

## Effect of dexmedetomidine & clonidine on intracranial pressure with help of optic nerve sheath diameter during laparoscopic surgery

S K. Gahlot<sup>1</sup>, Reema Chaudhary<sup>2</sup>, Chandra Shekhar Singh<sup>3\*</sup>

<sup>1</sup>Associate Professor, Department of Anaesthesia, GSVM Medical College, Kanpur, Uttar Pradesh, India

<sup>2</sup>Assistant Professor, Department of Anaesthesia, GSVM Medical College, Kanpur, Uttar Pradesh, India

<sup>3</sup>Associate Professor, Department of Anaesthesia, GSVM Medical College, Kanpur, Uttar Pradesh, India

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### Abstract

**Introduction:** Laparoscopic surgeries are not uncommon these days. Laparoscopic cholecystectomy and appendicectomy are usually done at most centers. One major requirement in preparation for surgery is formation of pneumo-peritoneum by insufflation of carbon dioxide gas. **Materials and Methods:** The prospective randomized study conducted in the Department of Anaesthesia and Department of Surgery, GSVM Medical College, and Associate LLRM Hospital, Kanpur from January 2019 to March 2020 on patients admitted from outpatients department for elective laparoscopic surgery. After getting written consent from patients or relatives and approval from ethical committee study initiated. Enrolled patients were admitted in institute at least one day prior to surgery, Pre anesthetic checkup of the patient to be included in the study was done on evening before surgery. Patients were counseled regarding adequate NPO, sedation, the anaesthetic and operative procedure. Investigations were done according to the institution's protocol. No hypnotic given to patients but tab Ranitidine 150mg and tab Alprazolam 0.25mg were give on night before surgery. **Results:** A total no of 70 patients in the age group of 18-55 years belonging to ASA grades I & II were enrolled in the study. They were divided into two groups (C and D) of 35 each. During observational study 3 patients dropped out from group C and 2 patients from group D due to poor quality of ocular sonography. 1 patient from group D was converted into open surgery. So, n=32 patients were taken for observation and result in both groups. **Conclusion:** We, hereby concluded with the help of the present study and available literature that premedication with Dexmedetomidine would be a better option than clonidine for laparoscopic surgeries in terms of intracranial pressure regulation (statistically significant  $p < 0.01$ ) and hemodynamic regulation. Less number of cases for study may be a limitation. So, study can be extended with big sample size for best result.

**Keywords:** Laparoscopic surgeries, appendicectomy, Dexmedetomidine, hemodynamic regulation.

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### Introduction

Laparoscopic surgeries are not uncommon these days. Laparoscopic cholecystectomy and appendicectomy are usually done at most centers. One major requirement in preparation for surgery is formation of pneumo-peritoneum by insufflation of carbon dioxide gas[1]. This pneumo-peritoneum formation leads to hemodynamic changes along with increased intracranial pressure. Pneumo-peritoneum causes increased intra-abdominal pressure resulting in increased venous pressures and a stasis of intracranial blood outflow. It results in progressive increase in intracranial pressure[2]. Carbo-peritoneum results in increased paco<sub>2</sub> which further causes increased cerebral blood flow and aggravates increased ICP. Catecholamine surge due to pneumo-peritoneum leads to hemodynamic variations and further increase in intracranial pressure[3].

Intracranial pressure can be best measured by invasive intracranial devices, but using invasive technique during laparoscopic surgeries is not feasible as it may lead to severe complications like hemorrhage, infections, equipment failure etc[4].

Using ocular ultrasonography, Optic nerve sheath diameter measurement is a novel, non-invasive, reproducible and safe technique for the assessment of ICP. Previous studies have proven that ONSD measurement is accurate alternative for diagnosing and assessing elevated ICP from various causes[5]. Alpha 2 adrenergic receptor agonists play very important role in managing hemodynamic instability due to different causes. Previous studies also proved effect of dexmedetomidine and clonidine (xylazine in animals) on cerebral blood flow and intracranial pressure[6]. This study evaluates and compares the influence of Dexmedetomidine and Clonidine on intracranial pressure using ultrasonographic measurement of ONSD, heart rate and mean arterial blood pressure during laparoscopic surgeries.

### Aims and objective

The aim will be following-

#### Primary aim

To compare effect of dexmedetomidine and clonidine on intracranial pressure by measuring optic nerve sheath diameter (ONSD) by ultrasonography in perioperative period in elective laparoscopic surgery.

#### Secondary aim

To compare effect of dexmedetomidine and clonidine on hemodynamic measures (HR and MAP) during study.

#### Materials and methods

The prospective randomized study conducted in the Department of Anaesthesia and Department of Surgery, GSVM Medical College, and Associate LLRM Hospital, Kanpur from January 2019 to March 2020 on patients admitted from outpatients department for elective laparoscopic surgery.

