



Research Article

DEXMETOMIDINE AND CLONIDINE AS PREMEDICATION IN ATTENUATION OF SYMPATHETIC RESPONSE DURING LARYNGOSCOPY AND TRACHEAL INTUBATION IN HYPERTENSIVE PATIENTS UNDERGOING OPEN CHOLECYSTECTOMY- AN OPEN LEVEL RANDOMISED CONTROL TRIAL

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ABSTRACT

Introduction: Laryngoscopy and tracheal intubation are often associated with tachycardia, hypertension and arrhythmias. It is because of the sympathetic adrenergic outflow caused by laryngeal tissue stimulation. The present study is designed to compare the effect of dexmedetomidine and clonidine administration on the sympathetic response prior to induction among hypertensive patients undergoing laryngoscopy and endotracheal intubation during open cholecystectomy. **Method:** A randomized double blinded study was conducted among 60 adult patients according to inclusion and exclusion criteria. They were randomly distributed into two groups (30 patients each). One group received Inj. Dexmedetomidine 0.5mcg/kg iv diluted in 100 ml normal saline over 15 mins. Another group received Inj. Clonidine 3mcg/kg IV diluted in 100 ml normal saline over 15 mins. **Result:** In this study the mean SBP, DBP, MAP after 1 min and 5 mins of laryngoscopy of patients were significantly higher in patients who received Clonidine compared to patients who received Dexmedetomidine. However no statistically significant difference was observed in heart rate. Rescue Medication was required more in clonidine group as compared to dexmedetomidine group though the difference was not statistically significant. **Conclusion:** It is concluded that both the drugs- Dexmedetomidine & Clonidine, are safe and recommended for attenuation of pressor response during laryngoscopy and tracheal intubation. Dexmedetomidine is more effective in attenuating the hemodynamic response to laryngoscopy & tracheal intubation in hypertensive patients undergoing open cholecystectomy than Clonidine.

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INTRODUCTION

Laryngoscopy and tracheal intubation are often associated with tachycardia, hypertension and arrhythmias. It is because of the sympathetic adrenergic outflow caused by laryngeal tissue stimulation^[1]. Furthermore, this hemodynamic instability may be associated with perioperative complications such as ventricular arrhythmias, myocardial ischemia, depression of myocardial contractility, intraocular hypertension, intracranial hypertension or even cerebrovascular accident. The effect is more deleterious in patients with hypertension. The magnitude of the pressor response is related to the duration of laryngoscopy and may be severe in case of difficult intubation.

Various measures have been used to attenuate these hemodynamic responses during both premedication and induction like deepening the level of anesthesia with high concentration of inhalational agents or intravenous anaesthetic agents, high dose of opioids or antihypertensive before induction. However most of the related studies are limited to normotensive population.

In present study, dexmedetomidine and clonidine, both α_2 agonist are used in two groups of hypertensive patients to attenuate the pressor response. Clonidine, an α_2 agonist has been extensively studied as an anaesthetic adjuvant. It causes sedation, reduces the hemodynamic response during laryngoscopy and intubation and produces perioperative hemodynamic stability^[2]. Dexmedetomidine is a highly selective α_2 agonist and has 8 times more affinity for α_2 adrenergic receptors as compared to clonidine^[3]. It has dose-dependent sedative, anxiolytic and analgesic effect. Preinduction administration of dexmedetomidine is known to reduce sympathetic outflow and maintain hemodynamic stability. It diminishes norepinephrine release and diminished sympathetic activity. This inhibition of sympathetic activity causes decrease heart rate and blood pressure. In spite of several studies on this 2 above drugs, no conclusive views could be yielded regarding superiority of either drug in attenuating the sympathetic response during laryngoscopy in the past. Moreover, after extensive literature search no such study is found in our region that has compared the effect of

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preinduction administration of dexmedetomidine and clonidine in perioperative hemodynamic stability in hypertensive patients. Hence the present study is designed to compare the effect of dexmedetomidine and clonidine administration on the sympathetic response prior to induction among hypertensive patients undergoing laryngoscopy and endotracheal intubation during open cholecystectomy.

METHODOLOGY

The study has been conducted after receiving the approval of the ethicalcum-screening committee of Agartala Government Medical College and GBP Hospital. Written informed consent has been obtained from all patients prior to procedure.

Study type: Experimental study

Study Design: Single centered, open level, superiority trial, parallel group, randomized control trial.

Study Setting: This study has been conducted in the general surgery operating room under the department of Anesthesiology in AGMC and GBP Hospital.

Study Duration: Two years [one and half year for data collection & 6 months for data analysis]

Study Population

The patients of both sexes who are known cases of hypertension under antihypertensive medication presently having elevated Blood Pressure {Systolic blood pressure (SBP)-120-129 & Diastolic blood pressure(DBP)<80 mmHg} or Stage 1 hypertension(SBP130-139&DBP80-89)[according to American Heart Association (AHA)2017guidelines], with normal Body Mass Index (20-24.99kg/sq. m) between 20-60 years under going elective open cholecystectomy.

ELIGIBILITY CRITERIA

Inclusion Criteria

- Age-20-60years
- Either sex
- Known Case of hypertension under antihypertensive medication presently having elevated BP (SBP-120-129 & DBP<80 mmHg) or Stage 1 hypertension (SBP 130-139 &DBP80-89) [according to AHA 2017 guidelines].
- Body Mass Index(BMI):- 20 –24.99 kg/sq. M
- ASA (American Society of Anesthesiologists) grading- Grade I and Grade II.

Exclusion Criteria

- Patient having Stage 2 hypertension, hypertensive crisis or hypertensive emergency.
- Patient receiving beta blocker as antihypertensive.
- Uncontrolled diabetes mellitus.
- Patients with acute coronary syndrome.
- Patients with bradycardia.

Recruitment

Recruitment of the subjects has been done from the hypertensive patients undergoing open cholecystectomy based on inclusion criteria.

