

A COMPARATIVE STUDY OF THE EFFICACY OF INTRAVENOUS PARACETAMOL VERSUS DEXMEDETOMIDINE ON PERIOPERATIVE HEMODYNAMICS IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Peritoneal insufflation to intraabdominal pressure > 10-14mm of Hg induces a significant alteration of hemodynamics. Paracetamol and Dexmedetomidine are both effective component with respect to multimodal analgesia in combination with opioids. Paracetamol has both analgesic and antipyretic effects, it is devoid of side effects like GI ulcerations, impaired platelet function and adverse cardiorenal effects. The anaesthetic and opioid sparing effects of dexmedetomidine in the early post operative period may decrease the risk of respiratory depression and incidence of post operative nausea and vomiting. **Materials & Methods:** The study is a clinical, observational study conducted at SSIMS-RC hospital. Sixty consenting, ASA I and II patients aged 18-60 years were randomly assigned to one of the following two groups. Group-P(n=30) received IV 1gm paracetamol infusion over 10 minutes before pneumoperitoneum and Group-D(n=30) received IV dexmedetomidine 1 µg/kg bolus over 10 minutes before pneumoperitoneum. Perioperative haemodynamic variables were recorded and compared. **Results:** Profiles of intraoperative haemodynamic changes were similar in both groups in respect to heart rate(HR), diastolic blood pressure, mean arterial pressure except in the systolic blood pressure where dexmedetomidine significantly reduced it in compare to paracetamol. **Conclusion:** Use of both dexmedetomidine and paracetamol were capable of controlling the haemodynamic status of patients undergoing laparoscopic cholecystectomy. However paracetamol perioperatively provides haemodynamic stability with less sedation whereas dexmedetomidine provides analgesia and cooperative sedation.

INTRODUCTION

Laparoscopy is a surgical procedure in which a fiberoptic instrument inserted through the abdominal wall to view the organs in the abdomen and permit surgery. Also called minimally invasive surgery or keyhole surgery. They are performed far from their location through small incision elsewhere in the body. Introduced in 1970, laparoscopy has undergone various advancement to do even major surgeries.

Laparoscopic surgeries have become recent trend in the surgical field, aim to achieve a satisfactory therapeutic result while minimizing the traumatic and metabolic stress. Advantages of laparoscopic surgical procedures include less tissue trauma, smaller incisional sites, lower risks of wound complications, reduced postoperative pain, shorter hospital stay, more rapid return to normal activities and cost savings. Laparoscopy requires the establishment of

pneumoperitoneum in order to provide adequate surgical exposure and maintain operative freedom. This insufflation of carbon di oxide can lead to various physiological changes. An emerging body of data addresses the haemodynamic, respiratory, immunological and stress response related to the pneumoperitoneum. The physiologic changes associated with laparoscopy include those associated with tilting the patient to facilitate instrumentation, surgical exposure, the pressure effects of instilled gas into a closed cavity and the systemic effects of the gas, almost universally CO₂ instilled (absorbed or embolise). Cardiovascular changes include increase in mean arterial pressure with no significant change in heart rate, decrease in cardiac output (10%-30%), and increase in systemic vascular resistance. These vasopressor responses are due to hypercarbia-induced release of catecholamines, vasopressin, or both.

The pneumoperitoneum and its consequent haemodynamic changes can be attenuated by pharmacological agents such as nitroglycerin, beta blockers and opioids, to provide haemodynamic stability during pneumoperitoneum but they have their own disadvantages.

This study was designed in a prospective, randomised fashion to compare the efficacy of intravenously administered dexmedetomidine and paracetamol on haemodynamic stress response during laparoscopic surgeries.

MATERIALS AND METHODS

Source of data

The study was conducted on patients posted for elective laparoscopic cholecystectomy in S. S INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTRE, DAVANGERE for 2 years. i.e., November 2023 to November 2025.

Method of collection of data

The study is a clinical, prospective randomized control study conducted at SSIMS-RC hospital. Written informed consent was obtained from patients or their legally authorized representatives, and the study was approved by the Institutional Ethics Committee, SSIMSRC.

