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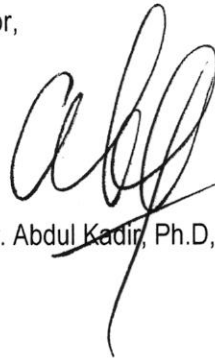
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Nata De Coco Patch as the Alternative Platform for Myringoplasty

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ABSTRACT

Introduction: The installation of a paper patch is a routine procedure in predicting hearing repair before performing a myringoplasty operation on a tympanic membrane that has rupture or perforation that fails to close. However, paper patches have various deficiencies such as being inelastic, non-transparent and easily torn. The nata de coco patch (NCP) which is a natural biopolymer formed on coconut media with the help of acetobacter xylinum with unique characteristics such as being alike to human skin, elastic, transparent and not easily torn is offered to be a prior and intra myringoplasty patch material replacing the paper patch.

Objective: To determine the effectiveness of NCP in accelerating the healing / closure of tympanic membrane perforation due to infection or trauma compared with paper patch.

Method: This study was an experimental study with complete random sampling of 42 ruptured tympanic membranes of chicken (laying hen) divided into 3 groups: NCP + group, paper patch and control (spontaneous healing).

Result: healing of tympanic membrane perforation by using NCP has started on day 4 of 56.8% and total closure on day 6th, meanwhile on the paper patch group only 7.2% closed by day 4th and total sample closure occurred on day 7th. In the control group 21.3% began closing on day 5 and total sample closure occurred on day 8.

Conclusion: In vivo NCP proved to accelerate the healing and closure of tympanic membrane perforation more quickly than either the paper patch or control group. We recommend NCP to be a platform material for myringoplasty in humans.

Keywords: Patch, bacterial cellulosa, perforation, tympanic membrane, laying hen

INTRODUCTION

Perforation of the tympanic membrane due to infection, trauma or other causes will cause hearing loss. Chronic middle ear infections are major causes of this condition. Permanent perforation of the tympanic membrane will ultimately reduce the productivity and quality of life of the sufferers. Operation as a standard therapy fails to respond to this challenge because it requires skill, complex tools at a high cost as well as a variety of risks that await. Experts examine a variety of patch materials for conventional actions which are more simple, quick and practical for the clinic. Nata de coco with the basic ingredient that can be cheaply and easily sourced from coconut water is obtained to be a candidate for making patches for transnasal myringoplasty action in the polyclinic.

The installation of a paper patch is a routine procedure in predicting hearing repair before performing a myringoplasty operation on a tympanic membrane that has ruptures or perforations that fail to close. However, the paper patch has various deficiencies such as being inelastic, non-transparent and easily torn. The bacterial cellulose nata de coco (NCP) bacterial patch with its uniqueness of being similar to human skin is offered to be an alternative to paper patch.

Syahrijuita (2017) succeeded in making nata de coco (NCP) patch which has unique characteristic is being alike to the human skin with a thickness of 0.16 mm, elasticity of 9.62 N / cm², 4 µL initial absorption, and is transparent and not easily torn compared to the paper patch used in clinics. Kim et al (2013) proved the same

thing both in vitro and in vivo that bacterial cellulose patches from mannitol media can accelerate the healing of perforation of the tympanic membrane. Even Silviera et al (2016) has used the bacterial cellulose patch in humans with results not unlike the use of deep m. temporalis fascia in tympanic membrane perforation patients with methods, skills, and time that are faster and more economical in terms of healing costs.

For NCP to be applicable to humans it is necessary to conduct in vivo research using experimental animals to provide a basis for their use in treating permanent tympanic membrane perforation in pediatric and productive adult patients with benign CSOM so that they do not experience hearing impairment and decreased quality of life. This study aims to determine and prove the effectiveness of NCP in healing tympanic membrane perforation in vivo compared to paper patch.

MATERIALS AND METHODS

This study was an experimental study with a complete randomized sample determination using both ears of 72 to 96 week-old laying chickens with 1500-2000 grams of weight that had been conditioned

cages and pre-research food. The study was divided into 3 groups namely the rupture group of tympanic membrane with NCP, the paper patch group and the group without NCP (control.)

