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EFFICACY AND SAFETY OF PREMEDICATION WITH INTRAVENOUS DEXMEDETOMIDINE ON HAEMODYNAMIC CHANGES IN LAPAROSCOPIC CHOLECYSTECTOMY

Anaesthesiology

Dr Avinash Shastri H Assistant Professor Department Of Anaesthesiology, Adichunchanagiri Institute Of Medical Sciences BG Nagara Bellur Karnataka

Dr Vidya Rani M Assistant Professor Department Of Anesthesiology Kanachur Institute Of Medical Sciences, Mangalore

Dr Praveen S* Assistant Professor Dept Of Anesthesiology Shimoga Institute Of Medical Sciences, Shimoga *Corresponding Author

ABSTRACT

Background: Hemodynamic changes during the laparoscopy procedure collectively leads to a raised arterial pressure due to increased systemic vascular resistance and declined cardiac output. Several adjuvant drugs have been tried in this regard yet the mixed results have reported. **Objective:** To analyse the efficacy and safety of Dexmedetomidine as a pre-anaesthetic medication, to analyse the effect of it on haemodynamic parameters, postoperative analgesia and occurrence of adverse events. **Materials and Methodology:** 60 patients in each group. Group I: patients received dexmedetomidine by IV infusion at 0.2 µg/kg/hr intraoperatively after endotracheal intubation. This dose was prepared in a 50 ml syringe by mixing Dexmedetomidine 200 µg (2 ml) in 0.9% saline (38 ml) to make a total capacity of 40 ml (final concentration attained was 5 µg/ml). While Group II patients received 0.9% saline at the same rate. **Results:** The variation in blood pressure (BP), heart rate (HR) in Group II was significantly higher than Group I from 5th min till end of the procedure. 53.47±18.5 min (Group I) and 61.32±20.3 minutes (Group II) were the average duration of surgery. Hoarseness of voice was the commonest side effect in both. While cough at emergence was significantly higher in group II. **Conclusion:** Dexmedetomidine, as an adjuvant anaesthetic, provided significant intraoperative hemodynamic control, significantly better post operative pain analysis with no significant side effect. Also, the smooth recovery with lesser grade of cough on emergence during extubation.

KEYWORDS

Dexmedetomidine, Hemodynamic changes, Laparoscopic cholecystectomy.

INTRODUCTION

Laparoscopic cholecystectomy ranks among the most frequently performed minimally invasive surgeries. The growing success of laparoscopic procedures is primarily due to their ability to minimize disruption of homeostasis, reduce patient trauma, lower morbidity and mortality rates, shorten recovery time and hospital stays, and ultimately decrease healthcare costs.[1,2] Although it has many advantages, there are some challenges with its effective anaesthetic supervision. These difficulties stem primarily from the significant changes in Haemodynamics brought about by the interaction of the patient's position, anaesthesia and pneumoperitoneum

Additionally, a greater arterial pressure, pulmonary vascular resistance, increased systemic, and even lower cardiac output are all caused by the haemodynamic changes that occur throughout the laparoscopic surgery.[3] Propofol, isoflurane, β-blockers, and antihypertensives are examples of mediators that have been employed as an adjunct medications in order to minimise haemodynamic changes linked to laparoscopic surgery with varying response.[4,5] These drugs lessen the need for analgesics and sedative, lessen the incidence of myocardial ischaemia, enhance perioperative haemodynamic stability, offer sedation, enhance renal function, alleviate anxiety, and diminish the neurohumoral "stress response" associated with major surgery.[6] Clonidine's impacts of clonidine as an adjuvant are discussed extensively. while Dexmedetomidine is a novel highly selective α2-adrenergic agonist that boasts ten-fold better α2: α1 receptor selectivity and a briefer duration of action than clonidine. It is a dynamic dextro-isomer of medetomidine.[7]

With little to no respiratory depression, dexmedetomidine produces sedative, anxiolytic, hypnotic, sympatholytic, and analgesic effects. There have been reports that it reduces the need for anaesthetics and analgesics during surgery, however the effects of dexmedetomidine during laparoscopic cholecystectomy have not been well studied.[8,9]

Therefore, we carried out research to evaluate the safety and effectiveness of dexmedetomidine as a pre-anaesthesia drug, as well as its impact on haemodynamic parameters, BIS-guided extubation time, propofol demand, and incidence of side effects.