Interventions

- OnegroupreceivedInj.Dexmedetomidine0.5mcg/kgivdilutedin100mlnormalsalineover 15mins.
- AnothergroupreceivedInj.Clonidine3mcg/kgivdilutedin100mlnormalsalineover15 mins.

Outcomes

- Hemodynamic measurements (heart rate, SBP, DBP, MAP) before and after laryngoscopy and tracheal intubation
- Heart rate
- SBP (Systolic blood pressure)
- DBP (Diastolic blood pressure)
- MAP (Mean arterial pressure)
- Proportion of patient received rescue medication in both group.

Sequence Generation

Permuted variable block randomisation has been done by online software Sealed EnvelopLtd.2017 to create a blocked randomization list online.

Allocation Concealment Method

It has been done by sequentially numbered opaque sealed envelope.

Rescue Drugs

Inj. Esmolol 0.5mg/kg iv over 1 min when MAP>130 mmHg, SBP>180mmHgorDBP>110 mmHg.

STATISTICALANALYSIS

For statistical analysis, data were entered into a Microsoft excel spread sheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPadPrismversion-5.Datahavebeensummarizedasmeanandstandarddeviationfor numericalvariables, count and percentages for categorical variables. Two-sample t-tests were used for a difference in mean involved in dependent samples or unpaired samples. Chi-squared test (χ^2 test) was used as statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true.

Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.

P-value \leq 0.05was considered for statistically significant.

RESULT AND ANALYSIS

Table 1 Association between age in group: drug used for study

Age in group	Drug used for study		
	Clonidine	Dexmedetomidine	Total
\leq30	4	5	9
Row%	44.4	55.6	100.0
Col %	13.3	16.7	15.0
31-40	11	13	24
Row%	45.8	54.2	100.0
Col %	36.7	43.3	40.0
41-50	8	2	10
Row%	80.0	20.0	100.0
Col %	26.7	6.7	16.7
51-60	7	10	17
Row%	41.2	58.8	100.0
Col %	23.3	33.3	28.3
TOTAL	30	30	60
Row%	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 4.4072;p-value:0.2207

In Clonidine, 4(13.3%) patients were \leq 30 years old, 11(36.7%) patients were 31-40 years old, 8 (26.7%) patient were 41-50 years old and 7(23.3%) patients were51-60years old. In

Dexmedetomidine, 5(16.7%) patients were ≤30 years old, 13(43.3%) patients were 31-40 years old, 2(6.7%) patient were 41-50 years old and 10 (33.3%) patients were 51-60 years old.

Association of Age in group with Drug used for study was not statistically significant (p=0.2207).

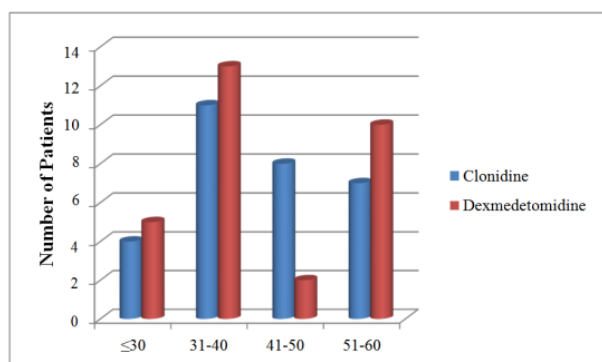


Table 2 Association between Sex: Drug used for study

Drug used for study			
Sex	Clonidine	Dexmedetomidine	TOTAL
Female	25	25	50
Row%	50.0	50.0	100.0
Col %	83.3	83.3	83.3
Male	5	5	10
Row%	50.0	50.0	100.0
Col %	16.7	16.7	16.7
TOTAL	30	30	60
Row%	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: >0.0001;
p-value: 1.0000 Odds ratio: 1.0000 (0.2572, 3.8881)

In Clonidine, 25(83.3%) patients were Female and 5 (16.7%) patients were Male.

In Dexmedetomidine, 25 (83.3%) patients were Female and 5 (16.7%) patients were Male. Association of Sex with Drug used for study was not statistically significant (p=1.0000).

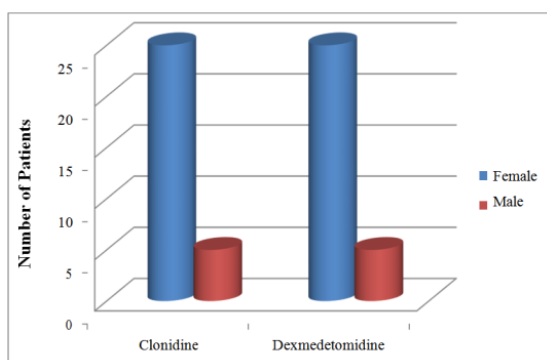


Table 3 Association between Any significant past illness: Drug used for study

Drug used for study			
Any significant past illness	Clonidine	Dexmedetomidine	Total
Hypothyroidism	2	2	4
Row%	50.0	50.0	100.0
Col %	6.7	6.7	6.7
No	25	24	49
Row%	51.0	49.0	100.0
Col %	83.3	80.0	81.7
T2DM	3	4	7
Row%	42.9	57.1	100.0
Col %	10.0	13.3	11.7

TOTAL	30	30	60
Row%	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: .1633; p-value: 0.9216

In Clonidine, 2 (6.7%) patients had Hypothyroidism and 3 (10.0%) patients had T2DM.

In Dexmedetomidine, 2 (6.7%) patients had Hypothyroidism and 4 (13.3%) patients had T2DM.

Association of Any significant past illness with Drug used for study was not statistically significant (p=0.9216).

