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Study of Effect of Dexmedetomidine in Reducing Hemodynamic Responses to Generalanaesthesia during Laparoscopic Cholecystectomy

Dr.Keka Pandey[1] ,Dr.ArchanaRoy[2],Prof.Dilip Adhikari[3] ,Dr.ShrawanSoni[4].

[1] Post Graduate student,Department of Anaesthesiology, Nil RatanSircar Medical College, kolkata

[2] Assistant Professor, Department of Anaesthesiology, Nil RatanSircar Medical College, Kolkata

[3] Professor and Head of the Department of Anaesthesiology, Nil RatanSircar Medical college, Kolkata

[4] Post Graduate student, Department of Anaesthesiology, Nil RatanSircar Medical College, kolkata

Corresponding Author : Dr.Archana Roy

Address of Corresponding Author :15/1B, Ultadanga Road, Kolkata, Pin – 700004, West Bengal

Email: roy.archana23@yahoo.in

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BACKGROUND: Laparoscopic cholecystectomy under general anaesthesia is associated with unique hemodynamic changes due to sympathoadrenal response .Dexmedetomidine , a highly selective α2 adrenergic agonist, with hypnotic, sedative, anxiolytic, analgesic and sympatholytic properties is being used nowadays to attenuate this. An optimum dose of this drugasadjuvant during general anaesthesia is yetto decide**:**
Aim: To study the effects of Dexmedetomidineat a lower dose to provide perioperative hemodynamic stability, sedation and analgesiaduringlaparoscopiccholecystectomy.
Alsoto see any adverse effects.
Methodology: Two hundredASA I and II patients of either sex, aged 18-60 years, posted for elective laparoscopic cholecystectomy were randomly allocated into two groups of hundred patientseach.GroupApatientsreceived intravenous Dexmedetomidine as loading does of 0.8 microgram/ kg over 10 minutes before induction as premedication followed by 0.4 microgram/ kg/ hour continuous infusion till completion of surgery while, the GroupBpatients received same dosage of normal saline at the same rate for the same duration through infusion pump.Heart rate, non-invasive blood pressure (SBP,DBP,MBP) and SpO2 were measured at the following times: before induction as baseline, after loading dose of dexmedetomidine, just after intubation, after 15 minutes of pneumoperitoneum and every 15 minutes thereaftertillcompletionofsurgery, just after infusion stopped and at the 1st, 2nd and 3rd postoperative hours, in group A and B, respectively. Sedation was assessed byRamsey sedation score (RSS)at 1, 15, 30 ,45, and 60 min postoperatively. The time to first request of rescue analgesia and total analgesic drug requirement in the first 24 h post operatively were also noted down.
Results: For statistical analysis SPSS (version 25.0) was used.It has been found that dexmedetomidinehas significantly reduced heart ratesystolic, diastolic and mean arterial pressures in group A patients as compared togroup B patients.
Conclusion: Dexmedetomidine effectively attenuatessympathoadrenal response and maintains hemodynamic stability in intra and postoperative period during laparoscopic cholecystectomy.
Keywords: Dexmedetomidine,laparoscopiccholecystectomy,hemodynamicstability,general anaesthesia.

I. INTRODUCTION

Laparoscopic cholecystectomy is one of the most frequently performed laparoscopic surgeries nowadays. Since the introduction of diagnostic laparoscopic surgery in the early 1970s

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and the first laparoscopic cholecystectomy proceduresbyPhillipeMouret in 1987laparoscopy has expanded impressively both in scope and volume. Increasing success of laparoscopic surgery can be attributed to the fact that it results in multiple benefits compared with open procedures, such as less trauma to patient, disturbance of homeostasis, morbidity, mortality, recovery time and hospital stay[1]. Nowadays efforts have been made to use the laparoscopic approach for gastrointestinal (e.g., colonic, gastric, splenic, hepatic surgery), gynecologic (e.g., hysterectomy), urologic (e.g., nephrectomy, prostatectomy), and vascular (e.g., aortic) procedures and are being done with variable success.

Laparoscopic cholecystectomy under general anaesthesia is also associated with various stress responses due to anaesthesia,pneumoperitoneum and the surgery itself[2, 3] .

