Original Research Article

Study to evaluate and compare the effect of addition of dexmedetomidine to lignocaine 2%+adrenaline on hemodynamic stability by parameters like heart rate, blood pressure, SpO2 and bleeding inearsurgery

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Abstract

Background: An ideal anaesthetic technique for ear surgeries should be such as to produce adequate analgesia for the surgical procedure, maximize patients comfort, reduce intraoperative bleeding as well as provide good pain relief and minimize nausea and vomiting postoperatively. Present study is aimed to evaluate the effect of adding 1 ug/kg of dexmedetomidine to lignocaine 2% and adrenaline during ear surgeries and assess the patients comparatively in terms of analgesia, hemodynamic stability and sedation. **Material and Methods:** Present study was single-center, prospective, randomized study, conducted in patients of age group 18-50 year, normal cardio respiratory status, ASA I/II, Patients undergoing ear surgeries under local anaesthesia, willing to participate. **Results:** In present study Total 100 cases were studied. Two groups were made as Group A - Received inj. Lignocaine 2% + Adrenaline and Group D - Received inj. Dexmedetomidine 1 ug/kg + Lignocaine 2% + Adrenaline. Both groups were comparable in terms of age, gender and type of surgery and no statistical significance was noted. Present study found that for first 10 mins vital parameters i.e. pulse rate, systolic blood pressure, diastolic blood pressure etc. increased and from 15 mins it started decreasing. Whereas grade of bleeding and sedation score were increasing. As compared between group A and group D the parameters were at a higher range in group A as compared to group D, majority of parameters had statistical significance. Rescue analgesia was required among group A at mean 25.54±11.55 min. No rescue analgesia was used among group D. Effect of analgesia was more among group D (549.8±66.71) as compared to group A (244.6±55.57), statistical significance was seen. **Conclusion:** Use of dexmedetomidine shows good results in terms of hemodynamic stability, analgesia, sedation and can be used in day to day ear surgeries.

Keywords: dexmedetomidine, VAS, rescue analgesia hemodynamic stability, analgesia, sedation, day care ear surgeries.

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INTRODUCTION

An ideal anaesthetic technique for ear surgeries should be such as to produce adequate analgesia for the surgical procedure, maximize patients comfort, reduce intraoperative bleeding as well as provide good pain relief and minimize nausea and vomiting postoperatively.[1] General anaesthesia is a more expensive option, associated with increased postoperative nausea and vomiting and hypotensive technique has to be ensured to minimize intraoperative bleeding.[2] Also coughing or straining during extubation

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can dislodge the implanted graft. Hospital stay and consequently expenditure is also increased in general anaesthesia patients. These complications could largely be easily avoided by use of local anaesthesia in ear surgeries.[3] α-2 agonists such as clonidine or more recently dexmedetomidine, may have some advantages as they produce arousable sedation, analgesia and a modest reduction in heart rate and blood pressure without respiratory depression, particularly important when the head is obscured by surgical drapes.[4] As the data available on use of dexmedetomidine as an adjuvant to local anaesthesia in ear surgeries are less, our study is aimed to evaluate the effect of adding 1 ug/kg of dexmedetomidine to lignocaine 2% and adrenaline during ear surgeries and assess the patients comparatively in terms of analgesia, hemodynamic stability and sedation.

MATERIAL AND METHODS

Present study was single-center, prospective, randomized study, conducted in Department of Anesthesiology, Vilasrao Deshmukh Government Medical College, Latur, India. Study duration was of 2 years (July 2019 - December 2021). Study was approved by institutional ethical committee.

Inclusion criteria: Age group 18-50 year, normal cardio respiratory status, ASA I/II, Patients undergoing ear surgeries under local anaesthesia, willing to participate.