Inclusion Criteria

- Adults between the age of 18 to 60 years.
- Patients with ASA physical status criteria I and II scheduled for elective laparoscopic cholecystectomy under general anaesthesia.
- Patients who are willing and able to give written informed consent.

Exclusion Criteria

- Patient refusal
- Age more than 60 years and less than 18 years.
- ASA physical status III or IV.
- Laparoscopic cholecystectomy converted to open surgery.
- Patients with acute cholecystitis.
- Patients allergic to paracetamol, dexmedetomidine.

Method

Pre anaesthetic check up was done on the previous day of the surgery with a detailed history, general physical examination, systemic examination, airway assessment and spine examination. Patient's weight and height was also recorded.

Investigations like blood grouping, complete haemogram, routine urine examination with urine albumin, sugar, microscopy and other relevant investigations, such as ECG, chest Xray, ultrasonography of abdomen were done.

A written, informed consent was taken from the patient prior to the scheduled operation and the procedure of general anaesthesia was explained in detail to the patient.

All patients were kept nil orally for 8-10 hours. Pre medication in the form of tab. Ranitidine 150 mg and

tab.alprazolam 0.5 mg was administered a night before the surgery.

On the day of surgery, the patient was shifted onto the operation table and intravenous access was established on the right forearm with 18G intravenous canula and ringer lactate /normal saline solution 10ml per kg was started. Baseline (pre operative) haemodynamic parameters like heart rate(HR), non invasive blood pressure(NIBP), electrocardiogram(ECG) and oxygen saturation(Spo2) and respiratory rate were recorded. The patient was placed in supine position, and was given infusion of 1gm paracetamol over 10 minutes for group P and infusion of 1µg per kg of dexmedetomidine over 10 min and after that patient was pre oxygenated with 100% O2 at 8 L per minute via anatomical face mask through Bain's circuit for 3 minutes.

Pre medication in the form of inj.glycopyrrolate 0.01 mg per kg, inj.midazolam 0.05 mg per kg, inj.fentanyl 2µg per kg was administered. Induction was carried out by inj.propofol 2mg per kg and intubation was achieved by inj.suxamethonium 2mg per kg. Intra operative muscle relaxation was achieved by inj.vecuronium 0.05mg per kg. The anaesthesia was maintained N2O:O2(3:2) and intermittent 0.6-1.5% isoflurane.

Intra operative monitors consisted of ECG,NIBP, End tidal CO2 and pulse oxymeter. Ventilation was adjusted to maintain end tidal CO2 between 35-40 mmhg. During surgery patient was placed in 15-20 degrees of Trendelenburg's position with left side tilting downwards. The intra abdominal pressure was maintained between 12-15 mmhg during the surgery. At the end of surgery, after removal of gall bladder and haemostasis, residual blood, fluids and CO2 were thoroughly suctioned and reversal was achieved by administering inj.neostigmine 0.05 mg per kg and inj.glycopyrrolate 0.01 mg per kg and the patient was extubated.

All patients were assessed intra operatively in terms of following parameters:

Heart rate
Systolic blood pressure
Diastolic blood pressure
Mean arterial pressure
SPO2

Sedation (Modified Ramsay sedation score)

At intervals of 5,15,30,45,60 and so on minutes starting from the completion of bolus dose infusion of study drugs.

Modified Ramsay Sedation Score

Score	Response
1	Awake and oriented
2	Drowsy but responds to verbal stimuli
3	Drowsy but rapidly responds to glabellar tactile stimuli
4	Drowsy but slowly responds to glabellar tactile stimuli
5	Irresponsive to stimuli

Statistical Analysis: Comparison of parameters was done using One Way ANNOVA and categorical data

was compared using Chi-Square Test, P Value < 0.05 considered as statistically significant.

RESULTS

This prospective randomised controlled study was done in 60 ASA I and II patients of either sex aged between 18 to 60 years, posted for elective laparoscopic cholecystectomy under general anaesthesia. The study was undertaken to compare the efficacy of intravenously administered dexmedetomidine and paracetamol to attenuate the hemodynamic response during laparoscopic cholecystectomy and the adverse effects.

