ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at: www.ijmacr.com

Volume – 3, Issue – 6, November - December - 2020, Page No. : 158 – 166

Comparative study between Dexmedetomidine Vs Clonidine as a hypotensive agent during endoscopic ENT surgeries

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Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Now a days ENT surgeries are widely performed through endoscope but excessive blood in the field of operation obscures visibility which may lead to increase duration of surgeries and endoscope related complications. In this comparative observational hospital based study, we compare and evaluate the effect of dexmedetomidine and clonidine to provide the better surgical field. We evaluate the clinical efficacy, safety and the advantages of the study drugs as a hypotensive agent for endoscopic ENT surgeries.

Methodology: 60 patients aged 18 to 50 years belonging to ASA grade I&II of either sex undergoing ENT endoscopic surgeries were randomly assigned to receive dexmedetomidine (group D) loading dose 1mcg/kg BW over 10mins before induction followed by a continuous infusion of 0.4-0.8mcg/kg/hr. and clonidine (group C) loading dose 3mcg/kg in 10mins followed by 0.3-0.5mcg/kg/hr continuous infusion. Preoperative baseline parameters such as HR, SBP, DBP, MAP, ECG were recorded after induction and every 15min throughout the surgery were recorded including Etco2 till patient shifted to recovery and prior shifting to PACU. visibility of the operative field was assesed by the surgeon according to Fromme and Boezaart scale , sedation using Ramsay sedation score and recovery characteristics were measured using modified Alderte score.

Results: The HR had lower in group D as compared to group C but not significant during the period of observation ($p>0.05$). MAP after infusion of study drug was significantly lower in group C compared to group D ($p<0.05$). The visibility of the operative field were slightly better in group C (0-2) as compared to group D (1-3) . Mean Ramsay sedation score, 15 mins was significantly higher in group D (3-4) as compared to group C (2-3), but 30 and 60mins postoperatively, we found no significant difference in mean Ramsay sedation score. The group C (28.11 4.79) as compared to group D (25.35 3.54) showed significantly longer time to achieve modified Aldret score of 9 and to dicharge the patients from PACU.

Conclusion: In our study we concluded that both the study drugs, α2 agonists 'Dexmedetomidine and Clonidine' used at doses (loading and maintainance infusion) provided hypotensive anaesthesia by significantly decreasing the mean arterial pressure without the need of an additional hypotensive agent which in return provided the oligaemic surgical field leading to better satisfaction of both patient and surgeon' we achieved the targed of MAP 60-70 mmHg by both the

study drugs with desirable hypotension in more effective and more stable manner.

Keywords: Dexmedetomidine, Clonidine, Endoscopic ENT surgeries, Ramsay sedation score

Introduction

Excessive blood in the field of operation obscures visibility and may lead to complications during the ENT Endoscopic Surgeries [1,2].To improve visibility of anatomical landmarks and structures, it is mandatory to keep bloodless surgical field. Induced hypotension results in an almost bloodless surgery, improved quality of surgical field and minimize the risk of injury to vital structures, intraoperative blood loss and the surgical time. This can be achieved with the use of local anesthesia, use of tropical vasoconstrictors or use of controlled hypotension with general anaesthesia.Controlled hypotension is a technique that is used to limit intra operative blood loss to provide the best possible field for surgery.Various agents such as inhalational anaesthetics[3],beta blockers[4,5], magnesium, total intravenous anaesthetic agent such as propofol, vasodilators such as nitrate and sodium nitroprusside and α2 agonists such as clonidine and dexmedetomidine are used in day to day practice to induce (controlled) hypotension. Ideally hypotensive agents should be easy to administer, with short time of onset, having effects that disappear quickly when administration is discontinued, have rapid elimination without toxic metabolite, have negligible effects on vital organs and have predictable and dose dependent effects[6]. α2 agonists have potentially favourable effects. In addition to their hypotensive effect, they have analgesic and sedative properties. They provide hemodynamic stability as a result of the central sympatholytic effect. There are few studies comparing the efficacy of these two drugs for inducing and maintaining controlled hypotension.Therefore In this study, we evaluated the hypotensive effect of clonidine / dexmedtomedine in patients undergoing Elective ENT endoscopic surgeries.