Exclusion criteria: Patient with ASA III, IV. History of bleeding disorders. Allergy to dexmedetomidine and local anaesthetics. Patient with heart disease. Pregnancy. Deranged kidney function test. Advanced liver disease. History of chronic use of sedatives, narcotics and alcohol. Patients with Bronchial asthma. Patients on Beta Blocker drugs. Extremes of ages. Patients undergoing mastoid surgeries under GA.

Patients attending and getting admitted under ENT department for surgical procedure were counselled and written informed consent was taken from the participants. Predesigned questionnaire schedule consisting of standard questions related to socio demographic factors, addiction, clinical profile etc. were interviewed. In addition, questionnaire also included questions on past and present medical history and health seeking behaviour. At the time of registration the baseline information was taken especially with respect to socio demographic factors, clinical findings and other investigations.

100 patients, were randomly allocated into two groups each of 50 participants

Group A - Received inj. Lignocaine 2% + Adrenaline

Group D - Received inj. Dexmedetomidine 1ug/kg + Lignocaine 2% + Adrenaline

In operation theater, monitors were attached and baseline parameters were noted. Preoperatively intravenous ranitidine 50 mg was administered after setting up an intravenous line. Monitoring included oxygen saturation, systolic and diastolic blood pressure, heart rate, respiratory rate, onset and total duration of analgesia, sedation score and grade of bleeding.

After preparing the part under aseptic precautions local infiltration was given by the surgeon with the above prepared solutions. In order to provide reliable distribution of local anaesthetic and eliminate operator bias, we chose a standardized technique of local infiltration administered by same surgeon, who is performing ear surgery. Patient's blood pressure, pulse rate, oxygen saturation was monitored at 5 min, 10 min, 15 min, 25 min, 30 min, 45 min, 60 min, 120 min, 180 min, 240 min, 480 min. Time of onset of analgesia and total duration of analgesia (by Visual analogue scale), sedation score (by Ramsay sedation scale) and grade of bleeding (by Boezaart grading scale) was noted. All data was collected and complied in microsoft excel. All statistical analyses were performed by using IBM SPSS statistics version 21.0 (SPSS Inc., Chicago, IL, USA) and openepi version 2.3.1. Descriptive statistics such as percentage (%), mean, range and standard deviation (SD) were used to describe the data. Chi square test was applied for qualitative data and student t test for quantitative type of data. A p value of <0.05 was regarded as statistically significant.

RESULTS

In present study Total 100 cases were studied. Two groups were made Group A - Received inj. Lignocaine 2% + Adrenaline, Group D - Received inj. Dexmedetomidine 1 ug/kg + Lignocaine 2% + Adrenaline.

Mean age among group A was 31.92±7.53 and among Group D was 31.9±8.2. Among both groups majority of cases belonged to age group between 25 to 35 years. Among group A 25 each were males and females respectively. And Among group D majority were females 28 and 22 were males. Among group A out of 50 respondents 24 underwent mastoid surgery, 24 T- plasty, 1 grommet insertion and 1 stapedectomy. Among group D out of 50 respondents 28 underwent mastoid surgery, 21 T-plasty and 1 stapedectomy. Both groups were comparable in terms of age, gender and type of surgery and no statistical significance was noted.

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Table 1: General characteristics

Variable	Group A (n=50)	Group D (n=50)	P value
Age in years			
18-25	12	14	0.98
25-35	20	21	
35-45	17	11	
>45	1	4	
Mean ± SD	31.92±7.53	31.9±8.2	
Gender			
Male	25	22	0.27
Female	25	28	
Type of surgery			
Grommet insertion	1	0	0.27
Mastoidectomy	24	28	
Stapedectomy	1	1	
Tympanoplasty	24	21	

Table 2: Preoperative vitals

Preoperative vitals	Group A	Group D	P value
PR	80.84±7.04	84.52±7.9	0.01*
SBP	117±5.73	121.64±7.05	0.0004*
DBP	75.4±4.65	78.56±4.45	0.0007*
RR	15±1	15.12±1.14	0.5
SpO_2	97.82±3.18	99.28±0.8	0.002*

Present study found that for first 10 mins vital parameters i.e. pulse rate, systolic blood pressure, diastolic blood pressure etc. increased and from 15 mins it started decreasing. Whereas grade of bleeding and sedation score were increasing. As compared between group A and group D the parameters were at a higher range in group A as compared to group D, majority of parameters had statistical significance. Rescue analgesia was required among group A at mean 25.54±11.55 min. No rescue analgesia was used among group D.

