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Application of Gamma Irradiated Amniotic Membrane as a Scaffold in Surgical Repair of Vaginal Wall Prolapse

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ABSTRACT

Background: The hardest difficult issues in female pelvic floor repair is surgical correction of vaginal wall prolapse. After conventional colporrhaphy, the recurrence rate is between 40 and 60%.

Aim of the work: To assess the effectiveness, symptom relief, healing, and infection rate of using Gamma irradiation sterilised amniotic membrane as a transplant vs traditional classical repair.

Patients and methods: From January 2019 to June 2020, a prospective study was done at Bab El-Sheria Maternity Hospital on a total of 40 patients (20 in each group). who was diagnosed with vaginal wall prolapse and had vaginal repair surgery.

Results: Fibrosis formation, vaginal dryness, and constipation were statistically non-significantly less common in the amniotic membrane group (p values=0.342, 0.661, and 0.487, respectively) in the current study.

Conclusion: As demonstrated in the previous study, this approach has provided us with satisfactory outcomes with no serious problems and significant postoperative improvement in dyspareunia.

Keywords: Vaginal Wall Prolapse ; Human Amniotic Membrane ; Gamma.

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INTRODUCTION

Because of the high recurrence rate, new surgical approaches and better long-term solutions are required¹. The use of synthetic and biological grafts in the repair of vaginal wall prolapse has been studied by surgeons. The use of an absorbable polyglactin mesh (Vicryl) to correct vaginal wall prolapse has shown little benefit (42%), and the use of a synthetic permanent polypropylene mesh for vaginal repair has shown a mesh erosion rate of 18%², de novo urgency rate of 20%, and dyspareunia of 22% postoperatively. In pelvic floor reconstruction cases, the increase of the mesh erosion or infection rate fourfold when the mesh was introduced vaginally in comparison to the abdominal route³.

The use of Amniotic Membrane as a possible biological graft material came to our attention because it is non-immunogenic, meaning it's not going to be rejected, and because it is a protein, the body will integrate and absorb it after attracting fibrin and collagen, providing the proper support^{4,5}.

Human amniotic membrane is a strong membrane produced from the membranes of the foetus⁶.

Antibodies or a cell-mediated immune response to human amniotic membrane have not been detected, implying low antigenicity and so the recipient will not reject it. As a result, systemic immunosuppressive medicines aren't required. Fresh human amniotic membrane has been described for transplantation by some surgeons, however it is not without danger of infection^{7,8}.

The amniotic membrane possesses antibacterial and antiviral characteristics, stores antibiotics and releases them over a few days, and has recently been discovered to manufacture effective natural antimicrobials. In addition to acting as an anatomical barrier, clinical studies show epithelialization has been facilitated by the amniotic membrane as a biologic dressing acting as a basement membrane substrate, facilitates epithelial cell migration, reinforces basal epithelial adhesion, allows cellular differentiation, and prevents cellular apoptosis, and inhibits inflammation and fibrosis⁹.

Fresh or dried amnion grafts are a potential supplementary treatment for reducing adhesion recurrence and boosting endometrial regeneration. Both grafts appear to be equally efficient; however, the dried amnion transplant has a few advantages,

including easier availability, prevention of cross-infection, and surgical application. The use of non-sterilized amniotic membrane is thought to enhance the risk of transfer of fungal, bacterial, or viral infections from donors¹⁰.

PATIENTS AND METHODS

This prospective study was conducted on a total of 40 patients with pelvic organ prolapse who participated in the study to investigate the value of amniotic membrane as a graft in classical repair in terms of effectiveness, symptoms relief, healing, and infection rate at Bab El-Sheri Hospital after receiving ethical committee approval and informed consent from the patients.

Study participants:

The patients with pelvic organ prolapse were divided into two groups: Group (1): 20 patients who underwent surgical vaginal repair with the application of sterilised (gamma irradiated) amniotic membrane; and Group (2): 20 patients who underwent surgical vaginal repair with the application of sterilised (gamma irradiated) amniotic membrane. Group (2): 20 patients who underwent surgical vaginal repair without the use of a graft.

Criteria for inclusion:

Patient age ranges from 20 to 40 years old, parity ranges from 1 to 5, and BMI ranges from 25 to 35 KG/M2.

Criteria for exclusion:

Increased intra-abdominal pressure is caused by chronic debilitating diseases and conditions.

Procedure for the research:

Multiple procedures are used to sterilise amniotic membranes, the final of which being gamma irradiation. For tissue allograft sterilisation, gamma radiation is claimed to be the most reliable and successful method. Many tissue banks have employed it to sterilise tissues. The clinical function of the amniotic membrane is unaffected by gamma radiation¹¹. The most frequent dose for sterilising medical goods is 25 kGy¹².

