Original Article

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Effect of Oral Moxonidine and Oral Clonidine in the Attenuation of the Hemodynamic Responses Seen During Laparoscopic Cholecystectomy - A Comparative Study

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Abstract

Background: Pneumoperitoneum created for laparoscopic surgeries result in various pathophysiological changes in the body especially on endocrine and cardiovascular system. Moxonidine, a newer drug acts selectively on imidazoline I1 receptor as agonist with weak α2 agonist. Its site of action mainly in the rostral ventrolateral medulla (RVLM) in medulla oblongata, locus of CVS regulatory center situated. It reduces central sympathetic outflow causing the reduction in blood pressure and heart rate. Clonidine is a selective α2 adrenergic agonist has beneficial effect of blunting hemodynamic responses due to intubation and pneumoperitoneum through its sympatholytic effects. This study compares the effect of oral Moxonidine versus oral Clonidine in attenuating hemodynamic responses to intubation and Pneumoperitoneum during laparoscopic cholecystectomy under general anaesthesia. **Subjects and Methods:** A total of 62 patients of ASA, PS I&II in the age group of 20-60 years of either sex scheduled for elective laparoscopic cholecystectomy were chosen for this prospective randomized double blind comparative study. They were randomly allocated to 2 groups, The Moxonidine (M) Group and The Clonidine (C) Group. Moxonidine Group receives Tab Moxonidine 0.2mg, 1 hour before induction and clonidine Group receives Tab clonidine 100mcg 1 hour before induction. Measurements: Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Oxygen Saturation (SpO_2) measured at the points of preoperative (baseline), at induction, after induction, after intubation, before pneumoperitoneum, 5, 10, 20, 30, 40, 50, 60 minutes after pneumoperitoneum, after end of pneumoperitoneum and after extubation. **Results:** The comparison of vital parameters (HR, SBP, DBP, MAP) showed, significant reduction in HR, SBP, DBP, MAP in both groups (raise was not more than 20% from baseline) after intubation and pneumoperitoneum without any significant side effects. Clonidine caused reduction in SBP, DBP, MAP compared to Moxonidine ($p<0.05$), which was statically significant. But difference in HR among two groups was not statistically significant. There was no complication noted in the study. Both the drugs were found to be safe. Thus we found that clonidine premedication is better drug for lap cholecystectomy than Moxonidine. **Conclusion:** The Study drugs Moxonidine and clonidine as premedication, found to bring perioperative hemodynamic stability in ASA 1&2 patients, during pneumoperitoneum. And Clonidine is more effective drug than Moxonidine in maintaining stable hemodynamics during pneumoperitoneum in laparoscopic cholecystectomy.

Keywords: Pneumoperitoneum, Moxonidine, Clonidine, Laparoscopic cholecystectomy, Hemodynamic response.

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Introduction

Laparoscopic surgeries have become the essence of core surgical practice in the present era. Laparoscopy is characterised by better maintenance of homeostasis in comparison to open procedures. Laparoscopic surgeries provides substantial advantages of less post-operative pain, reduced hospital stay, small scar for better aesthetics and early healing, better postoperative respiratory and gastrointestinal function.[1,2]

However the procedure is not devoid of its own cons, as it can create a set of hemodynamic changes due to creation of CO2 pneumoperitoneum which can bring erratic physiological changes on cardiovascular and respiratory system, which can be detrimental. These changes are not usually encountered with traditional open procedures which can pose great challenges to anaesthesiologists.[2]

So it is imperative to attenuate these effects to carry out the procedures safely. Since the advent of pneumoperitoneum newer drugs have been kept emerging in order to use to attenuate these responses. Moxonidine and clonidine have

been used and found useful for this purpose.[3,4,5,6]

Moxonidine is a relatively newer drug and used as antihypertensive. It has a weak affinity for alpha -2 adrenoceptor and stimulate imidazoline type 1 receptor in CVS regulatory center located at the medulla oblongata in the narrow space of rostral ventrolateral medulla (RVLM). Selective stimulation of imidazoline receptor inhibit central sympathetic activity which brings the reduction in blood pressure.[7,8,9]

Clonidine is an alpha-2 adreno receptor agonist. It has sympatholytic effect along with sedative and analgesic properties. Hence the beneficial effect of blunting hemodynamic response due to pneumoperitoneum. In addition, clonidine acts on cardiac baroreceptor reflex sensitivity and brings stability in blood pressure5. Hence this study was designed to assess effect of oral Moxonidine and clonidine in attenuation of hemodynamic responses seen during laparoscopic cholecystectomy.

