

The Impact of Local Anesthesia on Tympanostomy Tube Insertion for the Treatment of Chronic Otitis Media with Middle Ear Effusion in Adult Age Patients: A Prospective, Randomised, Controlled Study

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Abstract Objective: To conduct the important role of local anaesthesia in myringotomy and ventilation tube insertion for the treatment of otitis media with effusion (OME) in adult patients and improving hearing outcomes and limiting the use of general anaesthesia for this procedure. **Patients and Methods:** Ninety one adult patients aged between 20 and 69 years diagnosed with persistent chronic non suppurative otitis media with effusion lasting at least 1 month. The patients were randomly arranged either as a treatment group (71) or control group (15). **Results:** one week post operatively, the mean improvement in air conduction across 0.5, 1, 2, 4 KH were frequencies (20.46, 19.86, 23.53 and 36.05) post operatively comparing the pre operatively values (38.8, 43.55, 45.92 and 57 dB) and air bone gap (4.2) post operatively while (28.75) pre operatively for the study group patients with significant (p-value<0.001). While the air conduction values for the control group patients at the same frequencies were (20.35, 19.64, 26.07 and 43.33Db) post operatively and (35.7, 42.14, 47.85 and 67.50 Db) and Air bone gap (5.00) post operatively and (29.57) pre operatively with significant p-value<0.001). The mean procedure duration for study group was (15.48 minute) and (40.86 minutes) for the control group, also the procedure duration time cost was (21.64\$) for study group compared with the control group (576.66\$) for control group with significant p-value <0.001 on the same time of insignificant difference p-value=0.45 regarding to ABG mean (4.21) in the study group and (5.00) in the control group. **Conclusion:** our study have conducted that the use of topical anaesthesia for the purpose of myringotomy with ventilation tube insertion in the outpatient clinic is safe, fast, effective with less duration and less procedure time cost compared with the use of general anaesthesia inside the operation theatre for the same purpose.

Keywords Topical, Randomised, Air conduction, Air bone gap, Duration and cost

1. Introduction

Middle ear effusion (MEE) is a very common disease in children and adult, it may reach about 20% incidence in the young school-aged children [1], but it is less common in adult age group. The pathogenesis of middle ear effusion is complex with several factors thought to play a role in its aetiology, however the most common cause is the poor ability of the Eustachian tube to equalise negative pressure in the middle ear [2]. Although, it may be not clear whether the impairment of the Eustachian tube function is a cause or a

result of the middle ear effusion. Several previous studies [2] proved that adult patients with poor mastoid pneumatisation were considered to be a high risk group for the development of secretory otitis media (SOM) which was studied with previously published findings regarding the correlation between the degree of mastoid pneumatisation and the risk of development of chronic otitis media and SOM.

Negative pressure was considered as a general feature of the various forms of otitis media, and also its buffering action could not be properly regulated in absence of adequate mastoid pneumatisation. The actual cause of such negative pressure is not completely clear, but it could be result from an inflammatory condition such as SOM which triggered a process of middle deficiency or increased diffusion [3]. Regardless, the idea of improving the Eustachian tube function in a noninvasive manner via Valsalva or Politzer manoeuvres offers another potential treatment modality for OME. It is important to note that the Valsalva and Politzer

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manoeuvres have a small but key difference; the Valsalva manoeuvre is performed by an uncontrolled forceful attempt at expiration against a closed airway, whereas the Politzer manoeuvre is a controlled delivery of air into the nostril against a closed airway. The standardised controlled delivery of air provided by the Politzer manoeuvre makes it much more reliable and reproducible, and a preferred method for non-surgical intervention. The Otovent balloon is an autoinflation Valsalva device, and a review showed no significant changes in pure tone audiometry [4].

