Original Research Article

A study to compare the efficacy of dexmedetomidine with esmolol on haemodynamic response during laparoscopic cholecystectomy

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Abstract

Background: Laparoscopic surgery is a routinely performed surgery and it is desirable to have a stable intraoperative haemodynamic states by avoiding hypertension and tachycardia. Various drugs have been employed to attenuate these hemodynamic response. No single drug is satisfactory. Thus there is a need to find a simple efficient and reliably consistent method. **Aims**: The purpose of study is to compare the efficacy of dexmedetomidine with esmolol on haemodynamic response to pneumoperitoneum during laparoscopic cholecystectomy. **Materials and methods:** Prospective, randomized, controlled, single blinded study was conducted in department of Anaesthesiology on 60 patients aged between 20-60 years posted for elective laparoscopic cholecystectomy. They were randomly divided into two groups of 30 patients each Group-A(Dexmedetomidine + Standard Procedure) and Group-B(Esmolol + Standard Procedure)- The Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP) were recorded prior to induction, after the induction, after the intubation, 15 min, 30 min, 45 min, 60 min after creation of pneumoperitoneum, post pneumoperitoneum, after extubation. **Results**: Heart rate and systolic blood pressure were significantly lower in Group A after induction, after intubation, and maintained throughout intraoperative and postoperative period compared to Group B. Diastolic blood pressure were significantly lower in Group A after intubation, and maintained throughout intraoperative period and at extubation compared to Group B. Diastolic blood pressure were not significant after induction, at postoperative period. Mean blood pressure were significantly lower in Group A after induction, after intubation, and maintained throughout intraoperative period and at extubation compared to Group B. Mean blood pressure were not significant at postoperative period. **Conclusion**: Dexmedetomidine(1mcg/kg followed by o0.5mcg/kg/hr) is more effective agent than esmolol(1mg/kg followed by 0.5mg/kg) in attenuation of hemodynamic response to intubation and reduces the elevation of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure during and after pneumoperitoneum in laparoscopic cholecystectomy.

Keywords: Pneumoperitoneum, Laparoscopic cholecystectomy, Dexmedetomidine.

Introduction

Laparoscopic surgeries involves insufflation of a CO2 gas into the peritoneal cavity producing a pneumoperitoneum. This causes an increase in intra-abdominal pressure. Carbon dioxide is insufflated into the peritoneal cavity at the rate of 4-6 lit/min to a pressure of 10-15mm Hg. The pneumoperitoneum is maintained by a constant gas flow of 200-400 mL/min. Peritoneal insufflation induces alterations of hemodynamics, characterized by decrease in stroke volume and cardiac output, elevation of mean arterial pressure, and increase of systemic and pulmonary vascular resistance. Haemodynamic changes are accentuated in high-risk cardiac patients[1].

General anesthesia has been supplemented on occasions with intraoperative infusions of Propofol due to its intrinsic ability to inhibit catecholamine secretion, infusions of nitroglycerine or beta blockers to control perioperative stress. Again combined GA with epidural anesthesia is yet another strategy employed by anesthesiologists to control perioperative haemodynamic instability, with limited success.

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But the search for the ideal agent to control this instability in hemodynamics is still on. The pathophysiologic haemodynamic changes can be attenuated or prevented by optimizing preload before pneumoperitoneum and by vasodilating agents, α_2-adrenergic receptor agonists, high doses of opioids, and blockers.

Alpha 2 agonists produce diverse responses including analgesia, anxiolysis, sedation and sympatholytic, each of which has been reported in the treatment of surgical and chronic pain patients and in panic disorders as well. The food and drug administration(FDA) registered novel alpha-2 adrenergic agonists Dexmedetomidine. The α2 agonists dexmedetomidine decrease central sympathetic outflow and modify intraoperative cardiovascular responses to surgical stimuli and laryngoscopy. The reduction in tachycardia, hypertension and sympathetic activity may be of benefit in patients at risk of myocardial ischemia.

