

Mitomycin C-associated radiofrequency microelectrocautery used in myringotomy in an animal model

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Summary

This study aimed at describing an alternative surgical technique to the insertion of a ventilation tube in the tympanic membrane: myringotomy by radiofrequency alone and associated with mitomycin C. **Aim:** to show a surgical approach that can be simple to execute, not subject to complications arising from the ventilation tube. **Materials and Methods:** we compared myringotomy by microknife and by radiofrequency microcautery (0.3 mm and 0.7 mm tips) alone and associated with mitomycin C, considering the time of tympanic closure in Wistar rats. Experimental study. **Results:** there was a statistically significant difference between radiofrequency myringotomy and knife myringotomy. As we analyze the radiofrequency approach with the 0.7mm tip associated with mitomycin C (Wilcoxon test), the p value found was lower than 0.001, showing a statistical significance. The maximum tympanic membrane closure time was 44 days and the median found was 14 days. **Conclusion:** the radiofrequency myringotomy (with the larger diameter tip) associated with mitomycin C enhances the tympanic membrane healing time.

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INTRODUCTION

Otitis media with effusion (OME) is socially and economically relevant, as this condition is considered the most common cause of hearing loss in childhood and a cause of speech impairment and poor achievement in school. According to the American Academy of Pediatrics and the American Academy of Otolaryngology and Head and Neck Surgery, about 90% of children have OME at any time before entering school, usually between ages 6 months to 4 years. Most of these cases resolved spontaneously within 3 months.¹

Surgery is indicated in cases where the tympanic cavity effusion does not resolve spontaneously. The main purpose of surgery is to restore middle ear ventilation by eliminating negative intratympanic pressure. Thus, the mucosa is normalized, hair cells increase and the secretion potential is reduced.²⁻⁴

Myringotomy with ventilation tube (VT) placement is the procedure of choice from the moment a patient becomes a candidate for surgery.¹ This procedure is currently one of the most common surgeries in the US, and is the main reason children undergo general anesthesia.⁵

Inserting VT in the tympanic membrane, however, may cause several complications. Several published studies have described the consequences of placing VT, the main ones being: otorrhea, tympanic membrane perforation following VT extrusion, retraction and tympanic atelectasis, tympanosclerosis, and VT retention for long periods.⁶⁻⁹

Recent studies have demonstrated, by electron microscopy, the presence of biofilms on the surface of VTs. It has been suggested that bacterial clusters, named biofilms, are responsible for chronic otorrhea in patients undergoing tympanostomy with VT placement.^{10,11}

Aoki et al. showed that 2 months after tympanic cavity clearance, middle ear effusion and inflammation had regressed and pneumatic space had expanded.¹²

In 1978, Saito et al. initiated studies of electrocautery myringotomies, proving that burns caused by this method resisted healing to a greater extent.¹³

In 1982, Goode undertook the first CO₂ laser myringotomy in humans.^{14,15} Since then, several studies on this technique have been published.¹⁶⁻¹⁸

In 1994, the biomedical engineering department at our institution developed a device for performing highly precise and controllable electrosurgical microcauterization. Radiofrequency microelectrocautery has several advantages over other methods. The cost of operating this device ranges from 5 to 10% of laser costs. Furthermore, the tip is more accurate because it concentrates all the heat and different angles are possible according to the need. Laser may be limited by the angle of the incident rays.^{19,20}

The aim of our study was to evaluate the isolated microelectrocautery radiofrequency myringotomy technique with mitomycin C in an animal model. This technique

was compared with a microlancet approach. This study is thus part of a line of research aiming to investigate the various myringotomy techniques that are alternatives to VT insertion.

METHODS

This study was an experimental comparative trial done using Wistar rats, which was approved by the Institutional Review Board (number 03.173). Trichotomy was done prior to anesthesia for placing the microcautery pad. Anesthesia was attained using intramuscular ketamine (40-90 mg/kg) and xylazine (5-13 mg/kg).

A pilot study had demonstrated appropriate microelectrocautery parameters, as follows: power level 8 (about 30 watts) and temporized operation mode of 1.50 seconds.

The study consisted of 3 groups. The right ear (RE) was the control group in all groups, in which microlancet myringotomy (ML-RE) was undertaken. In group 1 (n = 12), radiofrequency microelectrocautery myringotomy (RF-LE) was carried out in the left ear (LE) using a 0.3 mm tip. In group 2 (n = 10), RF-LE was carried out with a 0.7 mm tip.

In group 3 (n = 15), RF-LE was carried out with a 0.7 mm tip, and associated with mitomycin C (RFMIT-LE). Following microcautery myringotomy, a small mitomycin C-soaked piece of gelfoam was placed for 10 minutes over the surgical wound and thereafter removed. The mitomycin C concentration was 0.4 mg/dl.

Procedures were documented and recorded with a video camera attached to the surgical microscope (DF Vasconcelos). Follow-up examinations were done every 4 days, and concluded upon healing (closure) of the myringotomy. The study was evaluated binomially, that is, myringotomies were either "open" or "closed." Myringotomy diameters were not measured in the days following the procedure.

Statistical Analysis

The median and interquartile range variables were described in the statistical analysis. The Wilcoxon test was applied for comparing right and left ears in each group. The Kruskal-Wallis test was applied for analyzing statistical differences among the left ears in the three groups. Due to variable asymmetry, rank transformation of the frequency values was done, after which the Tukey test was applied to detect differences among groups. The significance level was 5%.

Calculation of the sample size

Eleven rats in each group were needed for a difference of 1.5 standard deviations among the means of different techniques (microlancet and radiofrequency myringotomy with or without mitomycin C) to be detected with a 90% statistical power and a 0.05 significance level.

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