Till today general anaesthesia is the preferred method for laparoscopic procedures. Despite multiple benefits, any laparoscopic surgery always poses a challenge to its successful management[4] .During general anaesthesia stress and sympathetic stimulation may occur at the times of laryngoscopy, intubation and extubation.Creation of Pneumoperitoneum and resultant increased intra-abdominal pressure is immediately followed by an increased plasma renin activity and increase in plasma levels of norepinephrine and epinephrine.[4]The renin–angiotensin–aldosterone system is also activated. All these changes collectively lead to an elevated arterial pressure, increased systemic and pulmonary vascular resistance, and decreased cardiac output.The hemodynamic changes predispose the myocardium to ischemia that may be life threatening.

In modern anaesthesia different drugs have been used to prevent sympathetic discharge and to attenuate hemodynamic responses perioperatively.Drugs like isoflurane, propofol, β-blockers, and various antihypertensive have been used for this purpose with variable response [5, 6 ,7] . Effects of α2-adrenergic agonist clonidine have also been studied widel[8,9 , 10].These may reduce anaesthetic and analgesic requirements,provide sedation and anxiolysis, and attenuate neurohumoral "stress response" of major surgery. Thereby they promote perioperative hemodynamic stability, reduce myocardial ischemia and improve renal function . These may reduce circulating catecholamines level during surgery.[11]

Dexmedetomidine, which is the pharmacologically active dextro-isomer of medetomidine, is a newer highly selective α2-adrenergic agonist, approved by Food and Drug Administration (FDA) in 1999[16,17]. It has a ten-fold greater α2: α1 receptor selectivity and has a shorter duration of action than clonidine. It possesses hypnotic, sedative, anxiolytic, sympatholytic, and analgesic properties without producing significant respiratory depression. It also diminishes intraoperative requirement of analgesics and anaesthetics (including propofol). These properties have made it theoretically a suitable agent for use as a part of an anaesthetic regimen.[12-14]. Intravenous use of dexmedetomidine in the perioperative period had been found to decrease serum catecholamine levels and blunt the hemodynamic responses to laryngoscopy, endotracheal intubation, pneumoperitoneum and extubation, and provide sedation without causing significant bradycardia, hypotension, respiratory depression and postoperative nausea-vomiting; It has analgesic and anaesthetic sparing effects and decreases the intra and post-operative analgesic requirements also[15, 16] . However, when used in dosage 1 mcg/ kg body weight as loading dose and 0.5 mcg/kg as maintenance of anaesthesia incidence of hypotension, bradycardia and respiratory depression are much more . Search for an optimum dose of the drug that would produce maximum desired effect without causing significant adverse effect is going on. In this present study we have used lower loading and maintenance dosageofdexmedetomidine to get the desired effect without having significant side effects.

II. AIM ANDOBJECTIVE:

The aim of the present study is to study the effects of Dexmedetomidine to provide perioperative hemodynamic stability,sedation and analgesia and its adverse effects, like, hypotension, bradycardia or postoperative respiratory depression when used as an adjuvant to general anaesthesia in elective laparoscopic cholecystectomy.

III. METHODOLOGY:

The present study is a prospective randomized double blind placebo controlled observational study carried out in Nil Rattan Sircar Medical College Kolkata from to .After obtaining approval from the institutional ethical committee two hundred adult patients of either sex , aged between 18 to 65 years ,American Society Of Anaesthesiologists Physical status l and llscheduled for laparoscopic cholecystectomy under General anaesthesiawereselected and randomlyallocated into either of two groups : Group A and Group B

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,each having 100 patiens. Randomization was done using a sealed envelope technique.Written informed consent was obtained from each of them. Group: A received intravenous Dexmedetomidine as loading does of 0.8 microgram/ kg over 10 minutes before induction as premedication followed by 0.4 microgram/ kg/ hour continuous infusion till completion of surgery from the abdominal cavity by the surgeon, while, the Group: B received same dosage of normal saline at the same rate for the same duration through infusion pump

After overnight fasting,patients were taken in operation theatre. An intravenous access was done and an multichannel monitor attached for basic monitoring of heart rate (HR),non-invasive blood pressure (NIBP) , ECG and oxygen saturation (SpO_2). Balanced general anaesthesia was given for all the patients. Every patient received premedication with 0.2 mg glycopyrrolate intravenous, 2 microgram/ kg fentanyl and 4 mg ondansetron intravenously before induction of anaesthesia

