COMPARISON OF DEXMEDETOMIDINE WITH FENTANYL FOR SEDATION IN TYMPANOPLASTY (ENT SURGERIES) DONE UNDER MONITORED ANAESTHESIA CARE

Illendula Upendranath[1], Rupa Kumari Amarnath[2], Deepraj Singh Bais[3], Shravan Kumar M.

[1]Associate Professor, Department of Anaesthesiology, Dr. V. R. K. Teaching Hospital & Research Centre, Aziznagar, Telangana.
[2]Associate Professor, Department of Anaesthesiology, Government Medical College, Nizamabad.
[3]Professor, Department of Anaesthesiology, Government ENT Hospital, OMC, Hyderabad, Telangana.
[4]Resident, Department of Anaesthesiology, Osmania Medical College, Hyderabad, Telangana.

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. 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.

AIM OF STUDY

Is to "Compare Dexmedetomidine with Fentanyl for sedation in tympanoplasty (ENT Surgeries)". The objective of the study is to evaluate the efficacy of dexmedetomidine and fentanyl as an appropriate sedative drug for Monitored Anaesthesia Care in Tympanoplasty (ENT surgeries)

METHODS & MATERIALS

A total of 60 patients are being recruited into this study with regards to assess, Pain, Discomfort, Sedation, Peripheral Oxygen Saturation (SPO2) & Systolic Blood Pressure (SBP), Diastolic blood pressure (DBP), Mean arterial blood pressure(MAP) & Heart rate This study was undertaken at Govt. ENT Hospital Hyderabad. Sixty (60) patients undergoing Tympanoplasty surgery were taken for study. Thus the study contains 30 patients in Dexmedetomidine group-(Group D) and 30 patients in Fentanyl group (Group F)

RESULT

Dexmedetomidine provides less discomfort, better sedation, and analgesia when compared with fentanyl under monitored anaesthesia care (Conscious sedation). However, the risk of adverse effects requires monitoring for ready intervention. It provides a unique type of sedation, "conscious sedation" in which patients appear to be sleepy but are easily arousable, cooperative and communicative when stimulated. It is sedative and analgesic agent, with opioid-sparing properties and minimal respiratory depression.

KEYWORDS

Conscious Sedation, Dexmedetomidine, Fentanyl, Tympanoplasty.

HOW TO CITE THIS ARTICLE: Upendranath I, Amarnath RK, Bais DS, et al. Comparison of dexmedetomidine with fentanyl for sedation in tympanoplasty (ENT surgeries) done under monitored anaesthesia care. J. Evid. Based Med. Healthc. 2016; 3(16), 638-644. DOI: 10.18410/jebmh/2016/146

INTRODUCTION: 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 mobilization of the patient and the ability to test hearing intraoperatively.

Several drugs such as propofol, benzodiazepines and opioids have been used for MAC either alone or in combination.[1,2,3]

Dexmedetomidine is a highly selective α_2 adrenoceptor agonist with eight times higher specificity for receptor compared to clonidine. It provides excellent sedation and analgesia with minimal respiratory depression.[1] Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries under MAC.[2] Since the approval of Midazolam by FDA in 1985,[3] practitioners of all medical disciplines embraced the versatility provided by midazolam though the risk of losing airway control, hypoxia and hypotension with higher doses of midazolam has also

Submission 11-01-2016, Peer Review 27-01-2016,
Acceptance 10-02-2016, Published 25-02-2016.
Corresponding Author:
Dr. B. Deepraj Singh,
1-7-145/15, Musheerabad,
Hyderabad-500020, Telangana.
E-mail: drdeepraj@gmail.com
DOI: 10.18410/jebmh/2016/146

been recognized. Midazolam is the most frequently used sedative and has been reported to be well tolerated when used in MAC.[4] Dexmedetomidine has the both sedative and analgesic properties and has been used as a single agent in many painful procedures.[5] It also allows patients to respond to the verbal commands during sedation.[6] It has been used in various clinical fields such as sedation in ICU, awake intubation, shockwave lithotripsy, endoscopic examination,[7,8] and as an adjuvant to anaesthetics.[9,10]

Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action, a strong agonist at the μ-opioid receptors.

