HJOG An Obstetrics and Gynecology International Journal

Review

HJOG 2020, 19 (2), 77-82

The use of Bovine Pericardium Graft (BPG) in Anterior Colporrhaphy; a review of the literature and a retrospective study

O. Tsonis[1], Z. Barmpalia[1], F. Gkrozou[2], M. Paschopoulos[1], O. Papanikolaou[1]

[1]Department of Obstetrics and Gynaecology, University Hospital of Ioannina, Greece
[2]Department of Obstetrics and Gynaecology, University Hospital of Birmingham, UK

Corresponding Author

Dr Orestis Tsonis, MD, PhDc, SR in Obs and Gynae, Email address: orestis.tsonis@gmail.com

Abstract

Introduction: Bovine Pericardium Graft (BPG) is a non-synthetic mesh, used in cases of anterior vaginal prolapse reconstructive operation in Urogynecology. Little is known about the efficacy of this mesh and more empirical studies need to clarify its potential benefits as well as, mesh-associated complications of this type. The role of the mesh, though needs, further assessment. **Methods:** A review on the literature regarding the use of Bovine pericardium Graft in anterior colporrhaphy has been conducted. Retrospective data from our Department in the University Hospital of Ioannina Greece regarding 80 women, who underwent anterior colporrhaphy with the use of BPG, was analyzed and further evaluated. Women were examined using the POP-Q system after surgery and 24 months later. **Results:** Resolution of the prolapse was achieved in the vast majority of the patients (78/80 = 97.5%). Patients with 3rd stage of prolapse were 100% cured after surgery. Forty-eight patients had remaining prolapse of stage 1 and the remaining four patients achieved stage zero (0). **Discussion:** Although the number of patients is quite small and the data is retrospective, it seems that the BPG has a beneficial role in anterior colporrhaphy. International literature remains controversial in assessing its true value and potential risks. **Conclusion:** Retrospective data from the University Hospital of Ioannina, Greece, shows promising results in the use of Bovine Pericardium Graft use during anterior colporrhaphy.

Key words: Bovine pericardium graft, vaginal prolapse, POP-Q test, colporrhaphy, reconstructive pelvic floor surgery, pelvic pain, urinary incontinence

Brief summary:

The use of Bovine Pericardium Graft (BPG) in Anterior Colporrhaphy; a review of the literature and retrospective experience of its use at the University Hospital of Ioannina, Greece

Introduction

Vaginal prolapse affects, primary, a great number of menopausal women worldwide. This condition is presented most often with recurrent urinary tract infections as well as, stress urinary incontinence[1]. Due to the increase of life expectancy it is natural that a bigger number of women will seek medical treatment in cases of vaginal prolapse[2]. The majority of women proceed for medical advice in severe vaginal prolapses, since although POP is common only a small percentage of the patients perceive POP-symptoms[3]. Studies have shown that 10% of women will undergo a reconstructive pelvic organ prolapse operation during their lifetime, and approximately 30% of them will need further management due to high rates of recurrence[4]. Traditional colporrhaphy alone shows a failure rate of almost 70% accompanied with post-operative dyspareunia[5]. Treatment of pelvic organ prolapse (POP) necessitates the use of exogenous materials in order to minimize recurrence in these patients[6]. Some studies propose the use of meshes, although the evidence of their beneficial role remain ambiguous[3]. Bovine pericardium graft (BPG), a non-synthetic non-absorbable mesh, is used in cases of anterior vaginal prolapse where anterior colporrhaphy is performed[7]. In 1909, Ahfelt underlined the complexity of finding a permanent cure of cystocele, a fact that remains still an enigma when it comes to the choice of the optimal treatment approach[8].

Materials and Methods

In this review, all papers associated with the following keywords: "bovine pericardium graft" "mesh" "anterior vaginal prolapse" "anterior colporrhaphy" "cystocele" "anterior vaginal prolapse" "biomaterial" and of course "reconstructive pelvic floor surgery", were included. The search was based on the results found in PubMed and Google Scholar. Emphasis was given to empiric information through systematic reviews and clinical trials on humans. Due to the lack of the literature regarding particularly BPG use in anterior colporrhaphy, studies referring also to other mesh-reinforced repair gynecologic procedures were examined. Non-English literature was excluded. Relevant publications cited in literature found was also reviewed in order to conduct an appropriate research on the subject.