All the collected data were entered in Microsoft Excel spreadsheet, evaluated, compared and analysed using SPSS software version 26. Results were reported as mean+standard deviation, or proportions/percentages and presented in the form of table, graphs and charts as necessary.

Numerical variables (age in years, weight in kg, heart rate, blood pressure in mmHg, SpO₂) are entered as mean+standard deviation (SD).

For categorical variables, percentages are used (gender, ASA class, incidence of PONV, hypotension, bradycardia, pruritis, shoulder pain, rash

Table 1

Physiological effects of positioning	Trendelenburg	Reverse Trendelenburg
Cardiovascular:		
VR	↑	↓
CO	↑	↓
BP	↔	↓
Respiratory:		
Lung volumes	↓	↔
V/Q mismatch	↑	↔
Atelectasis	↑	↔

Table 1: Age wise distribution of study groups

Study Group	N	Range (years)	Mean ± Standard deviation	p-value	Significance
D	30	18 – 60	40.23 ± 10.76	0.919	Not significant
P	30	18 – 60	43.10 ± 11.51		
Total	60	18 – 60	41.65 ± 11.14		

Table 2: Comparison of groups on basis of mean body weight

Study Group	N	Range (years)	Mean ± Standard deviation	p-value	Significance
D	30	45 – 80	59.10 ± 13.21	0.998	Not significant
P	30	46 – 80	60.42 ± 12.22		
Total	60	45 – 80	59.78 ± 12.61		

Table 3: Comparison of groups on basis of ASA status

Study Group	ASA 1	ASA 2	TOTAL	p-value	Significance
D	15 (50%)	15 (50%)	30	0.710	Not significant
P	15 (50%)	15 (50%)	30		
Total	30 (100%)	30 (100%)	60		

Table 4: Comparison of groups on basis of Heart rate

Heart rate (beats per minute)	Group-D (n=30) (Mean ± SD)	Group-P (n=30) (Mean ± SD)	p-value	Significance
Base line	92.72 ± 15.45	92.80 ± 16.5	0.984	Not significant
5 min	90.70 ± 19.75	92.35 ± 15.6	0.720	Not significant
15 min	89.15 ± 16.68	92.55 ± 14.18	0.398	Not significant
30 min	86.80 ± 15.77	93.54 ± 13.44	0.180	Not significant
45 min	85.50 ± 13.83	92.00 ± 12.34	0.150	Not significant
60 min	82.15 ± 13.11	91.43 ± 13.48	0.095	Not significant

Table 5: Comparison of groups on basis of mean systolic blood pressure

SBP (mmHg)	Group-D (n=30) (Mean ± SD)	Group-P (n=30) (Mean ± SD)	p-value	Significance
Base line	124.00 ± 14.15	120.80 ± 15.32	0.404	Not significant
5 min	126.15 ± 20.40	116.10 ± 21.8	0.043	Significant
15 min	114.00 ± 19.75	120.91 ± 16.80	0.044	Significant
30 min	110.75 ± 14.90	125.57 ± 15.33	0.0003	Significant
45 min	112.30 ± 13.85	124.88 ± 14.17	0.0009	Significant
60 min	116.86 ± 10.91	125.35 ± 15.32	0.016	Significant

Table 6: Comparison of groups on basis of mean diastolic blood pressure

DBP (mmHg)	Group-D (n=30) (Mean ± SD)	Group-P (n=30) (Mean ± SD)	p-value	Significance
Base line	84.15 ± 11.32	83.78 ± 12.87	0.906	Not significant
5 min	82.90 ± 12.92	81.81 ± 11.11	0.727	Not significant
15 min	74.05 ± 16.75	76.25 ± 10.68	0.546	Not significant
30 min	82.95 ± 12.13	82.24 ± 8.70	0.795	Not significant
45 min	80.25 ± 9.51	82.59 ± 8.86	0.328	Not significant
60 min	79.86 ± 11.32	81.49 ± 14.34	0.626	Not significant

