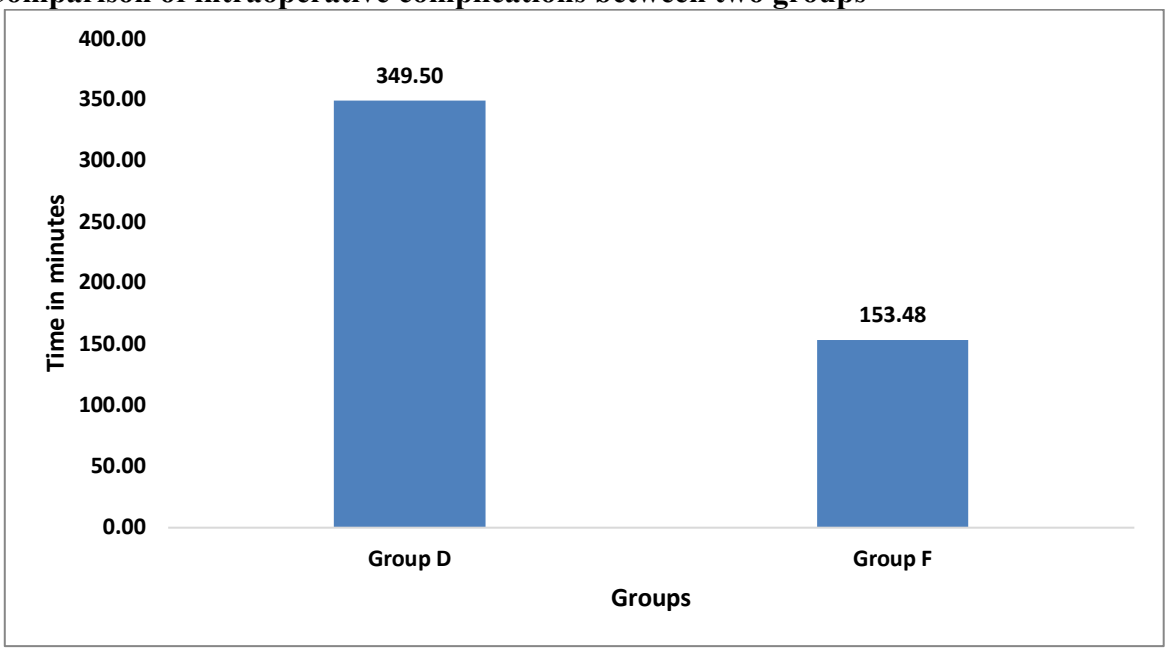

Figure 1: Graph showing mean time for first rescue analgesic request between two groups in minutes

Table 4: Difference between two groups with respect to bradycardia

	Group D No. of patients (%)	Group F No. of patients (%)	p value
No	35(87.5%)	39(97.5%)	0.201
Yes	5(12.5%)	1(2.5%)	
Total	40(100%)	40(100%)	

In group D 5(12.5%) patients had bradycardia and in group F 1(2.5%) patients had bradycardia. (p=0.201).

Table 5: Difference between two groups with respect to hypotension

	Group D No. of patients (%)	Group F No. of patients (%)	p value
No	35(87.5%)	39(97.5%)	0.201
Yes	5(12.5%)	1(2.5%)	
Total	40(100%)	40(100%)	

In group D 5(12.5%) patients had hypotension and in group F 1(2.5%) patients had hypotension. (p=0.201).

Table 6: Comparison of postoperative complications among two groups- PONV

	Group D No. of patients (%)	Group F No. of patients (%)	pvalue
No	38(95%)	34(85%)	0.263
Yes	2(5%)	6(15%)	
Total	40(100%)	40(100%)	

In group F 6(15%) patients and in group D 2(5%) patients had PONV. (p=0.263). There was no statistically significant difference between groups with respect to pheripheral oxygen saturation at all-time intervals(p>0.05).