The financial impact of otitis media on health care is enormous. Otitis media-related Medicaid expenditures in the United States were \$555 million for the 12.5 million covered children younger than 14 years in 1992. [5] Concurrently, national expenditures for treatment and disability associated with otitis media exceeded \$4 billion. Direct costs associated with childhood otitis media include office visits, diagnostic tests, medical treatment, and surgical procedures. Indirect costs for AOM are substantial, estimated at 61% to 83% of the total expense, (and include child school absence, caregiver absence from work or school, and cancelled family activities because of child illness [6]. With nearly 670,000 tympanostomy tube insertions annually in children in the United States [7] an average cost of \$2700 per procedure, the contribution to health care costs is approximately \$1.8 billion. This does not include additional costs related to follow-up care (which continues until after the tube extrudes), treatment of otorrhea, and management of any other sequelae or complications. A cost analysis based on chart review from one managed care organization showed that tympanostomy tube insertion is cost-effective for otitis media in children, but no large-scale studies or formal cost-effectiveness analyses are available to assess the generalizability of this claim [6].

Study design:

A comparative randomised controlled trial was carried out in our hospital between December 2017 and April 2018.

Setting: ENT Department, Taiba Hospital Kuwait.

Inclusion and exclusion criteria:

Patients aged from 19 to 76 years with hearing loss from persistent otitis media with middle ear effusion over a one-month period and an average air conduction of 25 dBHL or worse across 0.5, 1.0, 2.0 and 4 kHz were considered eligible for the trial. Any patient with nasopharyngeal mass, chronic sinusitis was excluded. All four frequencies were tested (if the patient was compliant) by our blinded audiologists (T.A) 4 weeks after treatment and recorded as before tympanostomy audiograms and repeated by the same audiologist one week post procedure.

2. Materials and Methods

Patients attended our ENT department Taiba hospital Kuwait, including 76 consecutive patients (39 male and 37 female) whose age was 20 to 75 years (mean of 50.92 ±

14.83years) for the study group and 15 consecutive patients (7 male and 8 female) whose age was 21 to 75 years (mean of 55.92 ± 14.01years) and planned to undergo myringotomy with grommet tube insertion for treatment of otitis media with middle ear effusion (OME). They were complaining of symptoms suspected OME including decrease hearing, ear blockage, tinnitus, ringing of ear, ear ache and dizziness. All patients were given a full history, ENT examination, pure tone audiogram, Tympanometry and CT nasopharynx with nose and para-nasal sinuses were done for all patients to exclude any nasopharyngeal masses. After a 1-month period of failed medical treatment and follow up, patients with persistent OME were advised for Myringotomy with ventilation tube insertion by the same otolaryngologist (R.A.) either under local or general anaesthesia. An informed consent for the procedure was taken from all patients as our Ministry of health roles in all Kuwait hospitals. At the time of entry into the ENT clinic, all patients were randomly allocated to a study group containing 76 patients and a control group involving 15 patients after failure of conservative medical treatment and both of otologist and audiologist were blinded about the arrangement of the patients from which group before the procedure and in the follow up visit. For each patient in the study group, the procedure started by application of emla cream (5%) {(one gram contains: Lidocaine 25mg, Prilocaine 25mg, Carbomer, Polyxyethelene hydrate, castor oil, Sodium hydroxide and water)} inside the external auditory canal and the drum using an insulin syringe connected to cannula applied to its tip after removal of the needle we put about one ml EMLA cream in side this syringe to make the cream reach the drum and the deep part of the external auditory canal more easy. Then we inform the patient to wait for ten minutes to start the procedure and then we would call the patient again and do suction for all EMLA cream then by the use of microscope, Myringotomy knife we did an incision in the antero-inferior portion of the tympanic membrane then we did suction by the use of a small suction tip cannula and then we inserted the Grommet ventilation tube in the incised drum and fixed it by the use of small crocodile and needle. After that we used 0 degree telescope and camera we showed the tube in place to the patient to be aware about what was the procedure and what was the result to be sure about his satisfaction. For the control group patients who were randomly booked for Myringotomy and Grommet tube insertion under general anaesthesia.

EMLA is composed of mixture of two well known local anaesthetics agent prilocaine and lidocaine. It is considered as an oil-in-water emulsion mixture. The oil phase composed of an eutectic mixture of the lidocaine and prilocaine. These constituents melt at room temperature so it is present in liquid form in the room temperature. This effect is best produced when the drugs were mixed in 1:1 ratio. In EMLA, the concentration of lidocaine and prilocaine achieved in the oil droplet is 80% though the overall concentration of both the active drugs is kept as low as 5% in the mixture. This is secondary to the emulsifiers present in the mixture. This

reduction in concentration is responsible for decreased systemic toxicity (8).