Subjects and Methods

Source of data

Present study was conducted on 62 willing patients of either sex, between age group 20-60 years. These were ASA 1 & 2 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia in hospitals attached to BMCRI Bangalore. After the due process approval from the ethical committee of the institution was obtained.

Method of collection of data

Study design: Prospective Randomized Comparative study
Study period: November 2018 - AUG 2019
Place of study: General hospitals attached to Bangalore Medical College and Research Institute

Group 'M': will receive Tab Moxonidine 0.2 mg oral as premedication 1 hour before induction: 31
Group 'C': will receive Tab Clonidine 150mcg oral as premedication 1 hour before induction: 31

Inclusion Criteria:

All adult patients of ASA-1 and 2 in the age group of 20 to 60 years of both sexes scheduled for elective laparoscopic cholecystectomy.

Exclusion Criteria:

- Patient with BMI >30, and with difficult airway
- Patients with hypertension, history of cardiac, pulmonary, renal, and liver disease.
- Patient with history of any psychiatric illness, epileptic disorder, parkinsonism and Raynaud's disease
- Patient with baseline SBP <100 and HR <60 are excluded
- History of allergy to Clonidine and Moxonidine
- Unwilling patients

Methodology

Following approval from the institutional ethical committee. present study was conducted in 62 patients over period of 12 months. The patient was selected and divided into two groups of 31 each by computer generated randomization table

Group M: Received oral tab Moxonidine 0.2mg 1 hour before induction

Group C: Received oral tab Clonidine 100mcg 1 hour before induction

Pre anaesthetic examination included detailed history and systemic examination as well as airway examination. Patients were enrolled for the study after meeting inclusion and exclusion criteria. Informed written consent was taken from the patient after explanation of the anaesthesia technique. All patients received premedication with tab Ranitidine 150mg and tab Alprazolam 0.5 mg night before surgery. The patients were kept nil per oral for 8 hours. A proforma was used to collect the data which include patient's particulars and intra-operative monitoring.

Anaesthetic Procedure

Study drug was given 1 hour before induction. On shifting the patient to the pre-operative room. In the operation theatre, an 18G intra venous cannula was secured on either upper limb. Monitors including NIBP, ECG, pulse oximeter were connected. Baseline hemodynamic parameters were documented.

Patients were premedicated with inj.Glycopyrollate 0.004mg/kg iv, inj.Midazolam 0.02mg/kg iv, inj.Fentanyl 2mcg/kg iv. After adequate pre-oxygenation with 100% O2 for 3 minutes, induction was done with inj.Propofol 2mg /kg. Patients were relaxed with inj.Vecuronium 0.1mg/kg, and ventilated for 3 minutes. Intubation was done with an appropriate size oral cuffed ETT.

Anaesthesia was maintained with inj.Vecuronium 0.02mg/kg iv, N2O: O2 @ 50:50, Sevoflurane- volatile anaesthetic agent with minimum alveolar concentration (MAC) of 0.6 -0.8. Patients were mechanically ventilated with volume control ventilation mode. Tidal volumes setting 6-8 ml/kg body weight and respiratory rate between 12-16 with a goal to maintain end tidal CO_2 between the range of 34-44mm Hg were set.

Pneumoperitoneum created using CO_2 and patient was positioned in 15° reverse Trendelenberg, intra-abdominal pressure maintained to 14mmHg. Throughout the study period, selected parameters (HR, SBP, DBP, MAP, SpO_2) were recorded as per proforma. Any change in hemodynamic variable >20% of either side of baseline was considered significant.

Sevoflurane, was utilized with variable concentration to negotiate any uptrend in MAP up to 20% from baseline. Time duration from creation of pneumoperitoneum to release of pneumoperitoneum was taken as the duration of pneumoperitoneum. At the end of surgery neuromuscular blockade was done with inj.Neostigmine 0.05mg/kg + inj.Glycopyrrolate 0.01mg /kg, patient extubated and shifted to recovery room.

Parameters measured

All patients were assessed for changes in hemodynamic parameters. Following Study parameters, Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Oxygen Saturation (SpO_2) were measured at preoperative (baseline), at

induction, after induction, after intubation, before pneumoperitoneum, 5, 10, 20, 30, 40, 50, 60 minutes after pneumoperitoneum, after end of pneumoperitoneum and after extubation.

The results were expressed as Mean+ Standard Deviation (SD). SPSS statistical software version 20 was used for the statistical analysis. Comparison between two groups at a time (inter-group comparison) was done using Student's unpaired t-test. P value of < 0.01 was considered highly significant, value > 0.05 was considered insignificant.

