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Review Article,

Tympanoplasty under Local Anesthesia (LA) Without Sedation.

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Abstract:

Background & Objectives: Local Anesthesia (LA)_is getting popularity in comparison to general anesthesia (GA) in underdeveloped and developing countries in many otolaryngological operations. The rationale for LA is the lack of trained anesthesia staff, lack of adequate anesthesia machines and monitoring equipment. LA is safe; and ability to perform more cases in a shorter period of time. This study aimed to find out patients compliance in the operative procedures under LA without sedation.

Methods: 7905 patents underwent tympanoplsty under LA without sedation from 1999 to 2019 in the different hospital of Bangladesh. Preoperative thorough counselling with psychological motivation, advantages of LA, intraoperative surgeon patient conversation and watching surgical steps on monitor, tests of facial nerve function were explained to the patient. LA with different Adrenaline concentrations (1: 1000 to 1: 200,000) was used either by injection or topically. Patients' satisfaction, vertigo, drowsiness, hangover, orientation and other parameters ware recorded.

Results: Amongst 7905 patients; male 56.2% and 43.8% was female. Maximum numbers (26.3) were found between 26 year to 35 year of age. Patients' intraoperative compliance showed excellent without sedation. Operative time was short with a bloodless field. The overall safety was good and needed shortest hospital stay (Hour/day); and of course very less expensive.

Conclusion: Patient's safety is the primary objective considered in all patients. The advantages recorded as day/hour care hospital stay, patients comfort, less bleeding, ability to assess patient's hearing during surgery and cost effectiveness

Key words: LA without sedation, tympanoplsty, safety, cost effectiveness.

Introduction:

The goal of successful tympanoplsty is to create a mobile tympanic membrane or an aerated mucosal-lined middle ear space and a sound-conducting mechanism between the mobile membrane and the inner ear fluids with a graft ± prosthesis. The tympanoplsty is mostly done either under LA or GA. Professor D. Plester in Tubingen, Germany first started practicing by using LA in ear surgeries¹. In both the anesthetic procedures have some advantages and disadvantages, but the surgeon mainly select which type of anesthesia he would love to use. LA decreases the operative time, improves hemostasis and allows intraoperative hearing assessment, minimum cost and no hospital stay. However, the method was

subsequently modified standard by using adrenaline (1:1000)injection to xylocaine/lidocaine to preparing different concentration to prolong the anesthesia time and to achieve less bleeding. A bloodless operative field is essential, because even a few drops of blood can obscure the surgical field². The techniques of headup tilt 20 to 30 degrees from the operating bed facilitate avoidance of venous obstruction, hypotension³. normocapnia, and controlled Tympanoplsty relies some particular challenges to the surgeon. One must consider the type of procedure being performed to decide upon how best this is delivered. The patient's co-morbidities are important, and the resources in low-income settings are considered to be relevant prior to

provide safe anesthesia. Many simple procedures can be performed under LA with or without sedation. In the developing countries, this may be a safe and effective way of providing anesthesia; LA avoids the risks of GA, the requirement of equipment necessary to provide a GA safely, and even the need of an anesthetist when a suitably trained person is not available⁴. GA offers comfort to the patient and ease to the surgeon, especially for patients who cannot tolerate the procedures under LA⁵. It has been observed in the published literature that sedation is given prior LA in all tympanoplsty operation. In this study author had been doing tymanoplasty under LA without sedation for the last 20 years. In this article, a retrospective study of more than 20 years' experience of the use of LA without sedation in tympanoplasty on 7905 patients in different hospital of Bangladesh has been demonstrated. It includes description of our technique, advantages, and limitations.

Objectives:

- This study is intended to be a sharing experience of using LA without sedation.
- It also aimed to find out patients compliance in the operative procedures without sedation.

Materials and methods:

Study design: retrospective study

Study sample: 7905 patients with indication of

chronic otitis media.

Sampling technique: Simple non-random

sampling

Study period: 20 years (1999-2019)

Study places:

- Bangladesh Medical College Hospital
- Popular Medical College Hospital
- Other district hospitals of Bangladesh

Inclusion criteria:

- Age: 16 year to 65 year.
- > Tympanic membrane perforation
- ➤ Chronic mucosal otitis media

Exclusion criteria:

- > Patients unfit for surgeries
- Chronic squamous otitis media/choleasteatoma

> Patients not giving consent.