Every patient waspreoxygenatedwith100% oxygenation for 3 minutes. Induction was achieved with intravenous Propofol 2mg/kg bodyweight.Laryngoscopy and intubation were facilitated by succinylcholine2 mg/ kg of body weight.Muscle relaxation was maintained with vecuronium 0.1mg/ kg thereafter. The lungs were ventilated by maintaining a tidal volume of 7ml/ kg, a frequency of 14 breaths/ minute and an EtCO2 of 25-40 mm of Hg with 70 percent nitrous oxide and 30 percent of oxygen and Isoflurane 0.4% in a closed circuit. In group A, IV dexmedetomidinewas given at 0.8 mcg/ kg over 10 minutes before induction. After induction of anaesthesia, injection dexmedetomidine 0.4 mcg / kg was continued as maintenance till completion of surgery, while on the other hand, in group B, same dose of preloading and continuous infusion of normal saline was given. Heart rate, non-invasive blood pressure (systolic,diastolic and mean) and oxygen saturation (SpO2) were measured at the following times: before induction as baseline, before induction after loading dose of dexmedetomidine, just after intubation, after 15 minutes of pneumoperitoneum and every 15 minutes during surgery till its completion, just after infusion stopped and at the 1^{st}, $2^{nd}$and 3^{rd} postoperative hours, in group A and B, respectively. Isoflurane was stopped 10 minutes before the end of surgery in both the groups. After completion of surgery, the neuromuscular blockade was reversed with 0.05 mg/kg neostigmine and 0.004 mg/kg glycopyrrolate. All the patients were extubated after full satisfaction of patient recovery i.e., ability to open eyes, follow verbal commands, maintain regular breathing pattern and were shifted to recovery room and monitored for haemodynamic, sedation, and requirement of supplemental analgesia. The time of first request of rescue analgesia has been recorded. For rescue analgesiainjectiondiclofenacsodium 1.5mg/kg was administered intramuscularly when visual analogue score was more than 4 .Total analgesic consumption of every patient in the first 24 hourspost operatively has been recorded.The degree of sedation was assessed in the postoperative period using the 6 point Ramsay sedation scale (RSS) at 1,15,30 ,45 and 60 min post operatively.Perioperativelypatients were also observed for any side effects, such as respiratory depression, bradycardia, hypotensionornausea and vomiting.

Table 7 : Ramsey Sedation Score :

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Score	Description
1.	Anxious and agitated or restless
2.	Cooperative, oriented, tranquil
3.	Drowsy but responds to command only
4.	Asleep with brisk response to glabellar tap
5.	Asleep with sluggish response to glabellar tap
6.	No response

Statistical analysis: All the data collected was subjected to analysis using statistical software package. Quantitative data were expressed in terms of mean, median and standard deviation (SD) and compared among both the study groups using unpaired 't' test or Mann Whitney test or ANOVA test. Qualitative data of both groups have been expressed in percentageandcompared usingchi square test.Pkopvalue< 0.05 was considered significant.

IV. RESULTS:

Table1: Demographic profile

	Group A	Group B	P value	Significance
Age (years)	35.94± 9.00	36.04 ±10.18	0.9414	NS
Sex(M/F)	68/32	72/28	0.5370	NS
BMI (kg/m^2)	22.02±1.52	22.22±1.45	0.3598	NS
ASA (I/II)	48/52	52/48	0.5716	NS

Table 1 shows that both the groups under study were comparable to each other withrespect to demographic parameters such as age,sex, body mass index (BMI)and ASA grade(P value >0.05).Duration of surgery were also comparable between the study groups.