\*Correspondence

**Dr. Chandra Shekhar Singh**

Associate Professor, Department of Anaesthesia, GSVM Medical College, Kanpur, Uttar Pradesh, India

E-mail: [chandrashekar77@gmail.com](mailto:chandrashekar77@gmail.com)

**Sample size**

70 patients

Formula for calculating sample size

$$n = \frac{[(Z_{\alpha/2} + Z_{\beta})^2 \times \{(p_1(1-p_1) + p_2(1-p_2))\}]}{(p_1 - p_2)^2}$$

**Study Design**

Randomized controlled trial

Patients will be selected randomly from each of the following group.

**Group C:** Patients undergoing laproscopic surgery with introduction of injection Clonidine with a loading dose of 3mcg/kg body weight (max 150mcg) during premedication; 15mins before induction of anaesthesia.

**Group D:** Patients undergoing laparoscopic surgery with introduction of injection Dexmedetomidine with a loading dose of 1mcg/kg body weight during premedication; 15mins before induction of anaesthesia.

**Inclusion Criteria**

- All patients between 18 to 55 years
- Patients in ASA I and ASA II.
- Admitted for elective laparoscopic surgery

**Exclusion Criteria**

- Patients not giving consent
- Age group <18 and >55 years
- ASA physical status grade higher than II
- Cases with difficult airway/intubation
- Laparoscopic cases converted into open surgery
- Patient with any intracranial pathology
- Patients with any intraocular /ophthalmic pathology
- Pregnant and lactating women
- Patients with history of allergy to dexmedetomidine and clonidine.

After getting written consent from patients or relatives and approval from ethical committee study initiated.

Enrolled patients were admitted in institute at least one day prior to surgery, Pre anesthetic checkup of the patient to be included in the study was done on evening before surgery. Patients were counseled regarding adequate NPO, sedation, the anaesthetic and operative procedure. Investigations were done according to the institution's protocol. No hypnotic given to patients but tab Ranitidine 150mg and tab Alprazolam 0.25mg were give on night before surgery.

All of the patients in each of the two groups were given Inj Pantoprazole 40mg IV, Inj Ondansetron 4mg in preoperative ward Ringer's lactate solution was started intravenously through 18G cannula.

On arrival in the operation theatre multi parameter monitor attached to the patients and their oxygen saturation, heart rate, ECG, non-invasive arterial blood pressure and respiratory rate were assessed. Inj glycopyrrolate 0.2mg IV was given to all patients. Immediately before induction, patients were randomly divided into two groups on basis of chit lottery system chosen by OT In-charge. The groups were:

**Group clonidine (C):** Premedicated with 3mcg/kg IV clonidine in NS

**Group dexmedetomidine (D):** Premedicated with 1mcg/kg IV dexmedetomidine in NS.

In both respected groups, calculated doses of Inj dexmedetomidine and inj clonidine were mixed with NS to make a volume of 50ml and slowly given intravenously in 10 mins.

Inj Fentanyl 2mcg/kg was given to all patients. Patients in both the groups were induced with 2mg/kg IV Propofol and in both the groups muscle relaxation was achieved using 0.08-0.12 mg/kg of Vecuronium. Patients were intubated with suitable size ET tube for female and males in both groups. The sedation was maintained with propofol infusion at the rate of 50-100 mcg/kg/min and intraoperative muscle relaxation was also maintained using intermittent 0.01-0.02mg/kg of vecuronium about every 20min or on arrival of spontaneous respiration, whichever is early. Anaesthesia maintained with N2O and O2 mixture in 60:40 ratio till the end of surgery.

After 3minutes of intubation and stabilization of patient; baseline HR, MAP and ONSD for comparison were measured in the supine position.

For ultrasonographic measurement of ONSD, application of a thick gel layer to the closed upper eyelids of patients done, a linear 15-6 MHz probe (M-Turbo; Fujifilm Sonosite Inc., Tokyo, Japan) was carefully placed on the gel. Adjustments were made, gently maneuvering the probe to ensure a good image of optic nerve exiting the globe opposite optic lens. Optimal contrast between the retrobulbar echogenic fat tissue and the optic nerve appearing as a vertical hypoechoic band ensures accurate measurement of the ONSD. ONSD was measured 3 mm behind the optic disc using an electronic caliper keeping probe in a transverse plane. Values from either eye were noted and the mean ONSD value was used for calculations.



After measurement of baseline parameters (HR, MAP AND ONSD), surgeon was asked to make pneumoperitoneum. The intra-abdominal pressure was monitored throughout the surgery and asked to keep up to 15mm Hg to maximum limit. 5 minutes after pneumoperitoneum , HR, MAP AND ONSD were measured and noted again in the same manner. After measurement, patient position changed to head up and slight left rotation for better laparoscopic orientation by surgeon in laparoscopic cholecystectomy and trendelenburg position made in laparoscopic appendicectomy cases. In this position and after 15 minutes of pneumoperitoneum next reading of parameters was done. At the end of surgery desufflation of carbon dioxide gas was done and all parameters were again measured after 5 minutes.

