



Brazilian Journal of
OTORHINOLARYNGOLOGY

www.bjorl.org



ORIGINAL ARTICLE

Treatment of tympanic membrane perforation using bacterial cellulose: a randomized controlled trial ☆, ☆☆



Fábio Coelho Alves Silveira^{a,*}, Flávia Cristina Morone Pinto^b,
Sílvio da Silva Caldas Neto^c, Mariana de Carvalho Leal^d,
Jéssica Cesário^e, José Lamartine de Andrade Aguiar^a

^a Graduate Program in Surgery, Department of Surgery, Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil

^b Nucleus of Experimental Surgery, Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil

^c Service of Otolaryngology, Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil

^d Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil

^e Medical Course, Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil

Received 22 March 2015; accepted 29 March 2015

Available online 8 September 2015

KEYWORDS

Tympanic membrane perforation;
Biopolymer;
Bacterial cellulose

Abstract

Introduction: Promising treatments for tympanic membrane perforation closure have been studied. Therapies derived from tissue engineering probably eliminate the need for conventional surgery. Bacterial cellulose is presented as an alternative that is safe, biocompatible, and has low toxicity.

Objectives: To investigate the effect on healing of direct application of a bacterial cellulose graft on the tympanic membrane compared to the conventional approach with autologous fascia.

Methods: Randomized controlled trial. Forty patients with tympanic membrane perforations secondary to chronic otitis media were included, and were randomly assigned to an experimental group (20), treated with a bacterial cellulose graft (BC) and control group (20), treated with autologous temporal fascia (fascia). We evaluated the surgical time, hospital stay, time of epithelialization and the rate of tympanic perforation closure. Hospital costs were compared. The statistical significance level accepted was established at $p < 0.05$.

Results: The closure of perforations was similar in both groups. The average operation time in the fascia group was 76.50 min versus 14.06 min bacterial cellulose in the group ($p = 0.0001$). The hospital cost by the Brazilian public health system was R\$ 600.00 for the bacterial cellulose group, and R\$ 7778.00 for the fascia group ($p = 0.0001$).

☆ Please cite this article as: Silveira FCA, Pinto FCM, Caldas Neto SS, Leal MC, Cesário J, Aguiar JLA. Treatment of tympanic membrane perforation using bacterial cellulose: a randomized controlled trial. Braz J Otorhinolaryngol. 2016;82:203–8.

☆☆ Institution: Service of Otolaryngology, Hospital das Clínicas, Universidade Federal de Pernambuco (UFPE), Recife, PE, Brazil.

* Corresponding author.

E-mail: fcasil@ig.com.br (F.C.A. Silveira).

PALAVRAS-CHAVE

Perfuração da membrana timpânica;
Biopolímero;
Celulose bacteriana

Conclusion: Bacterial cellulose grafts promoted the closure of the tympanic membrane perforations, and were demonstrated to be innovative, effective, safe, minimally invasive, efficacious and to have a very low cost.

© 2015 Associação Brasileira de Otorrinolaringologia e Cirurgia Cérvico-Facial. Published by Elsevier Editora Ltda. This is an open access article under the CC BY license (<https://creativecommons.org/licenses/by/4.0/>).

Tratamento do tímpano perfurado com enxerto de celulose bacteriana: ensaio clínico controlado e randomizado

Resumo

Introdução: Tratamentos promissores para o fechamento da perfuração da membrana timpânica vêm sendo estudados. Terapias provenientes de engenharia de tecidos provavelmente eliminarão a necessidade de uma intervenção cirúrgica convencional. A celulose bacteriana apresenta-se como uma alternativa por ser segura, de baixa toxicidade, biocompatível.

Objetivos: Investigar o efeito da aplicação direta do enxerto de celulose bacteriana na cicatrização de perfurações da membrana timpânica, comparado ao procedimento convencional com fásia autóloga.

Método: Incluíram-se 40 pacientes com perfuração da membrana timpânica por otite média crônica simples. Randomizados de 1 a 40, onde os ímpares (20) foram tratados com enxerto de celulose bacteriana (CB), e os pares (20), com enxerto de fásia temporal autóloga (fásia). Estudo clínico controlado e randomizado. O tempo cirúrgico e de hospitalização foram o tempo de epitelização e custos hospitalares.

Resultados: O fechamento das perfurações foi semelhante nos dois grupos. O tempo médio da cirurgia no grupo fásia foi de 76,50 minutos e de 14,06 minutos no grupo com celulose bacteriana ($p = 0,0001$). O custo hospitalar pela tabela do SUS foi de R\$ 600,00 para o grupo CB e R\$ 7.778,00 para o grupo fásia ($p = 0,0001$).

Conclusão: A celulose bacteriana promoveu o fechamento da perfuração do tímpano, mostrando-se inovador, seguro, eficaz, efetivo, minimamente invasivo e de baixo custo.

© 2015 Associação Brasileira de Otorrinolaringologia e Cirurgia Cérvico-Facial. Publicado por Elsevier Editora Ltda. Este é um artigo Open Access sob a licença CC BY (<https://creativecommons.org/licenses/by/4.0/deed.pt>).

Introduction

Promising treatments for closure of tympanic membrane perforation (TMP) have been studied, in search of outpatient, minimally invasive procedures that are effective, safe, affordable and technically feasible.¹⁻⁵ Among some innovative alternatives, the use of gelfoamTM and atelocollagenTM stand out, in association with fibroblast growth factor (β -FGF),¹⁻⁴ autologous serum, and chitin membranes.⁵

The establishment of a therapy developed from tissue engineering for treatment of TMP will probably eliminate the need for conventional surgery. However, it is critical to understand the factors that contribute to the success or failure of TMP treatment.⁴

An alternative material is cellulosic polysaccharide, obtained by bacterial synthesis. In previous studies, cellulosic polysaccharide proved to be a safe, low-toxicity,⁶ biocompatible⁷ product, with the ability to encourage cellular growth and differentiation – a feature that is promising for tissue engineering.⁸ Preclinical and clinical studies have demonstrated that this biomaterial was effective functioning as a mechanical barrier and as an adjunct in the treatment of ulcerative lesions⁹ and surgical wounds.¹⁰

The objective of this study was to investigate the effect of direct application of a bacterial cellulose (BC) graft on

the healing of tympanic membrane perforations, compared with a conventional procedure with autologous fascia.

Method

Forty patients with tympanic membrane perforations caused by otitis media were enrolled in a randomized controlled clinical study of spontaneous demand at Otolaryngology Service in a teaching hospital in Pernambuco state, Brazil, from 2013 to 2014. Patients with marginal, damp or cholesteatomatous perforations were excluded. Patients were randomly allocated to two groups: 20 in an experimental group, who were treated with bacterial cellulose membrane graft, and 20 controls treated conventionally with autologous fascia graft.

This study was approved by the Ethics Committee on Research, Health Sciences Center, Universidade Federal de Pernambuco, under CAAE 21109913.7.0000.5208, Opinion CEP/CONEP No. 527.461 of December 18, 2013.

Bacterial cellulose graft

Bacterial cellulose grafts were manufactured and supplied by PolisaTM, a Sugar Cane Experimental Station, Carpina City, Universidade Federal Rural de Pernambuco, Brazil.¹¹

Download English Version:

<https://daneshyari.com/en/article/4106085>

Download Persian Version:

<https://daneshyari.com/article/4106085>

[Daneshyari.com](https://daneshyari.com)