Results

Results were analyzed and tabulated. It was found that, there was no significant differences were found with respect to age, weight, gender [Table 1], time between premedication to anesthetic induction, duration of laryngoscopy and surgical procedure. There was no variation with respect to anesthetic technique among the study groups.

Table 1: ?

Vaiable	Monoxidine group (n = 31)	Clonidine (n = 31)	P value	
Age (Mean ± SD) (in years)	39.71 ± 8.24	38.16 ± 10.13	0.54	NS
Gender (Male/ Female)	16/15	14/17		
Weight(kg)	60.86 ± 6.98	63.57 ± 6.24	O.19	NS
ASA 1/2	28/3	28/3		

NS-not significant

Heart Rate

Statistical comparison was done between two groups of patients for heart rate changes. No significant variation was observed during- after intubation, before pneumoperitoneum and after pneumoperitoneum. There was significant rise in heart rate noted in- after 20 and after 30 minutes of pneumoperitoneum. In Moxonidine group compared to clonidine group which is statistically significant. Both the groups showed no significant increase in heart rate (rise was not more than 20% from baseline).

Table 2: Changes in Heart Rate (HR) among the two groups

Heart rate (bpm)	Monoxidine (n = 31) (Mean ± SD)	Clonidine (n =31) (Mean ± SD)	P value	
Basal (Pre op)	80.87 ± 12.80	90.06 ± 13.74	< 0.05	S
At induction	75.64 ± 12.85	78.90 ± 12.45	0.32	NS
After intubation	92.29 ± 15.32	88.06 ± 14.72	0.24	NS
Before PNP	86.29 ± 15.03	82.48 ± 12.70	0.25	NS
After PNP (5 min)	87.29 ± 14.08	81.38 ± 12.79	0.08	NS
After PNP (10 min)	87.12 ± 13.43	80.35 ± 13.22	0.04	NS
After PNP (20 min)	87.38 ± 13.31	78.93 ±11.09	<0.05	S
After PNP (30 min)	87.90 ± 11.50	80 ± 10.74	<0.05	S
At end of PNP	84.93 ± 13.13	79.74 ± 10.22	0.09	NS
After Extubation	93.16 ± 13.55	87.74 ± 12.42	0.12	NS

S-significant
NS-not significant

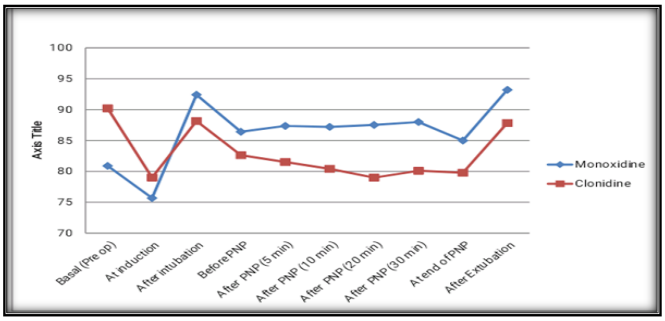

Figure 1: Changes in heart rate among the two groups

Blood Pressure

Clonidine group showed reduction in SBP, DBP and MAP in comparison to Moxonidine group ($p<0.05$) after intubation, pneumoperitoneum and after extubation, which was statistically significant.

Both groups showed no statistically significant increase in SBP, DBP and MAP (rise was not more than 20% from baseline).

Table 3: Changes in Systolic Blood Pressure (SBP) among the two groups

Systolic Blood Pressure (mm Hg)	Monoxidine (n = 31) (Mean ± SD)	Clonidine (n =31) (Mean ± SD)	P value	
Basal (Pre op)	126.19 ± 11.85	124.87 ± 10.67	0.62	NS
At induction	111.92 ± 11.15	107.92 ± 10.80	0.12	NS
After intubation	141.77 ± 12.87	120.19 ± 11.25	<0.05	S
Before PNP	133.48 ± 13.72	113.42 ± 10.09	<0.05	S
After PNP (5 min)	135.87 ± 11.07	115.16 ± 11.27	<0.05	S
After PNP (10 min)	134.32 ± 14.12	116.81 ± 12.15	<0.05	S
After PNP (20 min)	137.87 ± 9.71	115.35 ± 10.01	<0.05	S
After PNP (30 min)	133.77 ± 10.87	113.87 ± 9.75	<0.05	S
At end of PNP	129 ± 12.47	113.23 ± 10.99	<0.05	S
After Extubation	140.39 ± 10.94	119.74 ± 9.45	<0.05	S

