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Original Research Article

Conscious Sedation for Middle Ear Surgeries: A Comparative Study on Sedative Effect of Dexmedetomidine and Propofol Infusion in Mastoid Surgery

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Abstract

Background: In this study, we wanted to evaluate and compare the efficacy of dexmedetomidine with that of propofol in patients undergoing middle ear surgeries, with regard to sedation, analgesia, patient satisfaction and adverse effects.

Materials and Methods: This was a hospital based observational comparative study conducted among 60 patients who underwent elective middle ear surgery under local anaesthesia and sedation in the Department of ENT, in a tertiary care teaching hospital over a period of one and a half years after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants. For the purpose of this study the patients were randomly allocated in 2 groups -

Group D: Patients receiving Dexmeditomidine (1ug/kg over 10 minutes as loading dose and 0.4ug/kg/hr as maintenance dose), Group P: Patients receiving Propofol (75ug/kg/min over 10 minutes as loading dose and 50ug/kg/min maintainence dose).

Results: The onset of sedation in both the study groups was found to be statistically significant (p-value = 0.000). The time taken for the onset of sedation in group D was 15.00 minutes and in group P was 9.19 minutes respectively. The baseline means arterial pressures, the heart rates, the respiratory rates and the oxygen saturations of both the groups are comparable as the p-value is more than 0.005 which is statistically insignificant. Mean arterial pressure (MAP) measured at 60 minutes between the two groups was found to be statistically significant. Heart rate variation beats per minute (BPM), respiratory rate, oxygen saturation between the two groups, at baseline, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, 120 minutes, 135 minutes and 150 minutes was not found to be statistically significant. Respiratory rate measured at 90 minutes' mark was found to be statistically significant. Intergroup comparison of the mean values of the visual analog score (VAS) was done by student unpaired t test and the difference was found to be statistically significant. Association of rescue analgesia requirement between the two group was statistically significant (p = 0.000).

Conclusion: Dexmedetomidine is better than propofol and can be safely used as a sedative in middle ear surgeries without much change to the haemodynamics of the patients. Dexmedetomidine provides analgesia and therefore requirement of rescue analgesia in patients is reduced. Most patients were satisfied with the anaesthesia conducted by use of dexmedetomidine. Side effects between the two drugs were insignificant. Therefore, dexmedetomidine may prove to be a useful alternative to propofol for sedation in patients undergoing middle ear surgeries.

Keywords: Dexmedetomidine, Propofol, Infusion, Mastoid Surgery.

Introduction

The ear is one of the most important sensory organs of the human body. Surgery on the ear is always a challenge for the surgeon because of the complexity of the ear and the balance between preservation of the important functions and eradication of disease. [1] Middle ear diseases can occur in all ages of patients, from small children to the elderly. Many do not need surgery and can be treated conservatively but other conditions requiring surgery would include stapedectomy, tympanoplasty for otosclerosis, tympanoplasty for reconstructive surgery of the tympanic membrane, mastoidectomy for cholesteatoma etc. [2] Local anaesthesia with sedation or general anaesthesia can be applied to provide the required operating conditions for the surgeon to work but general anaesthesia is associated with more risks, the worse being respiratory depression. Optimal visualization of the ear anatomy is a requisite for the surgery and helps in decreasing the duration and blood loss and overall improves the surgical outcome. [3] Therefore, the preferable anaesthesia for these types of surgeries would be under local anaesthesia with sedation. The drug most commonly used for sedation under anaesthesia is propofol. Propofol has been the gold standard intra-operative sedation for day care surgeries mainly because of its rapid onset, recovery time and easy titratability. [4] Another drug that can be used for sedation is dexmedetomidine. Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist. It has hypnotic, sedative, anxiolytic, and analgesic properties. It does not produce significant respiratory depression as compared to propofol. [5] This study is a prospective study aimed at comparing the sedative and hypnotic effects of these two drugs. At the end of the study, we hope to find the best drug among the two for sedation under local anaesthesia for middle ear surgeries and that the results of this study can be helpful in assisting the anaesthesiologist to decide on which drug to use in regular clinical practice.

