

A STUDY TO EVALUATE THE EFFICACY OF DEXMEDETOMIDINE AND CLONIDINE PREMEDICATION ON HEMODYNAMIC STABILITY IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

Dhivakar S¹, Kavın Kumar S², Kirubahar R³

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Corresponding Author:
Dr. Dhivakar S,
Email: dhiva.kayel@gmail.com

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¹Post Graduate, Department of Anaesthesia, TSRMMCH&RC, India.

²Assistant Professor, Department of Anaesthesia, TSRMMCH&RC, India.

³Associate Professor, Department of Anaesthesia, TSRMMCH&RC, India.

Abstract

Background: Laparoscopic surgery is a modern surgical technique involving insufflation of gas (usually CO₂) into the peritoneal cavity, under pressure, to separate the organs from the abdominal cavity. Clonidine and dexmedetomidine, two alpha-2 adrenergic receptor agonists, are frequently used as adjuvants during anaesthesia for their analgesic, sedative, sympatholytic, and cardiovascular stabilising effects. **Objectives:** The main aim of the study is to compare the efficacy of dexmedetomidine and clonidine premedication on hemodynamic stability in patients undergoing laparoscopic cholecystectomy. **Materials and Methods:** This prospective randomised controlled trial study was conducted at Department of Anesthesia in SRM medical college, Trichy. A total of sixty participants were enrolled and randomly allocated into two groups, 30 participants each. Group D participants were given intra-venous Dexmedetomidine 1 µg/kg diluted with 10 ml of normal saline over 10 minutes and Group C participants were given intravenous Clonidine 2µg/kg of clonidine diluted in 10 ml of normal saline over 10 minutes before induction of general anaesthesia. The hemodynamic parameters such as heart rate, systolic and diastolic blood pressure were measured at baseline, premedication, induction, intubation, skin incision, CO₂ insufflation and extubation. Data collected were entered in Microsoft Excel and analysed in SPSS version 21.0. Data analysis was done using SPSS and continuous variables and categorical variables were interpreted using frequencies (mean ± SD) and proportions (%). Chi-square test is used to compare the variables. **Results:** Among the 60 study participant's patients who received dexmedetomidine had better haemodynamic control with respect to HR, SBP and DBP and post-operative analgesia than patients who received clonidine. **Conclusion:** Among alpha 2 agonists dexmedetomidine produce effective responses including analgesia, hemodynamic stability, sedation and sympatholysis during laparoscopic cholecystectomy.

INTRODUCTION

Laparoscopic surgical methods were found to have several advantages for the patients, including decreased tissue damage, earlier ambulation, shorter hospital stays, and fewer analgesic requirements.^[1] Laparoscopy is characterised by the production of pneumo-peritoneum with carbon dioxide (CO₂), which stimulates the sympathetic nerve system and causes pathophysiological changes.^[2] The main characteristic changes seen during intra-abdominal insufflation are increased arterial pressure, systemic

and pulmonary vascular resistance, and little variation in heart rate. Patients with coronary artery disease, pre-existing essential hypertension, ischemic heart disease, or elevated intracranial or intraocular pressure are adversely affected by these pathophysiological changes resulting in serious cardiac events.^[3]

In order to reduce this hemodynamic instability during this period, numerous agents and combinations of agents have been used. Research studies have shown the numerous effects of alpha 2 agonists like clonidine, dexmedetomidine, in the management of surgery and chronic pain patients,

including analgesia, anxiolytics, sedation, and sympatholytic.^[4,5]

Clonidine, a selective partial α_2 -adrenergic adjuvant has long been used to treat hypertension.^[6] When administered systemically during general anaesthesia, clonidine has been shown to reduce the need for perioperative analgesics, while when combined with local anaesthetics during spinal anaesthesia, it has been found to lengthen the period of both the motor and sensory blockade.^[7,8]

Dexmedetomidine is a highly selective, potent and specific alpha 2 agonist (1620:1 alpha 2 to alpha 1) and is seven to ten times more selective for alpha 2 receptors compared to clonidine. It has a shorter duration of action with an elimination half-life of two to three hours.^[9] Dexmedetomidine maintains the hemodynamic stability by decreasing plasma catecholamine concentration during anesthesia and decreases perioperative requirements of inhaled anesthetics.^[10]

Hence this study was conducted to compare the effectiveness of clonidine and dexmedetomidine on hemodynamic stability in laparoscopic cholecystectomy.

