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ARAŞTIRMA YAZISI / RESEARCH ARTICLE

İYATROJENİK VAJEN DARLIĞININ EMİLEBİLİR BİR OKSİDİZE REJENERE SELULOZ İLE GENİŞLETİLMESİ

DILATATION OF IATROGENIC VAGINAL STENOSIS WITH AN ABSORBABLE OXIDIZED REGENERATED CELLULOSE

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ÖZET

AMAÇ: Vajinanın iatrojenik olarak fazla daraltılması, çiftlerin cinsel hayatını olumsuz etkilemektedir. Bu durumun kesin tedavisi ise tekrar vajinanın genişletilmesi ile mümkündür. Bu çalışma, emilebilir oksidize rejenere seluloz kullanılarak uygulanan vajina genişletme işleminin sonuçlarını değerlendirmeyi amaçlamaktadır.

GEREÇ VE YÖNTEM: İatrojenik vajina darlığı nedeniyle ilişkiye giremeyen 29 hastaya, Nisan 2014 ile Ağustos 2020 tarihleri arasında, emilebilir oksidize rejenere seluloz kullanılarak vajina genişletme ameliyatı yapıldı. Bu ameliyatın sonuçları, özellikle hasta memnuniyetini değerlendiren standart ''Hasta Memnuniyet Ölçeği'' yardımıyla incelendi.

BULGULAR: Hastalar, ortalama 16 ay (14 - 24 ay) takip edildi. Drenaj ve antibiyoterapi ile tedavi edilmiş bir perianal hemotom vakası dışında perioperatif dönemde kaydedilmiş majör komplikasyon saptanmadı. Altı haftanın sonunda, 27 hasta ağrısız cinsel ilişkiye girebildiğini belirtti. Iki hastada ise, sırasıyla 4 ve 6 ay sonra, vajina genişletme ameliyatı tekrar uygulandı. Cerrahiden altı ay sonra, memnuniyet ölçeğindeki ''daha iyi'' ve ''çok daha iyi'' cevaplarına göre ameliyat sonrası hasta memnuniyet oranı %93 olarak saptandı.

SONUÇ: Emilebilir oksidize rejenere seluloz kullanılarak yapılan vajina genişletme ameliyatı, olumlu anatomik ve fonksiyonel sonuçlara sahip etkili ve güvenilir bir işlem gibi görünmektedir. Ancak, bu yöntemin güvenilirliğinin ve etkinliğinin tam olarak değerlendirilebilmesi için çok sayıda karşılaştırmalı çalışmaya ihtiyaç vardır.

ANAHTAR KELİMELER: Disparoni, Vajinal darlık, Vajina

ABSTRACT

OBJECTIVE: Iatrogenic vaginal stenosis adversely affects the sexual life of couples. The definitive treatment of this condition is possible by redilatation of vagina. This study aims to investigate the outcomes of vaginal dilatation procedure performed using an absorbable oxidized regenerated cellulose.

MATERIAL AND METHODS: 29 patients who could not have intercourse due to Iatrogenic vaginal stenosis underwent vagina enlargement surgery using an absorbable oxidized regenerated cellulose in the period of April 2014 to August 2020. The results were analysed with the help of the standard 'Patient Global Impression of Improvement Scale (PGI-I) which evaluates patient satisfaction in particular.

RESULTS: The mean follow-up period was 16 monts (14 - 24 months). No major perioperative complication was detected except from perianal hemotoma treated with antibiotics and drainage in a case. At 6th month follow up visit, 27 patients reported pain free sexual intercourse. Two patients needed re-dilatation 4 and 6 months later respectively.Based on the scores of patients as ''much better'' and ''very much better'' on the PGI-I scale, satisfaction rate was 93% at 6th month follow up visit.

CONCLUSIONS: Vaginal dilatation surgery with absorbable oxidized regenerated cellulose seems to be a safe and effective procedure with positive anatomical and functional results. However, many comparative studies are needed to fully the efficiency and safety of this procedure.

KEYWORDS: Dyspareunia, Vaginal stenosis, Vagina

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INTRODUCTION

A/The Vagina can be over narrowed due to pelvic organ prolapse surgeries, post-episiotomy scarring, excessive subepithelial plication or trimming of the vaginal mucosa at the time of posterior colporrhaphy procedures (1). Organic lesions like focal vestibulitis, lichen sclerosis, lichen planus, bowenoid papulosis, Bowen's disease or previous history of posterior vaginal wall prolapse repair with mesh and history of pelvic radiation therapy can lead to vaginal stenosis (2, 3).