Material and Methods

The present study was conducted in the Department of Anaesthesiology, Gandhi Medical College & Associated Hamidia Hospital, Bhopal. After approval of the institutional ethics committee, this comparative observational hospital based study was conducted on 60 patients of ASA grade I – II, aged between 18 to 50 years, of either sex, undergoing elective endoscopic ENT surgeries under general anaesthesia, were included in the study. Exclusion criteria were patient with uncontrolled hypertension, cardiovascular disease including rhythm disturbances. Patients having renal or hepatic dysfunctions. Patients having coagulation or bleeding and neurological disorders. All the patients were thoroughly examined and all patients underwent pre-anaesthetic check up prior to anaesthesia**.** Preoperatively patients were explained about the procedure and technique and written informed consent was taken. All the patients were kept nil orally for 6 hr prior to the surgery. 60 patients aged 18 to 50 years, belonging to ASA Grade I & II of either sex, were randomly divided in to two groups comprising 30 patients each: Group D : Dexmedetomidine Group[n=30]. Group C: Clonidine Group [n=30].

On the day of surgery, Preoperative base line parameters, such as HR, SBP, DBP, MAP, SPO_2, ECG was recorded after 5 min of settling in the operative room. An Intravenous line was secured with 18G cannula and patient IV infusion of ringers lactate started at rate of 5 ml /kg Bw. Following this, Group (D) were given Inj Dexmedetomidine as a loading dose of 1µ/kg diluted in 100 ml saline solution over 10 minutes before induction , followed by a continuous infusion of 0.4 – 0.8 µg/kg/hr. Similarly Group (C) received IV Inj Clonidine as a

loading dose of 3 µg/kg diluted with 100 ml normal saline over 10 minutes followed by a continuous infusion of 0.3 - 0.5 µg/kg/hr. After infusion of study drug all the patients were preoxygenated with 100 % oxygen for a period of 5 min. Inj glycopyrrolate (0.01 mg / kg), Inj. midazolam 0.05 µ/kg and Inj fentanyl (2 µg/kg) was given IV before induction of anesthesia. Anaesthesia was induced with thiopantone sodium (3-5mg/kg Bw IV) till loss of eyelash reflex over 30 second and mask ventilation was confirmed. Inj atracurium 0.5mg/kg body weight was given to facilitate laryngoscopy and intubation. Oxygenation continued by intermittent positive pressure ventilation. At the onset of apnea using laryngoscope, intubation was done with a well lubricated appropriate size cuffed endotracheal tube and anaesthesia was maintained with oxygen and nitrous oxide mixture (60:40), Isoflorane with intermittent use of inj. atracurium 0.1mg/kg body weight and controlled ventilation. An oropharyngeal pack was kept after intubation. To further reduce the amount of surgical bleeding and surgeons convenience, all the patients was positioned in approx 30% reverse trendelburg's position. 2 ml of Lignocaine - Adrenaline (1:10,000) mixture will be infiltrated at surgical site by the surgeon in all the patients. H R, MAP, SPO_2 and $EtCO_2$ were monitored throughout the surgery and recorded at baseline after loading dose of the study drug (Dexmedetomidine & Clonidine), after induction, every 15 minute throughout the surgery till patient shifted to recovery and prior to shifting to PACU (post anesthesia care unit). Heart Rate <45 beats/min considered as bradycardia, and was managed with 0.6 mg atropine intravenously, MAP < 60 mm Hg was initially managed with a 50% reduction in the infusion dose of study drug and further stoppage of the infusion if no response was obtained in 5 min. Mephenteramine 6 mg IV will be administered for the resistant hypotension.