Dexmedetomidine has analgesic, anxiolytic, sedative and sympatholytic properties. It might be useful adjunct for premedication, especially for patients susceptible to preoperative and perioperative stress. The hypnotic response is probably mediated by activation of the α2 adrenoreceptors. The α2 adrenergic mechanism causes dose-dependent reduction in blood pressure (BP) and heart rate (HR). Dexmedetomidine is proved to have antinociceptive effects and reduce the neurohumoral properties. These properties render dexmedetomidine an ideal preanesthetic medication for surgical procedures. Esmolol is a rapid onset, short acting selective beta-1

adrenergic antagonist. While it inhibits β_1 receptors of myocardium, it also inhibits β_2 receptors of smooth muscles of bronchial and vascular walls at higher doses.[7] Dose is 0.5-2 mg/kg. It is effective in blunting the increase in systolic blood pressure and heart rate, which occurs during tracheal intubation[2]. Elimination half-life is around 9 minutes[3]. The present study is undertaken to evaluate the comparision of Dexmedetomidine and Esmolol on perioperative haemodynamic response during laparoscopic cholecystectomy.

Materials and methods

Prospective, randomized, controlled, single blinded study was conducted in department of Anesthesiology and critical care, Gandhi hospital, secunderabad on 60 patients aged between 20-60 years posted for elective laparoscopic cholecystectomy. The study was done after obtaining approval of ethics committee of hospital and with written informed consent to evaluate the efficacy of dexmedetomidine and esmolol on haemodynamic response during laparoscopic cholecystectomy. Sixty patients who fulfill the following criteria were included in the study.

Inclusion criteria

ASA physical status I and II of either sex, age group 20-60 years undergoing laparoscopic cholecystectomy

Exclusion Criteria

Patients with history of hypertension, morbid obesity, Contraindication/allergy to either dexmedetomidine or esmolol being used in the study, renal insufficiency, hepatic insufficiency cardiopulmonary problems

Patients selected were explained regarding the surgical procedure, anesthesia and drugs to be used in their own language. A written informed consent was obtained in each case.

Sample size

Sixty patients (N=60) were divided into two groups group A (dexmedetomidine n=30), group B (esmolol n=30) were taken.

Pre-anesthetic evaluation was done on the evening before surgery with complete history, clinical, airway and systemic examination of cardiovascular and respiratory system was done.

All patients underwent Basic investigations for surgery. All the selected patients were allocated into two groups consisting of 30 patients each. Blinding was done by using SNOSE (sequentially numbered opaque sealed envelope) technique.

Group-A(Dexmedetomidine + Standard Procedure) – in this group, patients received a loading dose of 1microgram/kg of dexmedetomidine over a period of 15 minutes(15 minutes before induction), followed by maintenance with 0.5microgram/kg/hr throughout pneumoperitoneum.

Group-B(Esmolol + Standard Procedure)- in this group, patients received a loading dose of 1mg/kg of esmolol over a period of 5 minutes (5 minutes before induction), followed by maintenance with 0.5mg/kg/hr throughout pneumoperitoneum.

All patients included in the study were premedicated with tablet Alprazolam 0.5mg and tablet ranitidine 150mg orally at bed time the previous night before surgery. They were kept nil orally 10pm onwards on the previous night.

On arrival of patient in the operating room, an 18 gauge intravenous cannula was secured and an infusion of ringer lactate was started. the patients were connected to multiparameter monitor that records heart rate, noninvasive measurement of SBP,DBP,MAP, EtCO2 and continuous ECG monitoring and oxygen saturation. The baseline systolic, diastolic blood pressure, mean arterial pressure and heart rate were recorded. The cardiac rate and rhythm were also monitored from a continuous visual display of electrocardiogram from lead II.

All patients were premedicated intravenously 15 min prior to induction with inj.midazolam 0.05mg/kg, inj.ondansetron 0.1mg/kg, inj.fentanyl 1.5microgm/kg and inj.glycopyrrolate 0.2mg.

In the group A dexmedetomidine 1microgm/kg was given 15 min prior to induction followed by maintained with 0.5microgm/kg/hr throughout pneumoperitoneum. In the group B esmolol 1mg/kg was given 5mim prior to induction followed by maintained with 0.5mg/kg/hr throughout pneumoperitoneum.

The patients were preoxygenated with 100% O2 by face mask for 3min. Induction was done with inj.propofol 2mg/kg and after 30sec relaxation achieved with inj.succinyl choline 2mg/kg 90sec later the patient was intubated using a macintosh laryngoscope. Tracheal tubes of 7.0 mm and 8.5 mm were used for female and male patients respectively. Anesthesia was maintained by N2O(60%) and O2(40%). Intermittent boluses of vecuronium bromide intravenously.

