www.jmscr.igmpublication.org Impact Factor 3.79
ISSN (e)-2347-176x

IGM Publication Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

A Comparative Study of Dexmedetomidine Versus Midazolam-Pentazocine for Tympanoplasty Under Monitored Anaesthesia Care

Authors
Dr. Nazima Memon[1], Dr. Ramesh G.Pathak[2]
[1]Assistant Professor, Dept of Anaesthesiology, Dr Shankarrao Chavan Govt. Medical College Nanded
[2]Professor and Head, Dept of Anaesthesiology, Dr Shankarrao Chavan Govt. Medical College Nanded
Corresponding Author
Dr Nazima Memon
Email: *dr.nazima.memon@gmail.com, Mobile: 9324222310*

Abstract

Background: *Monitored Anaesthesia Care (MAC)is a planned procedure during which the patient undergoes local anaesthesia with sedation and analgesia. MAC is chosen for 10-30% of all surgical procedures. Tympanoplasty is one of the procedure done under MAC. The present study was designed to compare newly introduced alpha-2 agonist drug, Dexmedetomidine with intravenous midazolam and pentazocine given routinely in our set up.*

Objectives: *To compare intravenous dexmedetomidine with intravenous midazolam-pentazocine combination with respect to (i) Analgesic effect (ii) Sedation score (iii) Bloodless field during surgery (iv)Hemodynamic stability (v) Quality of anaesthesia. (vi) Postoperative analgesic requirement in 24 hours.*

Material and Methods: *Sixty patients, ASA physical status I and II, posted for tympanoplasty under local anaesthesia with sedation were included in the study. The patients were randomly divided into two groups- Group D: 30 patients received intravenous dexmedetomidine 1 mcg/kg over 10 min. followed by infusion 0.5 mcg/kg/hr till end of surgery. Group MP: 30 patients received intravenous midazolam 0.05mg/kg and intravenous pentazocine 0.5mg/kg followed by saline infusion at rate of 0.5ml/kg/hr. Vital parameters, sedation score (Ramsay Sedation score), Bleeding, requirement of rescue analgesic (IV Midazolam 0.01mg/kg and IV Ketamine 20 mg as and when required) and quality of anaesthesia noted.*

Results*: The analgesic effect was better in Group D than Group MP. Only 1 patient in Group D required rescue analgesic whereas 17 patients in Group MP required rescue analgesic. There was fall in heart rate and fall in blood pressure in Group D. No such changes in hemodynamics seen in Group MP. Quality of anaesthesia was better in Group D than Group MP. The mean postoperative requirement of analgesic was 1.6 ± 0.49 in Group D and 2.86 ± 0.34 in Group MP.*

Conclusion: *Intravenous Dexmedetomidine is an excellent drug for surgeries like Tympanoplasty done under monitored anaesthesia care. It not only improves intraoperative anaesthesia but also postoperative analgesia and thereby, improving the outcome of surgery.*

Keywords: *Tympanoplasty, Dexmedetomidine, Midazolam, Pentazocine, Monitored Anaesthesia Care.*

INTRODUCTION

Dexmedetomidine is a novel alpha-2 agonist sedative and analgesic introduced in December 1999 in clinical practice. Dexmedetomdine has multiple effects: (1) Sedation/hypnosis (2) Anxiolysis (3) Analgesia (4) Decreased sympathetic activity (5) Decreased Blood pressure and heart rate (6) Vasoconstriction at high doses[1]. It has minimal respiratory depression and patients are arousable with clear consciousness.

Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear (ossiculoplasty). Tympanoplasty is usually performed under local anaesthesia with sedation under monitored anaesthesia care or rarely under general anaesthesia. Various drugs and drug combinations are used for this purpose: Benzodiazepines, Opioids, Propofol and recently alpha-2 agonist Dexmedetomidine.

The present study was designed to compare the sedative and analgesic effect of intravenous Midazolam and intravenous pentazocine combination with intravenous dexmedetomidine introduced recently in patients undergoing tympanoplasty under monitored anaesthesia care.

AIMS AND OBJECTIVES OF STUDY

To compare the effects of intravenous dexmedetomidine with a combination of intravenous midazolam and intravenous pentazocine in patients undergoing tympanoplasty under monitored anaesthesia care with the following aims and objectives:

1. To compare level of sedation.
2. Assess the hemodynamic stability.
3. Requirement of rescue analgesic intraoperatively.
4. Additional analgesic requirements post operatively.
5. Complications if any.
6. Patient and Surgeon satisfaction score.