- The visibility of the operative field was assessed by the surgeon according to the scale proposed by Fromme and Boezaart. [7]

Fromme–Boezaart scale of surgical field grading

1. Grade 0: No bleeding
2. Grade 1: Slight bleeding; no suctioning of blood required
3. Grade 2: Slight bleeding; occasional suctioning required. Surgical field not threatened
4. Grade 3: Slight bleeding; frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed
5. Grade 4: Moderate bleeding; frequent suctioning required, bleeding threatens surgical field directly after suction is removed
6. Grade 5: severe bleeding: Constant suctioning required, bleeding appears faster than can be removed by suction, surgical field severely threatened and surgery impossible.

- A. Excellent (Grade 0–1)
- B. Good (Grades 2–3)
- C. Poor (Grades 4–5).

Sedation was assessed using Ramsay Sedation score[8].

Ramsay Sedation Scale

- Ramsay 1- Anxious, agitated, restless
- Ramsay 2- Cooperative, oriented, tranquil
- Ramsay 3- Responsive to commands
- Ramsay 4- Brisk response to stimulus
- Ramsay 5- Sluggish response to stimulus
- Ramsay 6- No response to stimulus

Complications such as desaturation due to laryngospasm, bleeding from surgical site or vomiting ,dry mouth were recorded and managed accordingly. Recovery characteristics were measured using Modified Aldrete's Score[9] (MAS)(R16 unknown) on arrival to the PACU

and every 30 min. Patients were discharged from the PACU after achieving a modified Aldrete's score of >9.

Modified Aldrete Score

Motoric activity	
▪ Spontaneous movement when addressed	2
▪ Weak spontaneous movements when addressed	1
▪ No movement	0
Breathing	
▪ Coughs on comment or cries	2
▪ Keeps the airway open	1
▪ Obstructed airways	0
Blood pressure compared to reference measurement*	
▪ Δ < 20 mm Hg	2
▪ Δ = 20 – 50 mm Hg	1
▪ Δ > 50 mm Hg	0
Consciousness	
▪ Awake	2
▪ Response to stimulus, reflexes intact	1
▪ No answer, reflexes absent	0
Oxygen saturation	
▪ 100 - 98 %	2
▪ 97 - 95 %	1
▪ < 95 %	0

*Reference measurement was performed 1½ minutes after administration of the spasmolytic agent.

Results

This study was conducted on 60 patients of ASA Grade I & II, undergoing elective endoscopic ENT surgeries under general anesthesia.