The incidence of iatrogenic vaginal stenosis is not exactly known due to unreported cases. However, any gynecologist can encounter with iatrogenic vaginal stenosis at a rate of four to six cases per year (1). Vaginal stenosis is considered as a very distressing condition that adversely affects the sexual life of couples. Although women are offered a trial of manual dilation with lubricants, the definitive treatment of iatrogenic vaginal stenosis is surgery. Z-plasty, vaginal advancement with flap, incision of ring or ridge and free skin graft are various treatment methods (1, 4, 5).

This study aims to investigate the outcomes of vaginal dilatation surgery using absorbable oxidized regenerated cellulose.

MATERIAL AND METHODS

Thirty-three women who complained of dyspareunia or apareunia due to iatrogenic vaginal stenosis were operated on at a tertiary centre from April 2014 to August 2020. All patients complained of interruption in sexual intercourse due to severe pain initiated by penile penetration. Regarding this complaint, an excessively narrowed vagina was confirmed by the measurement of genital hiatus. Genital hiatus is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

Data related to demographic characteristics, operation time, hospital stay, intraoperative and postoperative complications, side, initiation time for sexual activity and patient satisfaction were obtained from hospital records. Four patients who were lost to follow up were excluded from the study.

The same surgical team performed the vaginal dilatation operation under general anesthesia. All patients received local estrogen treatment for 4 weeks preoperatively. Patients were wrapped in sterile drapes in the dorsal lithotomy position. Antibiotic prophylaxis was provided by administering 2grams of second generation cephalosporins. A midline vertical incision was made on the perineum, from 1cm under the hymenal ring to the distal end of the posterior fourchette. In order to increase the genital hiatus length, any palpable scar tissue was incised up to transverse perineal muscle. Transverse perineal muscle was avoided to cut to prevent the disruption of perineal body structure. Absorbable oxidized regenerated cellulose (Surgicel®, Johnson & Johnson Wound Management, Ethicon Inc., Somerville, NJ, USA) was tailored to correspond to two distal free edges of mobilized perineal tissue and then laid over subcutaneous tissue of the vagina.

The corner of absorbable oxidized regenerated cellulose was primarily sutured to the perineal and vaginal epithelial layer with separate sutures of 2-0 absorbable polyglactin sutures. Bleeding control was performed with monopolar electro-coagulation. At the end of the surgery, a mold tampon made of a sponge and condom was inserted into the vagina. This mold tampon was removed 12 hours after surgery and patients were discharged from the hospital 24 hours later.

Follow up visits were undertaken 6 weeks later and 6 months later. At these follow up visits, genital hiatus length was measured. Anatomic success was defined as genital hiatus length measuring 2.5 cm to 4cm with respect to vaginal introitus (6).

Their initiation to sexual intercourse was recorded and satisfaction related to surgery was assessed at 6thmonths control examination with patients' answers of "much better" and ''very much better" on the Turkish version of the Patient's Global Impression of Improvement (PGI-I) scale. PGI-I is a validated, standard seven-item questionnaire used to assess improvement with therapy (very much better, much better, a little better, no change, a little worse, much worse and very worse)(7).

Ethical Committe

This study was approved by the Ethical Committee of Istanbul Medipol University Faculty of Medicine (AP:2019-44565788). Each patient was informed about the study design and their written informed consent was obtained.

RESULT

Demographic characteristics and operative data of 29 patients are shown in **Table 1**. No major perioperative complication was occurred except perianal hematoma emerging in one patient. This case of perianal hematoma was successfully treated by antibiotics and drainage so that she was able to start sexual activity 8 weeks later. No side effects related to the use of absorbable oxidized regenerated cellulose were reported.

Mean postoperative follow-up was 16 months ranging from 14 to 24 months. At the first follow up visit performed 6 weeks later, mean genital hiatus length(3.4 cm) was within a normal range (2.5 cm to 4 cm) in 28 patients. It was observed that absorbable oxidized regenerated cellulose was dissolved completely in all patients at the first follow up visit. Genital hiatus length measured 2.3cm in two patients who continued to complain of dyspareunia. These patients were re-examined 2 weeks later and genital hiatus measured 2.3 cm again. Thus, they underwent a second session of vaginal dilatation with the same technique four and six weeks later respectively. Both patients started sexual activity 14 weeks later.

Based on the scores of patients on the PGI-I scale assessed at the 6th-month follow up visit, 27 patients answered as "much better '' or ''very much better" after surgery. So, the overall satisfaction rate was 93%**(Table 2)**.

Table 1: Demographic and Operative Characteristics of the Patients

Characteristics	**Value** (mean±SD), n(range) or (%)
Age ,years	42.3±2.3
Body mass index, kg/m2	23.4 ±3.0
Vaginal delivery, n	1 (3.4)
Preoperative genital hiatus length, cm	4 (13)
Duration of surgery, min	2.12±2.4
Sexual activity initiation time, days	42 ±5.2
Duration of hospital stay, hours	41±2.4
Postoperative genital hiatus length, cm	3.4±2.5
Menopausal status ,n	24.6±1

SD=Standard Deviation, min:minutes, Data are presented mean +_ SD or n (%).