The present study is undertaken for comparison of dexmedetomidine and Fentanyl in undergoing tympanoplasty surgery for assessing the haemodynamic control, pain, discomfort and sedation under Monitored Anaesthesia care (conscious sedation).

PATIENTS AND METHODS: After obtaining approval from the Hospital Ethics Committee, patients of either sex undergoing tympanoplasty surgery under local anaesthesia were enrolled in this study to compare dexmedetomidine with Fentanyl at Govt. ENT Hospital Hyderabad.

Sixty (60) patients undergoing Tympanoplasty surgery under monitored anaesthesia care were taken for study, divided in two groups containing 30 patients in Dexmedetomidine group-(Group D) and 30 patients in Fentanyl Group (Group F).

Selection Criteria:

Inclusion Criteria: Prospective randomized study of 60 patients who underwent Tympanoplasty surgery under local anaesthesia were included in the study.

Criteria Includes:

1. Patients of either sex.
2. Patients between ages 18-60 years.
3. ASA Grade I or II: patients were awake, alert and oriented and their medical condition was stable enough to allow them to understand and use verbal numeric rating pain scale (VNRPS).

Exclusion Criteria:

1. Patients belonging to ASA class lll or IV.
2. Presence of co-morbidities.
3. Presence of coagulopathies.
4. Hypersensitivity to any of the drugs used in this study.
5. Pregnant and Lactating women.

Investigations Required:

- CBP, BT, CT.
- CUE.
- RBS, Blood Urea, Serum creatinine.
- Chest X-Ray, ECG.
- HIV, HBsAg.

Preoperative Assessment: A pre-anaesthetic check-up was done for all patients which included a detailed history, general physical and systemic examination. Basic investigations including a baseline ECG, HIV, HBsAg were done. Patients were kept nil per oral overnight. They were explained with regards to sedation, local anaesthesia as well as the operative procedure. The visual analogue scale (VAS) (0-10, where 0 indicated no pain, while 10 corresponded to maximum pain), was explained to the patient during the preoperative visit.

The patients were randomly divided into two equal groups, Group D (dexmedetomidine) and Group F (fentanyl).

In the operating room, following monitors were used:

- Pulse oximetry probe.
- B.P cuff for non-invasive blood pressure monitoring.
- 5 lead ECG.

On arrival in the operation theatre, after confirming adequate starvation, patient's heart rate, Non-invasive blood pressure, oxygen saturation, respiratory rate and ECG were monitored. Intravenous access was secured with 18G cannula and Ringer's lactate solution at 2 ml kg^{-1} was started. Oxygen was administered with Hudson's mask at 2 L min^{-1}. No sedative premedication was used.

All patients were premedicated with Glycopyrrolate 0.04mg/Kg, Ondansetron 0.8mg/kg

Group D (n=30) Dexmedetomidine 1 μg/kg over 10 min I.V infusion was given

Group F (n=30) Fentanyl 1 μg/kg I.V given

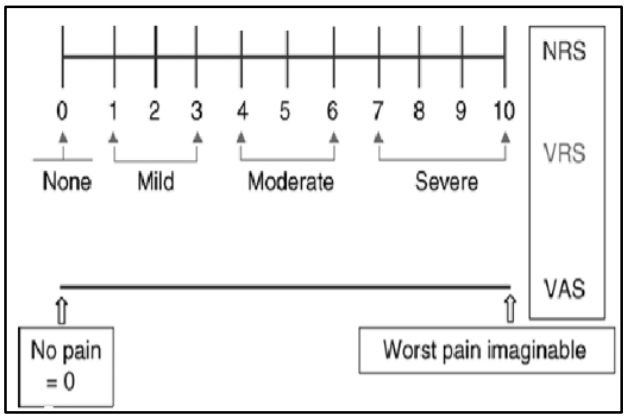
During this period the patients were assessed by

Scores for Pain, Discomfort, Sedation, Heart rate, Systolic Blood Pressure (SBP), Diastolic Blood pressure (DBP), Mean arterial Blood Pressure (MAP), and Peripheral oxygen saturation were recorded preoperatively (baseline), intraoperatively (at 5,10,15,20,30 & 45min), until the completion of surgery & Post-Operative monitoring at 30 mins. interval for next 2hrs.