All infusions stopped and injection Paracetamol 1 gm IV infusion given slowly. N2O stopped and 100% oxygen given to patients prior to extubation. On appearance of sign of decreased muscle relaxation (deglutination movement of thyroid cartilage), neuromuscular blockade was reversed by inj glycopyrrolate 0.01mg/kg and inj neostigmine 0.05mg/kg. All patients in each group were extubated comfortably and shifted to post op ward after assessment.

**Statistical Analysis**

Parametric data are collected and entered in master chart in Microsoft Excel Sheet. The significant difference of mean between the groups were calculated Using paired t test for testing the significant difference within the group. Unpaired t test used for testing significant

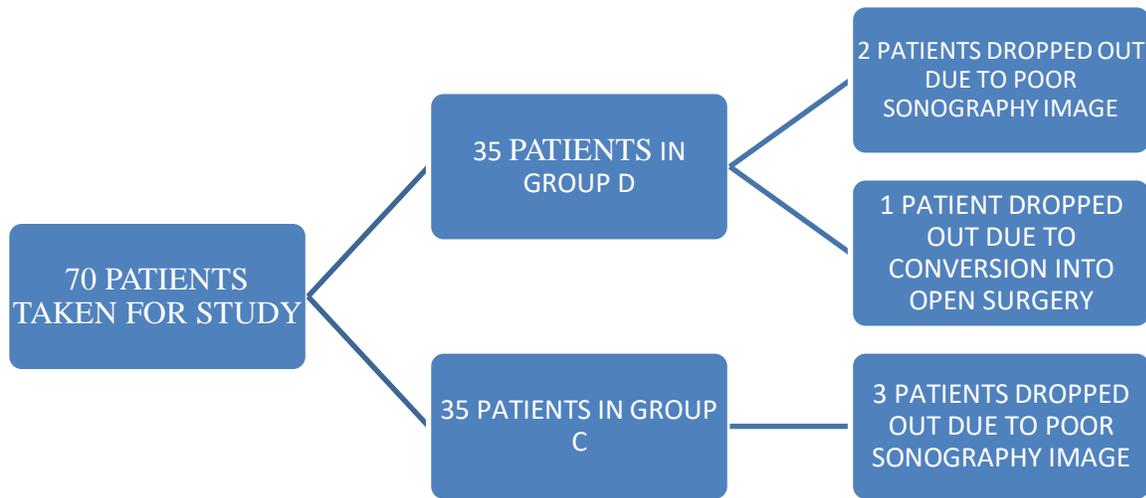
difference between two groups. Chi square test used to find out the association between the two groups. For all the purposes, probability value was considered as below

p value	Inference
<0.05	Significant
<0.01	Moderately significant
<0.001	Highly significant
>0.05	Insignificant

**Results**

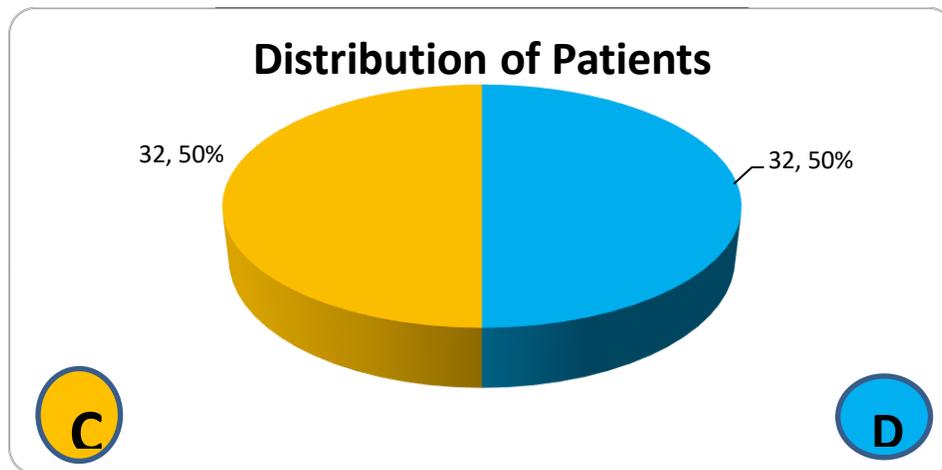
A total no. of 70 patients in the age group of 18-55 years belonging to ASA grades I & II were enrolled in the study. They were divided into two groups (C and D) of 35 each. During observational study 3 patients dropped out from group C and 2 patients from group D due to poor quality of ocular sonography. 1 patient from group D was converted into open surgery. So, n=32 patients were taken for observation and result in both groups.

Patients in group C were premedicated with inj clonidine 3mcg/kg and group D were premedicated with inj dexmedetomidine 1mcg/kg 15min before induction of anaesthesia.