Objective

- To compare the effectiveness of intravenously administered clonidine and dexmedetomidine for hemodynamic stability during laparoscopic surgery.

MATERIALS AND METHODS

Study Design

- A Prospective randomised controlled trail study
- Study area
- Department of Anesthesia, SRM medical college, Trichy
- Study duration
- Three months
- Study population
- Patients posted for laparoscopic cholecystectomy.

Inclusion Criteria

- Both sex
- Age group of the patients between 19-60 years
- Patients belonging to ASA grade I and II

Exclusion Criteria

- Participants not willing to give consent
- Patients with severe systemic illness
- Anticipated difficult airway with mouth opening less than 2 cm.
- Patients who are having history of allergy towards the study medicines
- Pregnant women

Sampling technique

- Convenient sampling
- Sample size: 60
- Data collection

Data was collected in Department of Anesthesia in SRM College, Trichy. After getting informed

written consent from the parents, this study was conducted among 60 patients posted for elective laparoscopic cholecystectomy. They were randomly allocated in to two groups Group C and D with n=30 each.

Group C – received 2 μ g/kg of clonidine diluted in 10 ml of normal saline intravenously before the induction of general anaesthesia

Group D- received 1 μ g/kg of dexmedetomidine diluted in 10 ml of normal saline intravenously before the induction of general anaesthesia.

In operating theatre, the baseline readings of Heart Rate (HR), Systolic Blood Pressure(SBP), Diastolic Blood Pressure(DBP) was measured followed by hemodynamic status was measured at premedication, induction, intubation, skin incision, CO2 insufflation and extubation. The incidence of side effects like hypotension and bradycardia was also recorded. Patient's sedation scores were noted according to Ramsay sedation scores at pre-induction and during postoperative period. Ramsay Sedation Scale is as given below

1. Anxious and agitated or restless or both.
2. Cooperative oriented and tranquil.
3. Drowsy but respond to commands.
4. Asleep, brisk response to light glabellar tap or loud auditory stimulus
5. Asleep, sluggish response to light glabellar tap or loud auditory stimulus
6. Asleep or unarousable.

Data was entered in Microsoft excel 2019 and analysed using software SPSS (Statistical Package of Social Sciences) version 21. Continuous variables and categorical variables were interpreted using frequencies (mean \pm SD) and proportions (%). Student t-test & Chi-square test was used for categorical variables. For comparing two groups of mean Student's t test was used to compare the statistical difference between the two groups. P value <0.05 is considered as statistical significance.

Ethical issues

- Participants were informed about the study and informed consent was obtained
- This study was presented to Institutional Ethical Committee of SRM Medical College, Trichy.

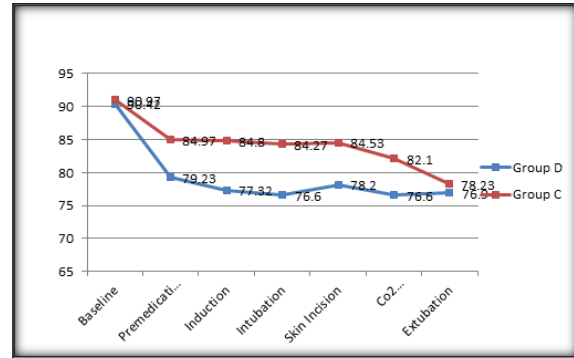
RESULTS

This double-blinded randomized controlled trial was conducted among 60 patients who underwent laparoscopic cholecystectomy randomly divided into two groups. The results are described as follows Table 1 describes the demographic data of participants. The mean age and weight of both groups were comparable and there was no significant difference. The gender distribution among groups was also comparable and there was no difference. The mean Ramsay score among Group C was 3.24 \pm 1.411 and 3.12 \pm 0.86 among group D.