Pain was measured by a verbal numeric rating pain scale (VNRPS) from 0 to 10(0: No pain, 10: The worst pain imaginable)

Visual Analogue Scale:

- 0-No Pain.
- 1, 2, 3-Mild pain.
- 4, 5, 6-Moderate pain.
- 7, 8, 9, 10-Worst ever felt pain.



Discomfort was assessed using an 11-point verbal numeric rating discomfort scale (VNRDS) from 0 to 10 (0: None, 10: Extreme discomfort);

Sedation was measured by Ramsay Sedation Score:

1. Patient anxious and agitated or restless.
2. Patient co-operative, oriented, and tranquil.
3. Patient responds to verbal commands while sleeping.
4. Patient exhibits brisk response to light glabellar tap or loud voice while sleeping.
5. Patient exhibits a sluggish response to light glabellar tap or loud voice.
6. Patient exhibits no response.

After administering the drugs and when RSS of 3 was achieved, the ENT surgeon administered LA using 2% lignocaine with adrenaline (6-7 ml) (1:2,00,000) in the post auricular area to block greater auricular and lesser occipital nerves in the incisura terminalis to block auriculotemporal nerve and the four quadrants of the external auditory canal. Surgery was commenced after confirming adequate analgesia. Intraoperatively heart rate (HR), Non-invasive blood pressures, SPO_2, were recorded every 5 mins. intervals in intraoperatively and every 30 mins interval post operatively for next 2hrs.

Respiration events were defined as oxygen saturation by pulseoxymetry (spo2) <92. A decrease in spo2 to <92% for >30sec was treated sequentially with verbal stimulation, Guedel airway and bag & mask ventilation.

Cardiovascular events were defined as a single episode variation in heart rate (HR) and Systolic blood pressure (SBP) by >20% from patients' baseline. If repeated or recurrent SBP<90mmHg, was treated with bolus of IV Ephedrine 6mg. Repeated or persistent >30 decrease in HR was treated with IV atropine 0.6mg and repeated as necessary.

The Surgical procedure lasted for 45 minutes in almost all the patients. After the completion of surgery patients were shifted to the PACU and were monitored for hemodynamic parameters, degree of analgesia and adverse events, at 30mins interval for next 2hrs post operatively. RSS was assessed immediately on arrival in the PACU and every 30 min thereafter till transfer to surgical ward. Requirement of postoperative analgesia was noted.

OBSERVATION AND RESULTS: The present study was undertaken in the Department of Anaesthesiology, Government E.N.T hospital, Osmania Medical College. Hyderabad. A total of 60 patients in the age group 18-60 years with ASA grade I & II undergoing elective tympanoplasty were recruited from Government E.N.T hospital for the present study to compare the effect of Dexmedetomidine with Fentanyl for sedation in Tympanoplasty (ENT surgeries).

Patients were divided into two groups of 30 each, Group F comprising of 30 patients received Inj. Fentanyl I.V. & Group D comprising of 30 patients received Inj. Dexmedetomidine I.V. Infusion

Mean arterial pressures, Heart rate, SPo2, Pain, Discomfort and Sedation were monitored before, during and after the surgery at designated intervals and the results were noted.

STATISTICAL ANALYSIS: The data thus collected was entered into an Excel sheet. It was further subjected to statistical analysis in MS Excel and SPSS v.16. Data was expressed in frequencies and percentages when qualitative and in Mean±SD when quantitative. Chi square test and Fisher's exact tests were applied for qualitative data. Unpaired Student T test was used for comparing the trends for all parameters in the two groups. A P value of <0.05 was considered significant.