Research Procedure:

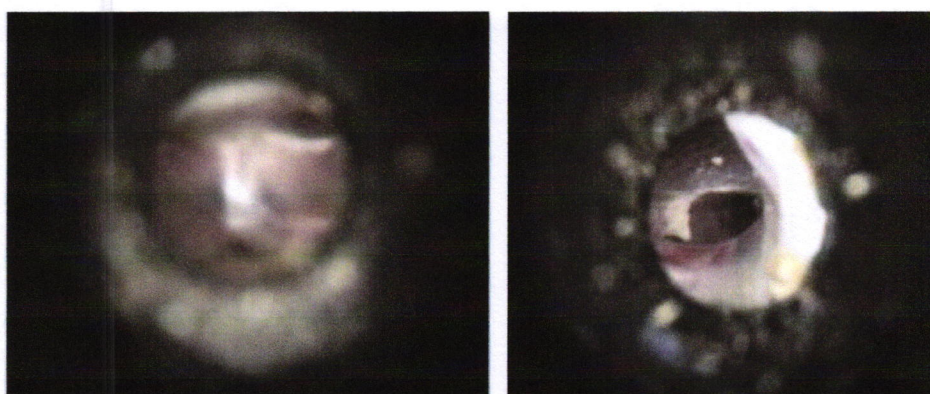
- a. Clean the ears of chicken with 70% alcohol and administer local anesthesia with Lidocain 2% using cotton for 10 minutes.
- b. Perform tympanic membrane perforation using micro hardspoon of 1.5mm diameter with the help of digital otoscope. Clean and let the perforation edge dry.
- c. Take action (b) in all three groups and create computerized documentation.
- d. On the third day, NCP Onlay was installed with mini tweezers and earpiece in the perforation group with NCP.
- e. Create computerized documentation of NCP installation results.
- f. Perform digital otoscopy examination every day until healing occurs
- g. Perform data collection and analysis
- h. Do statistical analysis of the data obtained

RESULTS

The results of the study are :

Table 1. Comparison the healing period of closure rupture tympanic membrane on laying hen using nata de coco patch(NCP +) Spontaneous (NCP-) and Paper patch.

| Perlakuan | Day 4th | Day 5th | Day 6th | Day 7th | Day8th | ammount |
|-----------|----------|-----------|----------|---------|----------|---------|
| NCP- | - | 3(21,3) | 3 (21,3) | 4(28,7) | 4 (28,7) | 14 |
| NCP+ | 8 (56,8) | 5 (36,0) | 1(7,2) | - | - | 14 |
| Paper | 1(7,2) | 2 (14,1) | 4(28,7) | 7(50,0) | - | 14 |
| ammount | 9 | 10 | 8 | 11 | 4 | 42 |



(a) Normal tympanic membrane (b) Tympanic membrane perforation
Figure 1. Image of chicken tympanic membrane before perforation (a) and after Perforation (b)