S*-significant
NS*-Not significant

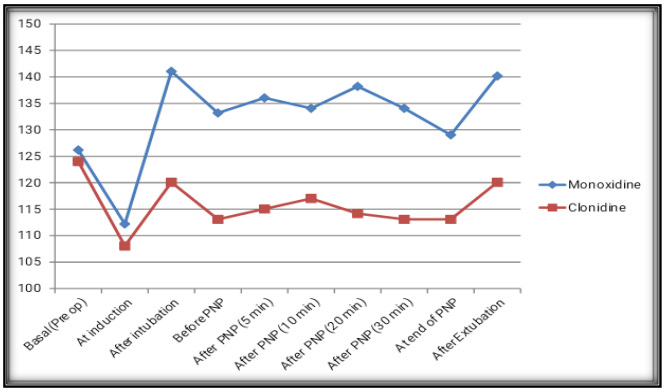

Figure 2: Changes in Systolic Blood Pressure (SBP) among the two groups

Table 4: Changes in Diastolic Blood Pressure (DBP) among the two groups

Diatolic Blood Pressure (mm Hg)	Monoxidine (n = 31) (Mean ± SD)	Clonidine (n =31) (Mean ± SD)	P value	
Basal (Pre op)	80.29 ± 7.54	77.71 ± 6.56	0.08	NS
At induction	73.96 ± 8.82	67.84 ± 7.82	<0.05	S
After intubation	88.80 ± 7.74	75.22 ± 7.34	<0.05	S
Before PNP	85.12 ± 9.18	72.45 ± 6.33	<0.05	S
After PNP (5 min)	87.64 ± 6.58	73.25 ± 7.65	<0.05	S
After PNP (10 min)	87 ± 7.50	72.84 ± 9.16	<0.05	S
After PNP (20 min)	85.45 ± 6.41	73 ± 9.41	<0.05	S
After PNP (30 min)	84.38 ± 7.42	72.64 ± 7.53	<0.05	S
At end of PNP	81.19 ± 7.12	72.16 ± 7.70	<0.05	S
After Extubation	86.06 ± 7.30	77.51 ± 8.45	<0.05	S

S*-Significant

NS*-not significant

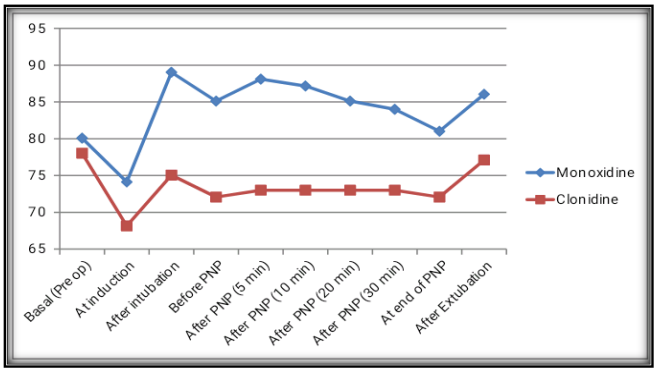

Figure 3: Changes in Diastolic Blood Pressure (DBP) among the two groups

Table 5- Changes in mean arterial pressure (MAP) in two groups

Mean Arterial Pressure (mm Hg)	Monoxidine (n = 31) (Mean ± SD)	Clonidine (n =31) (Mean ± SD)	P value	
Basal (Pre op)	95.35 ± 8.46	93.06 ± 6.86	0.15	NS
At induction	86.51 ± 9.08	81.12 ± 8.05	<0.05	S
After intubation	106.42 ± 8.87	90.12 ± 8.67	<0.05	S
Before PNP	101.1 ± 10.18	85.80 ± 7.24	<0.05	S
After PNP (5 min)	103.48 ± 7.52	87.19 ± 7.90	<0.05	S
After PNP (10 min)	102.65 ± 9.96	86.29 ± 8.43	<0.05	S
After PNP (20 min)	102.71 ± 7.16	86.64 ± 8.45	<0.05	S
After PNP (30 min)	100.42 ± 7.25	86.77 ± 7.55	<0.05	S
At end of PNP	97.26 ± 8.52	85.77 ± 7.71	<0.05	S
After Extubation	103.9 ± 8.81	91.23 ± 7.96	<0.05	S