Table 7: comparison of saturation of pheripheral 02(SPO2) in groups at various time interval

Group	Group D	Group F	p value
SPO2/baseline	98.05(±0.6)	97.98(±0.83)	0.64
SPO2/before induction	100(±0)	100(±0)	**NA**
SPO2/after induction	100(±0)	100(±0)	**NA**
SPO2/after intubation	100(±0)	100(±0)	**NA**
SPO2/1 min	100(±0)	100(±0)	NA
SPO2/3 min	100(±0)	100(±0)	NA
SPO2/5 min	100(±0)	100(±0)	NA
SPO2/10 min	100(±0)	100(±0)	NA
SPO2/pneumoperitoneum immediate	100(±0)	100(±0)	NA
SPO2/pneumoperitoneum 15min	100(±0)	100(±0)	NA
SPO2/pneumoperitoneum 30min	99.88(±0.33)	99.88(±0.33)	1.000
SPO2/pneumoperitoneum 45min	100(±0)	100(±0)	NA
SPO2/pneumoperitoneum 60min	100(±0)	100(±0)	NA
SPO2/post extubation immediate	100(±0)	100(±0)	NA
SPO2/post extubation 3min	98.43(±0.5)	98.25(±0.54)	.138
SPO2/post extubation 5min	97.95(±0.45)	98.25(±0.54)	**.**301
SPO2/post extubation 10min	97.8(±0.41)	97.88(±0.4)	.410

There was no statistically significant difference between groups with respect to mean oxygen saturation at all-time intervals($p>0.05$).

Discussion

The patients in our study, belonging to American Society of Anaesthesiologists (ASA) physical status class I and II posted for laparoscopic cholecystectomy were divided into 2 groups of 40 each. There was no significant difference regarding the age, gender and BMI between two groups. Dexmedetomidine is a highly selective α2 adrenergic agonist. It acts through three types of α2 receptors- α2A, α2B and α2C situated in brain and spinal cord. The action includes sedation, anxiolysis, analgesia and sympatholytic, the latter leading to hypotension and bradycardia. Activation of α2A receptors in brain stem vasomotor centre results in suppression of norepinephrine release and causes hypotension and bradycardia. Stimulation of α2A and α2C in locus ceruleus causes sedation. In the spinal cord, activation of both α2A and α2C receptors directly reduce pain transmission by reducing release of substance P. Rapid administration of a bolus dose of dexmedetomidine results in an initial transient increase in blood pressure and reflex decrease in HR because of peripheral alpha-2 adrenoceptor stimulation of vascular smooth muscle.

Different doses of dexmedetomidine have been used to attenuate the stress response to laryngoscopy, intubation, pneumoperitoneum and extubation from general anaesthesia. In Jain V et a[l8]- 1µg/kg body weight diluted in 0.9% normal saline to 20ml and administered 10mins before laryngoscopy and intubation. In Trikhatri Y et a[l9]- loading dose of 1µg/kg over 10 minutes before induction and maintained with 0.4µg/kg/hr. In khataria AP et al[10]- loading 1µg/kg over 15 min followed by maintenance 0.2 µg/kg/h. In Anita vig et al[11]- 1µg/kg diluted to 15ml with 0.9% normal saline over 10 minutes. Hence in the present study dexmedetomidine was administered 1 micro gram/kg over 10 min before induction and followed by infusion of 0.2 microgram/kg/hr throughout the surgery.

Fentanyl

Fentanyl is used for attenuation of sympathetic response to laryngoscopy and intubation. Blunting of sympathetic response is dose dependent. At high doses, fentanyl produces tissue accumulation andmay cause respiratory depression requiring mechanical respiratory support. Fentanyl attenuates, arterial pressure and HR increase during laryngoscopy and intubation. Different doses of fentanyl have been used to attenuate the stress response to laryngoscopy, intubation, pneumoperitoneum and extubation during general anaesthesia. In khataria AP et al[10]- loading 1µg/kg over 15 min followed by maintenance 0.2 µg/kg/h In Akheela MK et al[12]-fentanyl 2 µg/kg five minutes before induction of anesthesia. In Mahiswar AP et al[13]- fentanyl 2 µg/kg diluted upto5mL byadding 0.9%normal saline intra- venously over 60 seconds.

In our study, fentanyl was given at the dose of 1microgram/kg diluted with 0.9% normal saline over 10 min before induction and followed by infusion of 0.2 microgram/kg/hr throughout the surgery. 1microgram/kg was used to reduce the respiratory depression. Dexmedetomidine and Fentanyl as pre medication attenuates the hemodynamic response to laryngoscopyand endotracheal intubation. Hence, we thought it would be appropriate to compare the effectiveness of the two drugs for attenuation of the sympathetic response to laryngoscopy and endotracheal intubation.