MATERIALS AND METHEDOLOGY

This research was undertaken by the Department of Anaesthesiology in collaboration with the Department of General Surgery at Shivamogga Institute of Medical Sciences.

Estimation of samples size was calculated by using the formula: $4pq/d^2$
The Prevalence of laparoscopic cholecystectomy procedure conducted at our institute per year is about 11% of all the surgeries. Based on the above formula, p prevalence: 11%; q --- (100-p); d is the allowable error, 5% error for the present study. Hence our sample size was, 39.16: approximately 39 in each group. As there were additional cases, during our study period, we included 60 patients in each group for better outcome analysis.

Patients with either gender in the age group of 18-60years who needed a laparoscopic cholecystectomy and who were in ASA 1 or 2 status and provided authorization to be included in the research were recruited. Institutional ethical clearance was taken and Patients who met the study's inclusion criteria were enlisted and a Signed informed consent was acquired after delivering a detailed explanation of the study procedure in an easily understood language.

The day of surgery, after a regular pre-anaesthetic check-up, patients were wheeled into the operating room. ASA standard monitors were connected baseline parameters were recorded and followed up every 5min till the end of the procedure. Following adequate preloading, patients were administered premedication with IV Injection midazolam 1-2 mg bolus and Glycopyrrolate 0.01 mg/kg. After preoxygenation for 3 minutes with 100% oxygen, induction agent for general anaesthesia was inj. propofol 2 mg/kg, O_2 and N_2O was used for maintenance after endotracheal intubation aided by IV inj. Atracurium 0.5 mg/kg as muscle relaxant. Applying computer-generated randomization, the research participants were allocated evenly into:
Group I Following tracheal intubation, patients were administered DEXMEDETOMIDINE intravenously at an infusion rate of 0.2 µg/kg/hr during the procedure. The solution was prepared in identical 50 ml syringes by mixing 200 µg of dexmedetomidine (2 ml) with 38 ml of 0.9% saline, resulting in a total volume of 40 ml and a final concentration of 5 µg/ml
Group II Patients were administered 0.9% NORMAL SALINE at an equivalent infusion rate.

Pneumoperitoneum was induced, with intra-abdominal pressure maintained at 12-14 mmHg for the duration of the surgery. Throughout the procedure, non-invasive blood pressure (NIBP) and heart rate were monitored at 5-minute intervals.

Definitions: Hypotension, NIBP < 20% of the baseline or systolic BP <

90 mmHg. Bradycardia, Heart rate < 20% of the baseline or dropping to less than 50 beats/min. 0.02 mg/kg atropine will be administered in such cases.

After extubating the time to response to verbal commands from the patients had been recorded. The adverse events like postoperative nausea and vomiting, bradycardia requiring rescue medication, cough level at the time of emergence, hoarseness of voice, agitation and any other incidents were recorded. All the parameters had been tabulated and analysed by using SPSS software by applying the suitable statistical tests.

RESULTS

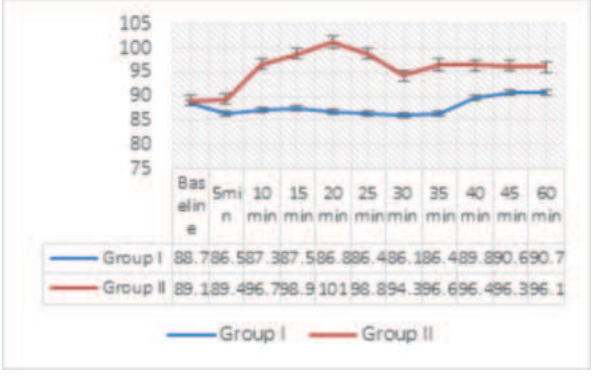
Table 1: Demographic Details And The Baseline Values

Parameters	Group I	Group II
Average age	46.73±8.6 years	45.5±3.8 years
Males	31 ()	33
Females	29	27
ASA 1	38	37
ASA 2	12	13
Average SBP	128.5±30.48	126.9±42.5
Average DBP	82.73±12.6	86.43±10.1
Average HR	78.6±6.3	80.4±3.7
Duration of the surgery	53.47±18.5 min	61.32±20.3 minutes

On comparing the basic parameters of the study population assigned to the two groups, we found no discernible differences.

