Use of a Novel Bioplastic in Myringoplasty: An Animal Model

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ABSTRACT

Objectives: To compare a bioplastic and an autogenous graft to close a tympanic membrane perforation in guinea pigs. Study design: A randomized, prospective pilot study. Year study conducted: March 2013 to March 2014.

Condition studied: Tympanic membrane perforation.

Subject studied: Animal model (guinea pig). Setting: The study was held in the Center of Laboratory Animals of the Universidad Panamericana, as they have guidelines for proper maintenance of experimental subjects according to the Mexican Official Standard Intervention. Myringoplasty was performed in 26 guinea pigs. Subjects acted as their own control in the left side, the bioplastic (alpha, omega-telactic poly (epsilon-caprolactone) diol and hexamethylenediisocyanate [PCLDEGHDI]) was put in place in an underlay manner; in the right side, auroto fascia was put in place in an underlay manner. The procedure was performed under endoscopic 0° vision. Outcome measurement: Perforation closure.

Results: Nonparametric statistics were performed with Fisher exact test and the Mann Whitney U test. We considered P < 0.05 statistically significant. The analysis was performed using the statistical program SPSS version 20.0 for the Mac OSX 10.6 operating system. We obtained similar closure rates between the 2 materials, and histological examination showed difference between the 2 sides. The bioplastic is a biomaterial that can be used as graft in myringoplasty. We require more studies to assess the effectiveness and efficiency as well as to corroborate an adequate safety profile for clinical use.

Disclosure: We want to thank Dr Martinez and his team, who donated the bioplastic.

INTRODUCTION

The concept of repairing a perforated eardrum was described by Berthold in 1787. In 1952 Zöllner and Wüllbrand describe the basic concepts to reconstruct the tympanic membrane and the sound conduction mechanisms of the tympanic cavity. The aetiology of these perforations may be due to trauma, acute or chronic middle ear infections, granules' placement or iatrogenic. We hypothesized that alpha, omega-telactic poly (epsilon-caprolactone) diol and hexamethylene diisocyanate [PCLDEGHDI] can act as graft and promote the generation of a functional neotympanum in an animal model of tympanic perforation.

Alpha, omega-telactic poly (epsilon-caprolactone) diol and hexamethylene was used in this study because disocyanate is a biodegradable segmented of polyurethane, is a flexible element polycaprolactone with a molecular weight of 2,000 g/mol, and disocyanates of aliphatic origin are nontoxic compared to their aromatic counterparts.

METHODS AND MATERIALS

We used a previously described animal model of chronic tympanic perforation, published in Otolaryngol Head Neck Surg September 2013 vol, 149 no. 2 suppl P332. Group 1. Under endoscopic vision 0°, perforation was confirmed, we scratched the edges of the perforation with 90° angled pick, then proceed to fill the eardrum with gel foam soaked in saline, placed the sheet of alpha, omega-telactic poly (epsilon-caprolactone) diol and hexamethylene diisocyanate [PCLDEGHDI] previously irrigated with PBS 1X solution, in an underlay manner. The follow up was performed with 2.7 mm endoscope at day 30 and day 60. At day 60 subjects were sacrificed by CO2 gas chamber. Then we approach the tympanic rim and removed the whole flap, sample was fix in 10% formalin. For group 2 we proceed in the same manner the difference was the graft used, the graft consisted in muscle fascia obtained in the abdominal region. For histological analysis the pieces were included in paraffin blocks, cuts were performed with a Leica RM2125 microtome each 10 microns, then were included in hematoxylin and eosin for histological analysis.

RESULTS

Descriptive analysis was performed using measures of central tendency, normally was determined by Kolmogorov Smirnov test, so nonparametric statistics was performed with Fisher exact and Mann Whitney U. We consider p < 0.05 statistically significant. The analysis was performed using SPSS version 20.0 for Mac OS X 10.6 operating system. RESULTS Of the 26 study subjects 4 subjects were removed, one died of unknown causes, one subject presented Chondritis, and 2 presented stenosis of both external ear. Therefore a 100% patency of the tympanic membrane perforation was obtained in 22 experimental subjects, who presented adequate evolution after tympanoplasty. The statistical analysis results are shown in figures.

DISCUSSION

One of the main limitations of this study was the sample size, however we demonstrated reproducibility of the model and the possible use of this bioplastic in clinical use. At present there is no animal model of chronic eardrum perforations, anecdotally, in the conception of this work we planned to use rabbit (Oryctolagus cuniculus) as an animal model but the asymmetric external ear anatomy and tortuosity of the ear makes it a bad model.

CONCLUSION

In this paper we demonstrated that the alpha, omega-telactic poly (epsilon-caprolactone) diol and hexamethylenediisocyanate [PCLDEGHDI] is a bioplastic that can be used as tympanic graft, we obtained a percentage similar to the gold standard (fascia) closure and did not show complications at short-term follow up; likewise with the use of this plastic, it does not require an extra approach to obtain the graft and its possible application with the endoscope, could reduce hospital costs and the possibility to use this procedure under local anesthesia in office.

BIBLIOGRAFIA