Original Article

Which is Better? 10% Xylocaine Packing vs. 2% Lidocaine Local Injection for Myringotomy: A Randomized Controlled Pilot Study

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Objective: To evaluate the efficacy of a less invasive method of administering local anesthesia (10% lidocaine packing) against the lidocaine local injection for pain control in myringotomy procedures.

Materials and Methods: The present study was a prospective, randomized controlled trial. Two local anesthetic procedures were randomly assigned to patients aged over 18 years who required a myringotomy. The patients were given either a 10% lidocaine-soaked cotton packing or a 2% lidocaine local injection. Pain scores during the anesthetic procedures, during the myringotomy procedure, and immediately following the myringotomy procedure were evaluated and compared between both groups.

Results: There were 20 patients who participated in this study, with 10 patients in each treatment arm. Baseline characteristics of patients in both groups were comparable. The 10% lidocaine packing group had significantly lowered pain score during the anesthetic procedure than did the 2% lidocaine group (0 vs. 7; *p*-value <0.001). There was no statistical difference in the other two pain scores between the two groups.

Conclusion: The 10% lidocaine packing method is a better method than the 2% lidocaine injection for anesthesia during myringotomy in terms of causing less pain during the anesthetic procedure.

Keywords: Anesthesia, Lidocaine, Local, Myringotomy, Topical

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Myringotomy is indicated for draining an infection of acute otitis media and for pressure equalization of the middle ear in cases of serous otitis media. This is a rather painful procedure and requires local anesthesia. There are two main local anesthetic methods used for this procedure[1-12]. The first is a local injection of an anesthetic agent into ear canal skin. This is the standard technique used with adults undergoing the procedure. Although this technique effectively controls the pain during the myringotomy procedure, it can cause a significant pain during injection[3,9,12]. The second is the local application of an anesthetic agent directly to the tympanic membrane. There are several anesthetic agents used for local application in myringotomy procedures, such as a cream that consists of an eutectic mixture of local anesthetics (EMLA®; Astra, Sodertalje, Sweden)[3], Bonain's solution (Cocaine+menthol+phenol)[6], Ametop cream (Smith and Nephew Healthcare, Ltd, Hull, UK)[7] and Xylocaine® (Astra, Sodertalje, Sweden) spray or lidocaine aerosol[5,8-11]. In 1992, one study showed that EMLA® was more effective than xylocaine spray[5]. But, the EMLA® may diffuse into the inner ear, causing damage to the cochlea and Organ of Corti[13,14]. In 2008, EMLA® and Ametop cream were shown to be effective anesthetic agents to be used in myringotomy procedures[7]. One company that manufactures Ametop gel has issued a warning its use in procedures that involve penetration into the middle

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ear may result in ototoxicity.

Several studies have shown that local application of lidocaine to the tympanic membrane using either the iontophoresis technique or 10% lidocaine aerosol effectively reduced pain during myringotomy without any reported complications[8-12]. However, the main disadvantage of the iontophoresis method is that it is cumbersome and time-consuming[7]. In the authors' hospital, the standard local anesthesia used in myringotomy procedures is a 2% lidocaine injection at four points: the anterior, inferior, posterior, and superior quadrants of the ear canal at its bony-cartilaginous junction. This anesthetic method causes significant pain during the injection[3,9,12]. As mentioned above, a 10% lidocaine aerosol is an effective local anesthetic option for myringotomy with a simple technique of application to the tympanic membrane. No study has been performed to compare the efficacy between lidocaine injection and lidocaine cotton soaked packing. The aim of this study is to evaluate the efficacy of using 10% lidocaine soaked cotton as an alternative anesthetic method compared with the traditional one.

Materials and Methods

The present study was a prospective, randomized (1: 1 ratio), open blinded, active controlled, parallel group pilot study, conducted at an ear nose and throat outpatient clinic in Srinagarind university hospital, Khon Kaen University, Khon Kaen, Thailand. The study period was between 1 October 2011 and 30 September 2012.

The authors enrolled patients aged over 18 years indicated for myringotomy procedures. Patients were excluded if they had a history of allergy to lidocaine or any of the following conditions: severe liver or kidney disease, arterioventricular or intraventricular heart block, Strokes-Adam syndrome, Wolff-Parkinson-white syndrome, pregnancy, infections or inflammation of ear canal or pinna, conditions causing pain around the ear or any other areas.

Eligible patients who were enrolled into the study completed consent forms prior to study participation. The two compared study arms included 10% lidocaine and 2% lidocaine group. The random allocation list was created by the lot drawing method with an opaque box containing mixed labels, in total number of 20, which were assigned for each group equally (block randomization with block size of 20 and 1: 1 ratio). The allocation was concealed in an opaque envelope to be opened immediately before performing each procedure. Allocation, concealment and intervention assignment processes were performed by the nurse which did not involve the study. Interviews were performed to be sure that the patients were not experiencing pain that may confound the results of the study. For the 10% lidocaine group, cotton soaked with 1 ml of 10% lidocaine was inserted into the ear canal guided by microscopy so that it made contact with the tympanic membrane. There was then a 10 minute waiting time before myringotomy procedure was started. For injection group, 1 ml of 2% lidocaine was injected using the technique mentioned above. All anesthetic and myringotomy procedures were performed by a single physician.

The primary measurement was pain level; during the anesthetic procedure, during the myringotomy procedure, and immediately following the myringotomy procedure. Pain level was recorded using a "0 to 10" numeric rating scale. Patient satisfaction was evaluated for the overall procedure-from the start of anesthetic procedure through the end of myringotomy procedure. The satisfaction score was recorded using a 5-level scale, with the levels defined as very satisfied, somewhat satisfied, neutral, somewhat unsatisfied, and unsatisfied. Complications from either the procedure, itself, or the anesthesia were observed for 2 hours after the myringotomy.