Review

Bovine Pericardium Graft, often referred as a type of non-synthetic xenograft, is vastly used in reconstructive operation such as, anterior colporrhaphy[4]. A randomized controlled trial of 2009[5], although regarding a small number of patients, illustrated that bovine pericardium mesh combined colporrhaphy does not have a higher rate of improvement nor complications compared with traditional colporrhaphy. Nevertheless, data shows that in case where urinary discomfort symptoms are experienced, perhaps BPG may have a better result, due to tension-free nature of the graft[2,9]. Some data suggests nonabsorbable grafts show advantages over absorbable ones, although its use is linked with higher rates of vaginal erosion, infection, fistula, dyspareunia and detrusor overactivity[4,10,11]. On the other hand absorbable synthetic grafts are accompanied with high rates of failure reaching almost 17%.[4] while other studies suggest a failure rate over 50%[6,5].

Furthermore a 2016 Cochrane review failed to provide enough evidence in order to compare xenografts in general with native tissue repair[12]. Nevertheless, the data is quite limited and empiric information paucity do not facilitate a more accurate overview of the available options when it comes to mesh-reinforced repair of anterior vaginal prolapse[4].

This type of graft shows encapsulation with limited host response[4]. Connective tissue, meaning collagen and extracellular matrix, is deposited on the surface of the material and at the same time fibroblast and

angioblast colonization is prevented[4]. BPG acts as a supportive structure due to its ability to permits cellular ingrowth. No remodeling phase is observed and the graft remains intact. A study proposed that BPG results in improved anatomical outcomes providing adequate support to the surrounding tissues[13,8].

Review of the literature reveals that grafts such as BPG which undergoes encapsulation are linked with higher rates of failure due to infection risk, limited strength repair and histological poorly tolerated[4]. Nevertheless, studies fail to clarify whether the high rates of failure are restricted to individuals or it is a result of late post-implantation[4].

There was insufficient data regarding the beneficial characteristics of BPG. However, there is a general consensus that the immune response of the host against these grafts, depends on BPG's chemical cross-link response and porosity[14]. Improving the properties of this graft shows a preference on its use by urogynecologists[15].

A metanalysis of 37 RCTs in 2016 by Maher et al.[16], concluded that the use of grafts such as BPG, often requires a repeat surgery and it is linked with further prolapse, stress incontinence or mesh exposure[12].

Retrospective experience

Our retrospective study includes patients undergoing anterior colporrhaphy with the use of BPG for the repair of stage 3 to 4 prolapse as indicated by Pelvic Organ Prolapse Quantification (POP-Q). All patients with prolapse of less than 3rd degree were excluded. Patient who had previously underwent reconstructive anterior vaginal wall operation as well as, patients who underwent hysterectomy were also excluded. All patients were operated during 2014-2017 in the Gynecologic Department of the University Hospital of Ioannina, Greece. Data was stored, collected and processed using SPSS model.

Results

Two hundred and four (204) patients were examined for this study, 124 of them were excluded. 94 had an anterior vaginal prolapse of a grade less than 3, 10 had already undergo a hysterectomy and the remaining 20 had a previous surgical treatment for this condition. All patients underwent an anterior colporrhaphy with a use of BPG. The duration of the procedure was almost 60 minutes. No difference in the operation times was noticed. The length of hospitalization was between 3 to 4 days, during which no excessive blood loss was noticed or any further complications. (table 1-2)

Eighty patients, meeting the criteria, were selected. All patients were assessed 24 months (range 23-25 months) after surgery. Six (6) patients complained

Table 1. Patients profile, demographics and history

NUMBER OF PATIENTS	**80**
Age in years	62±9
Vaginal Deliveries	2 (1-4)
Menopause	63 (78,75%)
Comorbidities	
Hypertension	41 (51,25%)
Diabetes Melitus	9 (11,25%)
Others	2 (2.5%)

Table 2. Prolapse symptoms and urinary tract dysfunction subjective perception

NUMBER OF PATIENTS	**80 (100%)**
Perineal mass feeling	78 (97,5%)
Stage of Prolapse	
Third Stage	52 (65%)
Fourth Stage	28 (35%)
Urinary Symptoms	
Stress Urinary Incontinence (SUI)	36 (45%)
Recurrent Uterine Tract infections	28 (35%)
Perineal Pain	8 (10%)
Voiding Dysfunction	15 (18,75%)

of mild urinary tension discomfort in the follow up check (7.5%). Seventy-eight (78) patients were cured for the condition (97.5%). In two cases, operation failure was noted and the persistent prolapse was assessed as degree 4 (2.5%). (table 3).