Table 3: Intra-operative and post-operative vitals

	At 5 min			At 10 min			At 15 min		
	Group A	Group D	P value	Group A	Group D	P value	Group A	Group D	P value
PR	86.08±6.41	82.8±7.16	0.009*	90.72±7.21	80.92±6.84	<0.00001*	85.88±8.31	78.72±7.02	<0.00001*
SBP	122.6±5.32	119.24±6.42	0.005*	123.88±5.64	116.28±6.41	<0.00001*	118±9.4	112.72±5.99	0.001*
DBP	78.6±4.44	75.64±4.86	0.001*	75.9±9.8	73.76±4.72	0.16	73.88±6.88	72±3.53	0.08
SpO2	100±0	100±0	-	100±0	100±0	-	100±0	100±0	0
RR	14.92±0.99	14.92±1.1	<0.0001*	14.88±0.99	14.76±1.04	0.55	14.72±0.96	14.8±1.05	0.5
Analgesia	2.79±0.85	3.36±1.06	0.003*	6±0	6.33±0.47	<0.00001*			
VAS	0.12±0.47	0	0.07	1.68±0.86	0	<0.00001*	0.72±1.58	0	0
Grade of bleeding	0.93±0.24	0.97±0.16	0.005*	1.08±0.27	0.98±0.14	<0.00001*	1.36±0.62	0.98±0.14	<0.00001*
Sedation score	1±0	1.38±0.48	<0.0001*	1±0	3.34±0.88	<0.00001*	1.78±1.43	4.58±0.87	<0.00001*

	At 25 min			At 30 min			At 45 min		
	Group A	Group D	P value	Group A	Group D	P value	Group A	Group D	P value
PR	82.36±8.09	75.92±7.3	<0.00001*	85.28±7.93	74.48±6.92	<0.00001*	83.68±6.49	73.92±6.41	<0.00001*
SBP	113.2±8.45	108.2±15.04	0.04	116.4±9.02	109.56±4.9	<0.00001*	114.82±8	109.6±4.88	<0.00001*
DBP	71.64±4.17	70.56±2.91	0.01	73.84±5.45	70.44±2.3	<0.00001*	74.6±6.12	70.28±2.15	<0.00001*
SpO2	100±0	100±0	0	100±0	100±0	0	100±0	100±0	0
RR	14.72±0.96	14.76±1.03	0.6	14.6±1	14.6±1	0.9	14.72±0.96	14.6±1	0.5
VAS	0.8±1.49	0	0	1.44±1.97	0	0	0.64±1.57	0	0
Grade of bleeding	1.4±0.66	1±0.2	<0.00001*	1.48±0.69	0.92±0.27	<0.00001*	1.5±0.78	0.86±0.34	<0.00001*
Sedation score	2.22±1.56	5.16±0.5	<0.00001*	2.34±1.58	5.24±0.42	<0.00001*	3.22±1.31	5.2±0.44	<0.00001*