1. Intra-abdominal pressure was restricted to 10-14 mmHg.

2.EtCO2 was maintained below 35 mmHg at any course of the procedure.

3.Atropine was kept ready to counter the bradycardia, and Inotropes were kept ready to counter any untoward hypotension.

At the end of surgery, neuromuscular blockade was reversed with inj. Neostigmine (40microgm/kg) and inj. glycopyrrolate(10microgm/kg).

The parameters recorded were Heart rate, systolic blood pressure, diastolic blood pressure , mean arterial pressure. The recordings were noted at various intervals as Preoperative, after induction, after intubation, 15min, 30min, 45min, 60min after creation of pneumoperitoneum, post pneumoperitoneum and post-operative period after 15min.

Statistical Analysis

Descriptive statistical analysis had been carried out in the present study. Results on continuous measurements were presented on Mean ± SD and results on categorical measurements were presented in Number. Student t test (two tailed, independent) had been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Significant figures

- Significant (P value:P< 0.05)
- Highly significant (P value : P<0.01)

Statistical software

The Statistical software namely Graphpad was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Results

Table-1: Comparison of age, weight and gender distribution between the groups(N=30)

	GROUP A	GROUP B	P VALUE A and B
MEAN AGE(yrs)	35.86+4.73	36.2+4.49	0.77
WEIGHT(kg)	55.53+10.36	55.57+10.94	0.988
MALE/FEMALE	15/15	16/14	1

The average age was 35.86 years in group A and 36.2 years in group B. Youngest patient in the study group was 28 years and oldest was 48 years. The average weights of the patients were 55.53 in group A and 55.57 in group B respectively. There was no significant difference in age and weight between the two groups. There was no significant difference in gender between the two groups.

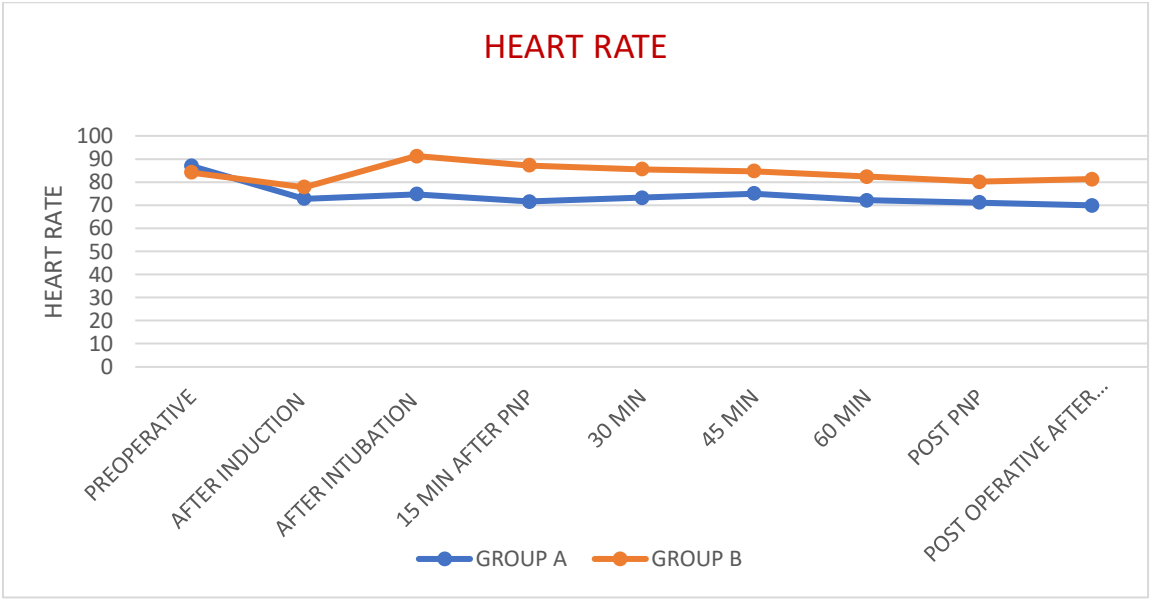

Fig. 1: Comparison of Heart rate in study

Statistical analysis of changes in heart rate at preoperatively, after induction, after intubation and different time intervals after creation of pneumoperitoneum are presented. The preoperative values of heart rate(HR) were comparable between the two groups with no significant difference. The heart rate were significantly less in dexmedetomidine group throughout study time compared with the esmolol group.