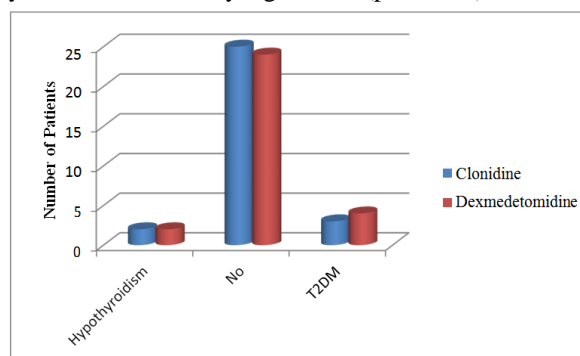


Table 4 Association between Rescue Medications: Drug used for study

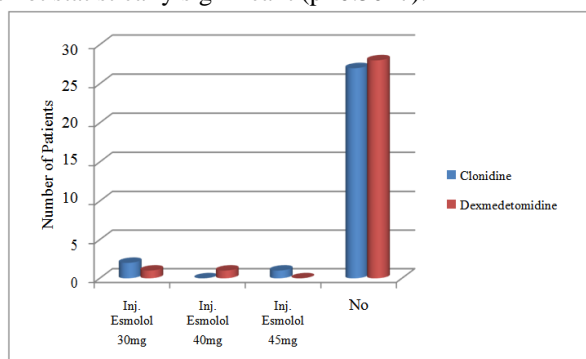
Drug used for study			
Rescue Medication	Clonidine	Dexmedetomidine	TOTAL
Inj. Esmolol 30mg	2	1	3
Row%	66.7	33.3	100
Col %	6.7	3.3	5
Inj. Esmolol 40 mg	0	1	1
Row%	0	100	100
Col %	0	3.3	1.7
Inj. Esmolol 45 mg	1	0	1
Row%	100	0	100
Col %	3.3	0	1.7
No	27	28	55
Row%	49.1	50.9	100
Col %	90	93.3	91.7
TOTAL	30	30	60
Row%	50	50	100
Col %	100	100	100

Chi-square value: 2.3515; p-value: 0.5027

In Clonidine, 2(6.7%) patients were used Inj. Esmolol 30 mg for Rescue Medication and 1 (3.3%) patient was used Inj. Esmolol 45 mg for Rescue Medication.

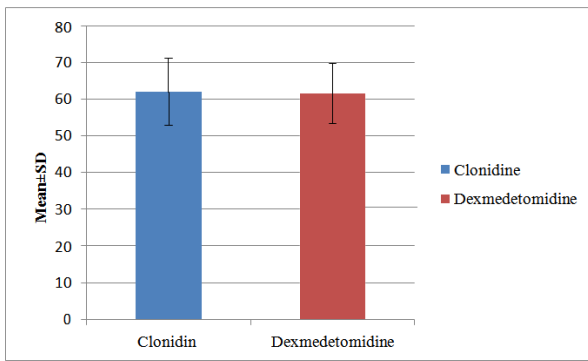
In Dexmedetomidine, 1(3.3%) patient was used Inj. Esmolol 30mg for Rescue Medication and 1(3.3%) patient was used Inj. Esmolol 40 mg for Rescue Medication.

Association of Rescue Medication with Drug used for study was not statistically significant (p=0.5027).



In Clonidine, the mean Age (mean±s.d.) of patients was 42.9667±10.2233.

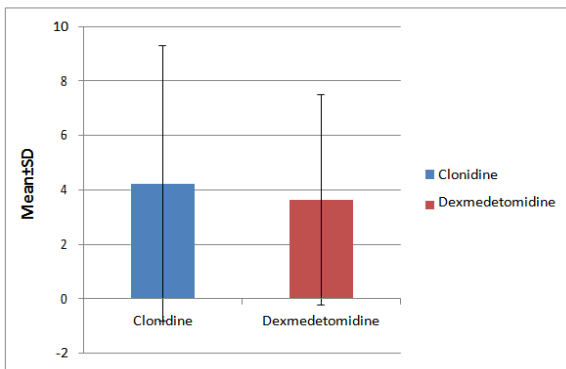
In Dexmedetomidine, the mean Age (mean± s.d.) of patients was 42.0333± 11.6456. Distribution of mean Age with Drug used for study was not statistically significant (p=0.7427).



In Clonidine, the mean Weight (mean± s.d.) of patients was 62.0000±9.0440.

In Dexmedetomidine, the mean Weight (mean±s.d.) of patients was 61.5333±8.1526.

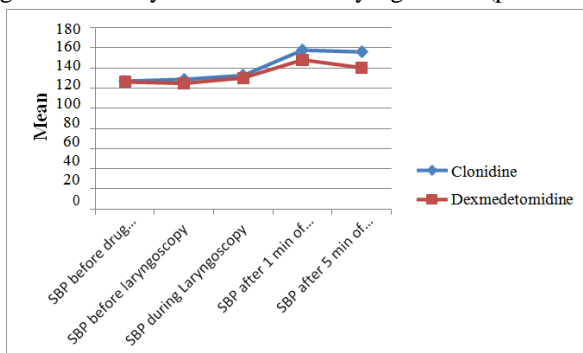
Distribution of mean Weight with Drug used for study was not statistically significant (p=0.8345).



In Clonidine, the mean Duration of Hypertension (in years) (mean±s.d.) of patients was 4.2333±5.0629.

In Dexmedetomidine, the mean Duration of Hypertension (in years) (Mean±S.D.) of patients was 3.6367± 3.8679.

Distribution of mean Duration of Hypertension (in years) with Drug used for study was not statistically significant (p=0.6099).

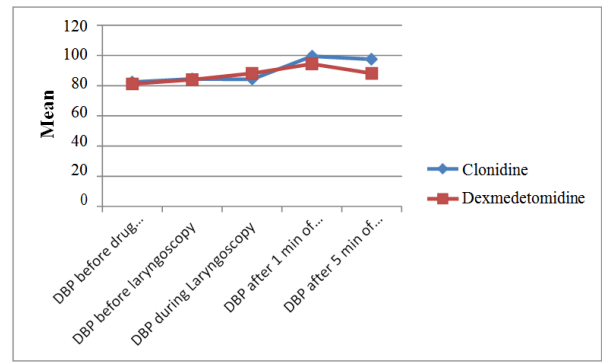


SBP before drug administration

In Clonidine, the mean SBP before drug administration (mean±s.d.) of patients was 126.9333±6.1191.

In Dexmedetomidine, the mean SBP before drug administration (mean±s.d.) of patients was 126.2667± 9.8923.