Both the groups were similar in the age distribution. Mean age was 29.5 in Fentanyl group and 30.33 in Dexmedetomidine group, but the difference was not statistically significant, thus making the groups comparable to each other.

Both the groups were almost similar in the gender distribution. Males were predominant in both groups, accounting to 56.67% in Fentanyl group and 63.33% in Dexmedetomidine group, but the difference was not statistically significant, thus making the groups comparable to each other.

At baseline before the surgery, the mean values of variable in the two groups were.

Sl. No.	Variable	Fentanyl Group		Dexmed Group		T test statistic	P value
		Mean	SD	Mean	SD		
1	Age (yrs.)	29.50	9.37	30.33	9.44	0.342	0.734
2	Weight (kgs.)	53.5	6.43	54.8	4.86	0.883	0.190
3	Pulse rate (bpm)	77.23	9.15	79.60	6.82	1.535	0.130
4	SBP (mm Hg)	120.57	6.76	122.10	11.02	1.139	0.259
5	DBP (mm Hg)	78.63	5.07	77.50	8.91	1.105	0.274

6	MAP (mm Hg)	95.76	5.16	92.00	9.09	2.270	0.027*
7	SpO_2	98.93	1.23	100.00	0.00	4.94	0.000*
8	Pain score	1.47	0.51	1.50	0.51	0.848	0.400
9	Discomfort score	1.47	0.51	1.50	0.51	0.848	0.400
10	Sedation score	2.00	0.00	2.00	0.00	NA	NA

Table 1: Baseline vitals of the groups

The baseline characteristics preoperatively were almost similar in both the groups, with whatever differences observed were statistically insignificant, except for Mean arterial pressures and SPO_2 levels.

The mean values of Heart rates in the two groups were as follows.

Sl. No.	Time (min)	Fentanyl Group		Dexmed Group		T test statistic	P value
		Mean	SD	Mean	SD		
1	Baseline	77.23	9.15	79.60	6.82	1.535	0.130
2	5 min	63.87	2.98	62.73	2.88	1.848	0.070
3	10 min	64.63	3.83	62.43	3.10	2.713	0.009*
4	15 min	62.83	3.20	62.40	2.99	1.057	0.295
5	20 min	63.00	4.14	62.60	2.74	0.982	0.330
6	30 min	61.93	2.83	62.90	2.94	1.673	0.100
7	45 min	62.93	3.07	62.00	2.65	1.640	0.106
8	60 min	63.80	3.12	62.80	2.78	1.683	0.098
9	90 min	63.80	3.12	62.80	2.78	1.683	0.098
10	120 min	62.47	2.66	62.70	2.34	0.923	0.360
11	180 min	62.50	3.97	62.27	2.60	0.858	0.394

Table 2: Pulse rate trend in the groups

There is no statistically significant difference between the two groups ($p>0.05$), when Pulse rates are compared.

During the surgery, the mean values of MAP (mm of Hg) in the two groups were as follows.

Sl. No.	Time (min)	Fentanyl Group		Dexmed Group		T test statistic	P value
		Mean	SD	Mean	SD		
1	5 min	63.87	2.06	65.68	2.09	3.612	0.001*
2	10 min	64.48	1.35	65.23	1.55	2.311	0.024*
3	15 min	64.73	1.45	64.37	1.43	1.394	0.169
4	20 min	64.51	1.69	64.93	1.51	1.431	0.158
5	30 min	64.89	1.57	65.43	1.74	1.656	0.103
6	45 min	64.81	1.53	65.20	1.34	1.464	0.148

Table 3: Intra op Mean Arterial Pressure (MAP)

The MAP levels were observed to be higher at all times noted among dexmed group than fentanyl group except at 15 min. The differences were statistically significant at 5 min and 10 min.