**Table 1: Distribution of Patients**

Groups	No. of Patients	Premedication with
Group C	32	CLONIDINE
Group D	32	DEXMEDETOMIDINE



**Fig 1: Distribution of Patients**

**Table 2: Age distribution**

Age in years	CLONIDINE group	DEXMEDETOMIDINE group
18-25	8	9
26-35	10	8
36-45	7	6
46-55	7	9
Total	32	32

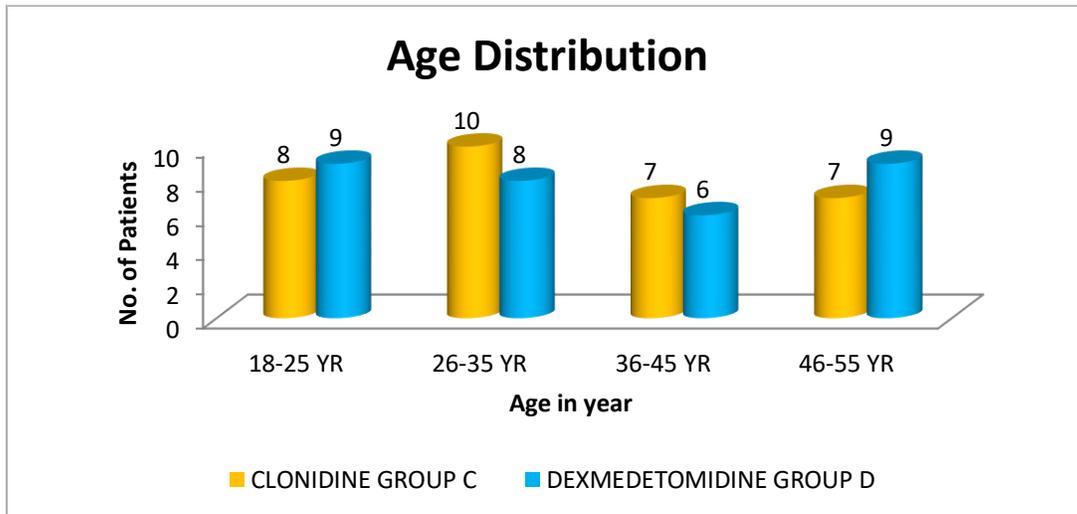


Fig 2: Age Distribution

Table 3: Sex distribution

Sex	CLONIDINE group	DEXMEDETOMIDINE group
Male	10	12
Female	22	20
Total	32	32

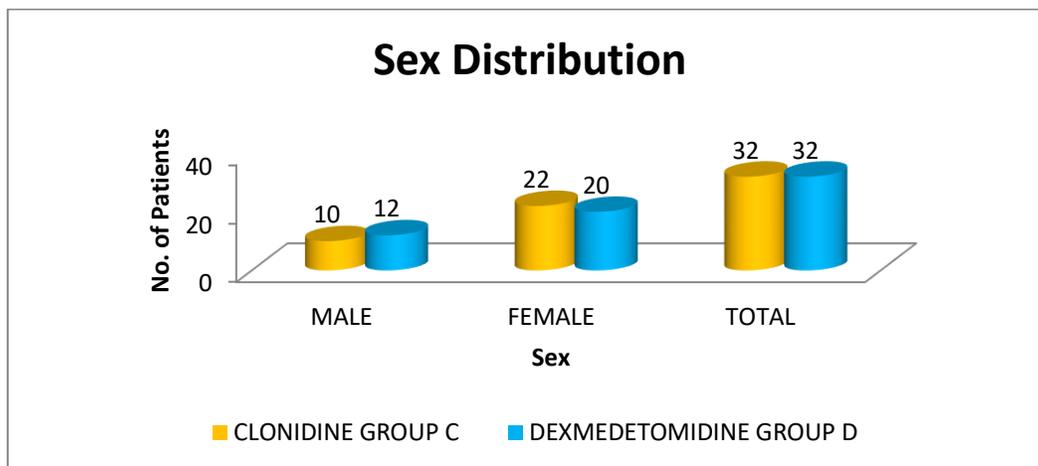


Fig 3: Sex Distribution

Table 4: Demographic Data

	GROUP C			GROUP D			T	p	Inf
	n	mean	SD	N	mean	SD			
AGE yr	32	34.2	11.24	32	35.5	11.82	0.436	>.05	NS
WT. kg	32	49.1	7.84	32	49.43	7.41	0.166	>.05	NS

Table 5: HR, MAP, ONSD values

HR	GROUP C			GROUP D		
	N	MEAN	HR	N	MEAN	HR
Base Line	32	80.6	Base Line	32	80.6	Base Line
5 Min After Pneumo	32	84.1	5 Min After Pneumo	32	84.1	5 Min After Pneumo
15 Min After Pneumo	32	83	15 Min After Pneumo	32	83	15 Min After Pneumo
5 Min After Desuffl.	32	82	5 Min After Desuffl.	32	82	5 Min After Desuffl.
MAP	N	MEAN	MAP	N	MEAN	MAP
Base Line	32	90.76	Base Line	32	90.76	Base Line
5 Min After Pp	32	93.3	5 Min After Pp	32	93.3	5 Min After Pp
15 Min After Pp	32	92.06	15 Min After Pp	32	92.06	15 Min After Pp