Table 2 Changes in the Heart Rate (beats/min)

Time	Group A	Group B	P value
Baseline	83.45 ± 3.53	85.05 ± 3.47	0.0015
Before induction	81.25 ± 2.28	85.35 ± 4.50	< 0.0001
After intubation	82.65 ± 1.53	89.75 ± 6.65	< 0.0001
AfterPneumoperitoneum:			
15 min	82.70 ± 1.05	84.60±9.13	0.0402
30min	82.45 ± 1.99	83.90 ± 5.55	0.0150
45 min	82.90 ± 1.64	85.50± 9.41	0.0071
60 min	81.80 ± 2.55	86.31 ± 4.72	< 0.0001
75 min	81.83 ± 1.63	83.07 ± 7.36	0.2036
90 min	82.± 2.43	85.10 ± 3.94	0.0001
After operation	82.25 ± 1.90	91.10 ± 3.52	< 0.0001
Post-operative:			
1 hour	81.90 ± 2.41	86.70 ± 2.82	< 0.0001
2 hour	82.45 ± 1.66	85.55 ± 3.47	< 0.0001
3 hour	81.15 ± 2.29	83.25 ± 3.92	< 0.0001

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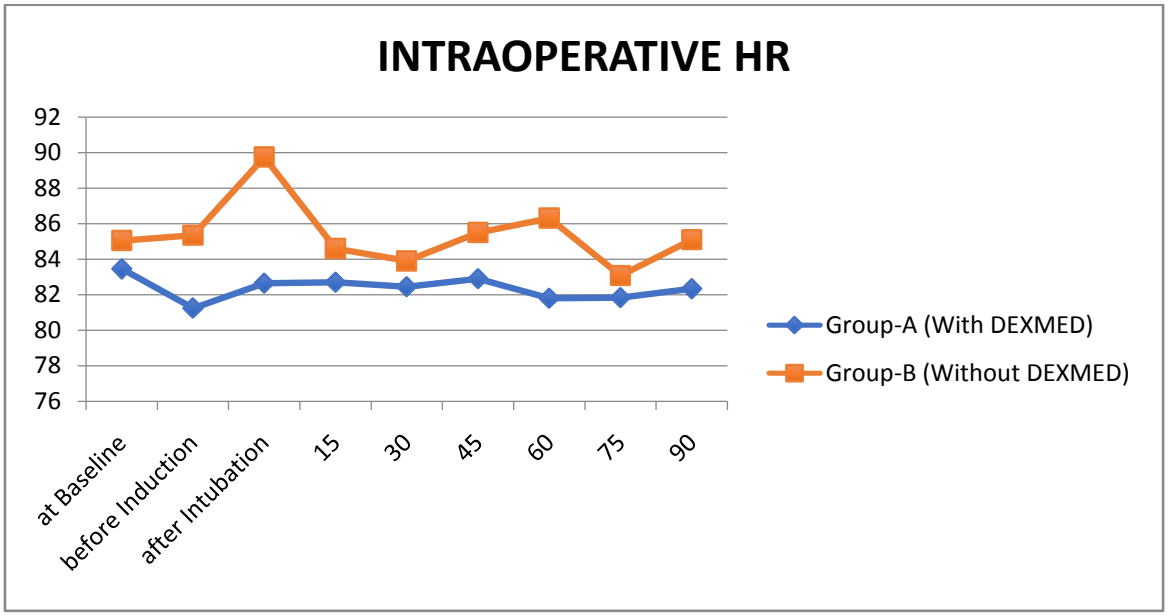

As shown in table 2 baseline heart rate (HR) before starting any infusion were comparable between the study groups.After starting the infusion patients in group B (Normal saline group) did not show any significant changes in the Mean HR before induction, after intubation,duringpneumoperitoneum, after operation and also in the postoperative period

On the other hand,HRdecreased significantly in group A patients (dexmedetomidinegroup)before induction, afterincubation, during pneumoperitoneum and after operation. The value of HR remained decreased in the postoperative period also for at least 3hrs.