After the surgery, the mean values of MAP (mm of Hg) in the two groups were as follows-

Sl. No.	Time (min)	Fentanyl Group		Dexmed Group		T test statistic	P value
		Mean	SD	Mean	SD		
1	60 min	64.50	1.09	64.36	1.30	0.988	0.327
2	90 min	64.50	1.09	64.36	1.30	0.988	0.327
3	120 min	64.06	0.86	64.47	1.71	1.584	0.119
4	150 min	64.01	0.88	64.41	1.69	1.560	0.117
5	180 min	63.96	2.19	64.52	1.55	1.540	0.129

Table 4: Post op Mean Arterial Pressure (MAP)

There is no statistically significant between two groups ($p>0.05$) when post op MAP trends compared.

The mean values of pain in the two groups were as follows.

Sl. No.	Time (min)	Fentanyl group		Dexmed group		T test statistic	P value
		Mean	SD	Mean	SD		
1	Baseline	1.47	0.51	1.50	0.51	0.848	0.400
2	5min	4.77	0.73	3.97	0.81	4.234	0.000*
3	15min	4.77	0.73	3.93	0.78	4.465	0.000*
4	30min	4.50	0.51	3.83	0.70	4.427	0.000*
5	45min	4.50	0.51	3.73	0.58	5.612	0.000*
6	60min	3.33	0.48	2.43	0.50	7.265	0.000*
7	90min	3.33	0.48	2.43	0.50	7.265	0.000*
8	120min	1.63	0.49	1.63	0.49	0.679	0.500
9	150min	3.32	0.48	2.44	0.43	0.667	0.489
10	180min	1.63	0.49	1.63	0.49	0.679	0.500

Table 5: Pain score trend in the groups

At all points of time after administration of fentanyl and dexmedetomidine, it was observed that the pain scores were less in dexmedetomidine group than fentanyl group and these were statistically significant (p= 0.00).

The mean values of discomfort scores in the two groups were as follows.

Sl. No.	Time (min)	Fentanyl Group		Dexmed Group		T test statistic	P value
		Mean	SD	Mean	SD		
1	Baseline	1.47	0.51	1.50	0.51	0.848	0.400
2	45 min	4.83	0.79	4.40	0.50	2.800	0.007*
3	60 min	3.90	0.71	3.47	0.63	2.763	0.008*
4	90 min	3.90	0.71	3.43	0.57	3.054	0.003*
5	120 min	1.67	0.48	1.67	0.48	0.679	0.500
6	150 min	1.68	0.48	1.60	0.43	0.658	0.478
7	180 min	1.67	0.48	1.67	0.48	0.679	0.500

Table 6: Discomfort score trend in the groups

From the above table it was observed that the discomfort scores were less in dexmedetomidine group than fentanyl group and these were statistically significant (p<0.05).

DISCUSSION: The reason for choosing the study is to compare Fentanyl, the most commonly used opioid with novel drug Dexmedetomidine, which has additional hypnotic, sedative and anxiolytic properties with very low respiratory depression for perioperative haemodynamic stabilization, sedation, pain and discomfort in elective tympanoplasty surgery.

Tympanoplasty is common surgical procedure in ENT surgeries done under local anaesthesia. Even though LA effectively reduces pain there is considerable amount of discomfort and anxiety associated with procedure. Sedation effectively reduces this anxiety and comforts the patients.
Patients were divided in two groups with 30 patients each. Group F patients received Inj. Fentanyl 1µ/kg and Group D patients received Inj. Dexmedetomidine 1µ/kg infusion over 10 mins before surgery.

All patients received premedication with antisialogogue, antiemetic and antacids.

Anaesthetic technique followed in all patients irrespective of the groups was uniform, conscious sedation (Monitored anaesthesia care).

In all patients average duration of surgery was around 45 mins. Both group of patients did not receive any analgesic during intraoperative and postoperative period as rescue analgesic for breakthrough pain.

Patients selected were between 18yrs and 60yrs of age. The mean age in two groups were similar in the age distribution. Mean age was 29.5(±9.37) in Group F and Mean age was 30.33(±9.44) in Group D. The difference was not statistically significant (p>0.05).