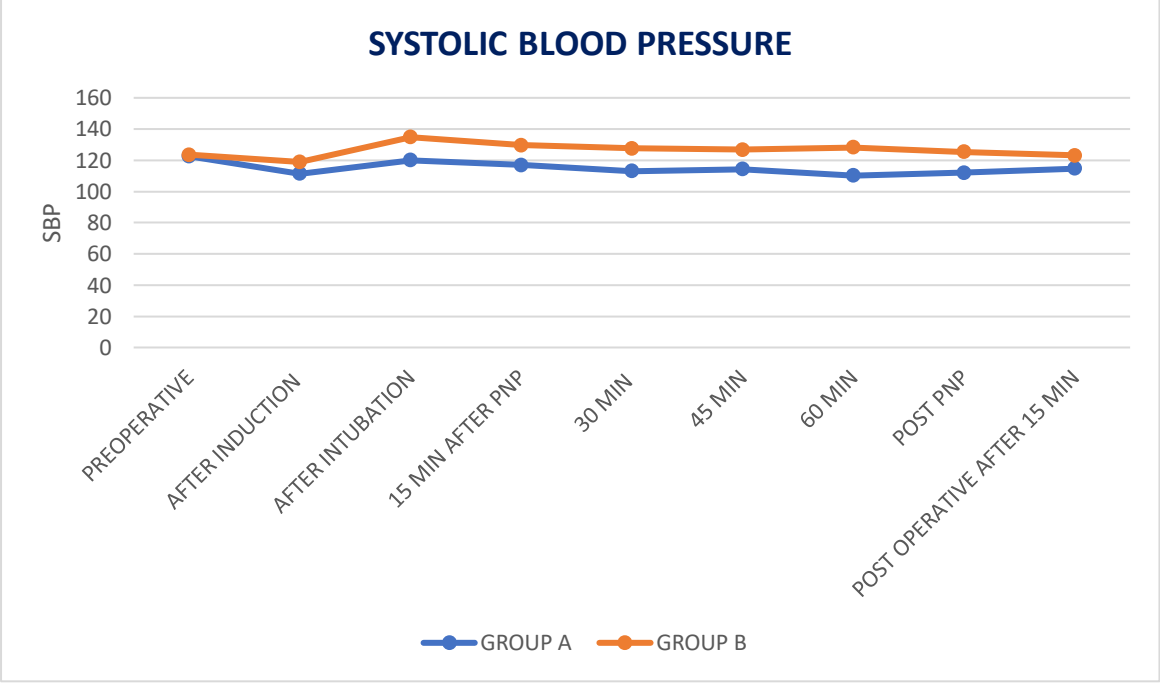

Fig. 2: Comparison of systolic blood pressure

Statistical analysis of changes in systolic blood pressure at preoperatively, after induction, after intubation and different time intervals after creation of pneumoperitoneum are presented.

The preoperative values of systolic blood pressure(SBP) were comparable between the two groups with no significant difference. The systolic blood pressure were significantly less in dexmedetomidine group throughout study time compared with the esmolol group.