Table 2: Assessment of patient satisfaction by PGI-I scale

Patient impression of global improvement (PGI-I)n (%)	
1: verymuch better	21 (72.4)
2: muchbetter	6 (20.6)
3: a little better	1 (3.4)
4: noimprovement	1 (3.4)
5: a littleworse	0
6: muchworse	0
7: verymuchworse	0
Satissfaction rate *	27 (93)

*defined as "very much better" and "much better"

DISCUSSION

The main goal of perineoplasty is the reinforcement of the pelvic floor. However, perineoplasty may sometimes result in excessive elevation of the perineum and subsequent dyspareunia.

Nichols stated that posterior colporrhaphy and perineorrhaphy are separate and distinct operations. He described the perineoplasty technique which should be performed by reconstructing the perineal body with a series of horizontal mattress sutures placed in the soft tissues medial to the pubococcygeal muscles (8). Other surgeons recommended reconjugation of the bulbocavernosus muscle to the superficial transverse perineal muscle laterally and rectovaginal septum in the middle (9, 10).

Perineoplasty procedure, when performed correctly, would correct the downward angle of the vagina so that penile movement at sexual intercourse would facilitate clitoral orgasm by pushing it against the pubic bone (11). When performed inappropriately, as is the case in excessive excision of the perineum and vaginal fibromuscular tissue, excessive levatorplasty, or using inappropriate suture or graft materials, iatrogenic vaginal stenosis can occur. Thereafter, an attempt for dilatation would be inevitable. Firstly, conservative management with self dilatation is recommended (8). In case self dilatation fails, there is an ongoing debate for further treatment. Most of the literature consists of non-comparative single-center case series with poor standardization and short term follow-up. To the best of our knowledge, this is the first study to report on the utilization of absorbable oxidized regenerative cellulose for dilating iatrogenic vaginal stenosis. This medical item is commonly used to stop bleeding and prevent tissue adhesion in clinical practice (12, 13). Ab-

sorbable oxidized regenerative cellulose was successfully used to construct the vagina in congenital vaginal agenesis cases (14, 15). Sharma et al used a transverse incision at the introitus, a 10 x 4 cm space was created and a vaginal mold covered with oxidized cellulose was put in the neovagina for treatment of vaginal agenesis (14). Dornelas at all used oxidized cellulose for vaginoplasty and anatomical, functional and histological evaluation was performed with vaginal biopsy at Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome and cervicovaginal agenesis (CVA)(15). The mean follow-up time was 14 months (range, 6-24 months), and it included clinical examinations and evaluation of the Female Sexual Function Index (FSFI). Neovaginal biopsies were taken at the time of surgery and 1-12 months after surgery. The histology of the samples was evaluated to determine squamous epithelialization of the neovaginal tissue over time, and the total collagen content of the neovaginas was compared with normal control subjects (15). Oxidized regenerated cellulose (surgical) is often used for hemostasis in primary post adenoidectomy bleeding, Lung Cancer Surgery, intestinal, vascular and gynecological surgery (16, 17). Also, a surgical sutures braided with absorbable oxidized regenerated cellulose were manufactured lastly (18). Oxidized cellulose has a proven local hemostatic efficacy and antibacterial activity and is safe and inexpensive (14). Also it was shown that successful closure of a difficult vesicovaginal fistula with surgical (19). Complying with the literature, no side effects related to the use of absorbable oxidized regenerative cellulose were observed in this study. The major limitation of our study is its relatively small cohort which is only made up by of patients who had iatrogenic vaginal stenosis due to colpoperineorrhaphy procedure. The power of this study is also limited by its retrospective and single center design and the lack of a control group. In addition, there were no patients who had vaginal stenosis because of pelvic radiotherapy and organic lesions such as Lichen Sclerosus and Bowen's disease. We think that these cases will be much more challenging and this product may be ineffective as tissue disruption and the inflammatory process is higher at pelvic radiotherapy and organic lesions such as Lichen Sclerosus or Bowen's disease. Another important point is surgical dilatation of the vagina with absorbable oxidized regenerative cellulose is a much easier and lower-cost procedure compared to vulvar flap or graft procedures (20). Also, operation time and healing process appear to last longer in vulvar flap or graft procedures (20).

Iatrogenic vaginal stenosis, occurring after excessive vaginal tightening or radiotherapy, is an important health problem that any gynecologist can face. At this point, vaginal dilatation with an absorbable oxidized regenerated cellulose seems to be a safe and effective procedure. However, large scale comparative studies are required to show the efficiency and safety of this procedure.

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