Table 2: Variation In The Heart Rate

Time of assessment	Group I	Group II	P value
Baseline	78.6±6.3	80.4±3.7	0.62
5min	78.4±9.8	88.13±7.4	0.051
10min	76.9±10.2	88.4±10.1	<0.05
15min	80.3±8.5	92.18±10.32	<0.05
20min	82.1±8.5	92.29±9.8	<0.05
25min	78.6±10.1	94.54±8.77	<0.05
30min	84.5±9.8	95.11±10.1	<0.05
35min	82.3±9.8	94.27±9.4	<0.05
40min	80.6±9.14	94.82±9.26	<0.05
45min	80.5±9.32	94.6±9.16	<0.05
50min	82.3±9.57	93.68±10.09	<0.05
55min	82.3±9.31	94.2±9.31	<0.05
60min	81.4±8.86	92.7±9.09	<0.05



Graph 1: Variation In MAP At Baseline And 5 Minutes After The Pneumoperitoneum Formed, Till The End Of The Procedure SBP, DBP and hence the MAP remained to be elevated in Group II than group I, with significant difference.

Table 3: Incidence Of Adverse Outcome

Parameter	Group 1	Group II	P value
Required Atropine administration	1	3	0.47
Cough level at the time of emergence:			<0.05
0	28	18	
1	19	17	
2	13	25	
3	0	0	
Hoarseness of voice	7	7	0.14
Agitation	2	2	0.3
Nausea and vomiting	2	5	0.11

Group II saw a considerably greater incidence of coughing than Group I. There remained no considerable difference in the incidence of other side effects.

Table 4: Comparison of Post-operative VAS score

Post-operative duration	Group I	Group II	P value
2nd hour	3.3±0.9	3.8±0.6	0.091
4th hour	3.3±0.87	4.2±0.7	<0.05
6th hour	3.1±0.8	4.49±0.74	<0.05
8th hour	2.6±0.9	3.6±0.73	<0.05
12th hour	1.9±0.42	2.4±0.81	0.074
Average analgesic dose (Tramadol)	52.7±18.3	84.79±10.71	<0.05
Average drug administered in mcg/kg/min	65.7±8.3	97.4±10.2	<0.05

DISCUSSION

Laparoscopic cholecystectomy is still among the most commonly performed surgeries in the field of general surgery. When undergoing laparoscopic surgeries, patients need to undergo general anaesthesia. Haemodynamic fluctuations on-table and post-operative morbidity, mortality, and even pain perception is lower with laparoscopic surgery as opposed to open surgery. On the other hand, the positioning and pneumoperitoneum development necessary for the surgery may cause acid-base imbalance, issues with respiratory, neuroendocrine and cardiovascular systems.[10] In this regard, various anesthetic drugs and other manipulations in the conventional methods have been tried and very few have been successful.

Using Dexmedetomidine, which is an α_2 agonist drug modulating the transmission of nociceptive signals acting on both supraspinal and spinal level. The primary impact of this would involve alterations in the cardiovascular system, resulting in a reduction in heart rate and systemic vascular resistance, along with an added benefit of reducing the need for opioids. With this, we had conducted the present study by administering, dexmedetomidine by IV infusion at 0.2 µg/kg/hour intraoperatively after endo-tracheal intubation to Group I (Case group) and 0.9% normal saline (Control) for the other group. This was like the dose compared by Jan S et al.[11]

Khare et al had administered dexmedetomidine preloading 1 µg/kg then intra-operative infusion 0.6 µg/kg/hr as the test drug compared it with normal saline.[12] Unlike these, Qin Ye et al had compared the effect of dexmedetomidine 0.4 as D1, 0.6 in D2, 0.8 among D3 µg/kg against normal saline (NS).[9]

In the present study, there was no significant difference in baseline parameters between the group. On further analysis of the vitals, we found that the control group had significant raise in the heart rate as well as the mean arterial pressure from the 5th minute after intubation till the end of the procedure, compared to the patients administered with Dexmedetomidine but no significant raise from the normal blood pressure range was observed. Meanwhile one patient in group I and three patients in Group II had developed bradycardia, requiring IV inj Atropine 0.6mg as a rescue medication.