The Egyptian Atomic Energy Authority will provide gamma irradiated Sterilized freeze-dried

(lyophilized) amnion grafts, which will be made according to the method of Antounians et al.¹³. This graft has the benefit of total sanitation and can be stored for up to 5 years once dried.

Which can be supplemented with a rectangular shaped amniotic membrane graft, which is attached bilaterally at four or six points to provide proper support to the urethra, bladder, and anterior vaginal wall. While on the posterior vaginal wall, between the rectal fascia and the vagina, an amniotic membrane graft can be inserted, anchored distally at the uterosacral ligaments and dorsally at the levator ani muscle. Extra amniotic membrane is cut away, usually 1-2 cm on each side.

Measures of success:

Symptom relief, healing period, infection, recurrence, and sexual activity are all monitored. All patients in both groups were followed up on for 3 to 6 months after surgery, with all symptoms being recorded. The data was then subjected to statistical analysis to determine the relevance of the amniotic membrane graft procedure.

Analytical statistics:

IBM SPSS statistics (Statistical Package for Social Sciences) software version 22.0, IBM Corp., Chicago, USA, 2013 and Microsoft Office Excel 2007 were used to code, tabulate, and statistically analyse the obtained data.

For quantitative normally distributed data, descriptive statistics were calculated as the minimum and maximum of the range, as well as the mean and SD (standard deviation), whereas qualitative data was calculated as number and percentage.

For quantitative variables, inferential analyses were conducted using the Shapiro-Wilk test for normality testing and an independent t-test in the case of two independent groups with normal data distribution. Inferential studies for independent variables in qualitative data were performed using the Chi square test for proportional differences and Fisher's Exact test for variables with small anticipated numbers. If the P value is less than 0.050, the result is significant; otherwise, it is non-significant.

RESULTS

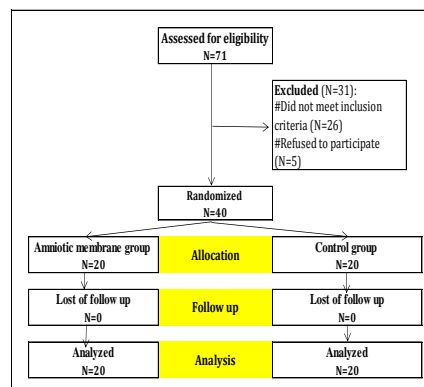


Fig. 1: Flow chart of the studied cases.

Variables	Measures	Amniotic membrane (N=20)	Control (N=20)	p-value
Age (years)	Mean±SD	33.8±4.6	34.3±4.4	^0.
	Range	27.0–40.0	27.0–40.0	
BMI (kg/m ²)	Mean±SD	30.5±2.7	31.0±2.5	^0.
	Range	26.0–34.0	27.0–35.0	
Parity	Median (1st–3rd IQ)	4.0 (3.0–4.0)	3.5 (3.0–4.0)	≠0.
	Range	2.0–5.0	2.0–5.0	
History of vaginal delivery		20 (100.0%)	20 (100.0%)	NA
History of episiotomy		17 (85.0%)	18 (90.0%)	§0.999
History of instrumental delivery		3 (15.0%)	2 (10.0%)	§0.999

IQ: Interquartiles. BMI: Body Mass Index. NA: Not applicable. ^Independent t-test. §Fisher's Exact test

Table 1: Comparison between the studied groups regarding baseline demographic characteristics

Table (1) shows that: No significant differences between the studied groups regarding baseline demographic characteristics; age, BMI, parity, history of vaginal delivery, history of episiotomy and history of instrumental delivery.

Presentations	Amniotic membrane (N=20)	Control (N=20)	p-value
Cystocele	19 (95.0%)	18 (90.0%)	§0.999
Rectocele	14 (70.0%)	12 (60.0%)	#0.507
Urinary incontinence	10 (50.0%)	11 (55.0%)	#0.752
Complain for more than one year	14 (70.0%)	11 (55.0%)	#0.327

#Chi square test. §Fisher's Exact test

Table 2: Comparison between the studied groups regarding baseline clinical presentations Table (2) shows that: No significant differences between the studied groups regarding baseline clinical presentations; cystocele, rectocele, urinary incontinence and complain for more than one year.

Findings	Amniotic membrane (N=20)	Control (N=20)	§p-value	Effect size Relative risk 95% CI
Occurred	0 (0.0%)	3 (15.0%)	0.231	NA
Not occurred	20 (100.0%)	17 (85.0%)		

§Fisher's Exact test. *Significant. Effect size: Effect of amniotic membrane relative to control. CI: Confidence interval. NA: Not applicable.