Anaesthetic techniques:

For the patients of control group the same anaesthesia doctor (A.S) is the one giving general anaesthesia for all patient. Premedication injection of midazolam 0.03 mg/kg intravenous for all patients. For all patients Attachment of basic monitoring (SpO₂, ECG and NIBP) and Pre-oxygenation with 100% oxygen were done. All the patients received injection fentanyl 1 mcg/kg intravenously and bolus dose of intravenous induction of propofol 0.75 mg/kg Injection. Maintenance of Anesthesia Was done with Oxygen/Nitrous Oxide sevoflurane face mask spontaneous ventilation. All the patients were monitored, End tidal co₂, continuous pulse oximetry and ECG monitoring, intermittent recordings of blood pressure and respiratory (respiratory rate, SpO₂), parameters were noted. Undesirable events like desaturation, hypoventilation (respiratory rate <8), inappropriate movements, were monitored. Patients were placed supine on the operating table with the head turned opposite to the ear to be operated. Appropriate head positioning is critical to maintain an open airway necessitating good communication with the surgeon allthrough the procedure. Emergence from Anesthesia with 100% O₂, Patients then transferred to the recovery room for continuity care monitoring. Postoperative pain was managed by IM / IV Pethidine or IV paracetamol. A digital stopwatch was used by the circulating nurse to record the duration of procedure starting from shifting the patient to the theatre till he was shifted outside the recovery room. The procedure itself is very quick and often takes less than 5 minutes to complete. A small hole is made in the tympanic membrane, and any fluid in the middle ear was sucked by the use of a small suction device. The tube is then carefully placed into the newly created hole. Then of all procedure including starting from shifting the patient to the operating theatre till shifting the patient from the recovery room the average time was calculated and the time cost for operation room also was calculated to compare the cost of average cost for both study and control groups.

Ethical considerations:

Ethical approval was obtained from Taiba hospital committee and an informed consent was taken from each patient.

3. Statistical Analysis

Statistical method:

The data were analyzed using SPSS program (version 22) SPSS_ software SPSS Inc. PASW Statistics for Windows, Chicago, Illinois, USA. The threshold of air conduction frequencies and air bone gap were before and after the tympanostomy with Grommets tube insertion were compared using parametric paired sample t-test. It was

considered significant at p-value <0.05. Non paired t-test was used to compare the mean air conduction threshold for both study and control groups after the procedure. Mean and standard deviation (SD) were estimated to describe the central tendency and the dispersion of parametric data and Student's t-test was used to compare between the two means. The level of significance was taken as p-value ≤ 0.05 and the results are presented in tables.

Result:

Ninety one patients satisfied the inclusion criteria and were recruited prospectively. Seventy six of them were randomly allocated as a study group, and the remaining fifteen were included in the control group. The pure tone audiometry results for all study and control groups were available. Baseline data for these patients are shown in Table 1. Mean age in treatment groups is (50.92) years (range 20-75) (39) male and (37) female and (55.53) years (range 21-75) (7) male and (8) female for the control group showing no statistical difference for both groups. All of them were complaining of persistent otitis media with middle ear effusion over one month. Random grouping to do tympanostomy with grommet tube under local anaesthesia (study group) and tympanostomy with grommet tube insertion under general anaesthesia (control group). Follow-up by doing pure tone audiometry 1 week after the procedure for all patients showing no significant difference in demographic data for patients in both groups.

Hearing outcomes:

The parameters we were measuring were air conduction threshold at (.5, 1, 2 and 4 KHz). The mean air conduction threshold in the study group was 38.8+/- (15.16), 43.55+/- (15.6) and 45.92+/- (21.82) and 57+/- 20 dBHL at 0.5, 1, 2 and 4 KHz frequencies before the procedure under local anaesthesia and 20.46+/- (11.8), 19.86+/- (10.39), 23.53+/- (15.49) and 36.05+/- (13.11) dBHL at 0.5, 1, 2 and 4 KHz frequencies after the procedure under local anaesthesia as shown in: table 2.