ONSD	GROUP C		GROUP D	ONSD	GROUP C	
	N	MEAN			N	MEAN
Base Line	32	0.43	Base Line	32	0.43	Base Line
5 Min After Pp	32	0.445	5 Min After Pp	32	0.445	5 Min After Pp
15 Min After Pp	32	0.455	15 Min After Pp	32	0.455	15 Min After Pp
5 Min After Des	32	0.44	0.014	32	0.439	0.018

Both groups were comparable with respect to age and weight Mean and Standard deviation of different parameters (HR, MAP and ONSD) in both group C and D at different time intervals are given below

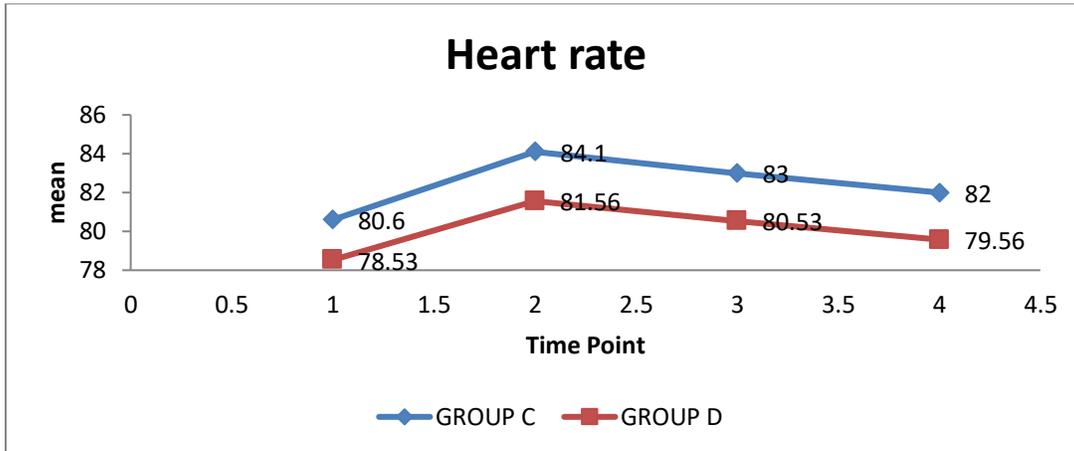


Fig 4: Heart rate

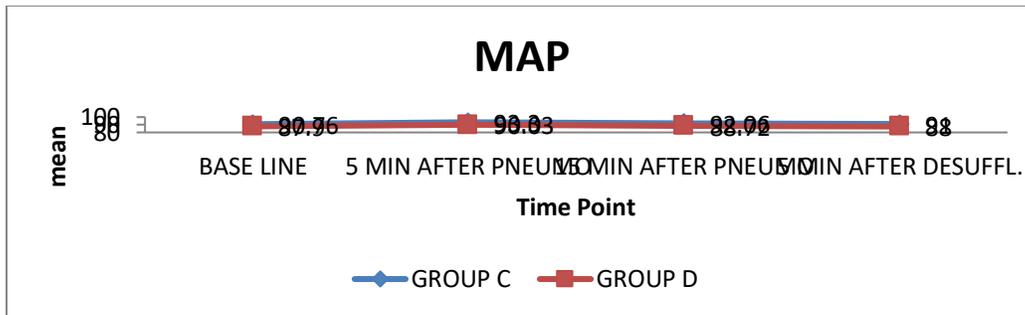


Fig 5: MAP

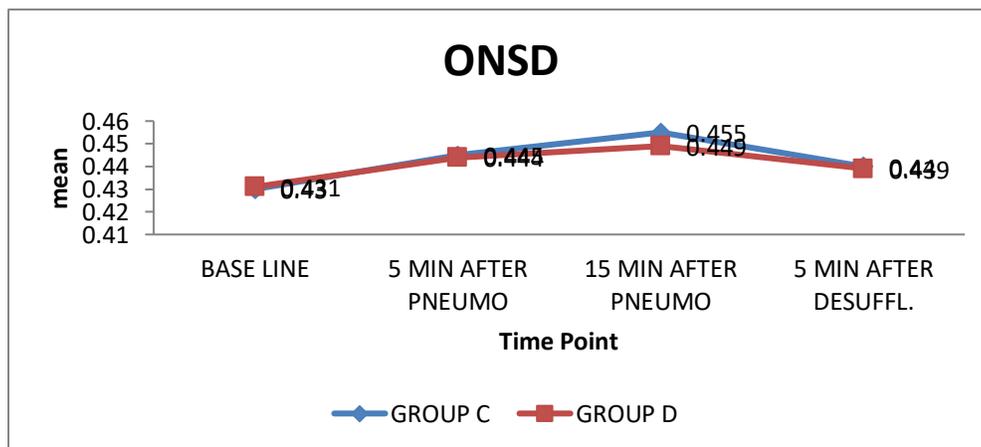


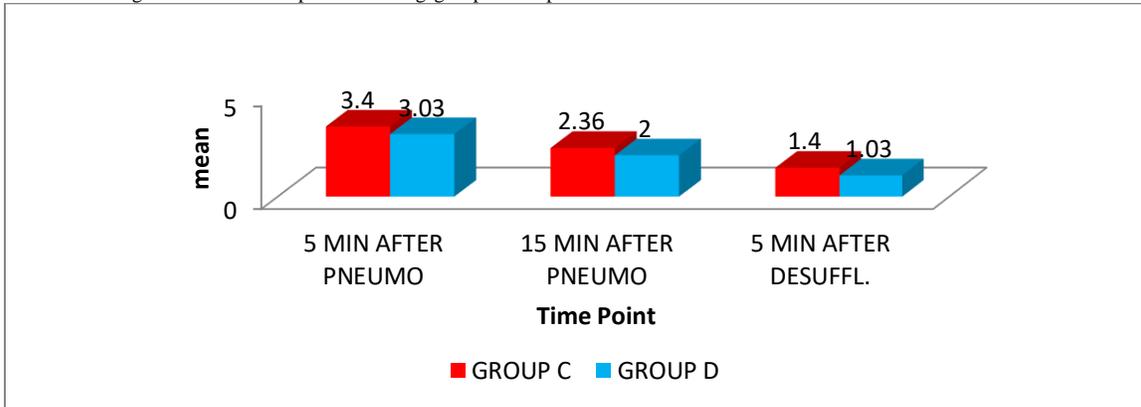
Fig 6: ONSD

**Table 6: Comparison Of Heart Rate Difference From Baseline At 5 Min After Pneumoperitoneum, 15 Min After Pp And 5 Min After Desufflation**

differential data from base line	GROUP C			GROUP D			Between the groups			
	N	MEAN	SD	N	MEAN	SD	T	T	p	inf
5 MIN AFTER PP	32	3.4	0.66	32	3.03	0.92	1.789857	2	<0.05	SIG
15MIN AFTER PP	32	2.36	0.79	32	2	0.74	1.821608	2	<0.05	SIG
5 MIN AFTER DES	32	1.4	0.71	32	1.03	0.71	2.018315	2.01	<0.05	SIG

Heart rate increased significantly in both groups, 5 minutes after formation of pneumoperitoneum with p value <0.001 and significant difference is seen in comparison among group C and D with p value <0.05. There is fall in heart rate in both groups after 15 mins of pneumoperitoneum but difference is still more than base line. This difference is also significant with comparison among groups with p