Table 3: Changes in the Systolic blood Pressure (SBP)

Time	Group A	Group B	P value
Base line	131.80 ± 7.65	127 ± 9.08	0.0001
Before induction	127.05 ± 6.37	130.10 ± 10.16	0.0118
After intubation	125.10 ± 4.80	138.70 ± 9.92	< 0.0001
After Pneumoperitoneum:			
15 min	124.30 ± 5.21	140.25 ± 8.22	< 0.0001
30 min	122.40 ± 5.13	141.35 ± 7.37	< 0.0001
45 min	120.35 ± 5.58	144.55 ± 6.84	< 0.0001
60 min	122.17 ± 6.28	135.00 ± 818	< 0.0001
75 min	122.58 ± 7.01	135.33 ± 14.69	< 0.0001
90 min	130.00 ± 1.53	129.88 ± 16.68	0.9688
After operation	124.45 ± 5.76	143.00 ± 10.15	< 0.0001
Post-operative			
1 HR	122.15 ± 5.72	141.25 ± 8.99	< 0.0001
2 HR	121.10 ± 5.63	142.80 ± 8.81	< 0.0001
3 HR	119.40 ± 5.85	135.30 ± 10.70	< 0.0001

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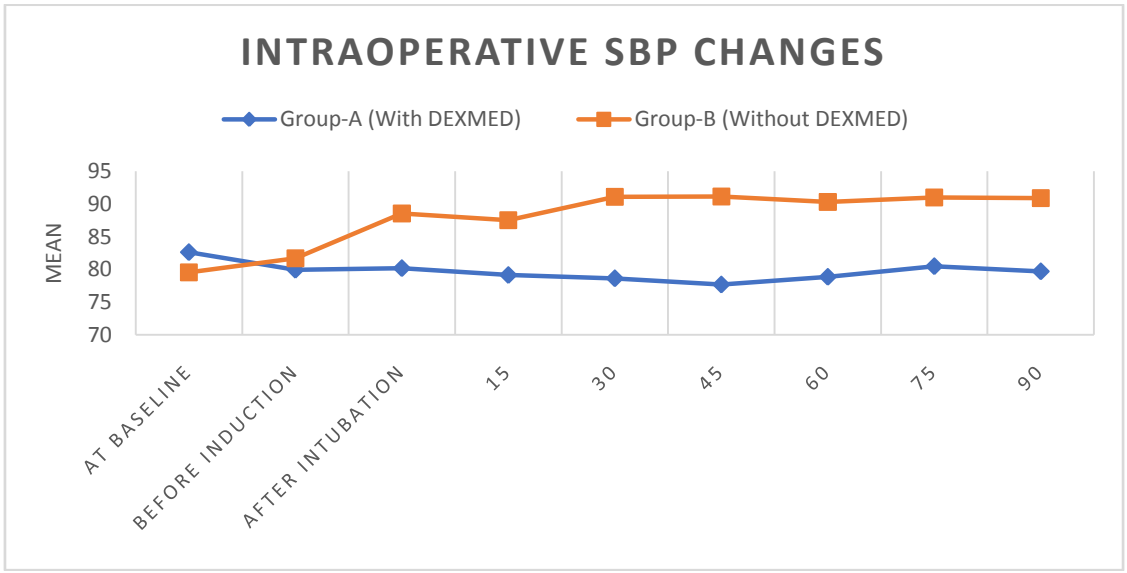

The value for mean SBP before starting the infusion were comparable between the study groups. (Table 3). In group B (NS group)mean SBP did not show any significant change before induction but there was a significant rise in mean SBP after intubation and after pneumoperitoneum.The mean SBP in group B remained in that same high level throughout the period of pneumoperitoneumand after operation also. The value returned to normal after 2 hrs in the postoperative period. On the other hand, in group A (dexmedetomidine group) there was a significant fall in mean SBP value (lesser than preinfusionvalues) when measured before induction (After having drug infusion for 10 min), of anaesthesia. The fall in mean SBP value was maintained even after intubation and after pneumoperitoneum,after operation and till 3 hours in the postoperative period in comparison to preinfusionvalues.So, there was better control of SBP in Group A (dexmedetomidine) in comparison to group B (NS).

Table 4 : Changes in diastolic blood pressure (DBP)

Time	Group A	Group B	P value
Baseline	82.65 ± 4.04	79.55 ± 6.63	0.0001
Before induction	79.95 ± 3.24	81.70 ± 8.95	0.0677
After intubation	80.20 ± 2.09	88.55 ± 7.72	<0.0001
After pneumoperitoneum:			
15 min	79.15 ± 2.82	87.55 ± 7.30	< 0.0001
30 min	78.65 ± 3.76	91.10 ± 7.45	< 0.0001
45 min	77.70 ± 4.32	91.15 ± 7.12	< 0.0001
60 min	80.50 ± 2.19	91.00 ± 4.39	< 0.0001
90 min	79.71 ± 4.12	90.88 ± 4.16	< 0.0001
After operation:	80.50 ± 3.04	98.10 ± 7.71	< 0.0001
Postoperative:			
1 hour	78.70 ± 3.43	91.10 ± 6.83	< 0.0001
2 hour	77.30 ± 3.24	88.65 ± 4.70	< 0.0001
3 hour	76.05 ± 4.00	84.25 ± 5.52	< 0.0001