Resolution of the prolapse was achieved in the vast majority of the patients (78/80 = 97.5%). Patients with 3rd stage of prolapse were 100% cured after surgery. Forty-eight patients had remaining prolapse of stage 1 and the remaining four patients achieved stage zero (0). In the group of 4th stage prolapse, two of the patients had a persistent 4th degree prolapse in the follow up at 24 months. Twenty-four patients of the latter group (30% of total and 85.71% of the group) were able to achieve a stage 1 prolapse after surgery and the remaining 2 patients, since 2 were already excluded due to operation failure, found to have a mild stage 2 prolapse.

No post-operative bladder injuries or vaginal erosions were noticed. From the twenty-eight patients complaining for recurrent uterine tract infections only one was still affected with a diagnosis of interstitial cystitis. Stress Urinary incontinence was cured in 97,2% of the patient complaining for this condition. As it is noted before, recurrence of the prolapse was noted in 2 patients of the group were stage 4 prolapse was found.

Discussion

Biological grafts such as BPG is introduced in Urogynecology with ambiguous results. Although international publications tend to link BPG with a variety of complications, our study shows significant such rates in the subject in search. It is essential to mention that this procedure was performed by urogynecologist specialized in reconstructive pelvic floor operation with an experience of different procedures and different graphs spanning more than 20 years. It is natural that pelvic floor operations demand a high level of expertise due to the proximity of these tissues[17]. Our study has limitations such as its retrospective nature, the small number of patients under examination and of course the limited number of urogynecologists performing these operations (2 in total). In this study no infection was noted and the failure rates were minimal perhaps due to the

Table 3. POP-Q system measurements pre- and postoperatively

PREOPERATIVE			**POSTOPERATIVE**			
Prolapse stage	POP-Q		Stage 0-1	POP-Q	Stage 2	POP-Q
3rd = 52	C	5±0.5	52 pt.	-10±0.5	0 pt.	-8±0.3
	D	2±0.7		-6±0.7		-7±0.3
	Aa (-3/+3)	2±0.7		-2.7±0.2		-0.8±0.3
	Ba (-3/+9)	2±0.5		-2.5±0.2		-0.7±0.4
	Ap (-3/+3)	2±0.5		-2.7±0.2		-2.8±0.3
	Bp (-3/+7)	2±1.3		-2.9±0.8		-2.9±0.6
4th = 28	C	9±0.5	24 pt.	-10±0.5	2 pt.	-8±1
	D	6±0.4		-6±0.7		-6±1
	Aa	2.7±0.3		-2.7±0.2		-0.8±0.3
	Ba	6±1.8		-2.7±0.2		-0.8±0.4
	Ap	2.7±0.3		-2.7±0.2		-2.8±0.3
	Bp	6±0.8		-2.9±0.4		-2.8±0.4

limited number of patients examined.

It seems that urinary discomfort was alleviated and no further recurrent urinary tract infections were noted in the majority of the patients under study, resulting in the beneficial role of BPG in cases were symptoms of urinary tract discomfort occur.

There are more than 40 techniques with or without a graft for treating this pathology, marking the failure of urogynecologist to develop the optimal approach[2]. Perhaps the success of these techniques lies in the expertise of an experienced surgeon.

When it comes to the use of grafts, there is insufficient data. A small number of RCTs is conducted and the results produced are quite conflicting. Also, there is a lack of studies focusing on the role of certain grafts in use[18]. Usually or reports examine a category of the grafts providing misleading conclusions[19].

Conclusion

Controversial data between the review of the literature regarding BPG and our findings underline the need to conduct further randomized control trial research in order to determine the beneficial role and the limitations of BPG used in anterior colporrhaphy. Nowadays, urogynecologists using BPG depend on their experience in using this graft for reconstructive pelvic organ prolapse surgeries. It is quite important for further data to be published and larger trials to be conducted in order to justify the true value of BPG in anterior colporrhaphy and by extent to reconstructive pelvic floor operations.