Table 1: Demographic data of participants

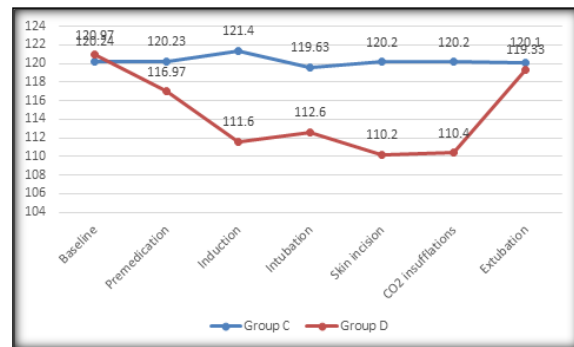
S No	Characteristics	Group C (n = 30)	Group D (n = 30)	p value
1	Age (years)	38.1±6.411	39.43±8.523	0.497
2	Weight (kgs)	62.4±4.112	63.44±4.124	0.332
3	Gender			
	Male	16 (53.3%)	18 (60%)	0.602
	Female	14 (46.7%)	12 (40%)	
4	Ramsay sedation score	3.12±1.411	3.24 ±0.86	0.692

Table 2 shows the heart rate of participants. The baseline heart rate was comparable and there was no significant statistical difference. The heart rate was higher among Group C during medication, induction, intubation, skin incision and Co2 insufflations compared with Group D and this difference was found to be statistically significant.

**Figure 1: Mean Heart rate among study group****Table 2: Heart rate of participants (n = 60)**

S No	Parameters	Group D (n = 30)	Group C (n = 30)	p value
1	Baseline	90.42±5.015	90.97±4.902	0.669
2	Premedication	79.23±4.978	84.97±4.464	0.001`
3	Induction	77.3±2.769	84.8±4.67	0.001
4	Intubation	76.6±3.19	84.27±4.84	0.001
5	Skin incision	78.2±1.75	84.53±5.104	0.001
6	CO2 insufflations	76.6±3.318	82.13±4.59	0.001
7	Extubation	76.9±2.78	78.23±6.90	0.331

Table 3 shows the Systolic blood pressure of participants. The baseline Systolic blood pressure was comparable and there was no significant statistical difference. The Systolic blood pressure was higher among Group C during medication, induction, intubation, skin incision and Co2 insufflations compared with Group D and this difference was found to be statistically significant.

**Figure 2: Systolic blood pressure****Table 3: Systolic blood pressure of participants (n = 60)**

S No	Parameters	Group C	Group D	p value
1	Baseline	120.24±5.15	120.97±3.76	0.533
2	Premedication	120.23±4.015	116.97±4.902	0.006
3	Induction	121.4±2.79	111.6±3.092	0.001
4	Intubation	119.63±2.942	112.6±3.32	0.001
5	Skin incision	120.20±3.033	110.2±3.23	0.001
6	CO2 insufflations	120.2±2.319	110.4±3.133	0.001
7	Extubation	120.1±3.083	119.33±2.537	0.295

Table 4 shows the Diastolic blood pressure of participants. The baseline Diastolic blood pressure was comparable and there was no significant

statistical difference. The Diastolic blood pressure was higher among Group C during medication, induction, intubation, skin incision and Co2

insufflations compared with Group D and this difference was found to be statistically significant (p value less than 0.05).

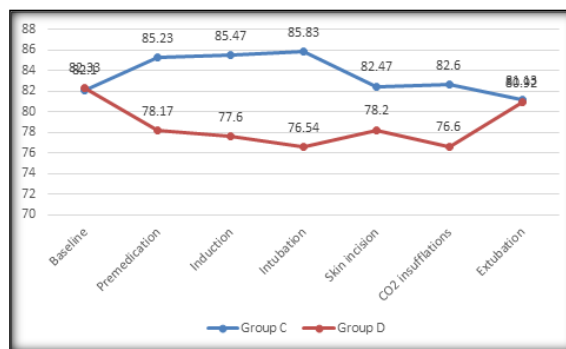


Figure 3: Diastolic blood pressure

Table 4: Diastolic blood pressure of participants (n = 60)