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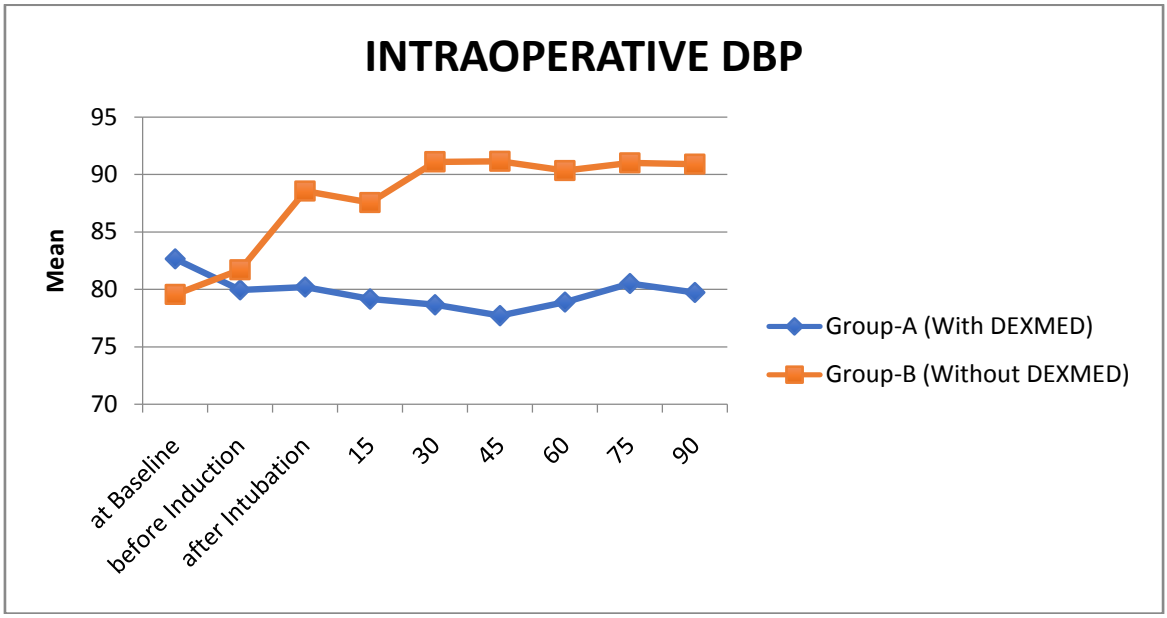

Table 4 shows the values of mean DBP recorded at different periods . It snows that there was a significant rise in mean DBP in group B (NS)after Intubation , after pneumoperitoneum, after operation and till 2 hours in the postoperative period. Thereafter it started to come down towards baseline value. On the other hand, in group A (dexmedetomidinegroup) there was a significant fall in mean DBP values (lesser than preinfusion baseline values) after induction. The fall in mean DBP value persisted even after intubation, duringpneumoperitoneum, after operation and till 3 hours in the postoperative period.

Table 5: Changes in Mean Arterial Pressure (MAP)

Time	Group S	95.45 ± 7.19	< 0.0001
Before induction	95.60 ± 3.48	97.90 ± 8.61	0.0142
After intubation	95.20 ± 2.57	105.40 ± 7.78	< 0.0001
After Pneumoperitoneum			
15 min	94.30 ± 3.11	105.05 ± 6.73	< 0.0001
30 min	93.25 ± 3.52	107.95 ± 6.59	< 0.0001
45 min	92.00 ± 3.46	108.85 ±.21	< 0.0001
60 min	93.05 ± 4.11	105.43 ± 5.81	< 0.0001
75 min	94.58 ± 3.12	105.50 ± 5.51	< 0.0001
90 min	96.42 ± 3.24	104.66 ± 9.13	< 0.0001
After operation:	95.15 ± 3.85	112.30 ± 7.99	< 0.0001
Postoperative:			
1 hour	93.20 ± 3.79	107.80 ± 6.15	< 0.0001
2 hour	91.95 ± 3.71	107.20 ± 4.31	< 0.0001
3 hour	90.50 ± 22	100.40 ± 3 5.72	< 0.0001

