Study Comparing Dexmedetomidine and a Combination of Fentanyl, Midazolam and Diclofenac Sodium on Hemodynamics, SpO_2 and Surgeon-Patient Comfort in Tympanoplasty Surgeries

Sivanand Veluri[2], M. Srinivas Reddy[1]

ABSTRACT

Introduction: Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic, and analgesic effect. Ideally it should result in less physiological disturbance and allow for more rapid recovery than general anaesthesia.Objective of the study was to compare Dexmedetomidine and a combination of Fentanyl, Midazolam and Diclofenac sodium on hemodynamics, SpO2 and surgeon-patient comfort in tympanoplasty surgeries.

Material and Method: A prospective double blind study of dexmedetomidine and a combination of fentanyl, midazolam and diclofenac on hemodynamics, SpO2 and surgeon-patient comfort in 150 patients of tympanoplasty surgeries was carried over a period of two years at Nova ENT hospital Hyderabad. Tympanoplaty surgeries are preferably performed under monitored anaesthesia care. 150 patients were randomly divided into 2 groups. Group D receiving dexmedetomidine bolus of 1mcg/kg /bw for 10 min followed by infusion at a rate of 0.04mcg/kg bw/min and group C patients received the combination drugs of fentanyy 2mcg/kg/bw, midazolam 0.02mg/kg/bw and diclofenac sod of 1mg/kg/bw.

Results: In group D, more patients (16%) have experienced a fall in systolic blood pressure of more than 20% compared to only 5.3% of patients in group C. In group D, more patients (12%) have experienced a fall in diastolic blood pressure of more than 15% compared to only 8% of patients in group C. It was observed that the SpO2 level of patients in group D i.e. receiving dexmedetomidine was satisfactory and majority had higher levels as compared to patients in the group C.

Conclusion: Dexmedetomidine group patients were found to be more comfortable.

Key words: dexmedetomidine, blood pressure, SpO_2

INTRODUCTION

Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic, and analgesic effect. Ideally it should result in less physiological disturbance and allow for more rapid recovery than general anaesthesia. It typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and analgesic drugs which is a common practice during various ENT surgical procedures. Tympanoplasty in ENT surgical procedures involves reconstruction of perforated tympanic membrane with or without ossiculoplasty. It is usually done under local anaesthesia with sedation under monitored anaesthesia care (MAC) or general anaesthesia. Patients may feel discomfort due to pain, noisy suction, manipulation of instruments and head and neck position. There are many advantages of local anaesthesia supplemented with intravenous sedation, such as less bleeding, cost effectiveness, postoperative analgesia, faster mobilisation of the patient, and the ability to test hearing intraoperatively.[1]

Dexmedetomidine is the most recent agent in this group of α2 agonists approved by FDA in 1999 for use in humans for analgesia and sedation4-8, sympatholytic and haemodynamically stabilizing properties. It is increasingly being used as a sedative for monitored anaesthesia care because of its analgesic properties, "co-operative sedation", and lack of respiratory depression. Although safe bradycardia and hypotension are the most predictable and frequent side effects. Dexmedetomidine has shown to consistently reduce anaesthetic requirements. In particular this review focuses on dexmedetomidine utilization as an infusion in Spine surgeries and ENT surgeries and to compare the efficacy of two different doses of dexmedetomidine infusion on intraoperative hemodynamics, requirement of anaesthetic agents and post operative sedation and analgesia.[2]

MATERIAL AND METHOD

A prospective double blind study of dexmedetomidine and a combination of fentanyl, midazolam and diclofenac on hemodynamics,SpO2 and surgeon-patient comfort in 150 patients of tympanoplasty surgeries was carried over a period of two years at Nova ENT hospital Hyderabad. Tympa-

[1]Associate Professor, Department of Anaesthesiology, Malla Reddy Medical College for Women, Suraram, Hyderabad, Telangana, India

Corresponding author: Dr. Sivanand Veluri, Associate Professor, Department of Anaesthesiology, Malla Reddy Medical College for Women, Suraram, Hyderabad, Telangana, India

How to cite this article: Sivanand Veluri, M. Srinivas Reddy. Study comparing dexmedetomidine and a combination of fentanyl, midazolam and diclofenac sodium on hemodynamics, SpO2 and surgeon-patient comfort in tympanoplasty surgeries. International Journal of Contemporary Medical Research 2016;3 (1):241-244.