MATERIAL AND METHODS

The present study was carried out in a tertiary health care centre. Sixty patients with American Society of Anaesthesiologists (ASA) status I/ II undergoing tympanoplasty under monitored anaesthesia care with local anaesthesia and sedation were included in the study. A written informed valid consent was obtained from all patients. The study was prospective, randomized double blind trial. Randomization was done by card method. The anaesthesiologist conducting the study, the patient and the anaesthesiologist who followed up patient in postoperative period were all blinded to keep the study double blind.

Inclusion Criteria

1. Age 18-50 years
2. ASA I/II
3. Patients undergoing tympanoplasty.
4. Weight 35-70 Kg.
5. Duration of surgery upto 90 minutes.

Exclusion Criteria

1. Patients refusal
2. Patients with pre-existing cardiac, neurological or other illness
3. Known hypersensitivity to drugs.
4. History of taking sedative drugs.
5. Pregnant patients
6. Obese patients

Preanaesthetic evaluation was done in all patients a day prior to surgery and all routine investigations like complete haemogram, Kidney function test, Liver function test, Random blood sugar and ECG (in patients with age > 40 years) were done. Xylocaine sensitivity test was also performed. Preoperatively patient was taken inside operation theatre. After confirming nil by mouth status, intravenous access established with 20 G venous cannula. Patient was explained the operative procedure and also the technique of anaesthesia to reduce anxiety of the patient. Monitoring was done with Heart rate, NiBP, Respiratory rate, SpO_2 and ECG. Oxygen was administered using nasal prongs @ 1-2 litre/min.

Sixty patients were randomly divided into two groups:

Group MP(n= 30): Patients received IV Midazolam 0.05mg/kg and IV pentazocine 0.5mg/kg diluted in 10ml normal saline over 10 minutes; followed by infusion of normal saline @ 0.5ml/kg/hr using an infusion pump.

Group D (n= 30) : Patients received IV Dexmedetomidine 1mcg/kg ; diluted in 10ml normal saline over 10 minutes; followed by infusion of dexmedetomidine and normal saline@ 0.5mcg/kg/hr using an infusion pump.

Vital parameters, sedation score (Ramsay Sedation score), Bleeding, requirement of rescue analgesic (IV Midazolam 0.01mg/kg and IV Ketamine 20 mg as and when required) and quality of anaesthesia noted. The patient was assessed after bolus infusion by use of Ramsay Sedation Score(RSS) and infusion was started immediately.

Table 1: Ramsay sedation score (RSS)[1,4]

Score	Response
1.	Anxious, agitated or restless or both
2.	Cooperative,oriented,tranqul
3.	Responding to commands only.
4.	Brisk response to light glabellar tap
5.	Sluggish response to light glabellar tap
6.	No response to light glabellar tap

The aim was to achieve Ramsay Sedation score of 3 or more. Whenever RSS score was < 3, IV Midazolam 0.01mg/kg and IV Ketamine 20 mg as and when required were given as rescue analgesic. The ear block was given when RSS score of 3 was achieved. The ear block was given with 2% lignocaine with adrenaline(1: 2,00,000) as follows:

1. To start with area over temporalis fascia was infiltrated to cover the donor graft.
2. The line of a post aural approach and over the surface of the mastoid and its tip was infiltrated to block the greater auricular nerve (C3), the lesser occipital nerve(C2-3), and the auricular and tympanic branch of Vagus(X) nerve.
3. Then infiltration was done from posterior to anteriorly towards the incisura and also local anesthetic agent was deposited in the posterior wall of the meatus.
4. Infiltration was done in front of tragus posterior to temperomandibular joint and neck of mandible to block the auricular branch of the auriculo-temporal nerve.
5. Four intraaural EAC injections in anterior (V), posterior (C3), posterosuperior (VII) and inferior(X) directions.

Surgery was started after confirming adequate analgesia. Intraoperatively, heart rate, Mean arterial pressure (MAP), Respiratory rate and SpO_2 was recorded every 5 min during bolus infusion and thereafter, every 15 min till the end of surgery. If patient had pain, Rescue infiltration with local anaesthetic agent was given. If still pain persisted, Rescue analgesia was given in form of IV Midazolam 0.01mg/kg and IV Ketamine 20mg as and when required for maximum 5 times. If still patient had severe pain, patient was given general anaesthesia. The infusion was stopped 10 minutes prior to the end of surgery.

