



RESEARCH ARTICLE

INFILTRATION ANAESTHESIA FOR TYMPANOPLASTY: A COMPARISON OF DEXMEDETOMIDINE AND CLONIDINE AS ADJUVANTS TO LIGNOCAINE AND ADRENALINE

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Abstract

Background: For many decennia, local anaesthetics have been utilised for wound infiltration analgesia. α -2 Adrenoceptors as adjuvants have an advantageous effect in prolonging the time of peripheral nerve blocks is a locally mediated action and not replicated by given systemically. An increasing impact on lignocaine-induced suppression of the C-fibre action potential is thought to be the cause of its synergistic activity with lignocaine in extending the duration. we evaluated Dexmedetomidine and clonidine when administered with lignocaine during infiltration anaesthesia for tympanoplasty.

Methodology: 50 patients of 18-60 years who were enrolled for tympanoplasty under local anaesthesia were arbitrarily split into two equal groups. 12 ml of 2% lignocaine with adrenaline + clonidine + 1 ug/kg were injected into Group C (n = 25), and 12 ml of 2% lignocaine with adrenaline + dexmedetomidine + 1 ug/kg were injected into Group D (n = 25). Hemodynamic parameters, sedation score, analgesia onset and duration, and bleeding severity were all chronicled. No differences in terms of analgesia's onset, Boezaart score, or its impact on hemodynamic parameters were observed. Dexmedetomidine protracted the duration of postoperative analgesia 1183.2 ± 343.59 min in comparison to clonidine 766.4 ± 185.89 min and with high sedation scores.

Conclusions: Dexmedetomidine was found to be superior to clonidine when used as an adjuvant to local anaesthetic in infiltration anaesthesia for tympanoplasty, with no difference in terms of onset of analgesia, grade of bleeding, or hemodynamic parameters.

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Introduction:-

Mitigation of pain is the sole quintessence of anaesthesia. Pain is a persecution of sensory and emotional experience resulting from actual or impending injury. An uncongenial psychological sensation that is often brought on by painful stimulation and is conveyed to the central nervous system via a specialised neural network ^[1] All surgical procedures, whether minor or major, are uniquely convoyed by anxiety, stress, and mild to moderate pain or disquiet, despite the fact that the invention of local anaesthetic has made it possible to successfully complete modest surgical operations without any pain. ^[2-4] The effect of LA on the vascular smooth muscle tone (vasoconstriction/vasodilatation) close to the site of its deposit affects how long it will take for it to take effect. The volume and concentration employed, the method (infiltrative versus regional peripheral nerve versus CNS blocks), the target tissue (fibre diameter and myelin sheath), and the plasma protein binding (drug-specific affinity) are

additional elements that affect the duration. Lidocaine, bupivacaine, tetracaine, benzocaine, and articaine are examples of current local anaesthetics.^[5]

A middle ear anaesthesia strategy should be able to give appropriate analgesia for the surgical process, maximise patient comfort, provide a clear microscopic field, deliver effective pain management, and prevent nausea and postoperative vomiting.^[6] In order to reduce and minimise blood loss, it is necessary to adopt a hypotensive technique under general anaesthesia, which is a more costly approach that is also linked to higher postoperative nausea and vomiting. The implanted graft may also become loose while being extubated if you cough or strain. Patients receiving general anaesthesia experience longer hospital stays, which increases costs. By using local anaesthesia during middle ear procedures, these problems might be substantially avoided.^[7]

Our hospital, a tertiary-level referral institution, receives a large number of patients from outlying areas. For them, having a day surgery under local anaesthesia is the best alternative because it entails a quick recovery, lower costs, a shorter hospital stay, and less time away from their regular jobs. Endomeatal and post-auricular infiltration anaesthesia with a local anaesthetic is frequently insufficient to ensure satisfactory patient compliance for the surgery. Patients may express discomfort and excruciating agony, particularly when annular lifting. In these situations, local anaesthesia should be combined with intravenous anaesthetics to achieve a successful surgical outcome. Airway access becomes a difficulty in the case of an emergency; hence sedation must be properly dosed.^[7]