noplaty surgeries are preferably performed under monitored anaesthesia care. 150 patients were randomly divided into 2 groups. Group D receiving dexmedetomidine bolus of 1mcg/kg /bwfor 10 min followed by infusion at a rate of 0.04mcg/kg bw/min and group C patients received the combination drugs of fentanyy 2mcg/kg/bw, midazolam 0.02mg/kg/bw and diclofenac sod of 1mg/kg/bw. Maximum fall in systolic blood pressure, diastolic blood pressure over the length of time of surgery as a percentage in comparision to the pre-operative values was noted. Similarly maximum change in SpO2 was also recorded. Surgeon and patient comfort index was calculated based on the responses of them to a questionnaire and assessment was also recorded and compared in the 2 groups. All data was analysed for statistical significance.

Surgeon's comfort index scores

Index	Response	Points
Blood less fields	Blood less	4
	Fair blood loss	3
	Disturbing blood ooze	2
	Troublesome bleeding	1
	Surgery abandoned	0
Patient state	Immobile and co-operative	2
	Moving and un co-operative	1
	Converted to GA	0
patient complaining of pain needing further LA administration	No	2
	Yes	1
	Converted to GA	0
ability to communicate with patient	Easily	2
	With extra effort	1
	Not possible as pt is very drowsy	0

If the response of the surgeon to the questionnaire reveals 7 to 10 points surgeon was considered comfortable and if the scoring was less than 7, surgeon was considered uncomfortable.

Patient comfort index

Index	Number / response	Points
Visual Analogue Scale (VAS)	9 or 10	2
	7 or 8	1
	Less than 7	0
Patient state	Relaxed and sleepy	1
	Anxious and agitated	0
Arousability of patient	easily arousable	1
	Arousable with loud verbal or physical means	0

Patient is regarded as comfortable if the score is 4 or 5 and uncomfortable if the score is less than 4.

RESULTS

It was found that more patients i.e. 24% and 70.7% in the group C had experienced fall up to 15% and 15-20% respectively than the patients in the group D. But in group D, more patients (16%) have experienced a fall in systolic blood pressure of more than 20% compared to only 5.3% of patients in group C (table 1).

Similarly for fall in diastolic blood pressure, it was found that more patients i.e. 25.3% and 66.7% in the group C had experienced fall up to 10% and 10-15% respectively than the patients in the group D. But in group D, more patients (12%) have experienced a fall in diastolic blood pressure of more than 15% compared to only 8% of patients in group C (table 2).

Table 3 shows a comparison of SpO2 level in both the groups. It was observed that the SpO2 level of patients in group D i.e. receiving dexmedetomidine was satisfactory and majority had higher levels as compared to patients in the group C.

When Surgeon's comfort index scores were compared in both the groups, it was found that there was not much difference. Thus the surgeon's were comfortable equally with both the group patients (table 4).

It can be seen from table 5 that patients in both the groups were equally comfortable with either of the drug they received.

Maximum fall in systolic BP	No. Of patients in group D	No. Of patients in group C
Up to 15%	14 (18.7%)	18 (24%)
15 – 20%	49 (65.3%)	53 (70.7%)
More than 20%	12 (16%)	04 (5.3%)
Total	75 (100%)	75 (100%)

Table-1: Comparison of fall of systolic blood pressure (BP) in the two groups

Maximum fall in diastolic BP	No. of patients in group D	No. of patients in group C
Up to 10%	13 (17.3%)	19 (25.3%)
10 – 15%	53 (70.7%)	50 (66.7%)
More than 15%	09 (12%)	06 (8%)
Total	75 (100%)	75 (100%)

Table-2: Comparison of fall of diastolic blood pressure (BP) in the two groups

SpO_2 level	No. Of patients in group D	No. Of patients in group C
Up to 95	53 (70.7%)	24 (32%)
90 – 94	16 (21.3%)	42 (56%)
Less than 90	06 (8%)	09 (12%)
Total	75 (100%)	75 (100%)

Table-3: Comparison of SpO2 level in the two groups

Surgeon's comfort index scores	No. of patients in group D	No. of patients in group C
7 – 10	71 (94.7%)	73 (97.3%)
Less than 7	04 (5.3%)	02 (2.7%)
Total	75 (100%)	75 (100%)