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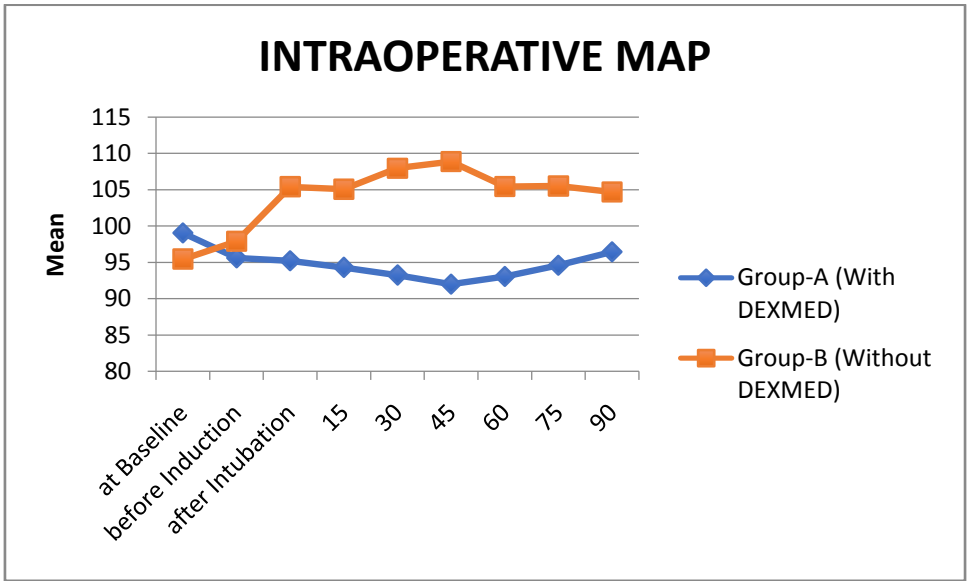

Table 5shows mean MAPrecorded at different points in both groups.It is evident from the table that baseline mean MAP values were comparable between the study groups. After starting the infusion, in group B (NS group) there was no significant change till before intubation. But there was a significant rise in mean MAP value noted after intubation, after and during pneumoperitoneumandalsoafteroperation. The rise in mean MAP noted till 2 hours in the postoperativeperiod. Thereafter it started to come down towards baseline value.

On the other hand, in group A (dexmedetomidinegroup) mean MAP values were significantly less than preinfusion baseline values before induction that is after receiving 10 min dexmedetomidine infusion. It remained significantly less even after intubation, after pneumoperitoneum and after operation till 3 hours in the postoperative period.

Table 6: Postoperative Ramsey sedation score (RSS):

Group	Time after extubation(min)	Number of patients (%)					
		RSS 1	RSS 2	RSS 3	RSS 4	RSS 5	RSS 6
Group A	1	5(5)	31(31)	48(48)	16(16)	0	0
	15	10(10)	26(26)	55(55)	9(9)	0	0
	30	15(15)	42(42)	45(45)	0	0	0
	45	24(24)	3 (63)	13(13)	0	0	0
	60	28(28)	68(68)	4(4)	0	0	0
Group B	1	62(62)	28(28)	10(10)	0	0	0
15	32(32)	50(50)	18(18)	0	0	0	
30	40(40)	55(55)	5(5)	0	0	0	
45	65(65)	35(35)	0	0	0	0	
60	85(85)	15(15)	0	0	0	0	

Table 6 shows the postoperative Ramsey sedation score (RSS) of both groups. RSS score of maximun3 is noted in group B (NS group) and it is 4 in group A (

Dexmedetomidinegroup). None of the patient in either group had RES score 5 or 6. In group B maximum RSS score of 3 was noted in 10% patients in 1st min and 18% patients at 15th min postextubation. In group A (dexmedetomidine group) maximum RSS score of 4 was noted in 16% patients at 1st min and 9% patients at 15th min postextubation.