In both groups Males were predominant accounting to 56.67% (17 male out of 30 members) in Fentanyl Group and 63.33% (19 males out of 30 members) in Dexmedetomidine Group. The difference was not statistically significant (P>0.05)

The differences in average weight in two groups was also statistically insignificant (P=0.109). Mean weights in Fentanyl group were 53.5(±6.43) and Mean weights in Dexmedetomidine group were 54.8(±4.86).

The difference in average preoperative pulse rate and blood pressures is also insignificant (P=0.130). Preoperative Mean pulse rate in Fentanyl group 77.23(±9.15) and in Dexmedetomidine group 79.60(±6.82). Preoperative systolic blood pressure (SBP) in Fentanyl group 120.57(±6.76) and in Dexmedetomidine group 122.10(±11.02) and Preoperative diastolic blood pressure (DBP) in Fentanyl group 78.63(±5.07) and in Dexmedetomidine group 77.50(±8.91) and differences observed were statistically insignificant. Mean preoperative

Mean arterial blood pressure (MAP) in Fentanyl group 95.76(±5.16) and in Dexmedetomidine group 92.00(±9.09). All patients were monitored in the intraoperative and postoperatively period for haemodynamics. Recordings were done at 5, 10, 15, 20, 30, 45, 60, 90, 120, 150 and 180 mins. The parameters recorded were pulse rate, Mean arterial blood pressure and saturation of oxygen (SPO_2).Statistical analysis of the derived parameters were carried out using unpaired "t" test and P values less than 0.05 was considered significant.

Intraoperatively Mean arterial blood pressure (MAP) levels were observed to be high among Dexmedetomidine group than Fentanyl group. MAP intraoperatively for Fentanyl group (Mean±SD) (63.86±2.06, 64.81±1.35, 64.73±1.45, 64.51±1.69, 64.89±1.87, 64.81±1.53) was compared with Dexmedetomidine group (65.68±2.09, 65.23±1.55, 64.37±1.43, 64.93±1.51, 65.43±1.74, 65.20±1.34). The differences were statistically significant at 5mins and 10mins. Postoperatively there is no statistically significant between two groups (p>0.05).

Subjective assessment of pain was studied at 0, 5, 15, 30, 45, 60, 90, 120 & 180mins intraoperatively and postoperatively by 10cm Visual Analog score (VAS) scale. Mean Pain scores by VAS showed statistically significant less pain score scores in Dexmedetomidine group when compared to Fentanyl group (P=0.00).

A significant number of the patients from Dexmedetomidine group had fall in heart rate by >20% from base line and bradycardia than Fentanyl Group. Five patients in Dexmedetomidine had bradycardia when compared to two patients in Fentanyl group (P=0.228). But the bradycardia improved spontaneously by talking to the patient and did not require any medication.

The main findings of this study is that Dexmedetomidine reduces pain and discomfort better than Fentanyl and difference is statistically significant. Dexmedetomidine acts as an analgesic by modulating both the sensory-discriminative component of the pain and also the motivational-affective and cognitive component of pain.

Santhisree M et al 2014:[11] conducted a study on Comparison of Dexmedetomidine with Fentanyl for Sedation, Pain and Hemodynamic Control during Central Line Insertion in Intensive Care Unit under Conscious Sedation; Patients were randomly assigned into two groups of 25 each, to receive either dexmedetomidine (1µg/kg) or fentanyl (1µg/kg) along with local anaesthetic (LA) field infiltration.

Pain, discomfort and sedation score were measured at 5 time points. Comparison between two groups revealed that fentanyl group had worst pain scores at LAI (after LA injection), than dexmedetomidine group (fentanyl 5[4-6] vs. dexmedetomidine 3[3-5]; P=0.015), which is statistically significant.