Distribution of mean SBP before drug administration with Drug used for study was not statistically significant (p=0.7547).



SBP before laryngoscopy

In Clonidine, the mean SBP before laryngoscopy (mean±s.d.) of patients was 128.6000± 6.2841.

In Dexmedetomidine, the mean SBP before laryngoscopy (mean±s.d.) of patients was 124.8667± 21.4938.

Distribution of mean SBP before laryngoscope with Drug used for study was not statistically significant (p=0.3650).

SBP during Laryngoscopy

In Clonidine, the mean SBP during Laryngoscopy (mean±s.d.) of patients was 132.4667±7.2527.

In Dexmedetomidine, the mean SBP during Laryngoscopy (mean±s.d.) of patients was 130.3333± 21.2900.

Distribution of mean SBP during Laryngoscopy with Drug used for study was not statistically significant (p=0.6054).

SBP after 1 min of Laryngoscopy

In Clonidine, the mean SBP after 1min of Laryngoscopy (mean±s.d.) of patients was 157.7333±8.7688.

In Dexmedetomidine, the mean SBP after 1min of Laryngoscopy (mean±s.d.) of patients was 148.1333± 8.8033.

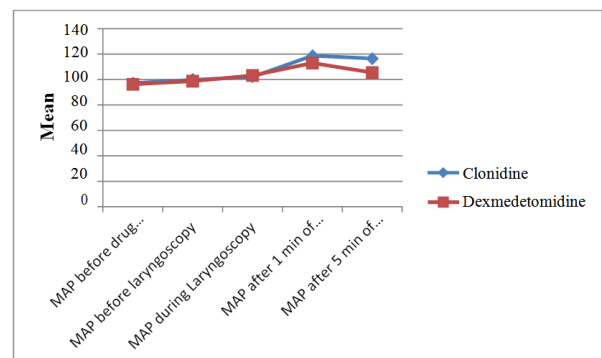
Distribution of mean SBP after 1min of Laryngoscopy with Drug used for study was statistically significant (p<0.0001).

SBP after 5 min of Laryngoscopy

In Clonidine, the mean SBP after 5min of Laryngoscopy (mean±s.d.) of patients was 155.9333±10.9101.

In Dexmedetomidine, the mean SBP after 5 min of Laryngoscopy (Mean±S.D.) of patients was 140.2667± 7.7501.

Distribution of mean SBP after 5min of Laryngoscopy with Drug used for study was statistically significant (p<0.0001).



DBP before drug administration

In Clonidine, the mean DBP before drug administration (Mean±S.D.) of patients was 82.3333±5.1484.

In Dexmedetomidine, the mean DBP before drug administration (mean±s.d.) of patients was 81.2000± 5.9793.

Distribution of mean DBP before drug administration with Drug used for study was not statistically significant ($p=0.4346$).

DBP before laryngoscopy

In Clonidine, the mean DBP before laryngoscopy (Mean± S.D.) of patients was 84.4000 ± 4.6801 .

In Dexmedetomidine, the mean DBP before laryngoscopy (Mean±S.D.) of patients was 84.0000 ± 5.8956 .

Distribution of mean DBP before laryngoscopy with Drug used for study was not statistically significant ($p=0.7720$).

DBP during Laryngoscopy

In Clonidine, the mean DBP during Laryngoscopy (Mean±S.D.) of patients was 84.1333 ± 16.5002 .

In Dexmedetomidine, the mean DBP during Laryngoscopy (Mean±S.D.) of patients was 88.1333 ± 4.3290 .

Distribution of mean DBP during Laryngoscopy with Drug used for study was not statistically significant ($p=0.2041$).

DBP after 1min of Laryngoscopy

In Clonidine, the mean DBP after 1min of Laryngoscopy (Mean±S.D.) of patients was 99.4667 ± 6.0329 .

In Dexmedetomidine, the mean DBP after 1min of Laryngoscopy (Mean±S.D.) of patients was 94.4000 ± 5.3922 .

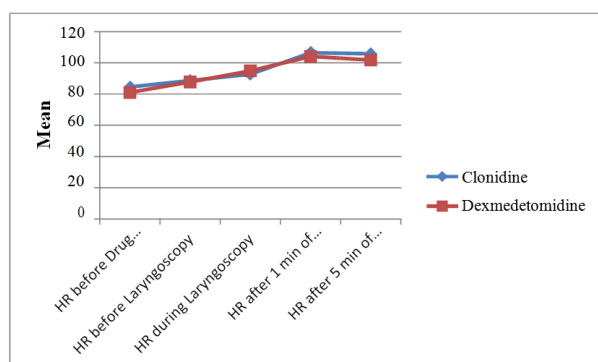
Distribution of mean DBP after 1min of Laryngoscopy with drug used for study was statistically significant ($p=0.0011$).

DBP after 5min of laryngoscopy

In Clonidine, the mean DBP after 5 min of laryngoscopy (Mean±S.D.) of patients was 97.4667 ± 6.7248 .

In Dexmedetomidine, the mean DBP after 5 min of laryngoscopy (Mean±S.D.) of patients was 88.2000 ± 6.5464 .

Distribution of mean DBP after 5 min of laryngoscopy with Drug used for study was statistically significant ($p<0.0001$).



MAP before drug administration

In Clonidine, the mean MAP before drug administration (Mean±S.D.) of patients was 97.2000 ± 4.7445 .

In Dexmedetomidine, the mean MAP before drug administration (Mean±S.D.) of patients was 96.2000 ± 6.7538 .

Distribution of mean MAP before drug administration with Drug used for study was not statistically significant ($p=0.5096$).

MAP before laryngoscopy

In Clonidine, the mean MAP before laryngoscopy (Mean±S.D.) of patients was 99.6667 ± 4.7585 .

In Dexmedetomidine, the mean MAP before laryngoscopy (Mean±S.D.) of patients was 98.6000 ± 6.2786 . Distribution of mean MAP before laryngoscopy with drug used for study was not statistically significant ($p=0.4613$).