Aims and Objectives

1. To compare the level of sedation and analgesia between the two groups.
2. To compare the patient satisfaction of anaesthesia and analgesia between the two groups.
3. To compare any adverse effects between the two groups.

Materials and Methods

This was a hospital based observational comparative study conducted among 60 patients who presented with elective middle ear surgery under local anaesthesia and sedation in a tertiary care teaching hospital over a period of one and a half years, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

Male and female patients aged between 18 -60 years, patients giving informed consent, ASA grade I and II undergoing middle ear surgery.

Exclusion Criteria

Patients below 18 years of age, patients not giving informed consent, ASA grade 3 and above, pregnant or lactating females, known drug allergies, use of alpha-2 agonists or antagonists therapy, active upper respiratory infection, psychological disorders, patients with respiratory dysfunction, patients with OSA, Obese patients.

The patients were allotted to one of the following groups -

Group D patients received Dexmeditomidine (1ug/kg over 10 minutes as loading dose and 0.4ug/kg/hr maintenance) and Group P patients received Propofol (75ug/kg/min over 10 minutes as loading dose and 50ug/kg/min maintainence).

All the patients were under monitored anesthesia care and premedicated using Injection Glycopyrolate 0.2mg, Injection Ondansetron 4mg.

After premedication the various loading doses and infusions of Dexmeditomidine or Propofol infused according to the allotted group. After reaching a Ramsay score of 3, the surgeons were asked to paint, drape and locally infiltrate the operative field with Lignocaine 2% and 1/100,000 Epinephrine and the surgery started.

Patient assessed for any movement during the infiltration of local anesthetic and hemodynamic parameters were measured every 5 minutes from the start of surgery for 15 minutes, thereafter every 15 minutes onwards till the end of surgery.

Analgesia recorded intraoperatively and postoperatively using a visual analog scale and the Iowa Satisfaction for Anesthesia scale was used to assess the patient's satisfaction.

Patient's requirement for rescue analgesia was noted and if required was given Injection Fentanyl 1ug/kg stat.

After the surgery patients were kept in monitored in the ward and asked to rate their satisfaction according to the IOWA satisfaction for anesthesia scale.

Adverse effects like hypotension, hypoventilation, nausea, vomiting, dry mouth were assessed, noted and treated accordingly with iv fluids and drugs if required.

Statistical Methods

Data was entered in MS excel and analysed using Statistical Package for Social Sciences (SPSS) software. Results were presented as tables.

Results

Table 1: Demographic Distribution

Group	Mean	Min	Max	SD	SE of Mean	P Value
D	39.33	27	51	6.310	1.152	0.465
P	40.77	32	51	4.998	0.898	
Age Distribution						
Sex	**Group**			Total		**P Value**
	D	P				
Male	24	21		45		0.898
Female	6	10		16		
Total	30	31		61		
Sex Distribution						

Applying the Mann-Whitney U test, it was found that there was no statistically significant difference between the two groups (p = 0.465) and both the groups were comparable as far as age is concerned. The sex distribution in the two groups applying Fischer's exact test was found out to be statistically not significant (p = 0.898).