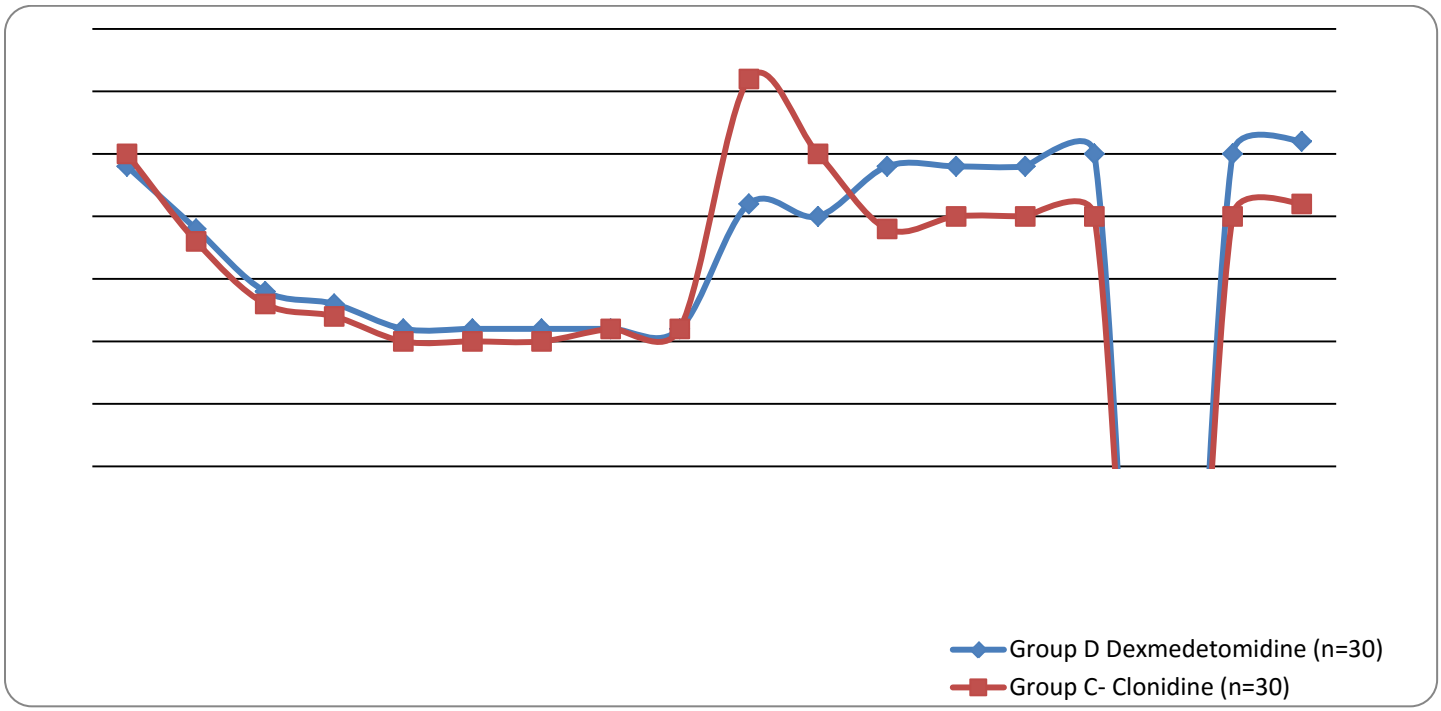
Patients were divided in to two groups comprising 30 patients each.Group D & Group C .Observation duly recorded, have been tabulated and statistically analysed in this section. Comparison of quantitative data between groups was done by unpaired t-test. A $p<0.05$ was considered clinically significant.

Table 1: Distribution of patient according to age, Gender, weight and duration of surgery

		Group D- DEX (n=30)	Group C – Clonidine (n=30)	P -Value
Age	Mean	34.46	38.60	
	SD	8.80	10.07	0.096(NS)
	Male	19(31.7%)	20(33.3%)	
Gender	Female	11(18.3C%)	10(16.7%)	0.787(NS)
Weight(kg)	Mean	59.56	62.83	
	SD	7.60	7.86	0.107(NS)
Duration of Surgery	Mean	95	90	
	SD	8.24	8.07	0.0209(NS)

There was statistically no significant difference in Mean age, weight and duration of surgery between two groups ($p>0.05$).

Graph 1: Comparison of Mean Heart Rate at different time intervals



The mean heart rate was significantly lower in group D as compared to group C during the period of observation ($P < 0.05$).In Group C, hypotension was seen in 2 patients (6.6%) and in group D bradycardia was seen in 1 patient (3.3%).settled down without any medication.