When compared with fentanyl group, dexmedetomidine appeared to have more analgesic effect, i.e., reduction in pain intensity to CVC insertion at all steps. However, no significant difference was observed in scores between the two groups 60 min after the procedure. The median pain score in fentanyl and dexmedetomidine groups results showed ranging from 0.015 to 0.7 of P value. Which is similar to the present study whose P value shows results ranging from 0.00 to 0.5.

This study demonstrates that Dexmedetomidine provides less discomfort, better sedation, analgesia when compared with fentanyl for central line insertion under conscious sedation in ICU. However, the risk of adverse effects requires monitoring for a ready intervention.

Samantaray A. et al:[12] evaluate the effects of dexmedetomidine on procedural pain and discomfort associated with central venous catheter insertion conducted a prospective, randomized, double-blind, placebo-controlled trial of 54 patients scheduled for planned CVC insertion was undertaken. Patients were randomly assigned into two groups of 27 each, to receive either dexmedetomidine (1µg/kg) or 0.9% normal saline, along with LA field infiltration. Pain and discomfort score was measured at 5 time points.

In this study, dexmedetomidine was able to reduce procedure specific pain and resulted in better comfort score for most of the time points during insertion of CVC. This action of dexmedetomidine can be partly explained by multidimensional model of procedural pain. Dexmedetomidine, not only acts as an analgesic by modulating the sensory-discriminative component of the pain, but also has a greater magnitude of effect in attenuating the motivational-affective and cognitive component of pain.

Although effective for analgesia and reduced discomfort, our study showed that dexmedetomidine was associated with increased sedation scores. 2 patients from dexmedetomidine group needed to be called repeatedly with mild prodding (OAA/Sscore-2) to ascertain level of sedation after initial LA injection (T2), which some time may hinder the patient cooperation needed by the physician, while inserting CVC.

Dexmedetomidine provides adequate analgesia and reduces the level of discomfort for the insertion of CVC along with field infiltration with LA. However the tendency for excessive sedation, unwanted cardiovascular events associated with dexmedetomidine render it less desirable for this purpose.

Candiotti KA, Bergese SD, et al.[13] Evaluated the safety and efficacy of two doses of Dexmedetomidine for sedation of patients undergoing a broad range of surgical or diagnostic procedures requiring MAC. Dexmedetomidine (DEX) is increasingly being used as a sedative for monitored anaesthesia care (MAC) because of its analgesic properties, "cooperative sedation," and lack of respiratory depression. This is randomized, multicenter, double-blind, Phase III Food and Drug Administration study.

DEX is an effective baseline sedative for patients undergoing MAC for a broad range of surgical procedures providing better patient satisfaction, less opioid requirements, and less respiratory depression than placebo rescued with midazolam and fentanyl.

Reetu, Verma et al,[14] studied "Efficacy and safety of intravenous dexmedetomidine in comparison to propofol for MAC in middle ear surgery", a Randomized controlled trial, made similar conclusions supporting the present study, suggested that dexmedetomidine is a better drug for MAC with minimal haemodynamic instability when compared to propofol.

SUMMARY AND CONCLUSION: A total of 60 patients between the age group of 18-60 years were included in the study. They were ASA I &II and scheduled for the elective tympanoplasty surgery under Monitored anaesthesia care.

Patients were randomized into 2 groups, as group F (Fentanyl group) received Inj. Fentanyl 1µ/kg bodyweight I.V and group D (Dexmedetomidine) received dexmedetomidine 1µ/kg body weight infusion over 10 mins. Patients fasted at least 8 hours before operation and did not receive any pre-operative sedative drug.

In both the groups haemodynamic parameters were monitored (MAP, Heart rate & SPO_2), Pain and Discomfort assessed by VNRPS and VNRDS respectively intraoperative at 5, 10, 15, 20, 30 & 45 mins and Post operatively at 30 mins interval for next 2 hrs.

Both groups were similar in the age distribution and difference was not statistically significant (P=0.735), p>0.05.

Both groups were almost similar in gender distribution. Males are predominant in both groups. The difference was statistically insignificant (P=0.598).