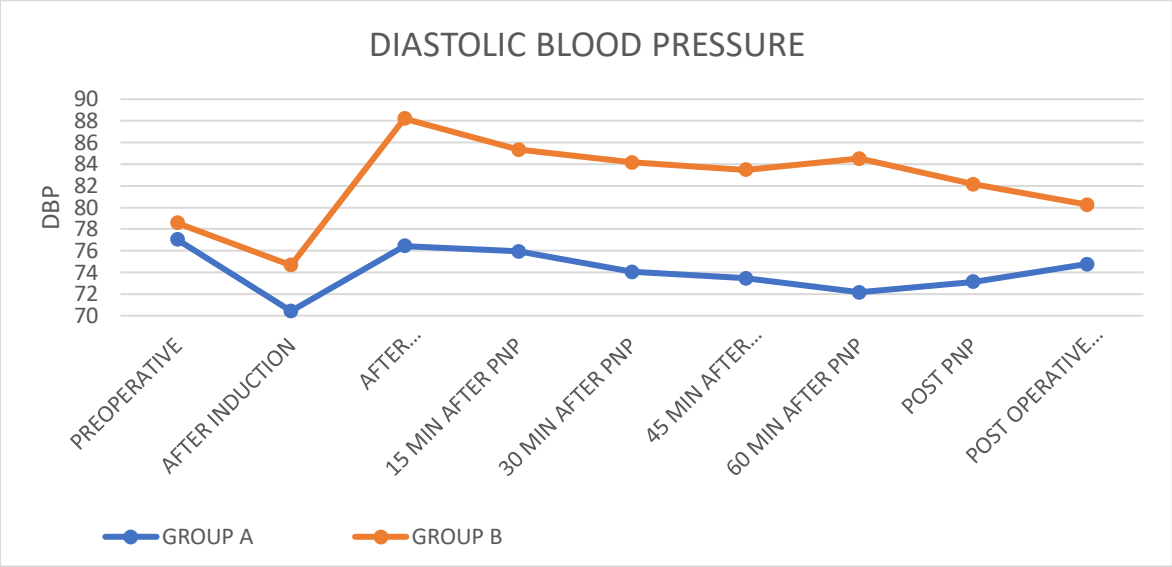

Fig. 3: Comparison of diastolic blood pressure

The preoperative values of diastolic blood pressure(DBP) were comparable between the two groups with no significant difference. The diastolic blood pressure were significantly less in dexmedetomidine group throughout study time compared with the esmolol group and not significant at postoperatively after 15 min(p=0.0517).

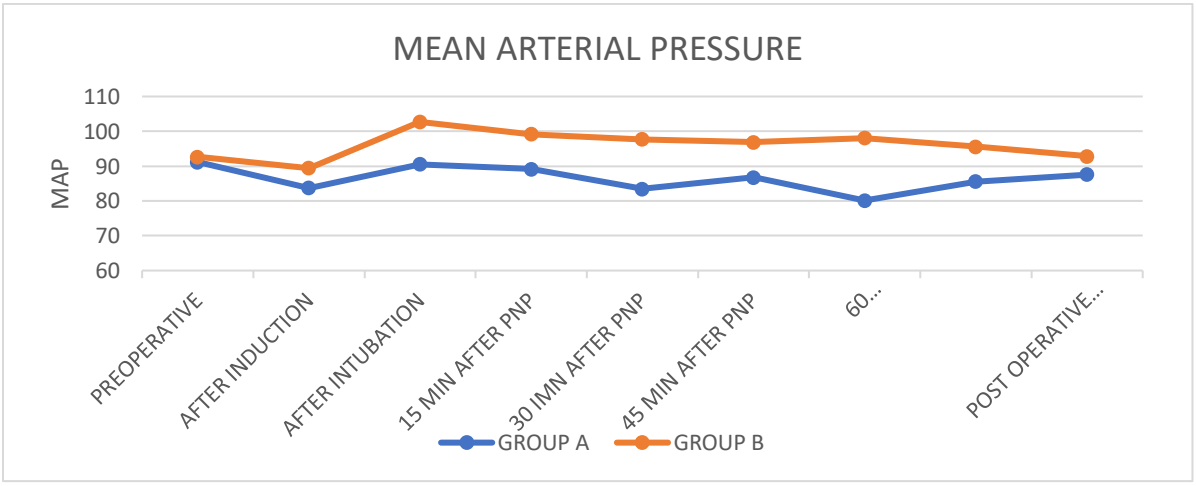

Fig. 4: Comparison of mean arterial pressure

The preoperative values of mean arterial pressure(MAP) were comparable between the two groups with no significant difference. The mean arterial pressure were significantly less in dexmedetomidine group throughout study time compared with the esmolol group and MAP was not significant postoperatively after 15 min(p>0.05).

Table-2: Comparision of adverse effects between two groups

	Hypotension	No Adverse Effect	P Value
Group A	3	27	0.2373
Group B	0	30	

In Group A, only three patients out of thirty had hypotension in the intraoperative period.

No such adverse effect was seen in Group B. there were no other adverse effects observed. This analysis was done by using Fisher's exact test which provided a P value of 0.2373 which is clinically not significant.