Table 2

Group	Mean	Min	Max	SD	SE	P Value
D	15.00	13	17	1.365	0.249	0.000
P	9.19	7	12	1.138	0.204	
Onset of Sedation in Both the Groups						
Group	Mean	Min	Max	SD	SE	P Value
D	108.5	70	150	18.011	3.228	0.304
P	112.2	90	150	15.372	2.761	
Duration of Surgery in Minutes between the Two Groups						
Baseline	Group	N	Mean	Min	Max	SD	P Value
MAP (mm Hg)	D	30	93.30	81	100	3.949	0.377
	P	31	94.06	84	100	4.234	
HR (bpm)	D	30	80.37	71	92	5.875	0.478
	P	31	79.42	71	94	6.060	
RR (bpm)	D	30	14.27	12	16	0.944	0.129
	P	31	13.77	11	16	10257	
SPO_2 (%)	D	30	99.33	96	100	1.093	0.818
	P	31	99.35	97	100	1.082	
Baseline MAP, HR, RR AND SPO_2 of Both the Groups							
	Group	Mean	SD	P Value			
Baseline MAP	D	93.30	3.949	0.377			
	P	94.06	4.234				
MAP 5	D	94.37	2.785	0.010			
	P	92.06	3.660				
MAP 10	D	93.13	2.177	0.013			
	P	91.35	2.893				
MAP 15	D	92.10	2.090	0.827			
	P	91.84	2.382				
MAP 30	D	93.07	1.837	0.718			
	P	92.23	1.564				
MAP 45	D	93.30	1.685	0.406			
	P	93.65	1.518				
MAP 60	D	68.70	8.453	0.000			
	P	56.97	10.809				
MAP 75	D	92.53	2.980	0.433			
	P	91.39	3.913				
MAP 90	D	91.53	2.161	0.747			
	P	91.29	3.247				
MAP 105	D	89.23	2.763	0.037			
	P	93.68	3.156				
MAP 120	D	91.57	3.025	0.382			
	P	92.39	2.362				
MAP135	D	92.17	2.151	0.251			
	P	91.03	3.016				

MAP 150	D	91.07	2.449	0.605
	P	91.29	2.545	
Variation of the Mean Arterial Blood Pressure between the Two Groups				

Onset of sedation in both the study groups was found to be statistically significant (p-value = 0.000). The time taken for the onset of sedation in Group D was 15.00 minutes and in Group P was 9.19 minutes respectively. It was found that there was statistically no significant difference between both the groups (p-value = 0.304) in respect to duration of surgery. The base line heart rates, the respiratory rates and the oxygen saturations of both the groups (as the p-value is more than 0.005 which is statistically insignificant) are comparable. The baseline values and then MAP at different time intervals were noted, 5 minutes interval upto the 15 minute mark was designated as MAP5, MAP10, MAP15 and then consequently every 15 minutes till 2 hours 30 minutes. Between the two groups, the MAP at baseline, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 75 minutes, 90 minutes, 105 minutes, 120 minutes, 135 minutes, and 150 minutes was not found to be statistically significant. MAP measured at 60 minutes between the two groups was found to be statistically significant (p value=0.000).

Table 3

	Group	**Mean**	**SD**	**P Value**
HR 0	D	80.37	5.875	0.478
	P	79.42	6.060	
HR 5	D	81.63	7.232	0.267
	P	80.94	6.678	
HR 10	D	78.10	11.385	0.828
	P	79.65	8.712	
HR 15	D	80.47	7.560	0.194
	P	82.81	7.454	
HR 30	D	81.23	10.663	0.478
	P	83.13	11.342	
HR 45	D	82.47	7.138	0.680
	P	83.55	6.840	
HR 60	D	81.57	8.211	0.497
	P	82.52	7.694	
HR 75	D	83.33	7.476	0.701
	P	84.52	8.951	
HR 90	D	82.70	6.238	0.024
	P	85.65	6.036	
HR 105	D	82.37	6.815	0.039
	P	86.16	7.331	
HR 120	D	82.40	8.033	0.608
	P	83.55	6.381	
HR135	D	83.03	5.898	0.238
	P	81.77	5.608	
HR 150	D	84.60	6.112	0.413
	P	83.48	5.310	
Variation of the Heart Rate between the Two Groups				
	Group	**Mean**	**SD**	**P Value**