Table-4: Comparison of Surgeon's comfort index scores in the two groups

Patient comfort index score	No. of patients in group D	No. of patients in group C
4 – 5	73 (97.3%)	74 (98.7%)
Less than 4	02 (2.7%)	01 (1.3%)
Total	75 (100%)	75 (100%)

Table-5: Comparison of Patient comfort index score in the two groups

DISCUSSION

150 patients were randomly divided into 2 groups. Group D receiving dexmedetomidine bolus of 1mcg/kg /bw for 10 min followed by infusion at a rate of 0.04mcg/kg bw/min and group C patients received the combination drugs of fentanyy 2mcg/kg/bw, midazolam 0.02mg/kg/bw and diclofenac sod of 1mg/kg/bw.

We found that for maximum fall of systolic and diastolic blood pressure, more number of patients in the Group D receiving dexmedetomidine were having fall of more than 20% and 15% respectively. But for SpO2 levels, these group patients were having better levels when compared to the patients in the group C who received the combination drugs of fentanyy 2mcg/kg/bw, midazolam 0.02mg/kg/bw and diclofenac sod of 1mg/kg/bw. From the point of view of comfort index of surgeon's and patients, we observed that there was no significant difference in the comfort index of the two groups.

Neha Garg et al[2] carried out a study among 60 patients who were randomly divided into 2 groups. Group A (inj. Dexmedetomidine 0.2 µg/kg/hr) and Group B (inj. Dexmedetomidine 0.4µg/kg/hr). They noted that fall in systolic BP was 15.7% in Group B compared to 3.5% reduction in Group A with respect to baseline. Difference was statistically very highly significant ($p<0.001$). The reduction in diastolic blood pressure was 13% in Group B compared to 3% in Group A. Difference was statistically very highly significant ($p<0.001$).

Padmaja A et al[1] observed that the mean sedation score in group D who received Dexmedetomidinewas 3.18± 0.19 and in other it was (group M) 3.03±0.21.($p>0.05$). Intra operative heart rate and mean arterial pressure in group D were lower than the base line values and the corresponding values in group M ($p<0.05$).No of patients receiving rescue fentanyl were more in group M(2 patients 1dose,5 patients 2 doses),in group D only 2 patients required single dose of rescue analgesic fentanyl($p<0.05$).

Ayoqlu H et al[3] in their study found that Group SD receiving Dexmedetomidine had less bleeding and lower bleeding scores ($P < 0.05$). In addition, this group received less intraoperative fentanyl ($P < 0.05$). Aantaa R et al[4] reported that the MAC of isoflurane was 0.85% end-tidal in the control group, 0.55% end-tidal with the low dose of dexmedetomidine, and 0.45% end-tidal with the high dose of dexmedetomidine.Ghodki PS et al[5] concluded that Dexmedetomidine is an effective anesthetic adjuvant that can be safely used in laparoscopy without the fear of awareness under anesthesia.

Khan ZP et al[6] concluded that dexmedetomidine decreased isoflurane requirements in a dose-dependent manner and reduced heart rate, systolic and diastolic arterial pressures. Sedation and slight impairment of cognitive function persisted for several hours after anaesthesia and the end of infusion of dexmedetomidine. Isoflurane did not appear to influence the pharmacokinetics of dexmedetomidine.

Feld JM et al[7] reported that during surgery, desflurane concentrations necessary to maintain the bispectral index at 45 to 50 were decreased, and blood pressure and heart rate were lower with in the dexmedetomidine compared with fentanyl group. In the postanesthesia care unit, pain scores and morphine use were decreased in the dexmedetomidine group. Durmus M et al[8] found that Dexmedetomidine decreased bleeding, postoperative analgesic requirements and intraoperative anaesthetic requirements and was associated with more stable haemodynamic responses to anaesthesia. Jalonen J et al[9] observed that Intraoperative intravenous infusion of dexmedetomidine to patients undergoing coronaryartery revascularization decreased intraoperative sympathetic tone and attenuated hyperdynamic responses to anesthesia and surgery but increased the propensity toward hypotension.