Table-3: Use of other drugs in both the groups

	Use of other Drugs	No use of other drugs	P Value
Group A	0	30	**0.4915**
Group B	2	28	

Only two patients in Group B developed hypertension during pneumoperitoneum which was managed with nitroglycerine infusion. Statistical analysis was done by using Fisher's exact test which provided a P value of 0.4915 which is clinically not significant.

Discussion

In laparoscopic surgery, CO2 is routinely used to create pneumoperitoneum. Elevated intra-abdominal pressure induced by pneumoperitoneum and CO2 itself produce some adverse effects on the cardiovascular system. Immediately after pneumoperitoneum, plasma level of norepinephrine, epinephrine and plasma renin activity is increased. Increased catecholamine level activates the renin-angiotensin-aldosterone-system (RAAS) leading to some

characteristic haemodynamic alterations, which included Decreased cardiac output (25-35%), Elevated mean arterial pressure and Increased systemic / pulmonary vascular resistance[4]. In present study the average age was 35.86 years in group A and 36.2 years in group B. The average weights of the patients were 55.53 in group A and 55.57 in group B

respectively. There was no significant difference in age and weight between the two groups. There was no significant difference in gender between the two groups. The preoperative values of heart rate(HR) were comparable between the two groups of group A 86.96+8.21 and group B 84.16+9.92 with no significant difference. The heart rate were significantly less in dexmedetomidine group throughout study time compared with the esmolol group(p= <0.05).

Kalpana S. Vora et al[58], conducted a randomized blind study consists of a total of 70 patients ASA I or II scheduled for elective laparoscopic surgeries were received bolus infusion of dexmedetomidine(group D) or saline(group S) 1mcg/kg/hr, followed by continuous infusion of same, at the rate of 0.5mcg/kg/hr. baseline mean HR was not significant between two groups (p >0.05). there was a significant reduction in HR following the loading dose of dexmedetomidine, after intubation, after 20 min of pneumoperitoneum, after 60 min of pneumoperitoneum, after infusion was stopped, after extubation, in group D as compared to group S.

Nandlal Bhagat et al[5], conducted a randomized single blind study with 120 patients of ASA I and II who underwent laparoscopic cholecystectomy. Prior to induction group D received 1mcg/kg of dexmedetomidine and group N received normal saline infusion over 20 minutes. Dexmedetomidine 0.5mcg/kg/hr in group D and volume matched NS in group N was continued throughout the surgery. Heart rate decreased intraoperatively by 5.7% from the baseline in group D while it increased in group N by 16% from baseline (p <0.0001).

Ritima Dhir et al[6], conducted a randomized study consisting of 60 patients of ASA I and II of either sex scheduled for laparoscopic cholecystectomy. Patients were divided into two groups. Group E received esmolol loading dose 0.5mg/kg in 30ml isotonic saline before induction followed by infusion of 0.05mcg/kg/min till the completion of surgery. Group C patients received 30ml of isotonic saline as loading dose and continuous infusion till completion of surgery. The baseline HR at 0 min was almost similar in both the groups. At 8th minute(time of intubation) HR increased significantly in group C as compared to group E and remained higher than group E till the end of surgery. Only 10% of patients in group E showed statistically significant(p=0.004) increase in intraoperative HR as compared with86.67% in group C.

Dhurjoti Prosad Bhattacharjee et al[7], conducted a randomized single blind placebo controlled study consisting of 60 patients of either sex undergoing laparoscopic cholecystectomy, were randomly allocated into three groups containing twenty patients each. group E received bolus dose of 500 mcg/kg IV esmolol before pneumoperitoneum followed by infusion of 100mcg/kg/min. group D received bolus dose of 1mcg/kg IV dexmedetomidine before pneumoperitoneum followed by infusion of 0.2mcg/kg/hr. group S received saline 0.9%. there is no significant difference was found between the preoperative HR and the HR values following intubation and before pneumoperitoneum among all three groups (p >0.05). However, following pneumoperitoneum, HR values in group E and group D were significantly lower compared to group S at 10, 20, 30, 40, and 50 min after pneumoperitoneum, following the release of CO2 and after extubation(p <0.05). On comparing patients in group E and group D, no significant difference in HR was found at any interval.