S No	Parameters	Group C	Group D	p value
1	Baseline	82.1±4.397	82.33±4.52	0.842
2	Premedication	85.23±2.015	78.17±3.122	0.001
3	Induction	85.47±4.607	77.6±2.729	0.001
4	Intubation	85.83±4.859	76.54±3.191	0.001
5	Skin incision	82.47±4.516	78.2±1.75	0.001
6	CO2 insufflations	82.6±5.463	76.6±3.318	0.001
7	Extubation	81.13±4.408	80.92±2.78	0.826

Figure 4 shows adverse events among participants. 3 and 2 of the participants had bradycardia among group C and D respectively. 10 and 3 of the participants had hypotension among group C and D respectively.

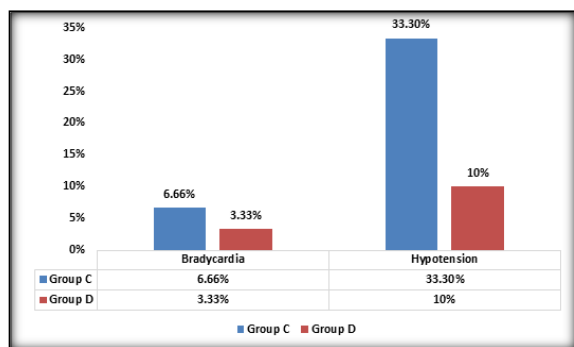


Figure 4: Adverse events

DISCUSSION

During laparoscopic procedures the creation of pneumoperitoneum results in significant hemodynamic changes occur that can be detrimental, particularly in elderly and hemodynamically susceptible patients. To maintain this hemodynamic stability recently alpha-2 receptor agonist like clonidine and dexmedetomidine was used. The main aim of this study to compare the efficacy of both these drugs during laparoscopic cholecystectomy. From the study we found that patients received intravenous dexmedetomidine had good hemodynamic stability and there was significant difference in HR, SBP and DBP when compared to patients who had intravenous clonidine. This is similar to a study conducted by Kumar et al.^[11] who also compared the effects of dexmedetomidine and clonidine premedication in 60 patients undergoing laparoscopic cholecystectomy

and found that both the drugs were effective in attenuating the hemodynamic response to pneumoperitoneum with equal efficacy but dexmedetomidine was more effective than clonidine.

Another study by Chiruvella et al.^[12] also studied IV 1 mcg/kg of dexmedetomidine and clonidine for attenuation of stress responses during laparoscopic cholecystectomy and found dexmedetomidine more effective than clonidine however chances of hypotension and bradycardia were more with dexmedetomidine which is also in consistent with our study report.

Gautam et al also state that dexmedetomidine was found to be more effective than clonidine in maintaining the hemodynamic stability during laparoscopic surgeries and these findings were comparable with our study report.^[13]

Sharma et al.^[14] also found that patients who received dexmedetomidine had better haemodynamic control and post-operative analgesia than patients who received clonidine which is similar to our study report.

Chahar et al also stated that 1mcg/kg of dexmedetomidine showed better control of haemodynamics as compared to 1mcg/kg of clonidine which is also comparable to our study report.^[15]

Talke et al.^[16] in their study showed that both HR and SBP reduced in response to the 1 h Dexmedetomidine infusion to the targeted plasma conc. of 0.45 ng/ml, which appears to benefit in peri-operative hemodynamic management in patients undergoing vascular surgery which is also comparable to our study report..

CONCLUSION

From our study we concluded that both alpha-2 receptor agonists were found to be effective in attenuating the hemodynamic response to pneumoperitoneum during laparoscopic surgeries but the effect of intravenous dexmedetomidine had good hemodynamic stability and also provides reliable postoperative analgesia and sedation when used as a premedication agent than clonidine.

Limitations

- Small sample size, single centered study and usage of low dose of drugs.
- The study can be done in large samples with different age group and with wider applicability.
- The study can be conducted using other divertional therapy.

Conflict of interest

Nil.

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