Procedure:

The procedure begins with preoperative patient counseling and motivation in the outpatient clinic. Many patients' question about neck stiffness for keeping still for a period of time, fear of pain and tolerability. They were reassured regarding movement of their head to other side time to time if needed and also they were taught how to cooperate during surgery. They were advised that you could go home the same day hours after operation with simple analgesics. At surgery, surgical field prepared in the standard fashion with the head on a head ring. The area was cleaned with aqueous povidone-iodine that filled the external auditory canal. The draping were applied in such a way that the patient could able to view the television monitor if he or she desired to watch the procedure. The author used self-prepared anesthetic solution (AS) with 2% lidocaine solution with 1:1000 to a concentration of 1:5000 to 1:20000 which was given by injection or topically. The concentration and dose based on the age and pre-existing cardiac disease (The total amount of injected AS should not exceed 7mg/kg body weight, 20 ml in average adult). In most patients, 12–15ml was needed. Injection is strictly extravascular; the syringe piston is usually withdrawn before each injection to assure extravasation. The preparation and administration of the solutions were done by the surgeon himself. Prior to infiltration, the patient was assured that he she might experience some temporary discomfort.

LA injection technique involved four quadrant anesthetizing points in the external auditory canal. 3–5 ml AS used to inject in the temporal region for taking temporal fascia graft. Then by using 26 gauge needle, 0.5 ml of each AS was injected in the canal in the 4 points of the external auditory canal namely 6-9-12-3 O' clock position. The bevel of the needle is directed toward the bone, and the AS was injected subperiosteally to avoid blebs or damage to the skin. The ME mucosa was anesthetized by placing the gel foam/small cotton ball soaked with AS through the tympanic membrane (TM) perforation. But in intact TM, 1ml of AS was instilled in the ME cavity once opened after elevation of the TM flap and left for 1-2 min to anesthetize the tympanic plexus. In the intraoperative & early postoperative period, patients were asked to score their discomfort for pain, noise, anxiety, irritation (uneasiness) and position of the body and neck by a means of questionnaire. The scores ranged from "0" to "4" for each question, "0" for no discomfort and "4" for severe discomfort. Additional questions were asked about the most disturbing sensation during the operation and whether they would prefer local anesthesia for a second procedure. Per operative bleeding & difficulties faced by the surgeon were also noted. Operating time was also recorded.

Results:

In our series, LA was used in 7905 patients, 4455 (56.2%) male and 3450 (42.8%) female. Their ages ranged from 16 to 65 years.

Table 1: Sample distribution of subjects according to age and gender (n 7905)

Gender	16-25	26-35	36-45	46-55	56 -	Total
	years	years	years	years	65	
					years	
Male	1030	1297	935	868	325	4455
	(13%)	(16.4%)	(11.8%)	(11%)	(4%)	(56.2%)
Female						
	946	1016	730	598	160	3450
	(12%)	(12.9%)	(9.3%)	(7.6%)	(2%)	(43.8%)
Total	1976	2313	1665	1466	485	7905
	(25%)	(29.3)	(21.1%)	(18.6)	(6%)	(100%)

In the early postoperative period, patients were asked to score their discomfort for pain, noise, anxiety, irritability (uneasiness) and position of the body and neck which were noted in Table 2.

Table 2: Scores for complaints by patients (n 7905)

Complaints	0	1	2	3	4
Anxiety Pain Noise Irritation	5356 (67.8%) 6987 (88.4%) 7694 (97.3%) 7697 (97.4%)	1995 (25.2%) 870 (11%) 165 (2.1%) 118 (1.5%)	501 (6.3%) 58 (0.7%) 37 (0.47%) 80 (01%)	469 (5.9%) 16 (0.2%) 17 (0.2%) 07 (0.09%)	14 (0.18%) 04 (0.05%) 02 (0.03%) 03 (0.04%)

On an average, duration of each surgeries were recorded & presented in Table 3.

Table 3: Average duration of each surgical procedure

Surgical procedure	Average required time (min)	
Tympanopasty	35	

Intra operative complications noted in Table 4.

Table 4: Complications encountered during surgery n=7905

Complications (Perioperative)	Number of patients		
Excess bleeding	15		
Nausea/vomiting	03		
Vertigo	00		
Facial nerve injury/paresis	03 (transient)		

Postoperative complications are shown in Table 5

Table 5: Postoperative complications

Complications (Postoperative)	Number of patients
Nausea/vomiting Disequilibrium/vertigo Facial nerve injury/paresis Sensorineural hearing loss Prosthesis	0 0 0
displacement Wound infection	0 3

Discussion:

Although it has been known that majority of tympanoplasty can be carried out under local anesthesia, only a small number of surgeons feel comfortable using this technique⁶. Less bleeding, effectiveness. postoperative analgesia, mobilization of the patient in a short time, no aspiration risk during or after the surgical procedures, release of anesthetic capacity for other major procedures, and that the hearing can be tested during surgery are the advantages of local anesthesia were documented in this study which is found in other literature⁷. In our questionnaire survey, patients scored their discomfort of pain corresponding to a value '0' means no anxiety, no pain, no noise and irritation. '1' indicating "very mild', '2' for "mild", '3' for "moderate" and '4' for "severe". Sensation of pain is related to personal psychological status and previous experiences. Personal variations are more important than the degree of surgical trauma. Patients should be assessed meticulously by the experienced surgeon so that local anesthesia is not to be performed in unsuitable patients. The less the patient is informed, the greater his or her anxiety will be. In our series pain score was '0' in 88.4% and severe pain '4' was recorded in only 0.02%. Most patients noted that they felt pain only at the beginning of injections of the local anesthetic and subsequently experienced no pain. So here it is possible by infiltrating AS properly in the external auditory canal in the four quadrant location. The method of LA without sedation is not found in any literature. In rating the most disturbing sensation, anxiety (0) 67.8%% of patients and 25.2% patients; the noise during the procedure complained '1' by 2.1% and irritation '1' in 1.5% of patients. It has been reported in the published literature that the intense sensation of noise and anxiety were the most common discomforts but the majority of patients preferred local anesthesia⁶⁻⁸. Adverse effects of LA did not found in many studies on local anesthesia for middle ear surgery⁹⁻¹². In this study the results some differ form the study in the opinion that the preoperative counselling was the prime factor of getting the study result.

The choice of patients in favor of local anesthesia for a similar procedure in spite of these discomforts has various reasons. Mobilization of the patient in a short time, little pain in early postoperative period and the chance of being informed by the surgeon during the procedure are the most common reasons. In highly anxious and less-educated patients, fear of not waking up again after general anesthesia may be another reason for preferring local anesthesia. From the surgeons' point of view, the ability to test hearing during surgery and less bleeding are the most striking advantages. In our study, hearing was assessed during the operations using free-field audiometry. In a successful hearing reconstruction, the patient heard whispered voice at 1m distance. This is valuable in all ear operations aiming to improve hearing in tympanoplsty.

Test of Facial Nerve (FN) action, by asking the patient to smile or close the eye lids, was a good alternative for FN monitoring in our study. It is an excellent advantage of LA without sedation.

The overall safety of LA is greater compared with GA, including elimination of the risk for laryngotracheal trauma by means of endotracheal intubation. Complications related to GA agents are avoided, especially cardiopulmonary and hepatic complications. There is less postoperative nausea and vomiting, and, in general, mobilization is early^{13,14}. Lidocaine (xylocaine) is the main anesthetic used in our operations. characterized by a rapid onset and intermediate duration of action ¹⁵⁻¹⁶. No adverse effects were found in our series. Addition of adrenaline prolongs its action and decreases its toxicity. The dose of lidocaine should not exceed 4.5mg/kg without adrenaline, but with adrenaline it can reach 7mg/kg. Toxicity may be avoided using strict extravascular injection of AS and avoiding rubbing the skin after injection¹⁷. In our study, it was found that the time of action of lidocaine was nearly doubled if adrenaline 1:1000 was added and increased by 2 fold again with 1: 20 000 adrenaline. This is in agreement with the opinion of Neal et al. 18, who stated that adrenaline causes vasoconstriction to arteries, reducing bleeding, and delays the absorption as well resulting doubling the duration of anesthesia. We also found that prolongation of lidocaine action which was also related to the site of injection

The cost-effectiveness of LA is agreed upon by many authors 19, 20. The shorter operative time took average 35 minutes, shorter hospital stay 30 minutes to hour and saving cost of GA/sedation all contribute to the low cost of LA cost effectively without sedation in this study. In a previous study carried in Al Azhar University Hospitals, the anesthetic drugs in LA cost less than 20% of the cost of anesthetic drugs of GA²¹. Because of the low cost, early recovery, and shorter hospital stay (day cases), LA without sedation was used successfully by the author in tympanoplasty in different tertiary level hospitals.

Conclusion:

Tympanoplsty under local anesthesia without sedation is safe, feasible and cost-effective. It causes less bleeding and is well tolerated both by patients and by the surgeon. Good patient selection and preoperative counselling are the most important factors for the success of LA without sedation. The majority of patients leave hospital within hours on the same day.

Disclosure:

The authors have no funding, financial relationships, or conflicts of interest to disclose.

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