Vinit K. Srivastava et al[8], conducted a prospective randomized study consisting of 90 patients of ASA I or II of either sex scheduled for laparoscopic cholecystectomy. Group D received loading dose of 1mcg/kg of dexmedetomidine before induction followed by maintenance of 0.5mcg/kg/hr. group E received esmolol loading dose of 1mg/kg before induction followed by maintenance of 0.5mg/kg/hr. group C received same volume of normal saline. There was no significant difference in preoperative HR between the groups. After administration of study drugs, there was a significant decrease in heart rate in group D(p <0.05). Intubation and pneumoperitoneum caused an increase in the heart rate in the group E (p <0.05), comparison to preoperative values, however this increase was not seen in group D (p>0.05).

The preoperative values of systolic blood pressure(SBP) in group A 122.53+4.23 and in group B 123.46+6.05 with no significant difference. The systolic blood pressure were significantly less in dexmedetomidine group throughout study time compared with the esmolol group(p <0.05).

Poonam S Ghodki et al[9], in their study of 30 patients of, ASA I and II, aged 18 to 50 years of either gender undergoing laparoscopic surgeries received loading dose infusion of dexmedetomidine 1mcg/kg over 15 min and maintenance infusion of 0.2mcg/kg/hr. Mean systolic blood pressure (SBP) to start with was 125 and fell to 113 with loading dose of Dex (p=0.009). after that minimal change was observed for entire duration of infusion.

Rajdip Hazra et al[10], in their study found that group D received dexmedetomidine 1mcg/kg over 15 min before induction, those were scheduled for elective laparoscopic cholecystyectomy. group K (Control group) received same volume of normal saline. Systolic arterial pressure was significantly higher in group K specially after intubation, at P30 and after extubation.

Nupur chakravorty et al[11], conducted a randomized study with patients undergoing elective laparoscopic cholecystectomy. Group E received esmolol 2mg/kg before extubation. The systolic blood pressure was significantly low before and after extubation compared to group N.

Vinit K. Srivastava et al[8], conducted a prospective randomized study consisting of 90 patients of ASA I or II of either sex scheduled for laparoscopic cholecystectomy. Group D received loading dose of 1mcg/kg of dexmedetomidine before induction followed by maintenance of 0.5mcg/kg/hr. group E received esmolol loading dose of 1mg/kg before induction followed by maintenance of 0.5mg/kg/hr. group C received same volume of normal saline. SBP values were statistically significantly lower in the group D after induction, intubation and all time observations of pneumoperitoneum, when compared with the group E (p <0.001). In group E, there was a statistically significant increase after intubation and during pneumoperitoneum period. In group D there was no statistically significant increase after intubation and at any time intervals of pneumoperitoneum. The preoperative values of diastolic blood pressure(DBP) in group A 77.03+8.43 and in group B 78.56+6.56 no significant difference. The diastolic blood pressure were significantly less in dexmedetomidine group throughout study time compared with the esmolol group and not significant at postoperatively after 15 min(p=0.0517).

Rajdip Hazra et al[10], in their study found that group D received dexmedetomidine 1mcg/kg over 15 min before induction, those were scheduled for elective laparoscopic cholecystyectomy. Group K (Control group) received same volume of normal saline. The diastolic blood pressure was significantly higher in group K specially after intubation, at P20, P30 and after extubation. It was significantly lower in group D.

Vinit K. Srivastava et al[8], conducted a prospective randomized study consisting of 90 patients scheduled for laparoscopic cholecystectomy. Group D received loading dose of 1mcg/kg of dexmedetomidine before induction followed by maintenance of 0.5mcg/kg/hr. group E received esmolol loading dose of 1mg/kg before induction followed by maintenance of 0.5mg/kg/hr. group C received same volume of normal saline. DBP values were statistically significantly lower in the group D after induction, intubation and all time observations of pneumoperitoneum, when compared with the group E (p <0.001). In group E, there was a statistically significant increase after intubation and during pneumoperitoneum period. In group D there was no statistically significant increase after intubation and at any time intervals of pneumoperitoneum. The preoperative values of mean arterial pressure(MAP) in group A 91.17+5.8 and group B 92.6+5.08 with no significant difference. The mean arterial pressure were significantly less in dexmedetomidine group throughout

study time compared with the esmolol group and MAP was not significant postoperatively after 15 min($p>0.05$).