Patients in the treatment group have statistically significant improvements in air conduction thresholds at all four tested frequencies, comparing the pre and post procedure at p-value <0.05.

Also for the control group the air conduction frequencies were 35.7+/- (12.98), 42.14+/- (14.89), 47.85+/- (23.91) and 67.50+/- (2.88) dBHL at 0.5, 1, 2 and 4 KHz frequencies and became 20.35+/- (12.32), 19.64+/- (10.27), 26.07+/- (18.62) and 43.33+/- (5.16) dBHL after the operation. There was a significant improvements in air conduction thresholds at all frequencies for control group patients but there was no statistically significant difference between the two groups as shown in Table 2).

The air bone gap (ABG) was 28.75+/- (8.72) dBHL before the procedure in the study group and it became 4.21+/- (4.62) dBHL after it and 28.57+/- (9.69) dBHL for the control group which became 5.00+/- (4.80) dBHL after the operation with p-value 0.45.

There is significant improvement for air bone gap for both study and control group comparing the result before and after tympanostomy with grommet tube insertion but there was no significant difference when comparing the two groups together as shown in table 2 and table 3 at P< 0.05 by using unpaired student T-test.

Procedure duration:

The mean duration for the procedure in the study group was (15.48+/- (1.30)) while in the control group it was (40.86+/- (8.16)) showing a significant difference at p value <.05 when using un-paired t –sample test.

The procedure duration in the study group was significantly shorter than that in the control group. shown in fig.1.

Procedure duration cost and its financial impact:

It was estimated as real cost and not patient charged. As shown in: table 3 which compared the mean of total time cost for the study group 21.64\$+/- (2.36) in the same time it was 576.66\$+/- (121.04) for the control group showing significance between both groups at P< 0.05 by using unpaired student T-test proving that myringotomy with grommet tube insertion under local anesthesia is more financially benefit than the same procedure under general anesthesia.

All patients for the study group and the control group showed significant improvement in all symptoms including improvement of hearing level, tinnitus, ear blockage sensation and no patient complained of any adverse effect after Emla cream. As shown in fig.2.

Table 1. Showing the age and sex of both groups with insignificant p-value

	Study group	Control group
Age(mean+/-SD)in years	50.92 +/- 14.83	55.53 +/- 14.01
Sex:		
Male	39 (51.3 %)	7
Female	37 (48.7 %)	8

Table 2. Showing the change in the Air conduction threshold at (0.5, 1, 2 and 4 KH) for both groups before and after tympanostomy showing significant p-value <0.05

Frequency (KHz)	Air cond. (dB) before Mean(SD)	Air cond. (dB) after Mean(SD)	Name of the test	p-value
Study group (0.5)	38.8+/- (15.16)	20.46+/- (11.8)	Paired sample t-test	0.000
Study group (1)	43.55+/- (15.6)	19.86+/- (10.39)		
Study group (2)	45.92+/- (21.82)	23.53+/- (15.49)		
Study group (4)	57+/-20	36.05+/- ()		
Control group (0.5)	35.7+/- (12.98)	20.35+/- (12.32)		
Control group (1)	42.14+/- (14.89)	19.64+/- (10.27)		
Control group (2)	47.85+/- (23.91)	26.07+/- (18.62)		
Control group (4)	67.50+/- (2.88)	43.33+/- (5.16)		
Air bone gap (study group)	28.75+/- (8.72)	4.21+/- (4.62)		
Air bone gap (control group) before	29.57+/- (9.69)	5.00+/- (4.80)		

Table 3. Showing (Duration, Cost and Air bone gap) comparison of both groups with significant (p-value 0.00) for duration and cost of procedure and not significant (p-value 0.45) for the air bone gap

	Study group	Control group	test	p-value
Duration of the procedure (minutes)	15.48+/- (1.30)	40.86+/- (8.16)	Independent sample test	0.00
Total cost (\$)	21.64+/- (2.36)	576.66+/- (121.04)	Independent sample test	0.00
ABG after procedure (dBHL)	4.21+/- (4.62)	5.00+/- (4.62)	Independent sample test	0.45