Table 7 : Comparison of groups on basis of mean arterial pressure

MAP	Group-D (n=30) (Mean ± SD)	Group-P (n=30) (Mean ± SD)	p-value	Significance
Base line	94.02 ± 15.15	93.89 ± 12.83	0.971	Not significant
5 min	92.76 ± 14.36	89.81 ± 12.25	0.395	Not significant
15 min	85.60 ± 17.30	87.98 ± 10.67	0.523	Not significant
30 min	91.29 ± 12.46	90.45 ± 11.2	0.075	Not significant
45 min	87.63 ± 13.01	89.76 ± 10.32	0.493	Not significant
60 min	87.03 ± 10.87	91.89 ± 10.76	0.087	Not significant

Table 8: Comparison of groups on basis of Oxygen saturation (SPO2)

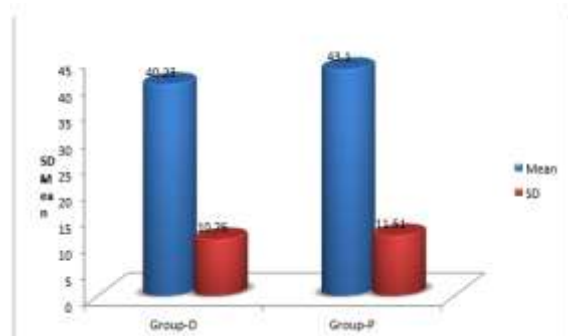
SPO ₂	Group-D (n=30) (Mean ± SD)	Group-P (n=30) (Mean ± SD)	p-value
Base line	98.6 ± 1.192	98.43 ± 1.104	0.576
5 min	99.07 ± 0.785	99.27 ± 0.74	0.314
15 min	99.1 ± 0.885	98.87 ± 0.73	0.270
30 min	99.2 ± 0.805	98.97 ± 0.85	0.280
45 min	99.1 ± 0.845	98.93 ± 0.868	0.454
60 min	99.1 ± 0.803	99.03 ± 0.702	0.309
	p-value <0.05 (Significant)		

Table 9: Modified Ramsay Sedation Score

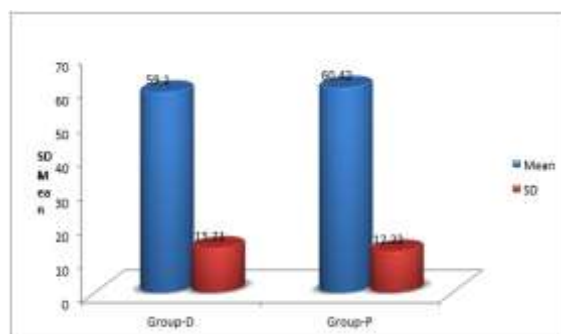
Study Group	N	Range (years)	Mean ± Standard deviation	p-value	Significance
D	30	3-4	3.10 ± 0.31	0.003	Significant
P	30	1-3	2.14 ± 0.70		
Total	60				

Table 10: Adverse effects

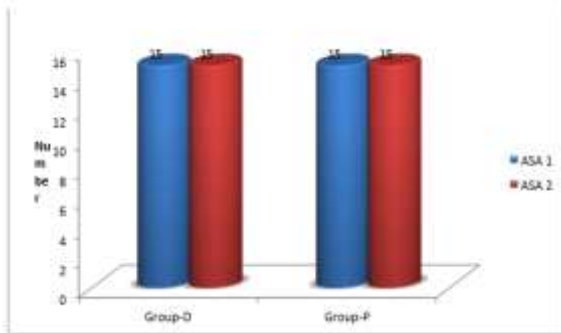
Adverse effects	Group - D		Group - P	
	No	%	No	%
Bradycardia	2	7	0	0
Hypotension	0	0	0	0
Nausea	0	0	0	0
Vomiting	0	0	0	0
Total	2	7	0	0