MAP during Laryngoscopy

In Clonidine, the mean MAP during Laryngoscopy (Mean±S.D.) of patients was 102.1000 ± 4.3419 .

In Dexmedetomidine, the mean MAP during Laryngoscopy (Mean±S.D.) of patients was 103.2000 ± 5.1822 . Distribution of mean MAP during Laryngoscopy with drug used for study was not statistically significant ($p=0.3765$).

MAP after 1min of Laryngoscopy

In Clonidine, the mean MAP after 1min of Laryngoscopy (mean±s.d.) of patients was 118.7333 ± 6.1640 .

In Dexmedetomidine, the mean MAP after 1min of Laryngoscopy (mean±s.d.) of patients was 112.9000 ± 6.5986 .

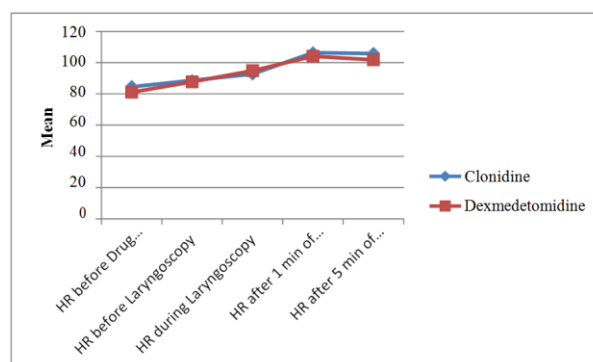
Distribution of mean MAP after 1 min of Laryngoscopy with Drug used for study was statistically significant ($p=0.0008$).

MAP after 5min of Laryngoscopy

In Clonidine, the mean MAP after 5 min of Laryngoscopy (mean±s.d.) of patients was 116.6333 ± 7.6134 .

In Dexmedetomidine, the mean MAP after 5min of Laryngoscopy (mean±s.d.) of patients was 105.4000 ± 6.3929 .

Distribution of mean MAP after 5 min of Laryngoscopy with drug used for study was statistically significant ($p<0.0001$).



HR before Drug Administration

In Clonidine, the mean HR before Drug Administration (Mean±S.D.) of patients was 84.5667 ± 7.6909 .

In Dexmedetomidine, the mean HR before Drug Administration (Mean±S.D.) of patients was 81.0667 ± 9.1083 .

Distribution of mean HR before Drug Administration with Drug used for study was not statistically significant ($p=0.1132$).

HR before Laryngoscopy

In Clonidine, the mean HR before Laryngoscopy (Mean±S.D.) of patients was 88.6000 ± 7.7397 .

In Dexmedetomidine, the mean HR before Laryngoscopy (Mean±S.D.) of patients was 87.7333 ± 10.0993 .

Distribution of mean HR before Laryngoscopy with Drug used for study was not statistically significant ($p=0.7105$).

Table 5 Distribution of mean Age: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age	Clonidine	30	42.9667	10.2233	26.0000	60.0000	40.5000	0.7427
	Dexmedetomidine	30	42.0333	11.6456	25.0000	60.0000	36.5000	

Table 6 Distribution of mean Weight: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Weight	Clonidine	30	62.0000	9.0440	45.0000	90.0000	59.5000	0.8345
	Dexmedetomidine	30	61.5333	8.1526	49.0000	80.0000	59.5000	

Table 7 Distribution of mean Duration of Hypertension (in years): Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Hypertension (in years)	Clonidine	30	4.2333	5.0629	0.5000	20.0000	2.0000	0.6099
	Dexmedetomidine	30	3.6367	3.8679	0.5000	15.0000	2.0000	

Table 8 Distribution of mean SBP before drug administration, SBP before laryngoscopy, SBP during Laryngoscopy, SBP after 1 min of Laryngoscopy and SBP after 5 min of Laryngoscopy: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
SBP before drug administration	Clonidine	30	126.9333	6.1191	110.0000	136.0000	129.0000	0.7547
	Dexmedetomidine	30	126.2667	9.8923	110.0000	138.0000	130.0000	
SBP before laryngoscopy	Clonidine	30	128.6000	6.2841	110.0000	140.0000	130.0000	0.3650
	Dexmedetomidine	30	124.8667	21.4938	24.0000	144.0000	130.0000	
SBP during Laryngoscopy	Clonidine	30	132.4667	7.2527	114.0000	150.0000	130.0000	0.6054
	Dexmedetomidine	30	130.3333	21.2900	30.0000	156.0000	136.0000	
SBP after 1min of Laryngoscopy	Clonidine	30	157.7333	8.7688	140.0000	180.0000	160.0000	<0.0001
	Dexmedetomidine	30	148.1333	8.8033	136.0000	176.0000	150.0000	
SBP after 5min of Laryngoscopy	Clonidine	30	155.9333	10.9101	140.0000	180.0000	152.0000	<0.0001
	Dexmedetomidine	30	140.2667	7.7501	130.0000	170.0000	140.0000	

SBP before drug administration

Table 9 Distribution of mean DBP before drug administration, DBP before laryngoscopy, DBP during Laryngoscopy, DBP after 1 min of Laryngoscopy and DBP after 5 min of laryngoscopy: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
DBP before drug administration	Clonidine	30	82.3333	5.1484	70.0000	90.0000	80.0000	0.4346
	Dexmedetomidine	30	81.2000	5.9793	70.0000	88.0000	81.0000	
DBP before laryngoscopy	Clonidine	30	84.4000	4.6801	72.0000	94.0000	82.0000	0.7720
	Dexmedetomidine	30	84.0000	5.8956	70.0000	90.0000	86.0000	
DBP during Laryngoscopy	Clonidine	30	84.1333	16.5002	0.0000	96.0000	86.0000	0.2041
	Dexmedetomidine	30	88.1333	4.3290	80.0000	96.0000	88.0000	
DBP after 1min of Laryngoscopy	Clonidine	30	99.4667	6.0329	88.0000	110.0000	100.0000	0.0011
	Dexmedetomidine	30	94.4000	5.3922	86.0000	110.0000	92.0000	
DBP after 5 min of laryngoscopy	Clonidine	30	97.4667	6.7248	86.0000	112.0000	98.0000	<0.0001
	Dexmedetomidine	30	88.2000	6.5464	80.0000	110.0000	90.0000	