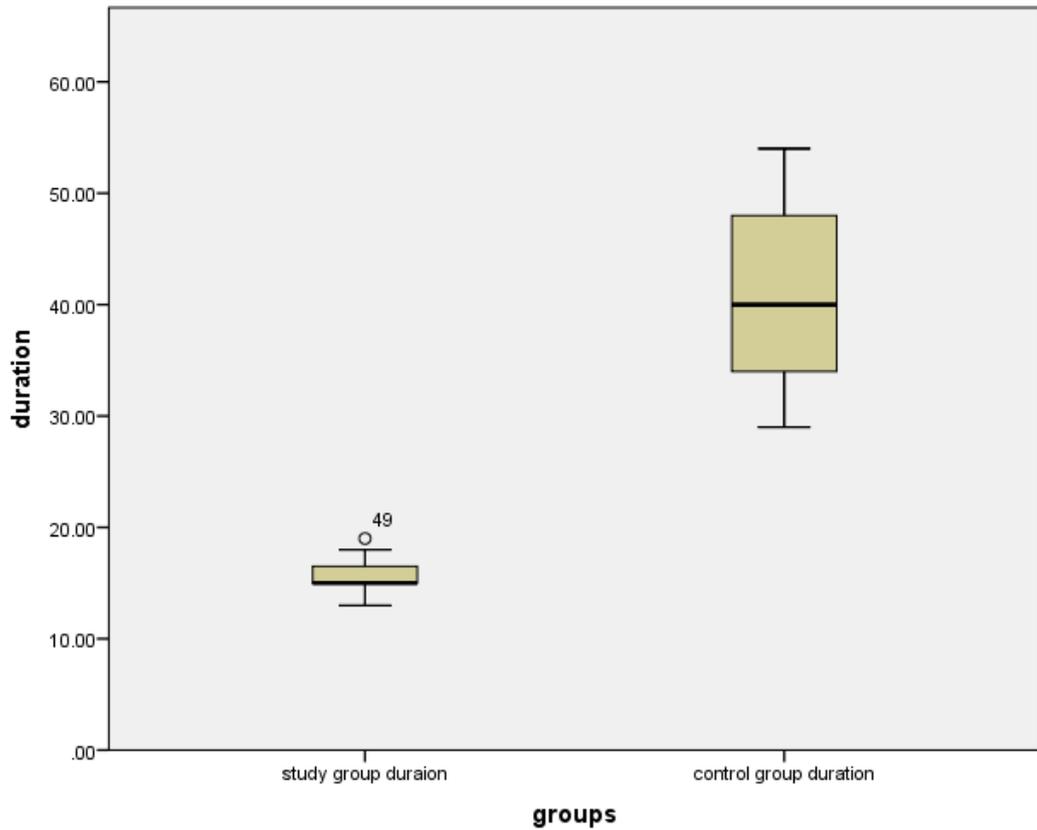


Figure 1. Pox plots showing a comparison between the duration of both groups

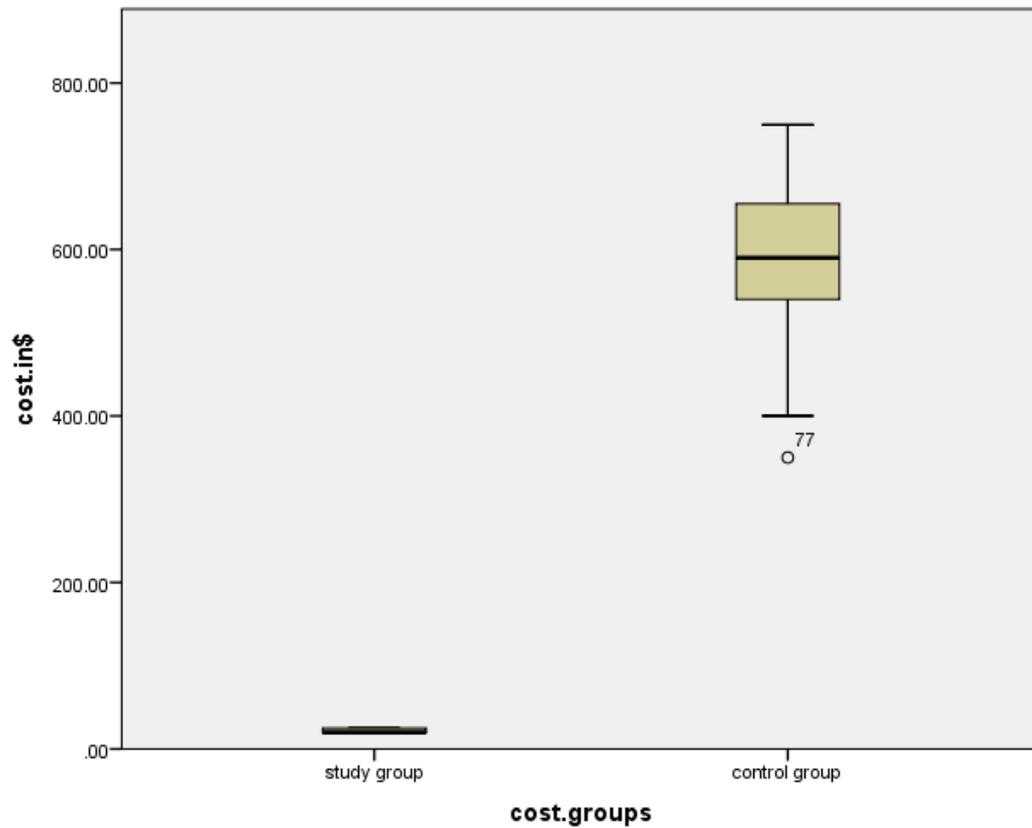


Figure 2. Pox plots showing a comparison between the duration cost of both groups

4. Discussion

Our study found that all patient for the study group and the control group showed significant improvement in all symptoms including improvement of hearing level, tinnitus, ear blockage sensation and no patient complained of any adverse effect after EMLA cream.

The strengths of the study:

The randomised blinded controlled trial design of this study reduced any potential bias. Also Sample size was calculated as 91 SOM adult patients randomly divided into two groups one group was (76 patients) study group and the other was (15 patients) control group (as shown in fig.3), in each, the otologist, audiologist and anaesthesiologist were un aware that the patient belonged to which group from the start give the study a power of 80% at the 5% level of significance.

As caring of the patient became more complex not only from the clinical point of view but also from the stand point of patient satisfaction and financial vie. From this point, a legitimate concern should be paid towards the efficacy, safety, applicability and financial impact for the patient with time saving.

Office based myringotomy with ventilation tube insertion is considered now the best management option for treatment of chronic otitis media with middle ear effusin especially in adult age group patient who can tolerate the procedure under local anaesthesia without pushing the patient to the theatre room under general anaesthesia with some times waiting list and unfit patients for general anaesthesia other times especially if getting the same outcome of both plane and this was conducted from our study.