RR 0	D	14.27	0.944	0.129
	P	13.77	1.257	
RR 5	D	14.50	0.855	0.002
	P	13.61	1.334	
RR 10	D	14.63	1.497	0.055
	P	14.03	1.140	
RR 15	D	14.67	1.373	0.055
	P	14.00	1.033	
RR 30	D	14.57	1.135	0.006
	P	13.68	1.301	
RR 45	D	14.17	1.234	0.009
	P	13.26	1.182	
RR 60	D	14.20	1.540	0.039
	P	13.42	1.259	
RR 75	D	14.10	1.348	0.105
	P	13.52	1.288	
RR 90	D	14.50	1.106	0.001
	P	13.45	1.234	
RR 105	D	14.17	1.262	0.040
	P	13.52	1.208	
RR 120	D	14.40	1.567	0.025
	P	13.48	1.151	
RR 135	D	14.20	1.270	0.089
	P	13.71	1.071	
RR 150	D	14.43	1.569	0.056
	P	13.68	1.249	
Variation of the Respiratory Rate between the Two Groups				
	Group	**Mean**	**SD**	**P Value**
SpO2 0	D	99.33	1.093	0.818
	P	99.35	1.082	
SpO2 5	D	99.27	0.944	0.136
	P	98.90	0.978	
SpO2 10	D	99.07	1.081	0.143
	P	98.68	1.013	
SpO2 15	D	99.17	1.147	0.020
	P	98.23	1.055	
SpO2 30	D	98.73	1.143	0.560
	P	98.58	1.057	
SpO2 45	D	99.03	1.351	0.213
	P	98.77	1.175	
SpO2 60	D	98.90	1.242	0.488
	P	98.71	1.160	
SpO2 75	D	98.67	1.184	0.523
	P	98.87	0.991	
SpO2 90	D	98.77	1.547	0.356
	P	98.65	1.112	
SpO2 105	D	98.73	1.202	0.360
	P	98.97	1.197	

SpO2 120	D	98.60	1.812	0.940
	P	98.77	1.117	
SpO2 135	D	98.90	1.322	0.945
	P	98.94	1.209	
SpO2 150	D	98.93	1.112	0.867
	P	98.84	1.214	
Variation of the Oxygen Saturation between the Two Groups				

The baseline values and then HR at different time intervals were noted; 5 minutes' interval up to the 15-minute mark was designated as HR5, HR10, HR15 and then consequently every 15 minutes till 2 hours 30 minutes. Between the two groups, the HR at baseline, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes,60 minutes, 75 minutes, 90 minutes, 105 minutes, 120 minutes, 135 minutes, and 150 minutes was not found to be statistically significant. The baseline values and then RR at different time intervals were noted; 5 minutes' interval up to the 15-minute mark was designated as RR5, RR10, RR15 and then consequently every 15 minutes till 2 hours 30 minutes. Between the two groups, the RR at baseline, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes,60 minutes, 75 minutes, 105 minutes, 120 minutes, 135 minutes, and 150 minutes was not found to be statistically significant. Respiratory rate measured at 90 minutes' mark was found to be statistically significant. The baseline values and then oxygen saturation (SpO2) at different time intervals were noted; 5 minutes' interval up to the 15-minute mark was designated as SpO2 5, SpO2 10, SpO2 15 and then consequently every 15 minutes till 2 hours 30 minutes. Between the two groups, the SpO2 at baseline, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, 120 minutes, 135 minutes, and 150 minutes was not found to be statistically significant.

Table 4

Group	**Mean**	**Min**	**Max**	**SD**	**SE**	**P Value**
D	2.67	2	4	0.661	0.121	0.000
P	6.65	5	8	0.798	0.143	
Distribution of the Visual Analog Scores between the Two Groups						
Group	Mean	Minimum	Maximum	SD	SE	P Value
D	15.00	13	17	1.365	0.249	0.000
P	9.19	7	12	1.138	0.204	
Time (mins) Taken to Achieve Ramsay Sedation Scale 3 between the Two Groups						
	Group	**Mean**		**SD**		**P Value**
RSS 30	D	2.93		0.254		0.000009
	P	2.39		0.495		
RSS 45	D	2.97		0.183		0.000030
	P	2.48		0.508		
RSS 60	D	2.93		0.254		0.002
	P	2.58		0.502		
RSS 75	D	2.97		0.320		0.000045
	P	2.45		0.506		
RSS 90	D	2.90		0.305		0.000034
	P	2.35		0.551		
RSS 105	D	2.90		0.305		0.000013