Graph 2: Comparison of Mean Arterial Pressure at different time intervals

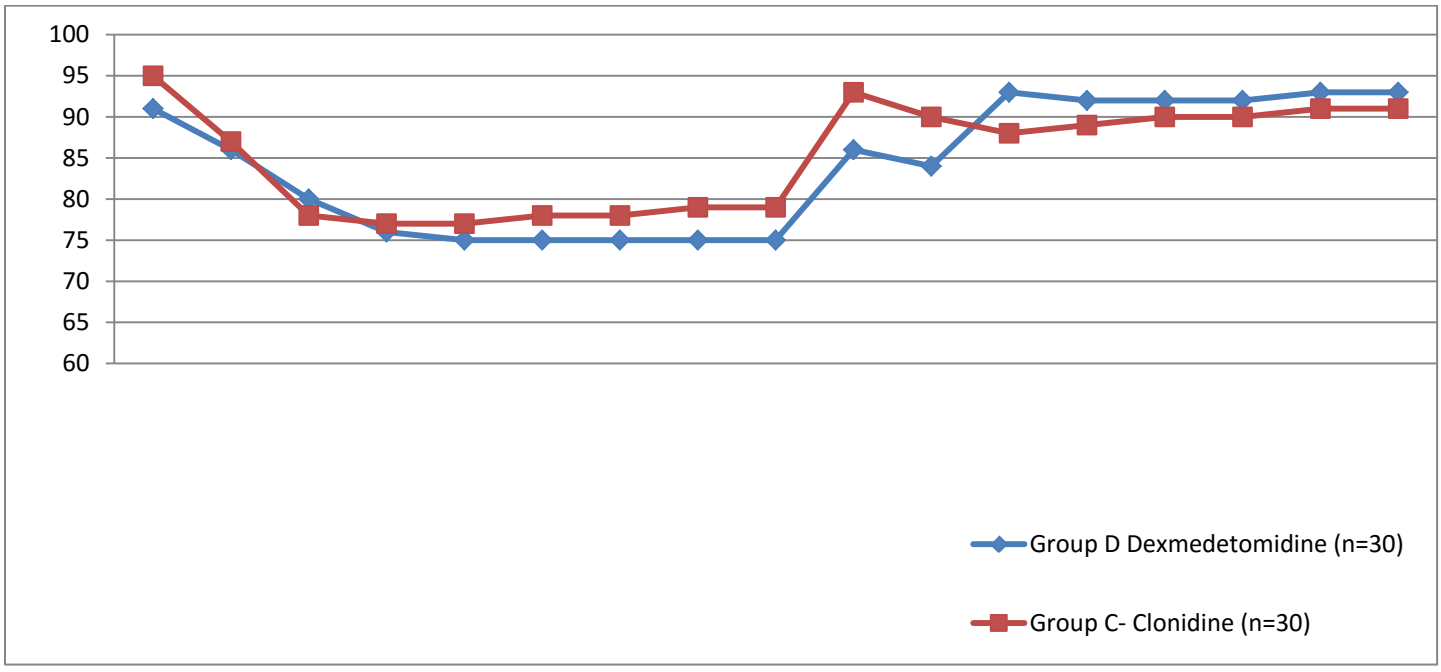
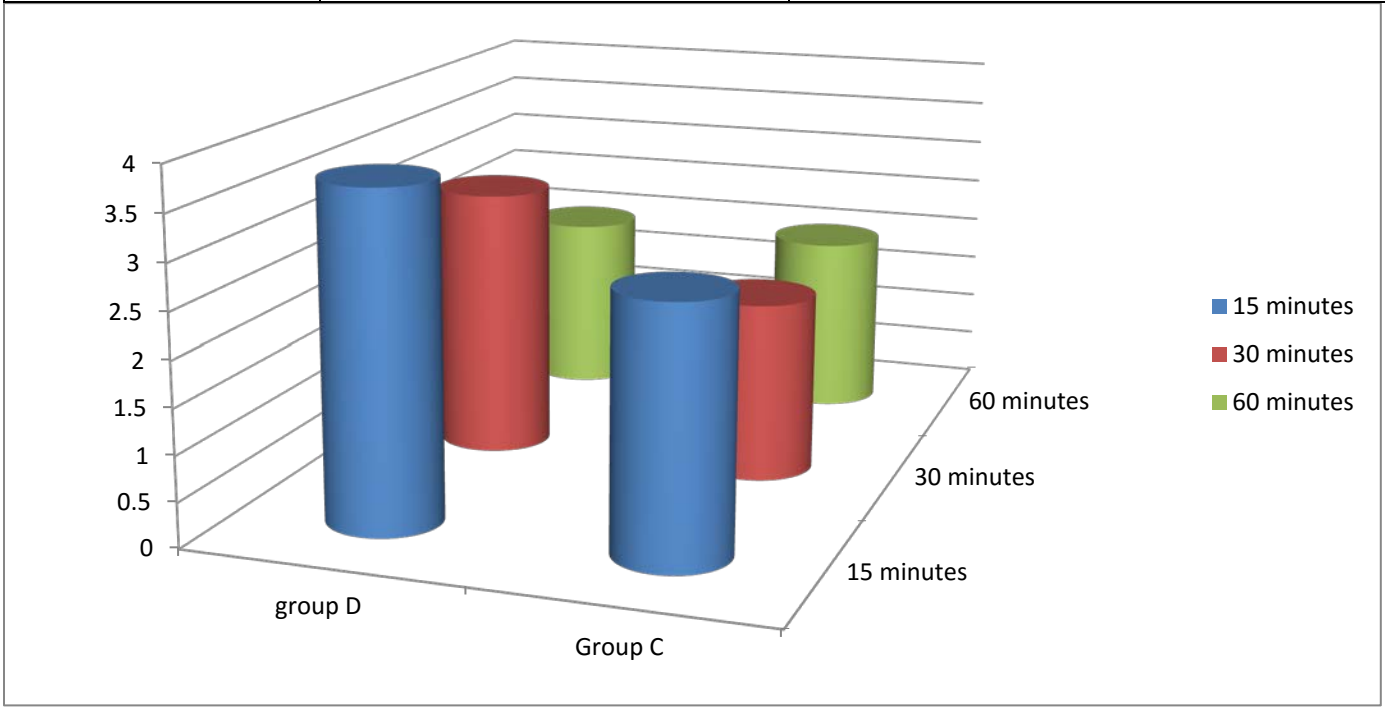