Like our observation, Jan S et al also observed that the HR, SBP and DBP of D_2 and D_3 groups has smaller fluctuations at T2-3 and T7 compared with NS and D_1 groups ($P < 0.05$).[11] The average pain score assessed by VAS was significantly reduced from the baseline from 2nd hour itself till 12 hours in Group I whereas in group II, the variation was yet on higher side reflecting Dexmedetomidine being the better agent in controlling post operative pain. Even in the Khare A. et al. trial, the control group's MAP rose noticeably over the baseline values after intubation and stayed above baseline throughout the whole investigation.[12] Srivastava VK et al had considered Esmolol as the comparative drug for Dexmedetomidine in maintaining the hemodynamic variation during the procedure, even they had observed a better control with Dexmedetomidine.[13]

In our study, the average drug used in postoperative analgesia in Group I and II were 65.7±8.3 and 97.4±10.2 mcg/kg/min respectively which indicated that the mean required dose of analgesics following dexmedetomidine infusion was significantly lesser. Similarly, in Khare A et al, 64.70 ± 9.81 and 94.04 ± 9.50 µg/kg/min were the required dose by the patients allocated in test and control group

respectively. As they had administered both pre- and intra-operative dose, the observed induction and intraoperative dose reduction were about 36% and 31%, respectively for test and control group.[12]

In our study, the cough level at the time of emergence among group I was distributed as, 28, 19 and 13 patients with level 0, 1 and 2 respectively whereas in group II it was 18, 17 and 25 patients with level 0, 1 and 2 respectively which was significantly higher. This score was obtained from the study by Sean C Minogue et al where the cough was graded based on a scaling system as Level 0: no cough; Level 1: mild, solitary cough; Level 2: moderate, recurrent cough, lasting more than five seconds, with no impact on extubation; Level 3: intense, persistent cough, extending more than five seconds, impacting extubation.[18] Seven patients each in both groups had hoarseness of voice, two each with agitation and two patients in group I and five in group II had nausea/vomiting, with no significant difference in the incidence. This could be due to the sedative and hypnotic effect of the drug.[12] In patients obtaining laparoscopic cholecystectomy, Qin Ye et al. discovered that intravenous infusion of 0.6μg/kg Dexmedetomidine prior to to induction can preserve haemodynamic stability, minimise cough at emergence, and mitigate postoperative discomfort.[9]

Compared to the NS group, coughing was less common in the D2 and D3 groups($P < 0.05$) in Jan S et al which is comparable with our findings.[11] Bhakri MH et al as well dexmedetomidine 1μg/kg before operation could reduce the overall incidence of PONV in patients undergoing the same surgery.[14] Tang C et al concluded that dexmedetomidine has better analgesic and anti-sympathetic effects.[19] Similarly, Ye Qin et al, the incidence of agitation in dexmedetomidine and normal saline group were, 0% vs. 6.67% respectively.[9] Kim SY et al, Mountain BW et al and Kang X et al also have reported the significant reduction in agitation among the patients who were administered with Dexmedetomidine.[15-17] One of the drawbacks of our study was that we did not assess the association between average propofol and dexmedetomidine requirement.

The reduction in the need for intraoperative anaesthetic and analgesic agents in patients premedicated with dexmedetomidine further highlights its role in enhancing overall perioperative management. This finding suggests that dexmedetomidine may contribute to improved recovery profiles and reduced postoperative pain, factors that can lead to shorter hospital stays and reduced healthcare costs

CONCLUSION

Dexmedetomidine when used as an adjuvant in premedication, provides optimum intraoperative hemodynamics during laparoscopic cholecystectomy, reducing perioperative fluctuations and enhancing surgical conditions. Patients benefited from improved haemodynamic control and smoother recovery, with no significant increase in adverse effects. These results support dexmedetomidine as a safe and effective option for optimizing haemodynamic stability in laparoscopic surgery. Future studies could further explore its role in other laparoscopic procedures and in different patient populations to expand its clinical applications.

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