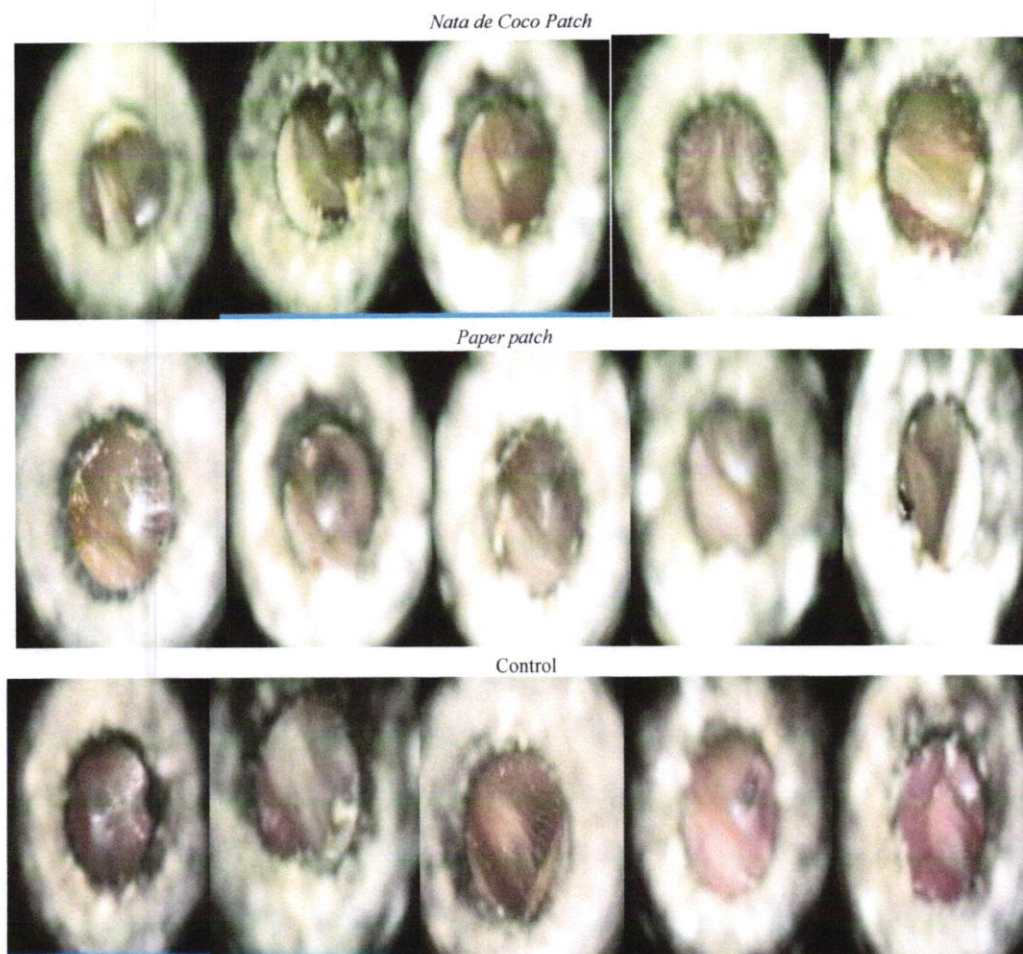


Figure 2. Image of the tympanic membrane based on the length of time of closure

DISCUSSION

From the results of this study in vivo it can be seen that healing perforation of tympanic membrane by utilizing NCP, 63% (9 ears) has experienced complete closure and cure on day 4th, and at day 6th 100% (14th) perforation the tympanic membrane has been healed. While in the control group with spontaneous healing without NCP use, only 7.2% (1) of the perforated tympanic membrane healed and later on day 8, all 14 (100%) of the perforated chicken tympanic membrane experienced complete healing and closure. While in the paper patch group 7.2% (1) rupture of the tympanic membrane healed on day 4 and 100% (14) rupture of the tympanic membrane will heal completely on day 7 This is in line with Kim et al (2013) study of the use of a bacterial cellulose patch with mannitol medium which was faster in scratching than

control mice although complete healing and closure was seen at day 7 with 3 (27.3%) tympanic membranes, and all perforation of the tympanic membrane will close on day 14 (2 weeks). In this study utilizing the tympanic membrane of the chicken, all perforations have been perfectly closed in just 8 days. This is possible because the cellulose bacterial patch used in this study using coconut water media has a natural content of various micronutrients that are more complex as opposed to just giving mannitol, yeast and peptone. In addition, the cellulose patch used by Kim et al requires an inoculation period for the manufacturing process, while in this study the nata de coco patch is only inoculated for 8 days. Compared to various other patch materials bacterial cellulose patches have many uniqueness that can explain the acceleration of healing experienced by rats and chickens,

one of them being that its surface contains nanostructures such as extra cellular matrix; it has biocompatibility, transparency and excellent mechanical properties with similar resilience to human skin and not as easily torn as is the case with paper patches. It is important to note that cellulose-based patches like nata de coco can be sterilized at

121 degrees Celsius without damaging physical properties such as its structure, transparency and elasticity.

The nata de coco patch is a natural biopolymer that is hypoallergenic and very hydrophilic, so the installation process does not require adhesive materials such as glue, ointment and so on and can be directly firmly attached to the tympanic membrane. Besides, the ability to store fluid is very useful to maintain the moisture levels and hasten the process of perforation wound healing. Although most of the tympanic membrane perforations in humans are due to infective process rather than trauma (rupture), which are mainly due to chronic Suppurative otitis media that are not fully cured and given inadequate therapy, but we prefer to perform tympanic membrane rupture to represent the perforation conditions in humans (due to) permanent perforation post infection; if the installation will be fixed patches must be done to the new injury as in the state of rupture.

In this study the installation of nata de coco patch is also done after 3 days of rupture so the closure of perforation is not primarily due to chemical factors that work on the surface of new wound. From statistical test results to compare acceleration of wound healing, the significance level $p < 0.05$, which means nata de coco patch has the ability to accelerate the healing process of tympanic membrane rupture in animals better than paper patches and controls. According to this result, we recommend it for its expediting efforts in accelerating the healing of tympanic membrane perforation both due to infection and trauma in humans.

CONCLUSION

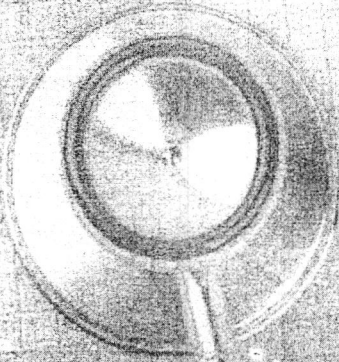
This study recommends further study on the utilization of bacterial cellulose patches in general and NCP in particular as one of the conservative therapies of membrane rupture / perforation of tympanic membrane in humans because in vivo NCP has been shown to accelerate the healing and closure of perforated tympanic membranes completely as compared to healing with paper patch or spontaneous healing (controls).

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