We considered EMLA as a sufficient local anaesthetic agent for the purpose of local anaesthesia for the external auditory canal and the tympanic membrane for myringotomy and grommet tube insertion. Some authors [9], considered the use of either 10% xylocaine solution or EMLA make enough topical aesthetic effect explaining the penetration of these drugs inside the skin through their trans cellular and intercellular diffusion, and also their penetration via hair follicles and sweat glands if applied directly on the skin. These topical aesthetic drugs produce their anaesthetic effect through inhibition of the initiation and propagation of sensory nerve stimulation of external auditory canal and tympanic membrane This is achieved by the base form of the drug by penetrating through the axolemma, the outer nerve sheet, and blocking the influx of sodium ions into the nerve cell, thereby dampening the generation of action potential. without any vehicle to maximizes drug delivery into the skin or a penetration enhancer which enters into the skin and alters it reversibly to promote the drug absorption, they advised to use cotton ball soaked with 10% xylocaine solution in contact with the tympanic membrane could be enough to give an effective aesthetic action to do ventilation tube insertion in children. Some authors [10], recommended 10% xylocaine solution than EMLA as it is easy to clean up

the ear canal but in our study we found EMLA cream gives a potent anaesthetic effect. Also surgery under local anaesthesia has a benefit of no need for laboratory tests also no need to postponed the surgery if the patient is mildly sick as in common cold, no need to admit the patient but the patient can do it in the outpatient clinic, it can avoid potential risk of general aesthesia, it can shorten the recovery time and enhance the safety, and it can give the costal saving.