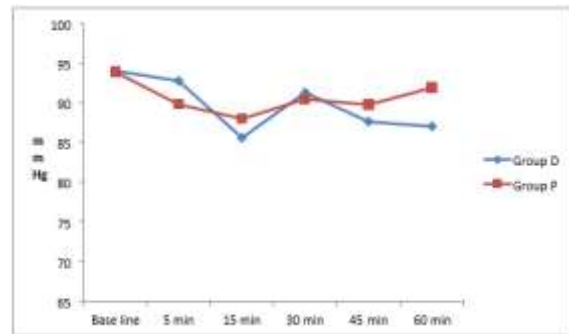
Graph 1: Age wise distribution of study groups



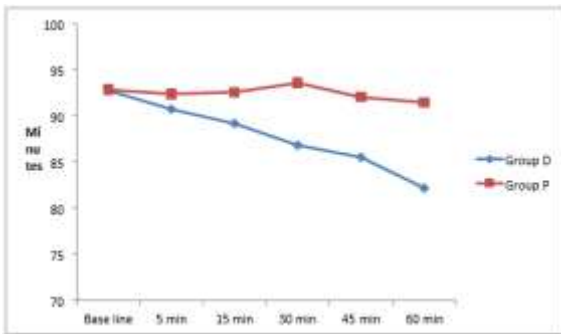
Graph 2: Comparison of groups on basis of mean body weight



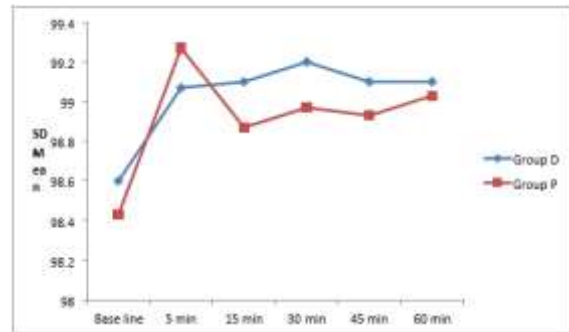
Graph 3: Comparison of groups on basis of ASA status



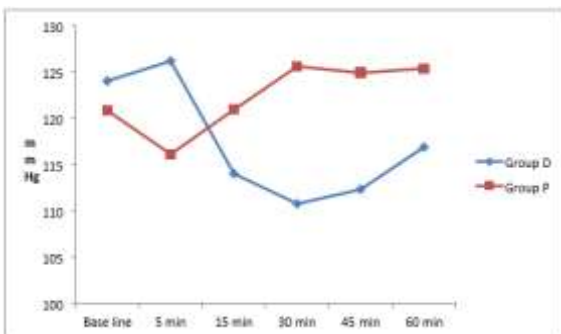
Graph 7: Comparison of groups on basis of mean arterial pressure



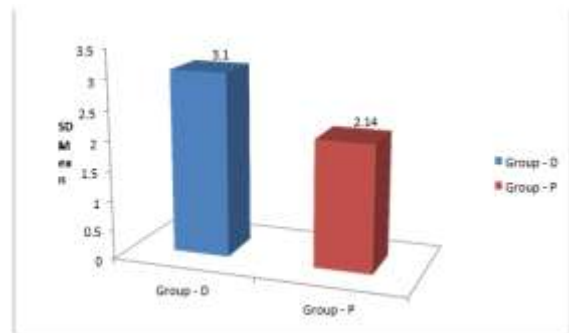
Graph 4: Comparison of groups on basis of Heart rate



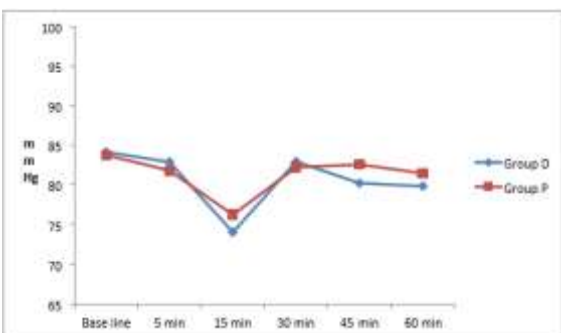
Graph 8: Comparison of groups on basis of Oxygen saturation (SPO2)