value <0.05. After 5 minutes of desufflation of CO2 gas, HR further decreased and difference from baseline is decreased significantly in both groups. This differential comparison is again significant between both groups. With p value <0.05. Heart rate change is more in group C than group D.



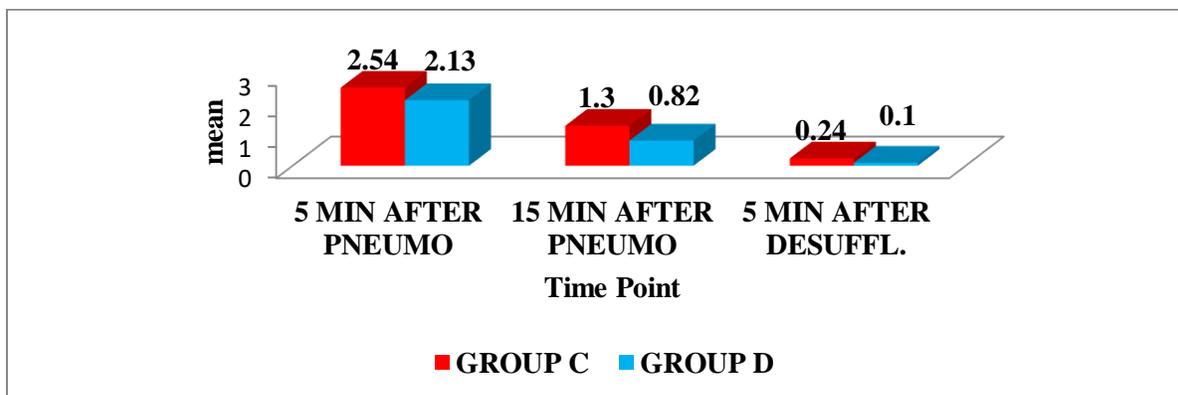
**Fig 7: Comparison of Heart Rate Difference from Baseline at 5 Min after Pneumoperitoneum, 15 min after Pp and 5min After Desufflation**

**Table 7: Comparison Of Mean Arterial Pressure Difference From Baseline At 5 Min After Pneumoperitoneum, 15 Min After Pp And 5 Min After Desufflation**

Differential data from base line	GROUP C			GROUP D			Between the groups			
	N	MEAN	SD	N	MEAN	SD	T	T	p	inf
5 MIN PP	32	2.54	0.76	32	2.13	0.78	2.062064	2.06	<0.05	SIG
15MIN PP	32	1.3	1.05	32	0.82	0.75	2.037487	2.03	<0.05	SIG
5 MIN AFTER DESUFF	32	0.24	0.72	32	0.1	0.97	0.63477	0.63	>.05	NON SIG

MAP increased significantly in both groups, 5 minutes after formation of pneumoperitoneum with p value <0.001 and significant difference is seen in comparison among group C and D with p value <0.05. There is fall in MAP in both groups after 15 mins of pneumoperitoneum but difference is still more than base line. This difference is also significant with comparison among groups with p value <0.05

After 5 minutes of desufflation of CO2 gas, MAP further decreased and difference from baseline is decreased significantly in both groups. This differential comparison is not significant between both groups. With p value >0.05. MAP change is more in group C than group D, after 5 min of PP and 15 min after PP but after 5 minutes of desufflation difference is not significant between clonidine and dexmedetomidine. In both groups MAP reached near baseline values.