Table (3): Comparison between the studied groups regarding postoperative infection

Table (3) shows that: Postoperative infection statistically was non-significantly less frequent in amniotic membrane group.

Findings	Amniotic membrane (N=20)	Control (N=20)	§p-value	Effect size Relative risk 95% CI
Occurred	20 (100.0%)	16 (80.0%)	0.106	NA
Not occurred	0 (0.0%)	4 (20.0%)		

§Fisher's Exact test. *Significant. Effect size: Effect of amniotic membrane relative to control. CI: Confidence interval. NA: Not applicable.

Table 4: Comparison between the studied groups regarding healing after two weeks

Table (4) shows that: Healing after two weeks statistically was non-significantly more frequent in amniotic membrane group.

Findings	Amniotic membrane (N=20)	Control (N=20)	§p-value	Effect size Relative risk 95% CI
Occurred	1 (5.0%)	4 (20.0%)	0.342	0.25 0.03–2.05
Not occurred	19 (95.0%)	16 (80.0%)		

§Fisher's Exact test. *Significant. Effect size: Effect of amniotic membrane relative to control. CI: Confidence interval.

Table 5: Comparison between the studied groups regarding fibrosis formation

Table (5) shows that: Fibrosis formation statistically was non-significantly less frequent in amniotic membrane group.

Findings	Amniotic membrane (N=20)	Control (N=20)	#p-value	Effect size Relative risk 95% CI
Occurred	2 (10.0%)	9 (45.0%)	0.013*	0.22 0.05–0.90
Not occurred	18 (90.0%)	11 (55.0%)		

#Chi square test. Effect size: Effect of amniotic membrane relative to control. CI: Confidence interval.

Table 6: Comparison between the studied groups regarding dyspaerunia

Table (6) shows that: Dyspaerunia statistically was significantly less frequent in amniotic membrane group.

Findings	Amniotic membrane (N=20)	Control (N=20)	§p-value	Effect size Relative risk 95% CI
Occurred	1 (5.0%)	5 (25.0%)	0.182	0.20 0.03–1.56
Not occurred	19 (95.0%)	15 (75.0%)		

§Fisher's Exact test. Effect size: Effect of amniotic membrane relative to control. CI: Confidence interval.

Table 7: Comparison between the studied groups regarding six-month recurrence

Table (7) shows that: Six-month recurrence statistically was non-significantly less frequent in amniotic membrane group.

DISCUSSION

Anti-inflammatory, anti-scarring, and anti-immunogenic characteristics are all found in amniotic membrane. It can also offer a moist environment and serve as an ideal substrate for epithelial development, both of which aid wound healing. As a result, amniotic grafts are commonly utilised to treat chronic diabetic foot ulcers, as well as a variety of ophthalmologic issues and wound dressings¹⁴.

Because mesh erosion or infection rate after vaginal wall prolapse repair is a major source of contention and is frequently linked to complications, using amniotic membrane as a possible biological graft material for reducing mesh erosion, infection rate, and postoperative complications was highlighted as a major point of interest⁵.

In this study, we compared the effectiveness, symptom relief, healing, and infection rate of using Gamma irradiation sterilised amniotic membrane as a graft with traditional classical repair.

From June 2020 to April 2021, a prospective study was undertaken at Bab El-Sheria Maternity Hospital on a total of 40 patients who presented with vaginal wall prolapse and underwent surgical vaginal repair.

A total of 71 patients were examined for eligibility, with 40 being accepted into the trial (20 in each group). Twenty-six patients were excluded from the study due to inclusion requirements, while five patients declined to participate. In the end, the study was based on the data of 40 patients who were split into two groups.

The current study found no significant variations in baseline demographic variables such as age, BMI, parity, history of vaginal delivery, history of episiotomy, and history of instrumental delivery across the analysed groups.

No significant differences were found between the analysed groups in terms of baseline clinical

manifestations, such as cystocele, rectocele, urine incontinence, or complaints lasting more than a year, according to our research.

The amniotic membrane group had a statistically non-significantly lower rate of postoperative infection (p value=0.231).

Our findings demonstrated that healing was statistically non-significantly more common in the amniotic membrane group after two weeks (p value=0.106).

Fibrosis formation was statistically non-significantly less frequent in the amniotic membrane group (p value=0.342), according to the current investigation.

Dyspaerunia was statistically considerably less common in the amniotic membrane group (p value=0.013), according to our findings.

Six-month recurrence was statistically non-significantly less frequent in the amniotic membrane group (p value=0.182), according to our findings.