	At 60 min			At 90 min			At 120 min		
	Group A	Group D	P value	Group A	Group D	P value	Group A	Group D	P value
PR	84.44±6.73	73.92±6.1	<0.00001*	83.68±5.11	73.76±6.2	<0.00001*	81.52±4.44	74±6.1	<0.00001*
SBP	116.48±8.25	109.64±5.14	<0.00001*	114±5.45	109.48±4.72	<0.00001*	113.16±5.02	110.84±4.49	<0.00001*
DBP	73.72±5.45	69.88±1.62	<0.00001*	73.72±4.78	70±2.07	<0.00001*	72.64±4.29	71.12±2.94	0.04*
SpO2	100±0	100±0	0	100±0	100±0	0	100±0	100±0	0
RR	14.84±0.98	14.68±1.02	<0.00001*	14.8±0.97	14.64±1.01	0.7	14.76±0.97	14.6±1	0.83
VAS	0.2±0.6	0	0	0±0	0	0	0±0	0	0
Grade of bleeding	1.91±0.89	0.92±0.27	0.78	1.34±0.59	0.97±0.14	<0.00001*	1.37±0.55	1±0	<0.00001*
Sedation score	3.24±0.86	5.14±0.4	<0.00001*	3.02±0.79	3.48±1.29	0.01	2.83±0.85	2.61±1.15	0.02*

	At 180 min			At 240 min			At 480 min		
	Group A	Group D	P value	Group A	Group D	P value	Group A	Group D	P value
PR	78.76±11.6	75.04±6.12	0.001	79.46±4.47	75.84±5.76	0.0005*	76.88±15.4	77.2±5.5	<0.00001*
SBP	112.92±4.61	111.56±4.45	0.8	112.9±4.1	112.4±4.47	0.2	111.92±2.58	111.6±4.71	<0.00001*
DBP	72.92±4.34	70.96±2.86	0.004	72±3.89	71.62±3.49	0.45	72.88±4.46	70.68±2.81	0.001*
SpO2	100±0	100±0	0	100±0	100±0	0	99±0	100±0	0
RR	14.72±0.96	14.6±1.01	0.7	14.69±0.95	15±1	0.72	14.74±0.96	14.8±0.97	0.94
VAS	0.24±1.17	0	0	2.65±2.89	0	0	8.59±14.1	0	0
Grade of bleeding	78.76±11.6	75.04±6.12	0.001	79.46±4.47	75.84±5.76	0.0005*	76.88±15.4	77.2±5.5	<0.00001*
Sedation score	112.92±4.61	111.56±4.45	0.8	112.9±4.1	112.4±4.47	0.2	111.92±2.58	111.6±4.71	<0.00001*

Effect of analgesia was more among group D (549.8±66.71) as compared to group A (244.6±55.57), statistical significance was seen.

Table 4: Analgesia

Effect of analgesia	Group A	Group D	P value
Mean ± SD	255.6 ± 55.57	549.8 ± 66.71	<0.00001*

DISCUSSION

Day care surgery under local anaesthesia is preferred option for them as it has advantage of rapid recovery, less expenditure, less hospital stay and thus minimum loss of their daily routine work.[5] However, endomeatal and post auricular infiltration anaesthesia with local anaesthetic is often inadequate in terms of ensuring adequate patient compliance for the procedure. Dexmedetomidine has been used successfully as the primary sedative with supplementary low dose propofol and midazolam for monitored anaesthesia care during awake thyroplasty, a procedure that requires the patient to verbalize when asked and otherwise remain immobile.[3] Surgeons reported satisfactory operating conditions and patient had no recall of the procedure and no pain.[3] It also has a role in awake craniotomy.[4] Thus, dexmedetomidine could be used in a similar way for ear surgery but has not been widely reported in the literature Present study showed that mean age among group A was 31.92±7.53 and group D was 31.9±8.2. Majority among both groups belonged to age group of 25 to 35 years. Group A had equal male female ratio and group D had 28 female and 22 males. Majority surgery carried out was for mastoid and T plasty among both groups. Shende S. *et al.*,[6] conducted a study among sixty patients of age group 18-60 years, presents study also showed similar results. Study by Tungana S. *et al.*,[7] showed that Mean Heart Rate (HR) and Mean Arterial Pressure (MAP) were significantly decreased from baseline in group ND as compared to group D ($p<0.001$). Study by Tungana S. *et al.*,[7] showed that rescue analgesic with IV fentanyl was administered in 8 patients and 42 patients respectively in groups ND and D. Patient and surgeon satisfaction scores were also significantly higher in group ND vs group D. A combination of Dexmedetomidine with Nalbuphine as an adjuvant for Monitored Anaesthesia Care in microscopic ear surgery was found to provide superior sedoanalgesia. Palai PK *et al.*,[8] conducted a prospective observational study and found that Time to rescue analgesia was greater for group D. Duration of postoperative analgesia was lasted longer in Group D as compare to Group C (690.00±80.12 vs 417.67±58.64 min, $p<0.001$) and sedation scores were higher in Group D. No difference was observed in both of the groups