Kalpana S. Vora et al[4], conducted a randomized blind study consists of a total of 70 patients ASA I or II scheduled for elective laparoscopic surgeries were received bolus infusion of dexmedetomidine(group D) or saline(group S) 1mcg/kg/hr, followed by continuous infusion of same, at the rate of 0.5mcg/kg/hr. Baseline MAP was not significant between two groups ($p>0.05$). Decrease in MAP was found after loading dose, after intubation, after 20 min of pneumoperitoneum, after 60 min of pneumoperitoneum, after infusion stopped, after extubation, in group D compared to group S, which was significant ($p<0.05$).

Rabie Soliman et al[12], conducted a study including 80 cardiac patients with ASA III-IV scheduled for elective laparoscopic cholecystectomy. The patients were randomly classified into two groups. Group D patients received a loading dose of 1mcg/kg dexmedetomidine over 15 min before induction and maintained with 0.3mcg/kg/hr infusion during the procedure. Group B received equal amount of normal saline. The mean arterial blood pressure was increased greatly after induction in the group C compared with the group D ($P<0.05$) and remained elevated during the procedures and post anesthesia care unit. There was attack of hypertension included 5 patients in group D and 14 patients in group C($p=0.035$).

Ritima Dhir et al[6], conducted a randomized study consisting of 60 patients of ASA I and II of either sex scheduled for laparoscopic cholecystectomy. Patients were divided into two groups. Group E received esmolol loading dose 0.5mg/kg in 30ml isotonic saline before induction followed by infusion of 0.05mcg/kg/min till the completion of surgery. Group C patients received 30ml of isotonic saline as loading dose and continuous infusion till completion of surgery. The baseline MAP at 0 min was almost similar in both the groups. At 8th minute(time of intubation) MAP increased significantly in group C as compared to group E and remained higher than group E till the end of surgery. Only 6.67% of patients in group E showed statistically significant increase in intraoperative MAP as compared with80% in group C.

Dhurjoti Prosad Bhattacharjee et al[7], conducted a randomized single blind placebo controlled study consisting of 60 patients of either sex undergoing laparoscopic cholecystectomy, were randomly allocated into three groups containing twenty patients each. group E received bolus dose of 500 mcg/kg IV esmolol before pneumoperitoneum followed by infusion of 100mcg/kg/min. group D received bolus dose of 1mcg/kg IV dexmedetomidine before pneumoperitoneum followed by infusion of 0.2mcg/kg/hr. group S received saline 0.9%. there is no significant difference was found between the preoperative MAP and the MAP values following intubation and before pneumoperitoneum among all three groups ($p >0.05$). However, following pneumoperitoneum, MAP values in group E and group D were significantly lower compared to group S at 10, 20, 30, 40, and 50 min after pneumoperitoneum, following the release of CO2 and after extubation($p <0.05$). On comparing patients in group E and group D, no significant difference in MAP was found at any interval.

Vinit K. Srivastava et al[8], conducted a prospective randomized study consisting of 90 patients of ASA I or II of either sex scheduled for laparoscopic cholecystectomy. Group D received loading dose of 1mcg/kg of dexmedetomidine before induction followed by maintenance of 0.5mcg/kg/hr. group E received esmolol loading dose of 1mg/kg before induction followed by maintenance of 0.5mg/kg/hr. group C received same volume of normal saline. MAP values were statistically significantly lower in the group D compared to group E after intubation, all time observations of pneumoperitoneum, post pneumoperitoneum and post-operative period ($p<0.001$). there was no significant increase in MAP in group D, compared to preoperative values at any time intervals of pneumoperitoneum, while it was a significant increase in group E during pneumoperitoneum($p<0.05$).

Conclusion

To conclude, Dexmedetomidine(1mcg/kg followed by o0.5mcg/kg/hr) is more effective agent than esmolol(1mg/kg followed by 0.5mg/kg) in attenuation of hemodynamic response to intubation and reduces the elevation of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure during and after pneumoperitoneum in laparoscopic cholecystectomy. only three patients in group Dexmedetomidine had hypotension as adverse effect. It was managed by fluid boluses and vasopressors. Only two patients in group esmolol developed hypertensive response during pneumoperitoneum. It was managed with nitroglycerine infusion.

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