Hemodynamic changes

Heart rate

In our study comparison between the mean heart rate values of patients in the two groups demonstrated that there is no statistically significant difference until injection of study drug ($p > 0.05$). The mean heart rate after injection of dexmdetomidine before induction, after induction, after intubation, after intubation (immediate, 1min, 3min, 5min, 10min), after creation of pneumoperitoneum, after extubation is lower than the baseline when compared with fentanyl at various interval which is statistically significant ($p<0.05$). Thus in our study there is significant difference found between group D and group F with respect to mean heart rate .Our study can be comparable with Jain V et al [l8], khataria AP et al [10] , aliaarabie et al [14], Trikhatri Y et al [l9]. The observations of our study demonstrate that dexmedetomidine completely abolishes the chronotropic response to laryngoscopy, intubation, pneumoperitoneum and extubation compared with fentanyl.

Systolic blood pressure and diastolic blood pressure

In our study mean SBP and DBP at baseline was comparable between two groups, there was no statistically significant difference. The mean Systolic blood pressure and diastolic blood pressure after injection of dexmeditomedine at various intervals like before induction, after induction, after intubation (immediate, 1min, 3min, 5min, 10min), after creation of pneumoperitoneum, after extubation is lower than the fentanyl at various interval which is statistically significant ($p<0.05$). and also from the baseline. This is in concurrence with study Jain V et al [8], aliaarabie et al[14]. sahilgarg et al [15].

Mean arterial pressure

In our study mean MAP at baseline was comparable between two groups, there was no statistically significant difference. The mean MAP after injection of dexmedetomidine at various intervals like before induction, after induction, after intubation (immediate, 1min, 3min, 5min, 10min), after creation of pneumoperitoneum, after extubation is lower than the fentanyl at various interval which is statistically significant ($p<0.05$). and also from the baseline. This is in concurrence with study Jain V et al[8], Trikhatri Y et al [9], khataria AP et al [10],

Ramsay sedation score

In our study there was statistically significant difference in the RSS between two groups at time intervals ($p<0.05$). This is in concurrence with study, Khataria AP et al [10], Trikhatri Y et al[9]. Sedation produced by alpha 2 agonists is uniquein the sense that the patients can be easily aroused to co-operate during procedures and also respond to the verbal commands and then can return to sleep like state when not stimulated. Sedation is dose-dependent and reaches its peak after 45–60 min. Sedation Decreases gradually after stopping the infusion

Time for first rescue analgesic request

In our study there was statistically significant difference in the mean time for first rescue analgesic request between two groups . ($p<0.05$). and patient with in group D had longer duration of analgesia compared with group F. Post-operative 24 hour analgesic requirements were much less in dexmedetomidine groups. Dexmedetomidine reduce inflammatory mediators and substance P induced by surgical trauma and thereby reduces postoperative analgesic requirements In Manne et al[3] time for first rescue analgesic request was 173 mins in group with dexmeditomedine 0.2µg/kg/hr , 249 mins in group with dexmeditomedine 0.4µg/kg/hr as in this study they started on infusion without giving loading dose duration is less compared to our study. In the study conducted by Jain V et al[8]- the dexmedetomidine group, one patient developed Hypotension and three patients had bradycardia .One patient required an injection of atropine for bradycardia, and no patient required vasopressors for correction of blood pressure.

Hypotension was managed by decreasing volatile nanesthetic concentration and infusing intravenous fluids. No side eff ects were noted in group Fentanyl. A Rabie et al[14], Bakri et al[16]– dexmedetomidine 1 µg/kg preoperative could reduce the incidence of PONV in patients undergoing laparosxcopic cholecystectomy.

Postoperative nausea and vomiting (PONV) are considered one of the most distressing symptoms that follow surgery under general anesthesia, with an incidence reaching as high as 30%. However, the incidence of PONV is higher after laparoscopic cholecystectomy compared to other types of surgery and the peak of PONV incidence in patients with laparoscopic cholecystectomy specially at 6 h and 12 h postoperative interval

Conclusion

This study demonstrates that dexmedetomidine is superior to fentanyl for attenuation of hemodynamic response and for reducing the total dose of the inducing agent. An intravenous infusion of dexmedetomidine at 1 µg/kg administered 10 min before laryngoscopy and endotracheal intubation followed by 0.2µg/kg/hr infusion can be recommended over fentanyl 1 µg/kg followed 0.2µg/kg/hr infusion to attenuate the sympathetic response to laryngoscopy and endotracheal intubation with minimal side effects.

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