S*-significant

NS*-not significant

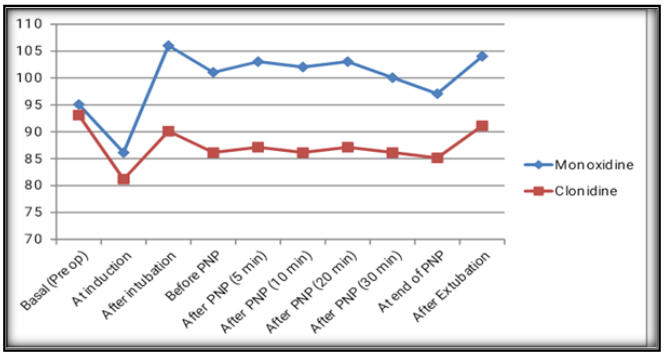

Figure 4: Changes in Mean Arterial Pressure (MAP) in two groups

Discussion

Laparoscopic surgeries require pneumoperitoneum. CO_2 has been the main stay in creating pneumoperitoneum [8]. This intern produces significant hemodynamic changes which are increase in heart rate and blood pressure. Thus it results in increase in systemic vascular resistance and mean arterial pressure (MAP), leading finally to decrease in cardiac output [2].

These responses may become detrimental to patient, resulting in increase of risk of perioperative adverse cardiac events and cerebrovascular events.

To reduce these hemodynamic responses wide variety of agents are being used [1,16] . In our current study two alpha-2 agonist (Moxonidine and Clonidine) were taken for the comparison regarding their efficacy in reducing stress response and intern their ability in reducing hemodynamic changes associated with laparoscopic cholecystectomy.

Moxonidine [4-chloro-N-(imidazolidin2-yliedene)-6-methoxy-2-methyl-5-pyrimidinamine] is an imidazole compound. It is a new generation alpha-2/imidazoline receptor agonist. It's a centrally acting antihypertensive, with site of action is thought to be rostral ventrolateral medulla. By inhibiting sympathetic activity centrally, it brings down arterial BP.[9,10]

Clonidine [2-((2,6-dichlorophenyl) amino)-2-imidazoline hydrochloride] is an imidazoline derivative, that is centrally acting alpha-2 agonist Clonidine pharmacology involves having agonist activity at central alpha 2 receptors in the posterior hypothalamus and medulla. Hence its action results in lowering of sympathetic outflow and finally reduction in blood pressure.[5]

C.G Raghuram et al evaluated effect of oral Moxonidine 0.3mg premedication in attenuating hemodynamic responses in laparoscopic studies compared with placebo and found that Moxonidine administered preoperatively created hemodynamic stability in the perioperative period. Significant rise in vital parameters were noted in placebo group and rise is not more than 20% from baseline in Moxonidine group which is statistically significant.[11,12,13,14,15,16,17]

Routray SS et al studied the effect of oral Moxonidine in the attenuation of hemodynamic responses seen during laparoscopic surgeries compared with placebo. They concluded that hemodynamic profile in Moxonidine group

was better than placebo.[18]

Das et al evaluated effect of oral clonidine 150mcg premedication in attenuating hemodynamic responses in laparoscopic cholecystectomy compared with placebo and concluded that preoperatively administered clonidine provided better perioperative hemodynamic stability and significant rise in vitals parameters was noted in placebo group and rise is not more than 20% from baseline in Clonidine group which is statistically significant.[14]

Malek J.et al evaluated effect of Moxonidine 0.3mg Oral in comparison to Clonidine 150mcg IV premedication in the attenuation of hemodynamic responses seen during laparoscopic cholecystectomy. They concluded that clonidine premedication provides better results compared to Moxonidine [15] .

In present study, both the groups showed significant reduction in HR/SBP/DBP/MAP (rise was not more than 20% from baseline value). Hemodynamic profile was stable in both the groups, the HR/SBP/DBP/MAP were stable throughout the procedure in both the groups.

We observed that the SBP/DBP/MAP was lower with Clonidine group at intubation, during pneumoperitoneum, at extubation than Moxonidine group and the difference found to be statistically significant. No significant side effects observed in both the groups.

In our study we compared oral Moxonidine 0.2 mg and oral Clonidine 100mcg premedication in patients undergoing laparoscopic cholecystectomy. We found that both drugs provide perioperative hemodynamic stability.

Conclusion

Both alpha -2 agonists Moxonidine and Clonidine are effective in attenuating hemodynamic responses to pneumoperitoneum during laparoscopic cholecystectomy and provide perioperative hemodynamic stability.

However, we conclude that clonidine being more effective drug than Moxonidine in maintaining stable hemodynamics during pneumoperitoneum in laparoscopic cholecystectomy in the study doses.

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