Complications like bradycardia (HR< 60beats/min), hypotension(MAP< 60mmHg) , desaturation (SpO_2 < 90%), nausea, vomiting and dry mouth were noted. Bradycardia was treated with IV Atropine 0.6mg, Hypotension was defined as fall in Blood pressure more than 30% of preoperative level or MAP < 60mmHg. This was treated with IV fluids. The incidence of other complications like nausea, vomiting and dry mouth were also noted.

At the end of surgery, patient was shifted in recovery room for hemodynamic monitoring, to assess postoperative pain relief and to note incidence of complications in postoperative period. The Sedation in postoperative period was also monitored. The postoperative analgesia was noted with VAS Score and analgesic given in postoperative period when VAS score < 4.Postoperative analgesic used was Intramuscular diclofenac 75 mg. Also number of diclofenac injections in postoperative period noted in first 24 hours.

The Quality of Anaesthesia was assessed as excellent, good or poor as judged by operating surgeon.

Statistical Analysis

Data analysis was done by Graph pad prism version 6.0. The collected data was tabulated and expressed as mean ± Standard deviation (SD). The results were analyzed by unpaired t test. Value of $p<0.05$ was considered significant.

Results

Sixty patients belonging to ASA I/II undergoing elective tympanoplasty under monitored anaesthesia care were enrolled in this study. The present study was designed to compare intravenous dexmedetomidine and combination of intravenous Midazolam and intravenous pentazocine in these patients.

A. Demographic profile: The patients were compared with respect to age, sex, ASA status, weight and duration of surgery. Both groups of patients were comparable.(Table 2) Data were expressed as Mean ± Standard deviation(SD).

Table 2: Demographic Profile.

Parameters	Group D	Group MP	p value	Significant/ Not significant
Age	29.7 ± 7.51	28.78 ± 5.57	p = 0.09	Not Significant
Sex	17/13	19/11		
ASA status	28/02	27/03		
Weight	55.89 ± 8.94	51.11 ± 8.66	p> 0.10	Not Significant
Duration of surgery	70.17 ± 12.21	68.04 ± 12.57	P = 0.0678	Not Significant

B. Mean Ramsay Sedation Score & Requirement of rescue local anaesthetic (LA) & analgesics in intraoperative period: From Table 3, Sedation achieved by Dexmedetomidine was better and required less supplementation with rescue local anaesthetic and rescue analgesics.The difference was statistically significant.

Table 3: Mean Ramsay Sedation Score & Requirement of rescue local anaesthetic (LA) & analgesics in intraoperative period.

Parameter	Group D	Group MP	p value	Significant/ Not Significant
Mean Ramsay Sedation Score	3.143 ± 0.47	2.190 ± 0.40	< 0.0001	Significant
Requirement of rescue LA infiltration Required/not required	7/23	22/8	p < 0.0001	Significant
Requirement of rescue analgesics in intraoperative period. Required/not required	2/28	17/13	p < 0.0001	Significant

C. Hemodynamic stability: From fig. 1 & 2, there was fall in Heart rate and Mean arterial pressure in Group D than Group MP. This provides an additional advantage of controlled hypotension[10] with good visibility in the surgical field and less graft failure.