Our study conducted that all patient of the study group and the control group showed a significant improvement in all symptoms including improvement of hearing level, tinnitus, ear blockage sensation and no patient complained of any adverse effect after EMLA cream. Dong_Hee-Lee 2016 [11] review, suggested that minor surgical procedures such as Grommet tube insertion can be successfully performed under local topical anesthesia even in paediatric population. Compared with general anesthesia in pediatric population, local anaesthesia can give psychological relief to children and their parent during the surgical procedure as well as postoperative care. It can reduce postoperative workload for the parent and nurses. It can make the medical service providers easier for the operation schedule and allocation of medical resources. Jacob w et al 2015, [12] conducted the safety and efficacy of an iontophoresis system (IPS) to achieve local anaesthesia in combination with a tube delivery system (TDS) for tube placement in pediatric patients in an office setting from their prospective, single-arm study. Patients were prepared for the procedure using behavioural support techniques and tube placement was attempted under local anaesthesia. No physical restraints were allowed and no anxiolytics, analgesics, or sedatives were permitted. Safety was assessed through the occurrence of adverse events and success rates for tube placement under local anesthesia were determined. Tolerability of the procedure was evaluated using the 5-point Wong–Baker FACES Pain Rating Scale and parental satisfaction was assessed using a postoperative survey.

Also all patients in both study and control groups showed a significant improvement of the hearing level at all frequencies and ABG after myringotomy and grommet tube insertion [10] conducted that the use of OtoLAM-PET insertion in the outpatient clinic is safe, feasible and clinically effective technique proving a significant advantage for both slandered cold knife and OtoLAM-PET insertion in the office above PET insertion under general anaesthesia. They advised their easy application without bleeding in the external auditory canal without placement of a knife inside the ear canal of a child patient. The laser heat tends to evaporate much of fluid causing lateralization of the tympanic membrane allowing easy insertion of the grommet tube but laser is more costively and not available in all clinics so our study conducted the use of cold knife myringotomy which give the result as laser with less cost especially in adult age group although it was costly efficient compared with myringotom and ventilation tube insertion under general anaesthesia as proved by. [10] in their study

comparing OR-PET with general anaesthesia with office based OtoLAM-PET.

In our study, we conducted 21.64\$ as a mean cost in the study group done under local anaesthesia and 576.66 \$ for the control group under general anaesthesia. Some literatures [2] proved that the minimum hospital charges for unilateral ventilation tube insertion performed by a pediatric otolaryngologist at a secondary or tertiary referral hospital are USD 200-220 if done under local anaesthesia and USD 400-420 if done under intravenous or face-mask inhalation anaesthesia. The minimum hospital charge increases to USD 520-550 for a single night of hospital observation after endotracheal inhalation anaesthesia. In the case of general

anaesthesia (intravenous, face-mask inhalation, or endo-tracheal inhalation), an additional charge of USD 80-85 is assessed for preoperative medical workup, including electrocardiogram, chest X-ray, and routine blood tests. Therefore, when outpatient TTI is performed under local anaesthesia, the burden of total medical costs can be decreased 2- to 3- fold, and patient charges can be decreased 1.5- to 2- fold.

Banigo A et al 2015 [13], conducted the use of nonsurgical intervention by the use of EarPopper for the treatment of middle ear effusion is an alternative method to ventilation tube but requiring a period of use and it is more costive 160\$ price.