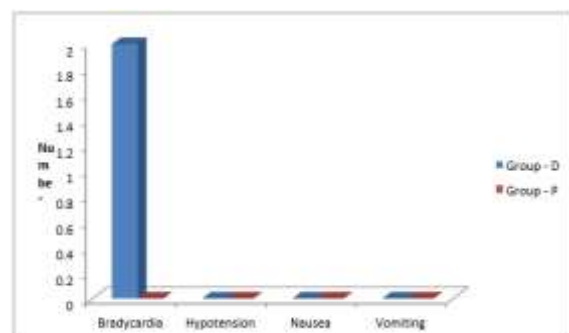
Graph 5 : Comparison of groups on basis of mean systolic blood pressure



Graph 9 : Modified Ramsay Sedation Score



Graph 6 : Comparison of groups on basis of mean diastolic blood pressure



Graph 10 : Adverse effects

All the data collected were entered in Microsoft excel spreadsheet, evaluated, compared and analysed using SPSS software version 31. Results were reported as mean \pm SD, or proportions/percentages are presented in the form of table, graphs and charts as necessary. The P-value in the distribution of age, weight, ASA status, SPO2, heart rate were not statistically significant. There was statistically significant fall in

systolic blood pressure noted in Group-D(P=0.020), whereas in diastolic blood pressure and mean arterial pressure there was no statistically significant difference in both Group-D and Group -P. Statistically significant difference observed in Modified Ramsay Sedation Scale between Group-D and Group-P(P=0.003). Dexmedetomidine was found to have significantly greater sedation than Paracetamol at the time of extubation.

Adverse Effects: There was severe bradycardia in 7% of Group-D patients. No other adverse effects were noted in both the groups.

DISCUSSION

Very few studies are available that compare intravenous dexmedetomidine with intravenous paracetamol infusion for attenuation of the haemodynamic responses to pneumoperitoneum during laparoscopic cholecystectomy.

Paracetamol due to its different mechanism of action interferes neither with platelet nor kidney function. Its analgesic action is not clear although its central level action has been hypothesized. Because of the lower adverse events compared to other NSAIDs, paracetamol be the preferred choice for perioperative baseline analgesia.

Dexmedetomidine, an α -2 adrenoreceptor agonist is being increasingly used in anaesthesia and critical care as they not only decrease sympathetic tone and attenuate the stress responses to anaesthesia and surgery, but also cause sedation, analgesia and anxiolysis. The bolus of 1 μ g/kg dexmedetomidine initially results in a transient increase of the blood pressure and a reflex fall in HR, especially in younger healthy patients. Given the propensity of the drug to produce hypotension and/or bradycardia when it is administered to volunteers or patients, it was important to determine an infusion rate that would maximise the anaesthetic and analgesic sparing effect although, minimising the occurrence of adverse cardiovascular side effects requiring therapeutic intervention.

Jung et al. in their comparative study showed significant advantage of dexmedetomidine at dose of 1 μ g/kg bolus. It is a safe sedative alternative to benzodiazepine or opioid combination in patients undergoing monitored anaesthesia care for a multitude of procedures because of its analgesic, co-operative sedation and lack of respiratory depression properties. Several findings lead to the conclusion that the major sedative and anti-nociceptive effects of Dexmedetomidine are attributable to its simulation of the α -2 adrenoreceptors in the locus coeruleus.

So, we have done a prospective randomised study to compare the effect of intravenous dexmedetomidine and paracetamol on haemodynamic response in patients undergoing elective laparoscopic cholecystectomy.

CONCLUSION

From the present study, it can be concluded that both regimes of dexmedetomidine and paracetamol were capable of controlling the haemodynamic status of patients undergoing laparoscopic cholecystectomy. However, paracetamol provides intra operative analgesia and haemodynamic stability with no sedation whereas dexmedetomidine provides analgesia and co-operative sedation.

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