Fig 1. Mean Heart rate changes in Group D and Group MP

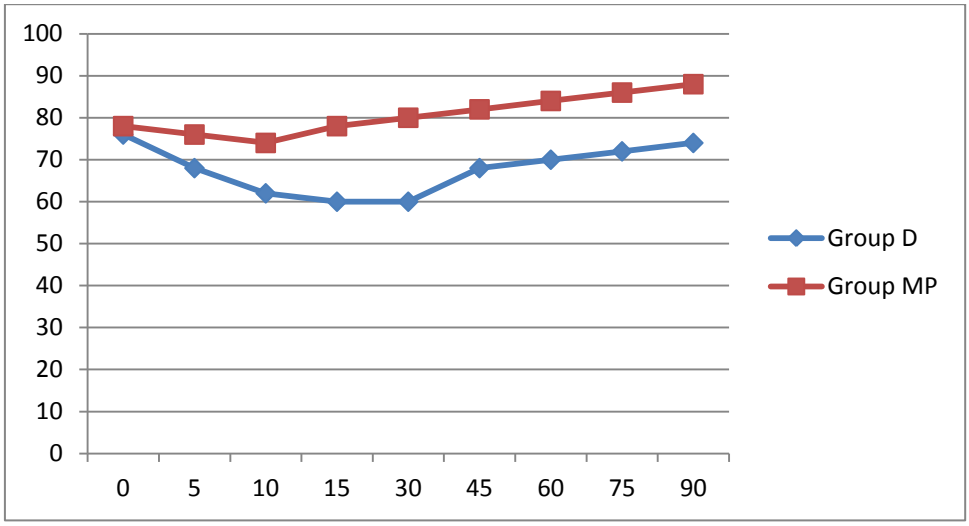
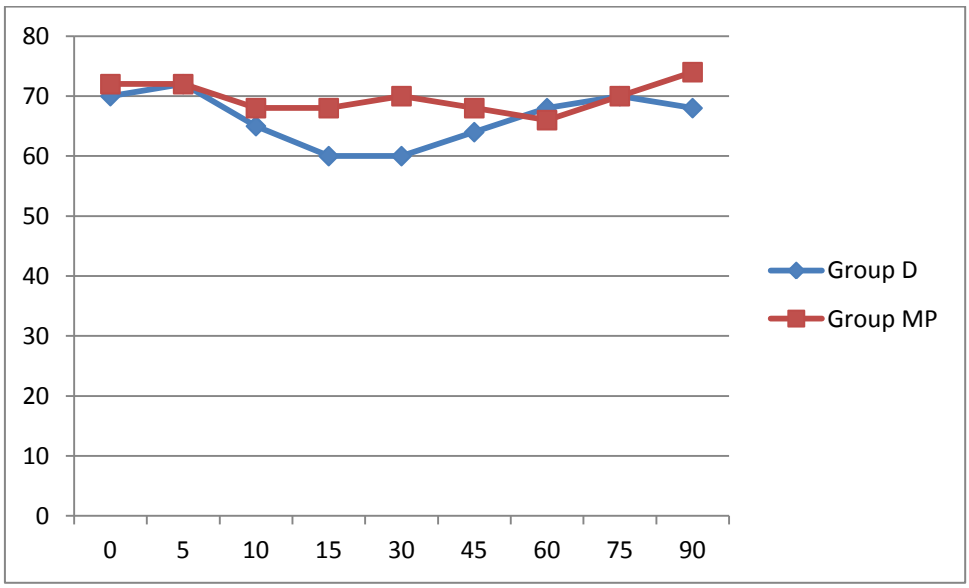


Fig 2. Mean Arterial pressure (MAP) in Group D and Group MP



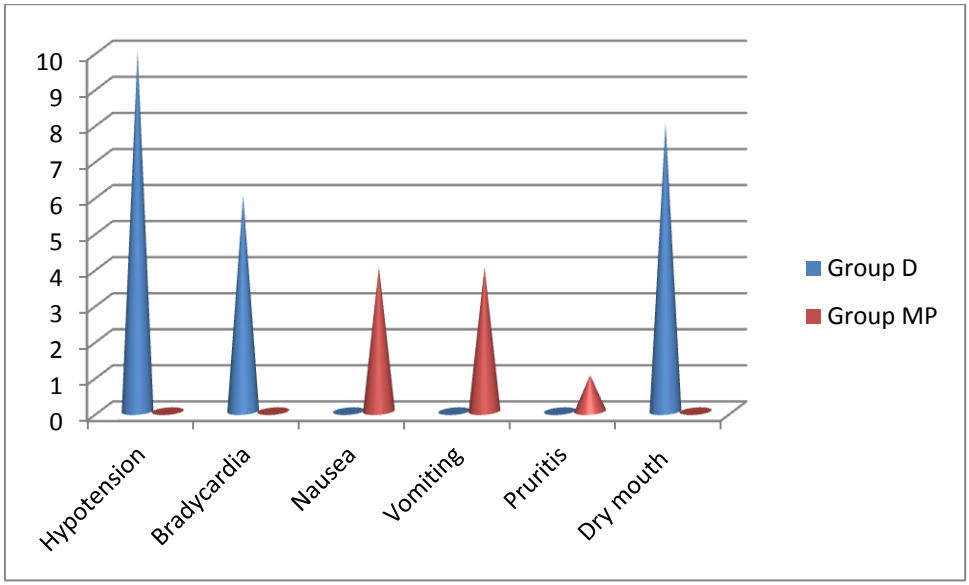
D. Mean VAS Score and Requirement of diclofenac in postoperative period: Mean VAS Score in Group D as seen in Table 4 was much higher than Group MP.