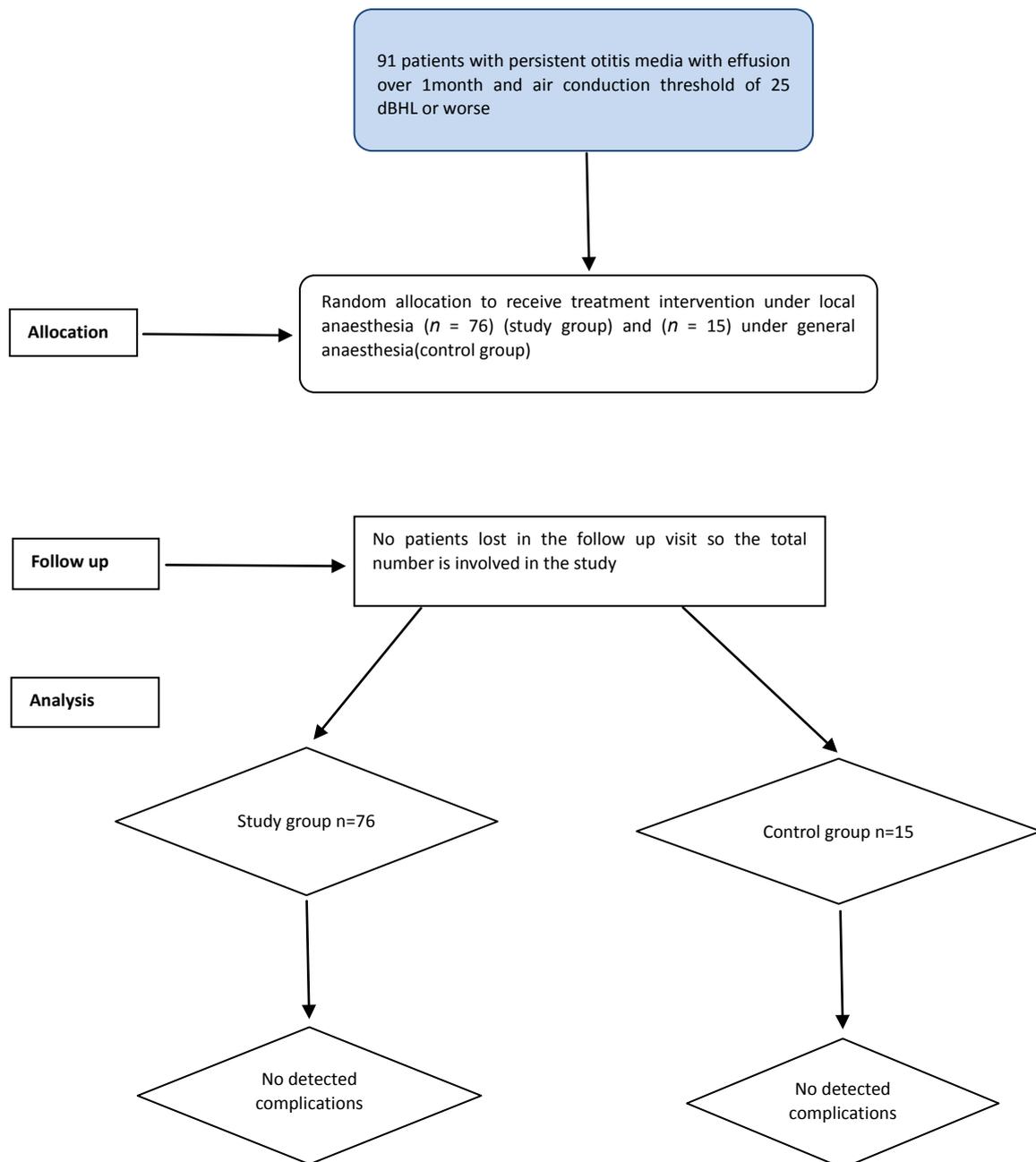


Figure 3. CONSORT flow diagram

5. Conclusions

We have conducted the use of topical anaesthesia with EMLA cream for the purpose of myringotomy with ventilation tube insertion in the outpatient clinic is safe, fast, effective with less duration and less procedure time cost compared with the use of general anaesthesia inside the operation theatre for the same purpose and also giving the same result if using the general anaesthesia also it is very useful for intra tympanic injection of corticosteroid in case of sudden sensory neural hearing loss or intra tympanic injection of oto-toxic material in case of tinnitus.

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