**Fig 8: Comparison of Mean Arterial Pressure Difference from Baseline at 5 Min after Pneumoperitoneum, 15 min after Pp and 5 min after Desufflation**

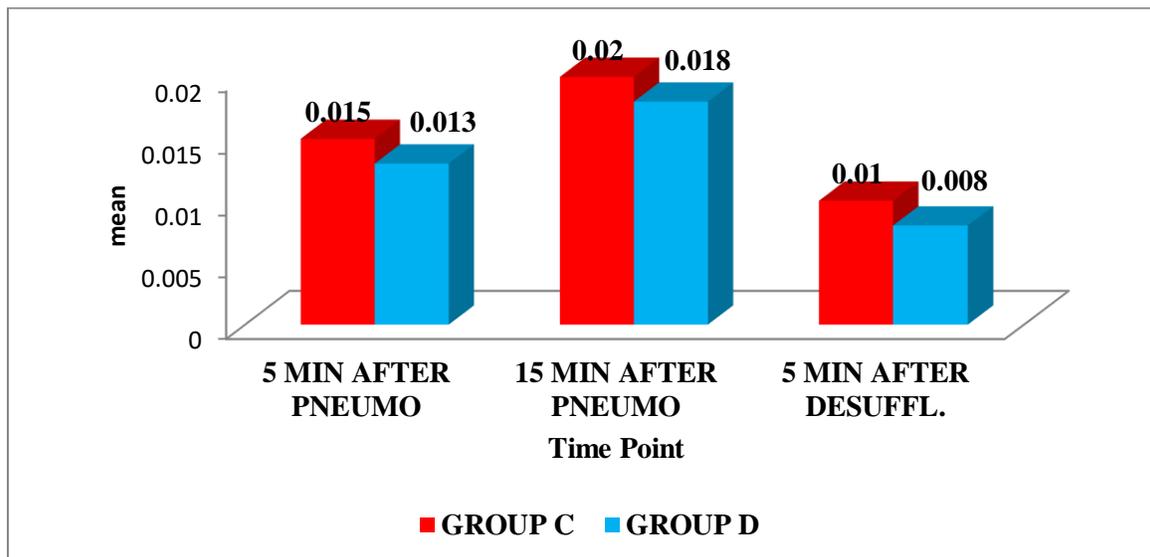
**Table 8: Comparison Of Optic Nerve Sheath Diameter (Onsd) Difference from Baseline at 5 Min after Pneumoperitoneum, 15min after Pp and 5min After Desufflation**

Differential data from base line	GROUP C			GROUP D			Between the groups			
	ONSD	N	MEAN	SD	N	MEAN	SD	T	T	p
5 MIN PP	32	0.015	0.007	32	0.013	0.005	1.273429	1.27	>0.05	NON SIG
15MIN PP	32	0.02	0.007	32	0.018	0.007	1.106567	1.1	>0.05	NON SIG
5 MIN AFTER DESUFF	32	0.01	0.007	32	0.008	0.006	1.188177	1.18	>0.05	NON SIG

ONSD increased significantly in both groups, 5 minutes after formation of pneumoperitoneum with p value <0.001 but non significant difference is seen in comparison among group C and D with p value >0.05

There is further rise in ONSD in both groups after 15 mins of pneumoperitoneum difference is still more than base line. This difference is again not significant with comparison among groups with p value >0.05

After 5 minutes of desufflation of CO<sub>2</sub> gas, ONSD started decreasing and difference from baseline is still significantly present within both groups. This differential Comparison is not significant between both groups. With p value >0.05. ONSD change is more in group C than group D, after 5 min of PP, 15 min after PP and after 5 minutes of desufflation but this difference is statistically not significant between clonidine and dexmedetomidine.

**Fig 9: Comparison Of Optic Nerve Sheath Diameter (Onsd) Difference from Baseline at 5 Min after Pneumoperitoneum, 15min after Pp and 5min After Desufflation**

### Discussion

Laparoscopic surgeries are very common these days at most of the medical centers. In laparoscopic surgeries main requirement is formation of pneumoperitoneum by insufflation of carbon dioxide gas through a cannula. Pneumoperitoneum formation, lead to increase in intraabdominal pressure. Hence despite multiple benefits, all laparoscopic surgeries are challenging from an anesthesia point of view, mainly due to significant alteration of hemodynamics and rise in intracranial pressure[7].

