J COLOPROCTOL (RIO J). 2017;xxx(xx):xxx–xxx

Journal of Coloproctology

www.jcol.org.br

Special Article

A randomized trial study on the effect of amniotic membrane graft on wound healing process after anal fistulotomy

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ARTICLE INFO

Article history:
Received 19 December 2016
Accepted 27 March 2017
Available online xxx

Keywords:
Anal fistula
Human amniotic membrane
Wound healing
Post-operative complication

ABSTRACT

Objective: Human amniotic membrane (HAM) used as a wound coverage for more than a century. The aim of this study is to evaluate the efficacy of amniotic membrane on wound healing and reduce post-operative complication.
Study design: Randomized clinical trial study.
Place and duration of study: Surgery Department, Shahid Faghihi Hospital, Shiraz, in the period of between Sep. 2014 and Nov. 2015.
Methodology: 73 patients with anal fistula were divided into two groups. The patients suffered from simple perianal fistula (low type) without any past medical history. Fistulotomy were performed for all of them and in interventional group HAM were applied as biologic dressing. Their wound healing improvement was evaluated post-operative in two groups.
Results: From 73 patients participated in the study, 36 patients were in control group and 37 patients were in intervention group. According to the analysis of images taken from the wound, the rate of wound healing was 67.39% in intervention group and 54.51% in control group ($p < 0.001$). Discharge, pain, itching and stool incontinency was lower in intervention group. Analysis of pathology samples taken from the wound showed no differences between two groups.
Conclusion: HAM application could lead to improvement of wound healing and reduced post-operative complications. In conclusion, HAM may act as a biologic dressing in the patients with anal fistula.

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http://dx.doi.org/10.1016/j.jcol.2017.03.006

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Please cite this article in press as: Leila G, et al. A randomized trial study on the effect of amniotic membrane graft on wound healing process after anal fistulotomy. J Coloproctol (Rio J). 2017. http://dx.doi.org/10.1016/j.jcol.2017.03.006

UNCORRECTED PROOF

Ensaio clínico randomizado sobre o efeito do enxerto de membrana amniótica sobre o processo de cicatrização após fistulotomia anal

Palavras-chave:
Fístula anal
Membrana amniótica humana
Cicatrização da ferida
Complicação pós-operatória

RESUMO

Objetivo: Membrana amniótica humana (MAH) tem sido usada para cobrir feridas por mais de um século. O objetivo deste estudo é avaliar a eficácia da membrana amniótica na cicatrização de feridas e reduzir complicações pós-operatórias.
Desenho do estudo: Ensaio clínico randomizado.
Local e duração do estudo: Departamento de Cirurgia, Shahid Faghihi Hospital, Shiraz, Irã, entre setembro de 2014 a novembro de 2015.
Método: 73 pacientes com fístula anal foram divididos em dois grupos. Os pacientes sofriam de fístula perianal simples (tipo baixo) sem histórico médico prévio. A fistulotomia foi realizada em todos eles e no grupo intervenção, MAH foi aplicada como curativo biológico. A melhora da cicatrização foi avaliada no período pós-operatório em dois grupos.
Resultados: De 73 pacientes que participaram do estudo, 36 pacientes eram do grupo controle e 37 pacientes do grupo intervenção. De acordo com a análise das imagens da ferida, a taxa de cicatrização foi 67,39% no grupo intervenção e 54,51% no grupo controle ($p < 0,001$). Secreção, dor, prurido e incontinência fecal foi menor no grupo intervenção. A análise das amostras patológicas retiradas da ferida não mostrou diferenças entre os dois grupos.
Conclusão: A aplicação de MAH pode levar à melhoria da cicatrização de feridas e reduzir as complicações pós-operatórias. Em conclusão, a MAH pode atuar como um curativo biológico nos pacientes com fístula anal.

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Introduction

Fistula-in-ano disease usually exists after anorectal infection. There are many treatment options for management of anal fistulas with minimum chance of incontinence and recurrence. Surgical managements have to eliminate the septic foci and any associated epithelized tract to avoid recurrence and preserve the anal sphincter function.

All of the options have different success rates. Fistulotomy used in the underlying sphincter tissue and is recommended for low fistulas with reported success rates varying from 29% to 53%. Success rates with plug have been comparable or inferior to the advancement flap (48–62%). The flap should consist of the part of the internal sphincter and mucosa with a broad base of blood supply and should be sutured without tension. The success rate can be raised by removing the underlying infected anal gland and curetting the rest of the tract.[1]

Setonisa less invasive approach with minimal damage to the sphincter. However the discomfort caused to the patient during the long time required for wound healing is the main disadvantage of this approach. However, a cutting seton can have better (up to 99%) success rate, it can cause severe discomfort to the patient and also, can have 18–25% incidence of incontinence. Draining seton can have 20–40% persistent fistula rate, but with a low incidence of incontinence.[2]

In 2006, ligation of inter sphincteric fistula tract (L.I.F.T.) introduced by Rojanasakul for the first time as a total sphincter saving procedure.[3] Healing rate after 6–7 weeks is usually ranging from 68% to 83%. Video assisted anal fistula treatment (VAAFT) described by Prof. Meinero, that is done with the rigid endoscope and the tract is cauterized, curetted and the internal opening is stapled.[4]

Cochrane database have described that no major difference was seen between the various techniques used if recurrence rates are concerned.[5] Thus there is no single method that is perfect and physician has to choose the surgery depending on his/her experience, the type of fistula and the other local conditions.

Many post-operative complications are because of dysfunction of wound healing. Vascularity of anal canal is important but the main reason is infection and lack of scare recovery due to scare situation and humid dressing. So, complications like pain, itching, discharge and recurrence occurred.

Human amniotic membrane (HAM) is the inner layer of the fetal membranes and has bio-compatibility, easy availability, elasticity and stability and it has been used as an alternative biomaterial for research in many surgeries and wound-healing procedures. Amniotic membrane has been used in different organs for example, many surgeons evaluated the efficacy of HAM as a biologic dressing in burn wounds or in corneal epithelium reconstruction with transplantation of epithelial cells on a lyophilized amniotic membrane (LAM) or in gastrointestinal tract surgeries.[6,7] Many studies assessed the efficacy of HAM as a biologic dressing in skin ulcers reported better outcomes in comparison to some other methods. Moreover, in a few studies, HAM has been evaluated in GI tract of animal models and the results showed accelerating wound healing process.[8] Uludag et al. used HAM patch in colon anastomosis in rats and reported that using HAM decreases dehiscence rate, intra-abdominal abscesses, anastomotic leakage, adhesion formation and intestinal obstruction.[9]

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