Table 2: Assessment of surgical field quality at different time of interval intraoperatively(Fromme Boezaart score)

Graph 3: Ramsay Sedation Score

Time of assessment	Group D –DEX (n=30)	Group C-Clonidine(n=30)
30min	3.5 ± 0.4	1.4 ± 0.3
60min	2.7 ± 0.5	1.2 ± 0.2
90min	3.8 ± 0.5	1.3 ± 0.2
End of Surgery	2.1 ± 0.2	0.9 ± 0.2



15 minute Postoperatively, Mean Ramsay Score was significantly higher in Clonidine group (3.733±.449) Dexmedetomidine group (2.833±.37) than (p=0.001) but 30 and 60 minute postoperatively, we found no significant difference in mean Ramsay Score (p>0.05).

Table 3: Incidence of side effects

Side effects	Group D Dexmedetomidine (n=30)	Group C- Clonidine (n=30)	Total N (%)
Laryngeal spasm	0(0.0%)	0(0.0%)	0(0.0%)
Hypotension	0(0.0%)	2(6.6%)	2(6.6%)
Bradycardia	1(3.3%)	0(0.0%)	1(3.3%)
Nausea/vomiting	0(0.0%)	0(0.0%)	0(0.0%)

Discussion

Clonidine is an antihypertensive drug with central effect on α 2 receptors used as premedication. It acts by

stimulation of pre and post synaptic α 2 agonist in the central nervous system and cause sedation ,analgesia ,and reduction of sympathetic tone.

Dexmedetomidine is highly specific α2 adrenoceptor agonist, which has similar effects as that of clonidine and causes reduction in BP and HR, sedation and analgesia. The mechanism of action of hypotension is mainly due to inhibition of central sympathetic outflow and also due to stimulation of presynaptic α2 adrenoceptors decreasing nor epinephrine release [10]

Unfortunately ,very few clinical trials are conducted to study the effectiveness of combining α 2 agonist (either clonidine or dexmedetomidine or comparing the two) as single dose or Infusion or both as hypotensive agent. In this study we compared the efficacy and safety of dexmedetomidine 1 µg/ kg loading dose followed by infusion @ 0.4 – 0.8 µg / hr or clonidine 3 µg / kg loading and infusion @ 0.3-0.5µg /kg/hr as hypotensive agent in endoscopic ENT surgery with attention on the Controlled hypotension, Quality of surgical field, Hemodynamic stability ,Sedation recovery profile of the patients posted for elective endoscopic ENT surgery.

