RECOMMENDATIONS

RECOMMENDATIONS

1. Longer follow up of patients is recommended to assess the long term endurance of the RFVF.

2. Larger sample size is recommended for a stronger statistical correlation.

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PROTOCOL

ASSESSMENT O ROLLED FORTIFIED VAGINAL FLAP FOR STRESS URINARY INCONTINENCE IN FEMALES WITH INTRINSIC SPHINCTERIC DEFICENCY

تقييم السدلة المهبلية المقواه لاصلاح السلس البولى الاجهادى عند النساء الذين يعانون من خلل الصمام الداخلي

Protocol of a thesis submitted
to the Faculty of Medicine
University of Alexandria
In partial fulfillment of the
requirements of the degree of
Master of Genitourinary Surgery

خطة بحث مقدمة
لكلية الطب
جامعة الاسكندرية
إيفاءً جزئيا
لشروط الحصول على درجة
الماجستير فى جراحة المسالك البولية و التناسلية

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INTRODUCTION

Stress Urinary Incontinence (SUI) is defined as the symptomatic complaint of involuntary leakage of urine on effort, exertion, sneezing or coughing and the sign of involuntary urinary loss from the urethra synchronous with exertion, sneezing, or coughing.[1]

Intrinsic Sphincter Deficiency (ISD) is defined as the disorder of the urethra due to intrinsic sphincter damage in which the urethra is usually well supported but there is opening of the bladder neck and posterior urethra during straining, which has been classified as type III incontinence. On urodynamics, ISD is defined as Abdominal Leak Point Pressure (ALPP) less than or equal to 60 cm H2O and a Maximal Urethral Closure Pressure (MUCP) of less than 20 cm H_20.[2-4]

The risk factors to develop SUI are age, Caucasian or Hispanic races, obesity, smoking, chronic cough, pregnancy and childbirth, nerve injuries to the lower back and pelvic surgeries.[5,6]

Stress Urinary Incontinence (SUI) due to intrinsic sphincter deficiency (ISD) is the most challenging in anti-incontinence repair. ISD women can have successful long-term surgical outcomes after Tension free Vaginal Tape (TVT) procedures. However, clinicians should consider the possibility of TVT procedure failure in ISD women who have extremely low Valsalva Leak Point Pressure (VLPP).[7] Rezapour et al determined the following cases as high-risk factors of failure: when patients are older than 70 years, when MUCP is below 10, and when the patients have an immotile urethra.[8]

Anterior vaginal wall slings (AVWS) have been used for decades in the treatment of SUI. Initially pubovaginal slings using autologous fascia, either rectus fascia or fascia lata, were the gold standards for treatment of SUI till the nineties.[9]

In an effort to reduce the morbidity and discomfort associated with fascial harvesting, synthetic tapes placed by a retropubic or transobturator route were developed and have been applied successfully for over a decade. Tension free vaginal tape procedure may have an acceptable rate of complications such as infection, organ injuries and erosions, but they are costly.[10,11]

Recently, Trans Obturator Tape (TOT) has been used for the treatment of SUI patients along with Tension-Free Vaginal Tape (TVT), but there have been only a few reports on its outcomes for SUI with ISD. O'Connor et al categorizes a group of patients with VLPP of less than 60 cm H2O who had TOT. They reported that the success rate of the group was only 25%, because the mesh tape of TOT, which was more horizontally placed, lacked support because it wrapped a smaller part of the urethra in comparison with that by TVT.[12]

The AVWS was originally described by Raz et al in 1989. This technique uses in situ vaginal wall over the bladder neck and proximal urethra as the sling material. It avoids morbidity of autologous fascial harvesting, does not have an increased rate of infection or erosion and is available at no cost. The advantages are its simplicity, need for only a small incision, short operative time and hospital stay and reliance on healthy well vascularized in situ tissue.[13]

A modified technique for the treatment of Stress Urinary Incontinence (SUI) in females is the Tension-Free Vaginal Flap (TVF) technique was described by

Fayed et al.[14] It is based on both concepts of TVT and vaginal wall sling procedures, in order to achieve similar success rate with low costs. A vaginal wall flap based on the mid urethra was created. The flap is 4 cm wide and 2 cm long, with the distal incision slightly longer than the proximal one. Minimal dissection of the flap maintains its adequate blood supply. Four corners sutures 1/0 were taken into the flap and passed into the anterior abdominal wall using Stamey needle. Sutures of each side were tied to each other with undue tension, the knots were away from the rectus sheath by 1 cm.[14]

The main drawback of using the vaginal wall as a sling is its tendency to stretch and weaken overtime. A modification of the TVF is the Rolled Fortified Vaginal Flap (RFVF).[13] The aim of this modification is to reinforce the vaginal wall flap and prevent its laxity over time especially for ISD patients to offer them an effective and durable alternative to the successful modern tapes.[13]

AIM OF THE WORK

The aim of the study is to assess the efficacy, outcome and complications of the rolled fortified vaginal flap (RFVF) operation in the treatment of stress urinary incontinence (SUI) in females with Intrinsic Sphincter Deficiency (ISD) admitted to the Genitourinary Surgery Department at Alexandria Main University Hospital.