Table 10 Distribution of mean MAP before drug administration, MAP before laryngoscopy, MAP during Laryngoscopy, MAP after 1 min of Laryngoscopy and MAP after 5 min of Laryngoscopy: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
MAP before drug administration	Clonidine	30	97.2000	4.7445	83.0000	105.0000	97.0000	0.5096
	Dexmedetomidine	30	96.2000	6.7538	83.0000	104.0000	97.5000	
MAP before laryngoscopy	Clonidine	30	99.6667	4.7585	85.0000	112.0000	99.0000	0.4613
	Dexmedetomidine	30	98.6000	6.2786	84.0000	106.0000	99.5000	
MAP during Laryngoscopy	Clonidine	30	102.1000	4.3419	91.0000	111.0000	102.5000	0.3765
	Dexmedetomidine	30	103.2000	5.1822	93.0000	113.0000	103.0000	
MAP after 1min of Laryngoscopy	Clonidine	30	118.7333	6.1640	119.5000	131.0000	119.5000	0.0008
	Dexmedetomidine	30	112.9000	6.5986	111.0000	132.0000	111.0000	
MAP after 5min of Laryngoscopy	Clonidine	30	116.6333	7.6134	106.0000	134.0000	116.5000	<0.0001
	Dexmedetomidine	30	105.4000	6.3929	96.0000	130.0000	106.5000	

Table 11 Distribution of mean HR before Drug Administration, HR before Laryngoscopy, HR during Laryngoscopy, HR after 1 min of Laryngoscopy and HR after 5 min of Laryngoscopy: Drug used for study

		Number	Mean	SD	Minimum	Maximum	Median	p-value
HR before Drug Administration	Clonidine	30	84.5667	7.6909	70.0000	70.0000	86.0000	0.1132
	Dexmedetomidine	30	81.0667	9.1083	70.0000	70.0000	80.0000	
HR before Laryngoscopy	Clonidine	30	88.6000	7.7397	72.0000	110.0000	88.0000	0.7105
	Dexmedetomidine	30	87.7333	10.0993	72.0000	108.0000	87.0000	
HR during Laryngoscopy	Clonidine	30	92.6667	7.6714	80.0000	114.0000	91.0000	0.3722
	Dexmedetomidine	30	94.8333	10.7353	80.0000	118.0000	94.0000	
HR after 1min of Laryngoscopy	Clonidine	30	106.4333	9.4310	90.0000	126.0000	110.0000	0.5726
	Dexmedetomidine	30	104.1000	20.4507	10.0000	120.0000	108.0000	
HR after 5min of Laryngoscopy	Clonidine	30	105.8667	8.7404	90.0000	122.0000	107.0000	0.0774
	Dexmedetomidine	30	101.8000	8.7785	80.0000	118.0000	101.0000	

HR during Laryngoscopy

In Clonidine, the mean HR during Laryngoscopy (Mean±S.D.) of patients was 92.6667±7.6714.

In Dexmedetomidine, the mean HR during Laryngoscopy (Mean±S.D.) of patients was 94.8333±10.7353.

Distribution of mean HR during Laryngoscopy with drug used for study was not statistically significant (p=0.3722).

HR after 1min of Laryngoscopy

In Clonidine, the mean HR after 1min of Laryngoscopy (mean±s.d.) of patients was 106.4333±9.4310.

In Dexmedetomidine, the mean HR after 1min of Laryngoscopy (Mean±S.D.) of patients was 104.1000±20.4507.

Distribution of mean HR after 1min of Laryngoscopy with Drug used for study was not statistically significant (p=0.5726).

HR after 5 min of Laryngoscopy

In Clonidine, the mean HR after 5 min of Laryngoscopy (Mean±S.D.) of patients was 105.8667±8.7404.

In Dexmedetomidine, the mean HR after 5 min of Laryngoscopy (Mean±S.D.) of patients was 101.8000±8.7785. Distribution of mean HR after 5 min of Laryngoscopy with drug used for study was not statistically significant (p=0.0774).

DISCUSSION

In present study, Dexmedetomidine and Clonidine, both α_2 agonist, were used in two groups of hypertensive patients undergoing open cholecystectomy to attenuate the pressor response during laryngoscopy and tracheal intubation. Total 60 patients were recruited in this study (n=30). Clonidine group=30 patients, Dexmedetomidine group=30 patients. In Clonidine, 4 (13.3%) patients were ≤ 30 years old, 11 (36.7%) patients were 31-40 years old, 8 (26.7%) patients were 41-50 years old and 7 (23.3%) patients were 51-60 years old. In Dexmedetomidine, 5 (16.7%) patients were ≤ 30 years old, 13 (43.3%) patients were 31-40 years old, 2 (6.7%) patients were 41-50 years old and 10 (33.3%) patients were 51-60 years old. Association of Age in the groups for study was not statistically significant (t(p)=0.2207). Mean±S.D value of Age in Clonidine group was 42.9667±10.2233 and that of Dexmedetomidine group was 42.0333±11.6456. Prevalence of age with both group was not statistically significant (p=0.7427).

In Clonidine, 25 (83.3%) patients were Female and 5 (16.7%) patients were Male. In Dexmedetomidine, 25 (83.3%) patients were Female and 5 (16.7%) patients were Male. Association of Sex with Drug used for study was not statistically significant (p=1.0000).

In Clonidine, the mean Weight±S.D of patients was 62.0000±9.0440 where as In Dexmedetomidine, it was 61.5333±8.1526. Distribution of mean weight with drug used for study was not statistically significant (p=0.8345).