In our study we observed that the HR was lower (bradycardia) in Group D as compared to group C. Basar et al [11] studied the effect of single dose of dexmedetomidine 0.5 µg/kg administration 10 min before induction of anesthesia and reported significant reduction in MAP and HR. The MAP however, was equally lowered in both the groups, but there was more reduction in MAP in group C patients as compared to group D patients .It is observed that this reduction in MAP is more at the time of laryngoscopy and intubation, this observation suggested that Clonidine is effective in blunting hemodynamic response of stress during laryngoscopy .

Das A et al.[12] Goksu et al.,[13] compared dexmedetomidine (D) and clonidine (C) in FESS surgery and indicated that the hypotension conditions created in both groups were similar. Similarly, the result of the present study showed a significant reduction of bleeding with dexmedetomidine, Group D experienced less bleeding and better visibility in surgery. reported better hemodynamic stability, visual analog scale for pain and clear surgical field with less side effects in DEX group.

Bajwa et al [14] compared the effect of nitroglycerine (N), esmolol (E), and dexmedetomidine (D) for induced hypotension in FESS surgery in 3 randomized groups. The desired MAP was achieved in all the 3 study groups .The mean total dose of opioids used was significantly lower in group D, compared to the groups E and N. The sedation scores were significantly higher in group D, compared with the group N. The anesthesia recovery time was significantly lower in group E and group N, compared with the group D. The recovery time was significantly longer in dexmedetomidine group, But in our study the Group D patients achieved aldrette score of more than 9 earlier then Group C (clonidine) patients. Hence the group D patients discharge earlier from PACU because of the shorter half-life of dexmedetomidine.[15,16]

The efficacy of dexmedetomidine in providing better surgical and less blood loss during controlled hypotension was also previously reported during tympanoplasty, septoplasty and maxilofascial surgery.[17,18] Observation and result of our study shows that group C patients had less amount of blood loss as compared to group D but its statistically not significant. Most of study compare dexmedetomidine with esmolol or nitroglycerine or placebo, we compared clonidine with dexmedetomidine. In our study both the drugs are equally compatible.

Very few references are available to support our study. Another clinical trial conducted by Aboushanab et al. [19] comparing the hypotensive effect of dexmedetomidine with that of magnesium sulfate during middle ear

surgeries, they demonstrated that dexmedetomidine infusion at rate of 0.4– 0.8 lg/kg/h succeeded to reduce the MAP to their target 60– 70 mmHg, despite this MAP is higher than that used in our study but the authors demonstrated the ability of dexmedetomidine to provide very good surgical field.

Conclusion

Thus the findings of our study conclude that the studied drug Dexmedetomidine is an effective and safe method of producing controlled hypotension in ENT endoscopic surgeries by maintaining better hemodynamics, minimizing blood loss, and providing better field of surgery as compared to Clonidine. In addition Dexmedetomidine provides benefit of reducing the analgesic requirements and providing postoperative sedation.

Limitations of study are clonidine and dexmedetomidine ; we compared them on their safe as well as known optimal premedicating doses for day care setting without the comprehension of their equipotent doses. However, a larger study with large sample size needs to be conducted to establish the author's point of view with solidarity.

Acknowledgement: Authors would like to thank all study participants for their valuable time. Authors would like to extend their gratitude to the staffs of the Department of Anesthesia, Gandhi Medical College, Bhopal, MP for their contributions and technical supports.

Ethical approval: The study was approved by the Institutional Ethics Committee GMC Bhopal

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How to citation this article: Akhilesh Yona, Rajni Thakur, Nijab Evane, Urmila Keshari, "Comparative study between Dexmedetomidine Vs Clonidine as a hypotensive agent during endoscopic ENT surgeries", IJMACR- November - December - 2020, Vol – 3, Issue - 6, P. No. 158 – 166.