Data on the use of Gamma irradiation sterilised amniotic membrane as a graft for vaginal wall prolapse repair is sparse and contradictory, to the best of our knowledge. The purpose of this study was to determine the efficacy and safety of amniotic membrane in the treatment of vaginal wall prolapse.

In a study conducted by Lau et al.¹⁵, fifty-three patients who had or were referred for mesh erosions after pelvic floor repair were given comprehensive advice on the use of an amniotic graft to treat erosions or vaginal defects, as well as follow-up to assess the efficacy and feasibility of using amniotic membrane as an inlay graft for complex mesh erosions.

According to Lau et al.¹⁵, surgical outcomes were satisfactory by all patients with good functional recovery, and none of the patients had complications such as recurrent prolapse, stress incontinence, wound infection, or pelvic pain. They also reported that five patients were still sexually active and two

patients complained of dyspareunia before surgery, but there was no complaint of dyspareunia after surgery, which matched our findings.

According to Lau et al.¹⁵, this approach may be a cost-effective and practical option for patients who have failed conservative treatment, have trouble with initial revision surgery, or have recurring erosions.

In addition, Leila et al.¹⁶ conducted a randomized clinical research in which 73 patients with anal fistula were included to determine the efficacy of human amniotic membrane (HAM) as a wound coverage for wound healing and reducing post-operative complications following anal fistulotomy.

According to Leila et al.¹⁶, wound healing rate in the intervention group was 67.39 percent compared to 54.51 percent in the control group, which was statistically significant ($p < 0.001$).

Human amniotic membrane application could promote wound healing and prevent post-operative problems, according to Leila et al.¹⁶. It could also operate as a biologic dressing.

Seifeldin⁵ enrolled 21 patients with vaginal wall prolapse for vaginal repair in a prospective study to see if using a fresh amniotic membrane graft for repair of site-specific defects in anterior and posterior vaginal wall prolapse was clinically and surgically feasible.

The advantage of trans-vaginal, para-vaginal repair with amniotic membrane graft, according to Seifeldin⁵, is that it provides support for all types of defects at the same time, including lateral, transverse, and midline defects, and it recreates proper support for the urethra, bladder, and anterior vaginal wall, as well as good suspension from the vaginal apex along the entire vaginal wall, anterior Graft insertion can also be used to treat a big enterocele by obstructing its descent.

The traditional anterior and posterior colpo-periorrhaphy is still the major procedure for vaginal wall prolapse repair, but reproductive and foetal tissues are a source of stem cells and a novel target for regenerative medicine, according to Seifeldin⁵.

Roshanravan et al.¹⁷ enrolled 8 mixed-breed female dogs in a prospective animal study to repair recto-vaginal fistulas using human amniotic membrane in an animal model. The dogs were randomly divided into two groups for standard recto-vaginal fistula repair and fistula repair with human amniotic membrane, and the fistulas were evaluated both grossly and microscopically after 6 weeks.

Roshanravan et al.¹⁷ found no differences between the two groups, and fistula healing appeared to have occurred in all dogs except for one who had a persistent patent fistulous tract, while healing score was higher in the HAM group than the standard group ($P = 0.029$), and they concluded that using human amniotic membrane (HAM) as a bio-prosthesis to repair recto-vaginal fistula would result in better surgical and histological.

The prospective study design and the fact that no patients were lost to follow-up are two of the study's

strengths. It's the first study to show that employing human amniotic membrane as a graft works in terms of efficacy, symptom alleviation, healing, and infection rate in traditional vaginal wall prolapse repair.

The study's shortcomings are worth noting. For starters, the sample size is smaller than in prior studies, and it is not a multicentric study, as Lau et al.¹⁵ covered a total of 53 patients, posing a high risk of publication bias. Second, the follow-up assessment should have been standardized and carried out by a third party who was unaware of the procedure. Finally, the relatively short-term postoperative follow-up of patients as Seifeldin⁵ tracked outcomes for 12 months postoperatively, which may underestimate the rate of prolapse recurrence, wound healing, or mesh erosion.

CONCLUSION

As demonstrated in the previous study, this approach has provided us with satisfactory outcomes with no serious problems and significant postoperative improvement in dyspareunia.

For better evaluation of the effectiveness and safety of Gamma Irradiated Amniotic Membrane Graft in vaginal prolapse repairs, more research are needed to better examine foetal graft materials and other surgical procedures for vaginal wall repairs.

The study adds to the body of knowledge and provides insight into future prospective studies with bigger sample sizes that demonstrate the long-term effects of Gamma Irradiated Amniotic Membrane Graft in Vaginal Prolapse Repairs.

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