This pilot study was intended to see the comparative effect of dexmedetomidine and clonidine on intracranial pressure changes by means of ONSD measurement and also their effect on hemodynamic changes.

### Optic nerve sheath diameter measurement

According to Bloomfield GL et al there is a correlation between high intra abdominal pressure with increased intra thoracic pressure leading to functional obstruction of cerebral venous outflow via jugular venous system and causing increased intracranial pressure. Fujii Y et al suggested that intra-peritoneal co<sub>2</sub> insufflation increases cerebral blood flow and claim it due to increased paco<sub>2</sub>. Dip F et al explained that optic nerve sheath being a part of duramater and the optic nerve surrounded by CSF, a change in pressure within subarachnoid space would be detected by ultrasonography. Abdullah Sadik Girisgin et al 2007, Amini A et al 2013, Hightower S et al

2012, Robba C et al 2016, Raboel P et al 2012, Bauerle J et al 2011 and many more in different studies explained the importance of sonographic optic nerve sheath diameter measurement as an alternative option for assessment of raised intracranial pressure[8].

In our study ultrasonographic measurement of ONSD done on either eye according to comfort as claimed by Uday Yanamandra et al in their study of ONSD measurement in both eyes that the difference in ONSD of both eyes is not significant and it is sufficient to measure ONSD of any eye. Throughout the study ONSD measurement was done 0.3cm behind the globe of eye which is also advised in study by Bauerle J et al Comparing ultrasound- and MRI-derived ONSD values, found acceptable agreement between both methods for measurements at a depth of 3 mm (r=0.72, p=0.002, mean difference < 5%). concluded, good reproducibility and accuracy of ONSD by ultrasound. H C Hansen et al 1996 suggest better ONSD measurement at 3mm behind the globe and in 2011 H C Hansen et al explained that elasticity of anterior part of sheath is sufficient for detecting pressure changes[9].

In our study intra-abdominal pressure kept up to 15mm hg and ICP raised in means of ONSD after initiation of pneumoperitoneum and further increased after 15 min in head up position (p<0.05) within both groups; as seen and stated by Halverson A et al its likely due to impaired venous drainage of the lumbar venous plexus. Kim MS et al found that mean values of ONSD at all the time points significantly

increased compared to baseline. In our study also, ONSD mean value significantly high from baseline in both groups[10].

In our study 1 patient in each group shows ONSD  $\geq 0.48$ mm after 5min. of pneumoperitoneum where 2 patients in dexmedetomidine group and 3 patients in clonidine group shows ONSD  $\geq 0.48$ mm after 15min. of pneumoperitoneum also. None patient shows such high diameter after desufflation.

#### Hemodynamic measurement

As stated by Mikami O et al in their studies in 1996 and 1998 that  $\text{CO}_2$  insufflation and increased intra-abdominal pressure is cause of catecholamine release causing hemodynamic variation. Previous studies by Karlsson BR et al 1991, Lee HW 1997, Nishant Sahay et al 2018 etc. stated that hemodynamic changes during laparoscopic surgeries can be challenged by use of alpha 2 adrenergic agonist clonidine and dexmedetomidine. In our study HR and MAP increased significantly from baseline after formation of pneumoperitoneum ( $P < 0.05$ ), as Joris et al 1993 demonstrated in their study. The intergroup difference in HR change was significant ( $P < 0.05$ ) and HR in clonidine group was more than dexmedetomidine, similarly change in MAP was also more in clonidine group. Hazra R et al 2014 and Pooja Gautam 2019 gave similar hemodynamic relation in comparative study between clonidine and dexmedetomidine, whereas in study by Bharti D et al 2016 shows decreased HR in clonidine group and no change in MAP.

Throughout the study oxygen saturation SPO<sub>2</sub>; remained 98% to 99% among all patients in both groups. This study was conducted in unconscious and paralysed patients, so our results may not be applicable to awake or nonparalysed patients. All demographic characteristics like age, sex, weight were matched and it was found that both groups has no differences from statistical point of view. Data represented in our study showed that statistically there is no significant difference in the ONSD changes from baseline during all time points between dexmedetomidine and clonidine group ( $p$  value  $> 0.05$ ). There is significant difference in heart rate and mean arterial blood pressure changes from baseline between both the groups ( $p$  value  $< 0.05$ ).

#### Side effects

After premedication with Dexmedetomidine 3 patients and with clonidine 2 patients experienced fall in heart rate, up to 54/min; no intervention done.

After premedication with clonidine 2 patients and none in dexmedetomidine showed fall of MAP up to 65 mm hg; no intervention done.

#### Limitations

- Skilled and expertise person are required for ocular sonography.
- Specialized equipments are needed.
- Institutional limitations for selection of cases.

#### Conclusion

We, hereby concluded with the help of the present study and available literature that premedication with Dexmedetomidine would be a better option than clonidine for laparoscopic surgeries in terms of intracranial pressure regulation (statistically significant  $p < 0.01$ ) and hemodynamic regulation. Less number of cases for study may be a limitation. So, study can be extended with big sample size for best result.

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