The adverse effects like vomiting was noted in 5 patients in Group A (dexmedetomidine group). There was no such effect noted I group B (NS group). There was no incidence of any other adverse effects like respiratory depression, hypotension and bradycardia noted in either grou

V. DISCUSSION:

Hemodynamic changes are frequently observed in patients undergoing laparoscopic surgeries mainly during, pneumoperitoneum, reverse Trendelenburg9position and also during extubation . Patients with normal cardiovascular function can tolerate these changes but patients with marginal cardiovascular function can suffer from complications. These adverse hemodynamic changes can be abolished with dexmedetomidine infusion and thus can prevent complications. This advantage of dexmedetomidine is due to the fact that it reduces the release of catecholaminesduring laparoscopic surgeries under general anaesthesia and thus attenuates increase in systemic vascular resistance and heart rate.

Dexmedetomidine, as discussed previouslyis a highly selectiveα2-adrenergic agonist . It acts through 3 types of with sedative anxiolytic ,analgesic , sympatholytic and antihypertensive effectsα2receptors namely α2A, α2B and α2C situated in brain and spinal cord. The resultant actions aresedation ,anxiolytic, analgesia and sympatholysis leading to hypotension and bradycardia. α2A receptors are present in the vasomotor centre of brainstem and when stimulated by the dexmedetomidine there is suppression of release of norepinephrine resulting in hypotension and bradycardia. Similarly, stimulation of α2A and α2C receptors by dexmedetomidinein locus ceruleusof brain causes sedation . In the spinal cord , stimulation of α2A and α2C by the action of dexmedetomidine reduces release of substance P and thus reduces transmission of pain . Stimulation of α2B receptors in vascular smooth muscles is also responsible for fall in BP observed with dexmedetomidine.

Based on these pharmacological properties the drug dexmedetomidine has been evaluated in the past bymany researchersto asses it's effects on hemodynamic responses during laparoscopic surgeries. It has been used as infusion throughout the duration of surgery with or without a bolus dose. Various infusion rate have been used by different researchers ranging from 0.1 to 10mcg / kg / h. However , higher infusion rate have been found to be associated with higher incidences of adverse effects.

In the present study the two groups under study were comparable to each other with respect to age sex BMI and ASA physical status. Here we have used a lower dose infusion along with bolus dose of dexmedetomidine so that desired action is obtained with less adverse effects. It is confirmed from this study that critical events during laparoscopic cholecystectomy such as laryngoscopy and intubation ,pneumoperitoneumand extubation is associated with significant hemodynamic changes and rise in Heart Rate and BP was seen in group B (NS group).Similar results have also been observed by Bhattermeeet al and Bhagat et alintheirstudies[13, 14.]Dexmedetomidine has been found to effectively attenuatethesehemodynamicchanges and provide stability. Similar results of dexmedetomidine on intraoperative hemodynamic are also observed by Reddy et al [15] Kakkeret al[16]and Panchgar et al[17]These studies also observed it's opioid sparing effect as the drug hasbeen found to reduce intraoperative and postoperative opioid requirement.

In our study , we have observed that dexmedetomidine has some sedative effect also which is due to the stimulation of α2A and α2C receptors by dexmedetomidine in locus ceruleus of brain. Sedation has been assessed by using Ramsey Sedation Scale (RSS) (Table 6) at 1, 15 30 ,45 and 60 min postoperative. (that is one hour postoperatively). Majority of the patients in Dexmedetomidine group i.e. group Aimmediatelyafter extubationhad RSS three whereas majority of patients without dexmedetomidine (group B) had RSS of one. This effect of dexmedetomidine is mainly dose dependant.[18].Complications like vomiting was obsered in only five patients in group A (dexmedetomidine group). No other complications such as bradycardia, hypotension or respiratory depression has been observed in any patientwhich can be explained by the lower bolus and maintenance dose of the drug used in the present study.

Conclusion: Dexmedetomidine in a lower dose as an adjuvant to general anaesthesia in laparoscopy cholecystectomy can provide stable hemodynamic responses both intra and postoperative period with minimum side effects.

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