	P	2.35	0.486	
RSS 120	D	2.93	0.254	0.000135
	P	2.48	0.508	
RS 135	D	2.90	0.305	0.000217
	P	2.45	0.506	
RS 150	D	2.90	0.305	0.064
	P	2.71	0.461	

Variation of Ramsay Sedation Score between the Two Groups

Group	**N**	**Analgesic Requirement**		**P Value**
		Yes	No	
D	30	8	22	0.000
P	31	30	1	
Total	61	38	23	

Requirement for Rescue Analgesia

Group	**Mean**	**Minimum**	**Maximum**	**SD**	**SE**	**P Value**
D	1.4563	-0.09	2.81	0.76190	0.13910	0.000003
P	0.5206	-0.81	2.18	0.63557	0.11415	

IOWA Satisfaction with Anaesthesia Scale for Patient Satisfaction

In group D, the minimum visual analogue score was 2 and the maximum score was 4. In group P, the minimum score was 5 and maximum score was 8. Intergroup comparison of the mean values of the visual analog score was done by student unpaired t test and the difference was found to be statistically significant. In group D, the minimum time taken to reach a Ramsay sedation scale of 3 was 13 minutes, and the maximum time taken was 17 minutes. In group P, the minimum time taken to reach a Ramsay sedation scale of 3 was 7 and the maximum time taken was 12 minutes. Intergroup comparison was done by student unpaired t test and the difference was found to be statistically significant. The RSS was taken 30 minutes after starting the infusion and consequently at 15 minutes' interval designated as RSS 30, RSS 45, RSS 60, RSS 75, RSS 90, RSS 105, RSS 120, RSS 135, RSS 150 till 2 hours 30 minutes. Between the two groups, the RSS at 30 mins., 45 mins., 60 mins., 75 mins, 90 mins., 105 mins., 120 mins., 135 mins. were statistically significant. RSS at 150 mins between the two groups was found to be not statistically significant. In group D, only 8 (26.6 %) patients required rescue analgesia and 22 (73.3 %) patients did not require any rescue analgesia. In group P, 30 (96.7 %) patients required rescue analgesia and 1 (3.2 %) patient did not require any rescue analgesia. Association of rescue analgesia requirement vs. group was statistically significant ($p = 0.000$). IOWA satisfaction with anaesthesia scale. In group D, the minimum score was -0.09 and the maximum score was 2.81. In group P, the minimum score was -0.81 and the maximum score was 2.18. In group D, 1 (3.33 %) patient had an IOWA satisfaction with anaesthesia score less than zero and 29 (96.66 %) patients had IOWA satisfaction with anaesthesia scores more than zero. In group P, 6 (19.35 %) patients had IOWA satisfaction with anaesthesia scales less than zero and 25 (80.64 %) patients had IOWA satisfaction with anaesthesia scales more than zero.

Table 5

Group	N	Nausea		P Value
		Yes	No	
D	30	3	27	0.289
P	31	1	30	
Total	61	4	57	
Number of Patients having Nausea				
Group	**N**	**Hypotension**		**P-Value**
		Yes	No	
D	30	2	28	0.538
P	31	1	30	
Total	61	3	58	
Number of Patients having Hypotension				
Group	**N**	**Bradycardia**		**p-Value**
		Yes	No	
D	30	1	29	0.309
P	31	0	31	
Total	61	1	60	
Number of Patients having Bradycardia				
Group	**N**	**Hypoventilation**		**p-Value**
		Yes	No	
D	30	0	30	1
P	31	0	31	
Total	61	0	61	
Number of Patients having Hypoventilation				
Group	**N**	**Dry Mouth**		**p-Value**
		Yes	No	
D	30	5	25	0.215
P	31	2	29	
Total	61	7	54	
Number of Patients having Dry Mouth				

In group D, the number of patients having nausea was 3 (10 %) and in the group P, the number of patients having nausea was 1 (3.22 %). Association of nausea versus group was statistically insignificant (p = 0.289). In group D, the number of patients who developed hypotension was 2 (6.66 %).In group P, the number of patients who developed hypotension was 1 (3.22 %). Association of hypotension versus group was not statistically significant (p = 0.538). In group D, only 1 (3.33 %) patient developed bradycardia. In group P, no patient developed any bradycardia as an adverse effect. Association of bradycardia versus the group was not statistically significant (p = 0.309). In both the groups, there was no patient who developed hypoventilation as an adverse effect. Association of hypoventilation versus group was not statistically significant. In group D, 5 (16.66 %) patients developed dry mouth as an adverse effect. In group P, 2 (6.45 %) patients developed dry mouth as an adverse effect. Association of dry mouth versus group was not statistically significant.