Table 4: Mean VAS Score and Requirement of diclofenac in postoperative period

Parameter	Group D	Group MP	p value	Significant/ Not Significant
Mean VAS Score In postoperative period	7.333 ± 0.79	3.048 ± 0.74	0.0027	Significant
Time when first dose of diclofenac required	292.93 ± 14.83	103.33 ± 10.28	$p < 0.001$	Significant
Total Requirement of diclofenac in first 24 hours	1.6 ± 0.49	2.86 ± 0.34	$p < 0.0001$	Significant

E. Incidence of Complications: Patients in Group D had hypotension, bradycardia and dry mouth which were easily treatable whereas patients in Group MP had nausea, vomiting and pruritis.

Fig 3. Incidence of Complications



F. Quality of Anaesthesia: Quality of Anaesthesia was assessed by asking operating surgeon. It was found that Quality of anaesthesia was better in Group D than Group MP.

Table 5: Quality of Anaesthesia in 2 groups

Quality of Anaesthesia	Group D	Group MP
Excellent	25	08
Good	4	17
Poor	1	5

DISCUSSION

Dexmedetomidine is a novel drug for patients being operated under monitored anaesthesia care. It provides appropriate anaesthesia and analgesia in intraoperative and postoperative period.

Procedures like tympanoplasty[4,6], septorhinoplasty[6], functional endoscopic sinus surgery[13], shock-wave lithotripsy[9], fibreoptic intubations[1] , impacted tooth extraction[2], cataract surgery[8] and diagnostic procedures[3] can be done using dexmedetomidine as a sole anaesthetic agent.

Dexmedetomidine is a specific and selective alpha-2 adrenoceptor agonist. By binding to the presynaptic alpha-2 adrenoceptors, it inhibits the release of norepinephrine, therefore, terminate the propagation of pain signals. Activation of the postsynaptic alpha-2 adrenoceptors inhibits the sympathetic activity which decreases blood pressure and heart rate.

In the present study, Dexmedetomidine was found to be more potent than midazolam and pentazocine combination for procedure like tympanoplasty. Dexmedetomidine provided effective anaesthesia and analgesia, hypotensive anaesthesia leading to oligaemic surgical field and reduced requirement of analgesics in intraoperative as well as postoperative period. Dexmedetomidine has a short distribution half-life of 5 min making it mandatory to administer dexmedetomidine via infusion to give maintenance dose of 0.2-0.7mcg/kg/hr following bolus dose of 1mcg/kg.

D.A.Vyas et al[5] 2013 compared hemodynamic stability and sedation under Dexmedetomidine vs Midazolam during tympanoplasty and modified radical mastoidectomy in 5o patients done under local anaesthesia. Patients were divided into two groups:

Group D: Inj. Dexmedetomidine 1µg/kg over 15min, followed by 0.5µg/kg/hr (n= 25).

Group M: Inj. Midazolam 0.05 mg/kg i.v. slowly, followed by 0.01mg/kg/hr (n= 25). They found that

inj. Dexmedetomidine could be a better alternative over inj. Midazolam for monitored anaesthesia care in ENT surgeries performed under local anaesthesia

Devangi Parikh et al[4] compared intravenous dexmedetomidine with intravenous midazolam and fentanyl in ninety patients undergoing tympanoplasty under local anesthesia randomly received either IV dexmedetomidine 1 μg kg^{-1} over 10 min followed by 0.2 μg kg^{-1} h^{-1} infusion (Group D) or IV midazolam 0.06 mg kg^{-1} plus IV fentanyl 1 μg kg^{-1} over 10 min (Group MF) followed by normal saline infusion at 0.2 ml kg^{-1} h^{-1} . Sedation was titrated to Ramsay sedation score (RSS) of three. Vital parameters, rescue analgesics (fentanyl 1 μg kg^{-1}) and sedatives (midazolam 0.01 mg kg^{-1}), patient and surgeon satisfaction scores were recorded.

They found that Dexmedetomidine was comparable to midazolam-fentanyl for sedation and analgesia in tympanoplasty with better surgeon and patient satisfaction.