The use of using adjuvants, like clonidine and Dexmedetomidine, to lengthen and enhance anaesthetic blocks is well-steadfast. Used as an effective antihypertensive for many years, clonidine is a mixed α -1 and α -2 adrenoreceptor agonist with predominant α -2 activity. When the prejunctional α -2 adrenoreceptors are stimulated, it causes sympatholysis and decreases peripheral norepinephrine release.^[8] It has been demonstrated that when used consistently, it can reduce the need for anaesthetic and analgesic medications.^[9] In addition, its usage as a nerve block adjuvant has been documented.^[10-11]

Imidazole compound, dexmedetomidine is a pharmacologically active dextroisomer of medetomidine that exhibits specific and selective α -2 adrenoceptor agonism.^[12] The spinal cord and brain both have these particular receptors. Dexmedetomidine's mode of action is distinct from other sedatives now in use. When it interacts with the α 2 receptor, synaptic vesicles receive negative feedback. As a result, the transmission of pain stimuli is blocked. This prevents the production of nor-epinephrine. Blood pressure (BP) and heart rate are reduced as a result of post-synaptic activation of α -2 adrenoceptors in the central nervous system. Analgesia, sedation, and anxiolysis result from the interaction of these effects.^[13] It is also known to cause bradycardia and hypotension.

It is administered intravenously for procedural sedation and as a sedative in intensive care units. Recently, dexmedetomidine is used as an adjuvant to local anaesthetics^[8,12] in neuraxial and peripheral nerve blocks. It accelerates the onset, increases the duration of LA, decreases intraoperative bleeding, and has a high surgeon satisfaction score.^[8,10,12,14-17]

Although research comparing these two α -2 adrenoceptor agonists in central neuraxial blocks^[18] and in peripheral blocks are available^[19-20] we were unable to locate many comparisons of them as an adjuvant to local anaesthetics in infiltration anaesthesia. Dexmedetomidine and clonidine were examined in this prospective study as an adjunct to local anaesthesia during infiltration anaesthesia for middle ear surgery.

Methodology:-

It was a randomised prospective study performed from January 2023 to May 2023 in the ENT operation theatre after approval from the Institutional Review Board. 50 adult patients of either gender posted for middle ear surgery under LA, with ASA physical status I and II were included. Randomization was used in a double-blind fashion, ie. the study drug was prepared by one anesthesiologist and the other anesthesiologist who monitored VAS was different but the ENT surgeon who gave the block (LA) was the same. Patients who participated in our study were split into two groups. The 25 patients in Group C (the clonidine group) got 12ml of inj. lignocaine 2% with adrenaline (1:2,000 dilution) and 1ug/kg of inj. clonidine as the LA. 25 patients in Group D (the Dexmedetomidine group) got injections of Lignocaine 2% with adrenaline (1:2,00,000 dilution) and injections of Dexmedetomidine 1ug/kg as the LA. Written informed consent was obtained ie. Study participants were counselled and thoroughly explained about the procedure and if they were willing to participate, they were included in the study.

We adhered to conventional fasting rules. Ondansetron 4 mg was injected intravenously prior to surgery after an intravenous line was established. An ECG, SpO₂, and a non-invasive BP monitor (drager monitor) were used for routine patient monitoring.

Haemodynamic parameters were first reported at baseline, then at the time the block was administered, at the beginning of the operation, and then every 15 minutes after that.

The duration from the local infiltration to the cessation of pinprick sensation in the retro auricular region is referred to as the "onset of analgesia." The research eliminated patients who were recalcitrant or required sedation. The time from the injection of the block to the patient's first request for analgesia with a VAS >3 was considered the total duration of analgesia. Total operating time is the amount of time from the beginning of the incision to the end of the last suture. The surgical site field was evaluated intraoperatively using the Boezaart score, the sedation score throughout the operation, and hemodynamic measures at the incision, annular lifting, and at the conclusion of the procedure. All patients had a 24-hour observation period following the end of OT. A 10-point visual analogue scale was used to evaluate the analgesic durations. VAS rating and

The surgical field was assessed by a 10-cm visual analogue scale and the 6-point scale described by Boezaart et al.⁴ and completed by the surgeon at the end of the case

Boezaart score ⁴	Description
0	No Bleeding
1	Slight bleeding – no suctioning required
2	Slight bleeding – occasional suctioning required. The surgical field is not threatened
3	Slight bleeding – frequent suctioning. Bleeding threatens the surgical field in a few seconds after suction is removed
4	Moderate bleeding – frequent suctioning. Bleeding threatens the surgical field immediately after suction is removed
5	Severe bleeding and constant suctioning required

A 10-point visual analogue scale and vital signs (pulse, blood pressure) were used to evaluate the analgesic durations at 30 minutes, 1, 4, 6, 8, and 24 hours after surgery. A rescue analgesic (injection of Diclofenac IV) was given when the patient reported pain or the VAS was more than 3. Drug side effects such as hypotension, bradycardia, and PONV were documented. PONV-free patients are those without nausea and vomiting who did not get antiemetics.