Bakhamees HS et al[10] noted that the intraoperative infusion of dexmedetomidine decreased the total amount of propofol and fentanyl required to maintain anesthesia, offered better control of intraoperative and postoperative hemodynamics, decreased postoperative pain level, decreased the total amount of morphine used and showed better recovery profile compared with placebo.

Aho M et al[11] observed that Dexmedetomidine infusion did not completely abolish the need for isoflurane but diminished its requirement by > 90% ($P = 0.02$). Venn RM et al[12] stated that from the clinician's and patient's perspectives, dexmedetomidine is a safe and acceptable sedative agent for those requiring intensive care. The rate pressure product is reduced in patients receiving dexmedetomidine, which may protect against myocardial ischaemia. Dexmedetomidine reduces the requirement for opioid analgesia.

Arain SR et al[13] concluded that Dexmedetomidine may be useful for perioperative sedation. It has a slower onset and offset of sedation compared with propofol. Dexmedetomidine was associated with improved analgesia and less morphine use in the postoperative period.

REFERENCES

1. Padmaja A, Varma T, Pavani PD. A Comparitive Study of Dexmedetomidine Vs Midazolam for Monitored Anaesthesia Care during ENT Surgical Procedures. IOSR Journal of Dental and Medical Sciences. 2015;14:100-104.
2. Neha G, Rama U, Hetal P. Dexmedetomidine infusion as an anaesthetic adjuvant for maintenance of anaesthesia in patients undergoing major surgeries (A com-

parison of two different doses). Int J Biomedical Res 2014;5:735-40.
3. Ayoglu H, Yapakci O, Ugur MB, Uzun L, Altunkaya H, Ozer Y et al. Effectiveness of dexmedetomidine in reducing bleeding during septoplasty and tympanoplasty operations. J Clin Anesth.2008;20:437-41.
4. Aantaa R, Jaakola ML, Kallio A, Kanto J. Reduction of the minimum alveolar concentration of isoflurane by dexmedetomidine. Anesthesiology. 1997;86:1055-60.
5. Ghodki PS, Thombre SK, Sardesai SP, Harnagle KD. Dexmedetomidine as an anesthetic adjuvant in laparoscopic surgery: An observational study using entropy monitoring. J Anaesthesiol Clin Pharmacol. 2012;28:334-8.
6. Khan ZP, Munday IT, Jones RM, Thornton C, Mant TG, Amin D. Effects of dexmedetomidine on isoflurane requirements in healthy volunteers. 1: Pharmacodynamic and pharmacokinetic interactions. Br J Anaesth. 1999;83:372-80.
7. Feld JM, Hoffman WE, Stechert MM, Hoffman IW, Ananda RC. Fentanyl or dexmedetomidinecombined with desflurane for bariatric surgery. J Clin Anesth. 2006;18:24-8.
8. Durmus M, But AK, Dogan Z, Yucel A, Miman MC, Ersoy MO. Effect of dexmedetomidine on bleeding during tympanoplasty or septorhinoplasty. Eur J Anaesthesiol.2007;24:447-53.
9. Jalonen J, Hynynen M, Kuitunen A, Heikkilä H, Perttilä J, Salmenperä M et al. Dexmedetomidine as an anesthetic adjunct in coronary artery bypass grafting. Anesthesiology. 1997;86:331-45.
10. Bakhamees HS, El-Halafawy YM, El-Kerdawy HM, Gouda NM, Altemyatt S. Effects of dexmedetomidine in morbidly obese patients undergoing laparoscopic gastric bypass. Middle East J Anaesthesiol. 2007;19:537-51.
11. Aho M, Erkola O, Kallio A, Scheinin H, Korttila K. Dexmedetomidine infusion for maintenance of anesthesia in patientsundergoingabdominalhysterectomy. Anesth Analg. 1992;75:940-6.
12. Venn RM, Grounds RM. Comparison between dexmedetomidine and propofol for sedation in the intensive care unit: patient and clinician perceptions. Br J Anaesth. 2001;87:684-90.
13. Arain SR, Ebert TJ. The efficacy, side effects, and recovery characteristics of dexmedetomidine versus propofol when used for intraoperative sedation. Anesth Analg. 2002;95:461-6.

Source of Support: Nil; **Conflict of Interest:** None

Submitted: 05-12-2015; **Published online**: 20-12-2015