Similar finding was found by Gupta SK *et.al.* 11(2020) in a comparative study of dexmedetomidine & clonidine for attenuation of hemodynamic response during laryngoscopy & intubation where they found no significance for age, sex, weight between these two groups. In our study, in group Clonidine, 2 (6.7%) patients were used Inj. Esmolol 30 mg for

Rescue Medication and 1 (3.3%) patient received Inj. Esmolol 45 mg for Rescue Medication. In Dexmedetomidine, 1 (3.3%) patient received Inj. Esmolol 30 mg for Rescue Medication and another (3.3%) patient received Inj. Esmolol 40 mg for Rescue Medication. Association of Rescue Medication with Drug used for study was not statistically significant (p=0.5027). Kumar S *et. al.*⁶ (2014) also found no significant side effect and no significant interventions required between Clonidine & Dexmedetomidine group. This finding is similar to our study.

In Clonidine, the mean SBP before drug administration (Mean±S.D.) of patients was 126.9333±6.1191. In Dexmedetomidine, the mean SBP before drug administration (Mean±S.D.) of patients was 126.2667±9.8923. Distribution of mean SBP before drug administration with Drug used for study was not statistically significant (p=0.7547). In Clonidine, the mean SBP before laryngoscopy (Mean±S.D.) of patients was 128.6000±6.2841. In Dexmedetomidine, the mean SBP before laryngoscopy (Mean±S.D.) of patients was 124.8667±21.4938. Distribution of mean SBP before laryngoscopy with Drug used for study was not statistically significant (p=0.3650).

In Clonidine, the mean SBP during Laryngoscopy (Mean±S.D.) of patients was 132.4667±7.2527. In Dexmedetomidine, the mean SBP during Laryngoscopy (Mean±S.D.) of patients was 130.3333±21.2900. Distribution of mean SBP during Laryngoscopy with Drug used for study was not statistically significant (p=0.6054). In Clonidine group, the mean SBP after 1 min of Laryngoscopy (Mean±S.D.) of patients was 157.7333±8.7688. In Dexmedetomidine group, the mean SBP after 1min of Laryngoscopy (Mean±S.D.) was 148.1333±8.8033.

Distribution of mean SBP after 1 min of Laryngoscopy with Drug used for study was statistically significant (p<0.0001). In Clonidine group, the mean SBP after 5 min of Laryngoscopy (Mean±S.D.) was 155.9333±10.9101. In Dexmedetomidine group, the mean SBP after 5 min of Laryngoscopy (Mean±S.D.) of patients was 140.2667±7.7501. Distribution of mean SBP after 5 min of Laryngoscopy with Drug used for study was statistically significant (p<0.0001). Overall Dexmedetomidine was found more effective in maintaining SBP than Clonidine.

Such a result was found by Laha A *et.al.* 5 (2013) where SBP at 1,2,3 & 5 mins was significantly less in dexmedetomidine group. Lee CW *et.al.* 8(2017) found that dexmedetomidine as compared to Clonidine significantly lowers SBP at 1, 3, 5 mins. Hussain SY *et. al.* 12(2018) found that SBP was significantly lower at 1,3,5&10 min in group Dexmedetomidine as compared to group Clonidine. Kavi C *et. al.* 14 (2015) also found that SBP was more significantly attenuated with Dexmedetomidine than Clonidine.

In Clonidine, the mean DBP before drug administration (Mean±S.D.) of patients was 82.3333±5.1484. In Dexmedetomidine, the mean DBP before drug administration (mean±s.d.) of patients was 81.2000±5.9793. Distribution of mean DBP before drug administration with used for study was not statistically significant (p=0.4346). In Clonidine, the mean

DBP before laryngoscopy (Mean±S.D.) of patients was 84.4000± 4.6801. In Dexmedetomidine, the mean DBP before laryngoscopy (Mean± S.D.) of patients was 84.0000± 5.8956. Distribution of mean DBP before laryngoscopy with used for study was not statistically significant (p=0.7720). In Clonidine, the mean DBP during Laryngoscopy (Mean±S.D.) of patients was 84.1333±16.5002. In Dexmedetomidine, the mean DBP during Laryngoscopy (Mean±S.D.) of patients was 88.1333±4.3290. Distribution of mean DBP during Laryngoscopy with used for study was not statistically significant (p=0.2041). In Clonidine, the mean DBP after 1min of Laryngoscopy (Mean±S.D.) of patients was 99.4667± 6.0329. In Dexmedetomidine, the mean DBP after 1 min of Laryngoscopy (Mean±S.D.) of patients was 94.4000±5.3922. Distribution of mean DBP after 1min of Laryngoscopy with used for study was statistically significant (p=0.0011). In Clonidine, the mean DBP after 5min of laryngoscopy (Mean±S.D.) of patients was 97.4667±6.7248. In Dexmedetomidine, the mean DBP after 5 min of laryngoscopy (Mean± S.D.) of patients was 88.2000± 6.5464. Distribution of mean DBP after 5 min of laryngoscopy in both the groups was statistically significant (p<0.0001). But Dexmedetomidine was more effective than Clonidine in stabilizing DBP.

Similar result was found by Laha A *et.al.* 5 (2013) where DBP at 1,2,3&5mins was significantly less in dexmedetomidine group. Hussain SY *et. al.*12 (2018) found that DBP was significantly lower at 1,3,5& 10 min in group Dexmedetomidine as compared to group Clonidine. Lee CW *et.al.* 8 (2017) found that dexmedetomidine as compared to Clonidine significantly lowers DBP at 3 & 5 mins. Kavi C *et. al.*14(2015) also found that DBP was significantly attenuated. Hazra R *et. al.*21 (2014) found that Dexmedetomidine more effectively attenuates hemodynamic response than Clonidine.