IV Dexmedetomidine is increasingly being used as a sole anaesthetic agent in Monitored Anaesthesia Care. As use of dexmedetomidine is associated with mild alteration in hemodynamics, vigilant monitoring is required in these patients.

CONCLUSION

Thus, on the basis of present study, We conclude Dexmedetomidine is a very useful anaesthetic agent in otological surgeries esp. tympanoplasty along with local anaesthetic agent as:

1. It is a good hypnotic, sedative and anaesthetic agent.
2. It provides controlled hypotension[10] and a clear surgical field with less bleeding.
3. It is associated with faster recovery and less requirement of analgesic in postoperative period.
4. It does not have abuse potential and does not accumulate.
5. Minimal respiratory depression.

REFERENCES

1. Bergese SD, Patrick Bender S, McSweeney TD, Fernandez S, Dzwonczyk R, Sage K. A comparative study of dexmedetomidine with midazolam and midazolam alone for sedation during elective awake fiberoptic intubation. Journal of Clinical Anesthesiology. 2010 Feb;22(1):35-40. doi: 10.1016/j.jclinane.2009.02.016.
2. C. Yu,S. Li,F. Deng,Y. Yao,L. Qian. Comparison of dexmedetomidine/fentanyl with midazolam/fentanyl combination for sedation and analgesia during tooth extraction. International Journal of Oral and Maxillofacial Surgery. September 2014;volume 43, Issue 9,Pages 1148-1153
3. Dere K, Sucullu I, Budak ET, Yeyen S, Filiz AI, Ozkan S, Dagli G.A comparison of dexmedetomidine versus midazolam for sedation, pain and hemodynamic control, during colonoscopy under conscious sedation.European journal of Anaesthesiology; July 27 (7); 648-52
4. Devangi A Parikh, Sagar N Kolli, Hemangi S Karnik, Smita S Lele, Bharati A TendolkarA prospective randomized double-blind study comparing dexmedetomidine vs. combination of midazolam-fentanyl for tympanoplasty surgery under monitored anesthesia care. Journal of Anaesthesiology clinical pharmacology. Year : 2013 | Volume : 29 | Issue : 2 | Page : 173-178
5. Dhara A. Vyas, Nikunj H. Hihoriya, Rina A. Gadhavi. A comparative study of dexmedetomidine vs midazolam for sedation and hemodynamic changes during tympanoplasty and modified radical mastoidectomy Int J Basic Clin Pharmacol. 2013; 2(5): 562-566.
6. Durmus M, But AK, Dogan Z, Yucel A, Miman MC, Ersoy MO.Effect of dexmedetomidine on bleeding during tympanoplasty or septorhinoplasty. European journal of Anaesthesiology 2007, May ; 24 (5); Pg.447-53
7. Hall JE, Uhrich TD, Barney JA, Arain SR, Ebert TJ. Sedative, amnestic, and analgesic properties of small-dose dexmedetomidine infusions. Anesth Analg. 2000;90:699–705.

8. Hyo-Seok Na, In-Ae Song, Hong-Sik Park, Jung-Won Hwang, Sang-Hwan Do, and Chong-Soo Kim. Dexmedetomidine is effective for monitored anesthesia care in outpatients undergoing cataract surgery. Korean J Anesthesiol. 2011 Dec; 61(6): 453–459.
9. Kaygusuz K.; Gokce G; Gursoy S; Ayan S; Miraroglu C, Gultekin Y. A comparison of sedation with dexmedetomidine or propofol during shockwave lithotripsy: a randomized controlled trial. Anaesthesia Anaesthesiology 2008 Jan; 106(1); 114-9
10. Nasreen F, Bano S, Khan RM, Hasan SA. Dexmedetomidine used to provide hypotensive anesthesia during middle ear surgery. Indian J Otolaryngol Head Neck Surg. 2009;61:205–7.
11. Precedex prescribing information. Hospira, Inc., April, 2004.
12. Takahiko Kamibayashi, Mervyn Maze; Clinical uses of α-2 Adrenergic agonists. Anaesthesiology Nov 2000 ; vol 93; Pg. 1345-49
13. Tarek Shams, Nahla S El Bahnasawe, Mohamed Abu-Samra and Ragaa El-Masry Induced hypotension for functional endoscopic sinus surgery: A comparative study of dexmedetomidine versus esmolol Saudi J Anaesth. 2013 Apr-Jun; 7(2): 175–180.