Sedation score was assessed by Ramsay Sedation Score [1 = awake, conscious, no sedation; 2 = calm and compose; 3 = awake on verbal command; 4 = brisk response to gentle tactile stimulation; 5 = awake on vigorous shaking; 6 = unarousable]. Sedation scores were recorded just before the initiation and at predefined time periods during surgery.

Results:-

Without a single dropout, all sixty enrolled patients finished the research study. None of the patients needed sedation and intraoperative analgesia. There were no differences in the demographic characteristics between the two groups (Table 1).

There were no discernible differences between the two groups in the length of the procedure or the time at which analgesia began. When compared to Group C, Group D's analgesia duration was substantially longer ($p = 0.0001$). (Table 2).

The dexmedetomidine group considerably outperformed the clonidine group in terms of sedation score (Table 3). There was no discernible difference between the two groups in terms of bleeding (Boezaart score) (Table 4). Mean blood pressure (MAP) and pulse rate in the two groups throughout various points of surgery were equivalent hemodynamically ($p > 0.05$) (Table 5).

Discussion:-

Middle ear procedures constantly concern local insinuation analgesia, which is portrayed as the injection of the upswept quantity of local anaesthetics with or without adjuvants in the various tissue (planes) perioperatively.^[21] The surgeon can assess hearing and spot intraoperative complicacies while under local anaesthesia.

Additionally, it does not have the drawbacks of general anaesthesia, shortens hospital stays, and costs less money. However, sympathetic stimulation brought on by the concern of a cognizant and aware patient may result in greater bleeding and a higher risk of graft failure. Due to the microscopic type of surgery, even the smallest movement might perturb the surgeon. Surgery performed under local anaesthesia requires the patient's participation, which may be attained by preoperative counselling and the use of the proper sedative.

Both clonidine and dexmedetomidine, α -2 adrenoceptor agonists, have been explored at various levels as appurtenant to local anaesthetics to protract the time of block and postoperative analgesia in a variety of peripheral blocks^[19,20] as well as central neuraxial blocks.^[22] However, there isn't much research that compares these two medications directly when used as adjuvants to local anaesthesia infiltration. We only included tympanoplasty in our study to ensure that the kind, nature, and duration of discomfort were all consistent.

When administered as an adjuvant to mepivacaine in brachial plexus block, Singelyn et al.'s^[23] minimal dosage of clonidine (0.5 μ g/kg) resulted in a protracted duration of analgesia. With dosages greater than 0.5 μ g/kg ie. 1-1.5 μ g/kg, no further advantages were discovered.^[19,22-24] Based on other research^[4,19,25] that supported the analgesic effectiveness of dexmedetomidine 1 μ g/kg rather than 0.5 μ g/kg and 0.75 μ g/kg, we chose to utilise clonidine and dexmedetomidine at a dosage of 1 μ g/kg in our study.

In our investigation, it was discovered that Group Dexmedetomidine's analgesia duration was substantially longer than that of Group Clonidine (1183.23 $\pm$ 43.59min) compared to Group C's (766.41 $\pm$ 85.89min), with a p-value of 0.0001. The findings matched those of Shende et al.,^[26] who found that group Dexmedetomidine's results were higher than group Clonidine were, with a p-value of 0.001. Dexmedetomidine (456 $\pm$ 97 min) had a considerably longer analgesic duration and higher block quality than clonidine (289 $\pm$ 62 min), according to Swami et al.^[19], with a p-value of 0.001. Similar results were also reported by Harshavardhan HS.^[20]

At the peripheral level, α -2 agonists have analgesic effects by inhibiting nerve action potentials and reducing norepinephrine release; this effect is receptor-independent. The central analgesia and sedation brought on by α -2 agonists are induced by the inhibition of substance P release in the nociceptive pathway and by stimulation of -2 receptors in the locus ceruleus. Though α -2 adrenergic agonists, dexmedetomidine and clonidine function similarly, Dexmedetomidine, on the other hand, has an eight-fold stronger selectivity for -2 adrenoceptors. Dexmedetomidine's sedative and antinociceptive effects are principally brought about through stimulation of the locus ceruleus' α -2 adrenoceptors. More specifically for α -2, dexmedetomidine It is a lot more potent sedative and analgesic than clonidine because it relays the sedative and analgesic characteristics via an adrenoceptor subtype.