Prior to this time, no study has been conducted to compare the efficacy of a local lidocaine injection and lidocaine packing, So the present study was designed as a pilot study which sample size might not be definitely calculated. However, the rationale for sample size was accounted for by the study of Robert C and Carlin WV[3].

Demographic data were recorded and analyzed using descriptive statistics. The pain outcomes were compared between the two groups by using the Wilcoxon rank sum test. The proportions of satisfaction between the two groups were compared by using the Fisher Exact test. The significant *p*-values were defined if less than 0.05. The present study reviewed and approved by the Ethics Committee for Human Research, Khon Kaen University (HE541223).

Results

There were 20 patients who participated in this study, with 10 patients in each treatment arm. All of them can participate until the end of the study. The average age of the patients was 51 years old. Most patients were male (60%) and had co-morbid diseases (60%). Categorized by treatment arm, the 10% lidocaine

packing group had a higher mean age (58.5 vs. 44.5 years) compared with the 2% lidocaine group (Table 1). The proportion of male patients was somewhat higher in 2% lidocaine group than in the 10% lidocaine packing group (70% vs. 50%), as shown in Table 1.

The 10% lidocaine packing group had significantly lowered pain scores during the anesthetic procedure than the 2% lidocaine group (0 vs. 7; *p*-value <0.001). The other two pain scores (pain during the procedure and immediately after the procedure) were comparable between the two groups (Table 2). Most patients were satisfied with the overall evaluation (Table 2). Nine out of ten patients in both groups gave the procedure a "very satisfied" rating. No complications were detected after the myringotomy in any of the patients.

Discussion

This small randomized controlled trial study showed that the 10% lidocaine cotton packing procedure was better than the standard 2% lidocaine injection in terms of pain during the anesthetic procedure. There was no difference between the groups in terms of the other pain scores (pain during myringotomy and directly after the procedure) and overall satisfaction (Table 2). Both anesthetic procedures were considered equally safe due to there being no reported complications.

Table 1. Demographic data of patients who received a myringotomy with either 2% lidocaine injection or 10% lidocaine packing procedure

Demographic Data	Total (n = 20)	Local anesthesia	
		2% lidocaine injection (n = 10)	10% lidocaine packing (n = 10)
Age (year)			
Mean ± SD	51.50±16.81	44.50±18.28	58.50±12.39
Range	21 to 78	21 to 69	43 to 78
Gender, n (%)			
Male	12 (60.0)	7 (70.0)	5 (50.0)
Female	8 (40.0)	3 (30.0)	5 (50.0)
Underlying disease, n (%)			
DM	6 (30.0)	2 (20.0)	4 (40.0)
Hypertension	4 (20.0)	1 (10.0)	3 (3.0)
Valvular heart disease	1 (5.0)	1 (10.0)	-
No underlying disease	12 (60.0)	7 (70.0)	5 (50.0)
Drug allergy, n (%)			
Norfloxacin	1 (5.0)	-	1 (10.0)
None	19 (95.0)	10 (100.0)	9 (90.0)

Table 2. Pain scores and overall satisfaction rated by patients who received a myringotomy with either 2% lidocaine injection or 10% lidocaine packing procedure

Outcomes	Type of local anesthesia		*p*-value
	2% lidocaine injection (n = 10)	10% lidocaine packing (n = 10)	
Pain score during anesthetic induction	7 (3-9)	0 (0-3)	<0.001
Pain score during procedure	3 (0-5)	4.5 (0-8)	0.656
Pain score after procedure	0.5 (0-5)	0.5 (0-5)	0.672
Very satisfied, n (%)	9 (90%)	9 (90%)	0.999

Data shown as median (range), unless indicated otherwise

Local lidocaine has been shown to be an effective pain reliever in cases of acute otitis media, before myringotomy, and after the myringotomy procedure[12,15-17]. A randomized, placebo-controlled trial compared 2% lidocaine drops with saline drops in patients with acute otitis media[15]. The lidocaine group had 50% lower pain score than the control group at 10 and 30 minutes. Lidocaine absorption was proposed to be increased in the inflamed tympanic membrane[15]. According to the results of the present study, the lidocaine soaked cotton is assumed to be an effective anesthetic method.

In addition, the lidocaine may be effective 10 minutes after application as stated above in the "Methods" section, as well as in a previous study[15]. At least three studies also showed that local lidocaine was beneficial in pain reduction after myringotomy procedures both in an ambulatory setting and during the postoperative period[12,16,17]. These findings may indicate that lidocaine soaked cotton can be used after myringotomy, either with or without tube replacement.

There are some limitations to the present study. Delayed pain assessment (such as at 3 to 6 hours after the myringotomy) was not performed. The present study was conducted as an ambulatory-based study. The outcomes were immediately evaluated in both groups. The sample size was also small. Further large studies may be needed to confirm the results. However, it showed that there was a significant beneficial effect on pain reduction using the anesthetic procedure. Finally, due to the nature of the anesthetic procedure, this could not be a blind study.

Conclusion

The 10% lidocaine packing method is a better method than 2% lidocaine injection for myringotomy in terms of decreased painful experience during the administration of local anesthesia.

What is already known on this topic?

Lidocaine local injection is generally accepted to be used for myringotomy. Unfortunately, it is a cause of significant pain during anesthetic induction. Other non-invasive local anesthetic methods also have been reported. No comparative study between xylocaine packing method and lidocaine injection method has been reported.

What this study adds?

The present study shows that the xylocaine packing method is as effective as lidocaine local injection in pain control for myringotomy. This technique also has an advantage of not causing a significant pain during anesthetic induction.

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Potential conflict of interest

The authors declare no conflicts of interest.

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