MAP before drug administration (Mean±S.D.) of patients in Clonidine group was 97.2000±4.7445. In Dexmedetomidine, the mean MAP before drug administration (Mean±S.D.) of patients was 96.2000± 6.7538. Distribution of mean MAP before drug administration with used for study was not statistically significant (p=0.5096). In Clonidine, the mean MAP before laryngoscopy (mean± s.d.) of patients was 99.6667± 4.7585. In Dexmedetomidine, the mean MAP before laryngoscopy (mean±s.d.) of patients was 98.6000±6.2786. Distribution of mean MAP before Laryngoscopy with used for study was not statistically significant (p=0.4613). In Clonidine, the mean MAP during Laryngoscopy (mean±s.d.) of patients was 102.1000±4.3419. In Dexmedetomidine, the mean MAP during Laryngoscopy (Mean±S.D.) of patients was 103.2000±5.1822. Distribution of mean MAP during Laryngoscopy with used for study was not statistically significant (p=0.3765). In Clonidine, the mean MAP after 1 min of Laryngoscopy (Mean±S.D.) of patients was 118.7333±6.1640. In Dexmedetomidine, the mean MAP after 1min of Laryngoscopy (Mean± S.D.) of patients was 112.9000± 6.5986. Distribution of mean MAP after 1min of Laryngoscopy with used for study was statistically significant (p=0.0008). In Clonidine, the mean MAP after 5 min of Laryngoscopy (Mean± S.D.) of patients was 116.6333± 7.6134. In Dexmedetomidine, the mean MAP after 5 min of Laryngoscopy (Mean± S.D.) of patients was 105.4000± 6.3929. Distribution of mean MAP after 5 min of Laryngoscopy with used for study was statistically significant

(p<0.0001). Overall Dexmedetomidine was more effective than Clonidine.

Similar result was found by Kohli AV *et. al.* 3(2017) found that Dexmedetomidine causes better attenuation of press or response as compared to Clonidine. Hussain SY *et. al.*12 (2018) found that MAP was significantly lower at 3, 5 & 10 min in group Dexmedetomidine as compared to group Clonidine. Lee CW *et al* 8 (2017) found that dexmedetomidine as compared to Clonidine significantly lowers MAP at 1, 3 & 5 mins. Also Kavi C *et al* 14 (2015) found that MAP was significantly attenuated.

In Clonidine, the mean HR before Drug Administration (Mean±S.D.) of patients was 84.5667±7.6909. In Dexmedetomidine, the mean HR before Drug Administration (Mean±S.D.) of patients was 81.0667± 9.1083. Distribution of mean HR before Drug Administration with used for study was not statistically significant (p=0.1132). In Clonidine, the mean HR before Laryngoscopy (Mean±S.D.) of patients was 88.6000±7.7397. In Dexmedetomidine, the mean HR before Laryngoscopy (Mean± S.D.) of patients was 87.7333±10.0993. Distribution of mean HR before Laryngoscopy with used for study was not statistically significant (p=0.7105). In Clonidine, the mean HR during Laryngoscopy (Mean±S.D) of patients was 92.6667±7.6714. In Dexmedetomidine, the mean HR during Laryngoscopy (Mean±S.D) of patients was 94.8333±10.7353. Distribution of mean HR during Laryngoscopy with used for study was not statistically significant (p=0.3722). In Clonidine, the mean HR after 1 min of Laryngoscopy (Mean±S.D) of patients was 106.4333±9.4310. In Dexmedetomidine, the mean HR after 1 min of Laryngoscopy (Mean±S.D) of patients was 104.1000±20.4507. Distribution of mean HR after 1min of Laryngoscopy with used for study was not statistically significant (p=0.5726). In Clonidine, the mean HR after 5min of Laryngoscopy (Mean±S.D) of patients was 105.8667±8.7404. In Dexmedetomidine, the mean HR after 5 min of Laryngoscopy (Mean±S.D.) of patients was 101.8000± 8.7785. Distribution of mean HR after 5 min of Laryngoscopy in both the groups was not statistically significant (p=0.0774).

Similar finding was found by Gupta SK *et.al.* 11(2020) in A comparative study of dexmedetomidine & clonidine for attenuation of hemodynamic response during laryngoscopy & intubation where they found no significance for HR between these two groups.

SUMMARY AND CONCLUSION

In the present study age, demographically both Dexmedetomidine & Clonidine groups were comparable as there was no significant statistical difference in terms of age, sex & weight. Further, there was no statistically significant difference of past illness like Hypothyroidism and T2DM between the groups. Rescue Medication was required more in clonidine group as compared to dexmedetomidine group though the difference was not statistically significant.

In this study the mean SBP after 1min and 5mins of Laryngoscopy of patients were significantly higher in patients who received Clonidine compared to patients who received Dexmedetomidine.

DBP after 1 min and 5 min of laryngoscopy of patients was significantly higher in Clonidine group as compared to Dexmedetomidine group.

The mean MAP after 1 min and 5 min of laryngoscopy of patients was significantly higher in Clonidine group compared to Dexmedetomidine group.

No statistically significant difference was observed in heart rate before Drug Administration, before Laryngoscopy, during Laryngoscopy, after 1 min of Laryngoscopy and after 5 min of Laryngoscopy with either drugs used in this study.

The effects of dexmedetomidine and clonidine in attenuating the pressor response in the present study were similar to most of the previous studies as reflected from the statistically significant difference in blood pressure (SBP, DBP & MAP) at 1 min & 5 min after laryngoscopy.

However no significant change in heart rate was found in the study as claimed by previous researchers.

In the present study, 30 numbers of hypertensive patients were recruited in two groups (dexmedetomidine & clonidine) to compare the hemodynamic changes and demand of rescue medicines. Though there was significant rise in blood pressure at 1 min & 5 min after laryngoscopy but there was no significant change in heart rate which may be further evaluated by recruiting larger sample size.

Limitations of the Study

In spite of every sincere effort my study has lacunae. The notable shortcomings of this study are:

- The sample size was small. Only 60 cases are not sufficient for this kind of study.
- The study has been done in a single centre.
- The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.
- Ongoing COVID 19 pandemic and lockdown has further hampered the study.

CONCLUSION

It is concluded that both the drug – dexmedetomidine & clonidine, are safe and recommended for attenuation of pressor response during laryngoscopy and tracheal intubation. Dexmedetomidine is more effective in attenuating the hemodynamic response to laryngoscopy & tracheal intubation in hypertensive patients undergoing open cholecystectomy than Clonidine.

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