Weights in both groups ranged from 44kgs to 66kgs, but the difference was no statistically significant (P=0.190)

Preoperatively Heart rate, Pain and discomfort levels statistically insignificant (P>0.05) except for Mean arterial pressure and Spo_2.

Intra operatively & Post operatively MAP levels intra operatively higher at all times noted among dexmedetomidine group than the fentanyl Group and difference was statistically significant, Post operatively insignificant.

Heart rate and SPO_2 were statistically insignificant intraoperatively and Post operatively.

Pain and Discomfort scores are less at times intraoperatively in dexmedetomidine group and there were statistically significant. Post operatively insignificant.

Sedation scores were less in dexmedetomidine group up to 45 mins of surgery and these were statistically significant than Fentanyl group. After 45mins in the postoperative period sedation scores were similar and statistically insignificant.

CONCLUSION: Dexmedetomidine provides less discomfort, better sedation, analgesia when compared with fentanyl under monitored anaesthesia care (Conscious sedation). However the risk of adverse effects requires monitoring for ready intervention. It provides a unique type of sedation, "conscious sedation" in which patients appear to be sleepy but are easily arousable, cooperative and communicative when stimulated. It is sedative and analgesic agent, with opioid-sparing properties and minimal respiratory depression.

REFERENCES

1. Cormack JR, Orme RM, Costello TG. "The role of alpha2-agonists in neurosurgery." Journal of Clinical Neuroscience 2005;12(4):375–8.
2. Paris A, Tonner PH. "Dexmedetomidine in anaesthesia." Current opinion in anaesthesiology 2005;18(4):412-418.
3. The American Society of Health-System Pharmacists, Inc. "Midazolam Injection." USA: National Institutes of Health. 1 March 2009.
4. Classen DC, Pestotnik SL, Evans RS, et al. "Intensive surveillance of midazolam use in hospitalized patients and the occurrence of cardiorespiratory arrest." Pharmacotherapy 1992;12(3):213–16.
5. Eren G, Cukurova Z, Demir G, et al. Comparison of dexmedetomidine and three different doses of midazolam in preoperative sedation. J Anaesthesiol Clin Pharmacol 2011;27:367-72.
6. Hall JE, Uhrich TD, Barney JA, et al. Sedative, amnestic, and analgesic properties of small-dose dexmedetomidine infusions. Anaesth Analg 2000;90:699-705.
7. Bergese SD, Khabiri B, Roberts WD, et al. Dexmedetomidine for conscious sedation in difficult awake fibreoptic intubation cases. J Clin Anaesth 2007;19:141-4.
8. Siddappa R, Riggins J, Kariyanna S, et al. High-dose dexmedetomidine sedation for paediatric MRI. Paediatr Anaesth 2011;21:153-8.
9. Bekker A, Sturaitis M, Bloom M, et al. The effect of dexmedetomidine on perioperative haemodynamics in patients undergoing craniotomy. Anaesth Analg 2008;107:1340-7.
10. Bulow NM, Barbosa NV, Rocha JB. Opioid consumption in total intravenous anaesthesia is reduced with dexmedetomidine: A comparative study with remifentanil in gynaecologic video laparoscopic surgery. J Clin Anaesth 2007;19:280-5.
11. Santhisree M, Prasad PK, Lakshmi BS, et al. Comparison of dexmedetomidine with fentanyl for sedation, pain and hemodynamic control during central line insertion in intensive care unit under conscious sedation. Int J Sci Stud 2014;2(8):1-4.
12. Samantaray A. Effects of dexmedetomidine on procedural pain and discomfort associated with central venous catheter insertion. Indian J Anaesth 2014;58:281-6.
13. Candiotti KA, Bergese SD, Bokesch PM, et al. Monitored anesthesia care with dexmedetomidine: A prospective, randomized, double-blind, multicenter trial. Anesth Analg 2010;110:47-56.
14. Gupta R, Verma R, Agarwal S, et al. Dexmedetomidine and propofol for monitored anaesthesia care in the middle ear surgery. Indian J Otol 2014;20(2):70-74.