Discussion

Group D patients received intravenous injection dexmedetomidine infusion whereas group P received intravenous injection propofol infusion. In the study, we found that the mean age of the patient

in group D was 39.33 (± 6.310) and in the group P, the mean age of the patients was 40.77 (± 4.998). The distribution of the age between the two groups was found to be statistically insignificant with a p-value of 0.465. In our study, in group D there were 24 (80 %) male patients and 6 (20 %) female patients, and in group P there were 21(67 %) male patients and 10 (32 %) female patients. The distribution of sex across the groups was found to be not statistically significant with a p-value of 0.898. The time to achieve adequate sedation was found to be shorter in case of group P as compared to group D which is consistent to the studies done by Ufuk et al. [6] We found that the duration of surgery was not statistically significant. The main finding of our study was that dexmedetomidine and propofol provide similar advantages in the hemodynamic stability of patients during sedation for middle ear surgeries. The study done by Bialka et al. [7] showed similar results. Not much difference was observed between the various vital parameters in both study groups except for the mean arterial blood pressure, which was decreased at the 45 and 60 minute mark which is consistent with the studies done by Wang et al. [8] Pain is a main factor and the cause of anxiety and discomfort for most patients undergoing surgery. Patients in group P complained of more pain and were associated with a higher visual analog score as compared to the patients in group D. Group D patients were associated with less requirement of rescue analgesia. We also observed that almost all of the patients in group P (96.7 %) required rescue analgesia in the form of fentanyl as compared to group D (26.6 %). This finding is consistent with the findings of Arain et al. [9] Although the level of sedation achieved by all patients was sufficient for the surgery to be conducted, the Ramsay sedation scores at different points of time showed significant difference between the two groups. Group D was associated with higher RSS scores as compared to the patients in group P which was consistent with the study done by Kuyrukluyildiz et al. The IOWA satisfaction with anaesthesia scale is a great scale to gauge the satisfaction of patients undergoing a procedure. [10] In our study, we found that patients in group D were more satisfied with their anaesthesia than the patients in group P. This might be due to the fact that dexmedetomidine provides analgesia in addition to its sedative effects. This is consistent with the studies done by Barends et al. [11] In our study, it was found that 3 (10 %) patients in group D had nausea and only 1 (3.22 %) patient in group P had nausea. The association of nausea between the two groups was statistically not significant. We also found that only 2 (6.66 %) patients in group D had hypotension whereas only 1 (3.2 %) patient in group P had hypotension and the association of hypotension between the two groups was not significant. It was also found that only 1 (3.33 %) patient developed bradycardia in group D whereas no patient who developed bradycardia was seen in group P which is consistent with the study done by Verma et al. [12] Dry mouth is a known side effect of an α-2 agonist and was seen in 5 (16.66 %) patients in group D as compared to 2 (6.45 %) patients who had dry mouth in group P. The association of dry mouth between the two groups was not statistically significant. This is consistent with the findings of Verma et al. [13]

Conclusion

Dexmedetomidine is better than propofol and can be safely used as a sedative in middle ear surgeries without much change to the haemodynamics of the patient. Dexmedetomidine provides analgesia and therefore requirement of rescue analgesia in patients is reduced. Most of the patients were satisfied with the anaesthesia conducted by use of dexmedetomidine. Side effects between the two drugs were insignificant. Therefore, dexmedetomidine

may prove to be a useful alternative to propofol for sedation in patients undergoing middle ear surgeries.

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