regarding other parameters including onset of analgesia, mean pulse rate, mean blood pressure and grade of bleeding at different time intervals ($p<0.05$). Similar findings were seen by present study. Mohamed A. El-Begermy *et al.*,[9] conducted a retrospective study. Patients showed initial increase in BP due to apprehension, which was abolished with diazepam; a second increase in BP and HR occurred at 3-10 min. Managutti A *et al.*,[10] compared local anaesthetic with two concentrations of adrenaline (1:80,000 and 1:2,00,000), there was immediate rise in the heart rate, systolic blood pressure and diastolic blood pressure in local anaesthetic with higher concentration of adrenaline when compared to local anaesthetic with lower concentration of adrenaline which showed no significant rise in pulse, systolic blood pressure while the diastolic blood pressure decreased from the normal value after administration of the local anaesthetic. Ketabi *et al.*,[11] in 2012, they noted a decrease in SBP, DBP and HR in plain lignocaine group and increase in those parameters in patients administered with lignocaine containing adrenaline. They concluded that the adrenaline in the local anaesthetic showed minor effects on the cardiovascular parameters. Chaudhry *et al.*,[12] in 2011 showed that the SBP increased 2-5 minutes after the injection of local anaesthetic while the DBP decreased following injection in all patients. Moshaver *et al.*,[13] noted that HR, BP and MAP were elevated significantly at the first 2 minutes after injection of local anaesthetic with 1:1,00,000 adrenaline and no such fluctuations were noted in patients injected with 2% lignocaine with 1:2,00,000 adrenaline. Fernieini EM *et al.*,[14] noted that heart rate increased once again 5 minutes after injection and sustained for 10 minutes. They concluded that the increase in heart rate prior to injection was due to the release of endogenous catecholamine and the delayed increase in heart rate was due to the adrenaline content in the local anaesthetic. Niwa *et al.*,[15] in 2001 concluded that lignocaine adrenaline is safe to use since the hemodynamic changes are very minimal in patients with cardiovascular diseases. P Eniya *et al.*,[16] found that there was a statistically significant difference between dexmedetomidine and lignocaine in parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure at all time intervals after tracheal intubation, with dexmedetomidine being the most effective. Sedation scores were more with dexmedetomidine. No adverse effects were noticed in patients of both groups. Dexmedetomidine attenuates the hemodynamic stress response to laryngoscopy and intubation more effectively when compared with lignocaine 1.5 mg/kg IV, without any adverse effects. In summary, the advantages of performing ear surgery under local anaesthesia and conscious sedation include less bleeding, reduced pain in the immediate postoperative period, early mobilization, cost-effectiveness and the ability to test hearing restoration during surgery.[5]

CONCLUSION

In dexmedetomidine group pulse rate, systolic blood pressure, diastolic blood pressure, respiratory rate all the vital parameters were maintained at the lower range as compared to control group. In dexmedetomidine group, VAS score was also good, no rescue analgesia was needed, grade of bleeding and sedation score both were at lower range. Study concluded that use of dexmedetomidine shows good results in terms of hemodynamic stability, analgesia, sedation and can be used in day to day ear surgeries.

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