All of the patients were cooperative at the beginning of the procedure, but as time went on, at the time when the annulus was lifted, 64% of patients were relaxed and composed, and 12% of patients were awake on verbal commands, whereas in group clonidine, 56% of patients were in Ramsay score II and none in score III with p value 0.04; sedation score remained the same until the end of the procedure, but it decreased in group clonidine, making the difference significant. Similar changes in sedation were seen by Swami et al. and Seema et al., with patients feeling more at ease and arousable.

When Swami et al.^[19] and Shinde et al.^[26] evaluated these two α -2 adrenoceptors as adjuvant to local anaesthetics in brachial plexus blocks, they found no such variation in onset. Additionally, we too found no difference in the groups' analgesic onset times.

Although both groups had decreased levels of intraoperative bleeding, we could not identify a statistically significant difference between them, which is consistent with other research observations.^[19,26] The contributing impact of clonidine and dexmedetomidine in lowering blood pressure through sympatholysis may be an explanation for the decreased bleeding at the surgical site.

We come to the conclusion that dexmedetomidine was superior to clonidine in terms of extending the duration of postoperative analgesia and sedation score when added as an adjuvant to local anaesthetic in infiltration anaesthesia for tympanoplasty. There were no differences in terms of analgesia's onset, Boezaart score, or its impact on hemodynamic parameters.

Tables

Table 1:- Demographic Parameters.

	Group D (n= 25) Mean $\pm$SD	Group C (n = 25) Mean $\pm$SD	P VALUE
Age (Years)	32.72 $\pm$ 10.16	33.72 $\pm$ 12.38	0.75
Weight (Kgs)	56.2 $\pm$ 7.71	56.6 $\pm$ 13.22	0.89
Gender Male: female	10 :15 (40: 60 %)	8:17(32:68)	0.5597
ASA I:II	20 :5(80:20%)	19:6(76:24%)	0.7354

Table2:- Intraoperative parameters.

	Group D (n= 25) Mean $\pm$SD	Group C (n = 25) Mean $\pm$SD	P VALUE
Duration of surgery(min)	162 $\pm$ 29.5	149.6 $\pm$ 29.93	0.134
Duration of Analgesia(min)	1183.2 $\pm$ 343.59	766.4 $\pm$ 185.89	<0.0001
Onset of analgesia (sec)	88.56 $\pm$ 4.416	89.6 $\pm$ 4.609	0.419

Table 3:- Ramsay Sedation Score.

	Sedation Score	Baseline	At Incision	Annulus Lift	End of Surgery
Group D (n= 25)	1	25 (100%)	5(20%)	6(24%)	5 (20%)
	2	0	15(60%)	16(64%)	16(64%)
	3	0	5(20%)	3(12%)	4(16%)
Group C (n= 25)	1	25(100%)	10(40%)	11(44%)	14(56%)
	2	0	15(60%)	14(56%)	11(44%)
	3	0	0	0	0
P Value			0.01	0.04	0.0025

Table 4:- Boezaart score⁴.

Bleeding score	Group D (n= 25)	Group C (n= 25)	P value
1	8(40%)	8(40%)	0.8003
2	16(64%)	15(60%)	
3	1(4%)	2(8%)	
4	-	-	
5	-	-	

Table 5:- Intraoperative Haemodynamic Parameters.

Hemodynamic variables	Time duration	Group D (n= 25)	Group C (n = 25)	P VALUE
Mean Arterial pressure	Baseline	96.85	96.8	0.142018569
	Incision	94.29	94.88	
	Annulus lift	91.92	92.05	
	End of Surgery	86.61	89.57	
Heart rate	Baseline	80.16	80.4	0.237010694
	Incision	77.04	76.88	
	Annulus lift	78.56	78.56	
	End of Surgery	78.88	79.12	

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