Compliance with ethical standards

Conflict of interest

All authors declare no conflict of interest,
nor they received funding of any kind for this study.

Ethical approval

The study involving human participants performed by the authors is approved by Ethical Committee, University Hospital of Ioannina.

References

1. Martucci RC, Ambrogini A, Calado AA, Zerati M, El M, Muller A. Pubovaginal Sling With Bovine Pericardium for Treatment of Stress Urinary Incontinence. 2000;26(2):208–14.
2. Dodero D, Bernardini L. The Use of Tutomesh for a Tension-Free and Tridimensional Repair of Uterovaginal and Vaginal Vault Prolapse: Preliminary Report. Surg Res Pract. 2015;2015:1–8.
3. Lang P, Whiteside JL. Anterior compartment prolapse. Curr Opin Obstet Gynecol. 2017;29(5):337–42.
4. Trabuco EC, Klingele CJ, Gebhart JB. Xenograft use in reconstructive pelvic surgery: A review of the literature. Int Urogynecol J. 2007;18(5):555–63.
5. Guerette NL, Peterson T V, Aguirre OA, Vandrie DM, Biller DH, Davila GW. Anterior repair with or without collagen matrix reinforcement: a randomized controlled trial. Obs Gynecol. 2009;114(1):59–65.
6. Araco F, Gravante G, Overton J, Araco P, Dati S. Transvaginal cystocele correction: Midterm results with a transobturator tension-free technique using a combined bovine pericardium/polypropylene mesh. J Obstet Gynaecol Res. 2009;35(5):953–60.
7. Lazarou G, Powers K, Pena C, Bruck L, Mikhail MS. Inflammatory reaction following bovine pericardium graft augmentation for posterior vaginal wall defect repair. Int Urogynecol J. 2005;16(3):242–4.
8. Maher C. Anterior vaginal compartment surgery. Int Urogynecol J. 2013;24(11):1791–802.
9. Hosseini J, Hosseini S, Hosseini MA, Rezaei Y. Pericardium in Reconstructive Urologic Surgeries: A Systematic Review and Meta-Analysis. Urol Int. 2018;
10. Agarwala N, Cohn A. Experiences with a xenograft (acellular bovine collagen matrix) in gynecologic fistula repairs. J Minim Invasive Gynecol.

2006;13(5):483–5.
11. Rostaminia G, Ferzandi T, Shobeiri SA. Vaginal Mesh and Pain Complications. In: The Innovation and Evolution of Medical Devices [Internet]. Cham: Springer International Publishing; 2019 [cited 2019 Mar 8]. p. 263–79. Available from: http://link.springer.com/10.1007/978-3-319-97073-8_13
12. Campbell P, Jha S, Cutner A. Vaginal mesh in prolapse surgery. Obstet Gynaecol. 2018;20(1):49–56.
13. Rizvi RM. Graft and mesh use in vaginal surgery. 2017;67(December):1895–900.
14. Gebhart JB, Schmitt JJ. Surgical Management of the Constricted or Obliterated Vagina. Obstet Gynecol. 2016;128(2):284–91.
15. Verma RS, Venugopal JR, Cherian KM, Mathapati S, Bishi DK, Ramakrishna S, et al. Biomimetic acellular detoxified glutaraldehyde cross-linked bovine pericardium for tissue engineering. Mater Sci Eng C [Internet]. 2012;33(3):1561–72. Available from: http://dx.doi.org/10.1016/j.msec.2012.12.062
16. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev [Internet]. 2016 Feb 9 [cited 2019 Mar 8];(2). Available from: http://doi.wiley.com/10.1002/14651858.CD012079
17. Mooradian DL. Allografts and xenografts in soft tissue repair: Current use and future trends [Internet]. Extracellular Matrix-derived Implants in Clinical Medicine. Elsevier Ltd; 2016. 41–62 p. Available from: http://dx.doi.org/10.1016/B978-0-08-100166-0.00004-9
18. Cox A, Herschorn S. Evaluation of current biologic meshes in pelvic organ prolapse repair. Curr Urol Rep. 2012;13(3):247–55.
19. Maher CM, Feiner B, Baessler K, Glazener CMA. Surgical management of pelvic organ prolapse in women: The updated summary version Cochrane review. Int Urogynecol J. 2011;22(11):1445–57.

Received 28-02-20
Revised 04-05-20
Accepted 07-05-20