PATIENTS

This prospective study will be conducted on twenty female patients presenting with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) admitted to the Genitourinary Surgery Department at Alexandria Main University Hospital.

METHODS

Twenty female patients with Stress Urinary Incontinence (SUI) due to Intrinsic Sphincter Deficiency (ISD) will undergo rolled fortified vaginal flap (RFVF) procedure. Patients will be recruited from the Genitourinary Surgery Department at Alexandria Main University Hospital.

Technique of Rolled Fortified Vaginal Flap (RFVF) procedure includes fashioning a rectangular anterior vaginal wall flap then cauterization of its surface. Two diagonal rows of zero prolene sutures are taken through the flap to further fortify the vaginal flap. The two threads are passed to the suprapubic area and tied over the rectus sheath loosely. In this way no tension is applied on the flap[13]

Data will be collected through direct interviewing with the patients, clinical examination, urodynamic testing and operative findings. A specially designed questionnaire will be utilized to collect the required information.

The patients will be evaluated pre-operatively, 1 month and 6 months postoperatively. Patient evaluation will be done as follows:

- Assessment of primary outcome both subjectively and objectively:
  - Subjective evaluation by interviewing the patients and filling of The International Consultation on Incontinence Modular Questionnaire (ICIQ).[15,16]
  - Objective evaluation by using cough stress test in the sitting and standing positions with half full and full bladder. Also urodynamic filling cystometry will be done to assess VLPP.
- Assessment of secondary outcome as regards:

- Operative data time and complications. Postoperative hospital stay, pain, analgesic requirement and complications. Effect on sexual life of the patient.

An informed consent will be obtained from all cases after explaining the objectives of the study to them. They will be notified that whether they accepted or not to share in the study; nothing will be taken against them and they will have the same quality of medical care.

RESULTS

The results obtained will be tabulated and analyzed with the use of appropriate statistical methods.

DISCUSSION

The reported data will be discussed in view of achievement of the aim and will be compared to available works in the literature.

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ARABIC SUMMARY

الملخص العربي

خلل الصمام الداخلي من العوامل المهمة المسببة للسلس البولي الإجهادى. وقد أبرزت التطورات الحديثة في الدراسات الديناميكية للتبول إمكانية التشخيص الدقيق لخلل الصمام الداخلى. وقد تم التأكيد على أهميه هذا الموضوع بعد نسبة الفشل العالية من العمليات الجراحية لتصحيح السلس البولى نتيجة خلل الصمام الداخلي ونظرا لارتفاع معدل انتشار السلس البولي خاصة عند النساء، فإنه يعتبر مشكلة صحية اجتماعية هامة تؤثر على الأنشطة اليومية ونوعية الحياة ، وتؤثر هذه المشكلة على الجوانب المادية والفكرية والجنسية للشخص كما يؤثر على وضعه الاجتماعي ويقلل من جودة الحياة والثقة بالنفس.

ولهذا تم إجراء الدراسة الحالية للكشف عن أثر عملية السدلة المهبلية المقواة في علاج السلس البولي الاجهادى بسبب خلل الصمام الداخلي لتقييم الجدوى الفنية للعملية ، والتعرف على المضاعفات التي قد تنتج جراء العملية ، وتكشف عن أثر العملية على جودة حياة النساء اللاتي يعانين من السلس البولي الاجهادى ، و لتحقيق هذه الأهداف أدرجت عشرين امرأة تعاني من السلس البولي الاجهادى بسبب خلل الصمام الداخلي في دراسة مستقبلية ، ولقد خضع جميع المرضى إلى أخذ التاريخ الطبي ، والفحص السريري ، بالإضافة إلى اختبارات بعينها مثل اختبار السعال ، س اختبار تلميح، والدراسات الديناميكية للجهاز البولي ، تم تقييم جودة الحياة باستخدام النسخة العربية من المشاورة الدولية على سلس البول وحدات استبيان - سلس البول - النموذج القصير ، ولقد تم تتبع جميع النساء لمدة ٦ أشهر للكشف عن مضاعفات ما بعد الجراحة وتحديد التغيرات في جودة الحياة.

تم إجراء عملية السدلة المهبلية المقواة لجميع المرضى ، وأجريت العملية تحت التخدير الشوكي في موقف استخراج الحصاة الظهرية ، مع تركيب قسطرة البول حتى تبقى المثانة فارغة في جميع الأوقات ، وبعد ذلك تم استخدام مباعد المرجح لاظهار الأنسجة المهبلية. وتم عمل سدلة مستطيلة من جدار المهبل الأمامي، ثم تم كي سطح السدلة المهبلية ؛ وتبع ذلك وضع صفين قطرس من خيوط البرولين مقاس الصفر ، ثم تم خياطه السدلة على نفسها ، ثم علقت السدلة المهبلية من الجانبين التي يتم تمريرها في المنطقة فوق العانة عن طريق مرور إبرة ستامى من خلال شقين في البطن ، وارتبطت الغرز مع بعضها البعض.

شملت هذه الدراسة ٢٠ مريضة يشكين من السلس البولي الاجهادى بسبب خلل الصمام الداخلى. متوسط أعمارهن ٤٣.٠ ± ٨.٧ عاما. أظهرت نتائج دراسة ديناميكية التبول قبل الجراحة أن أقصى ضغط لاختبار "فالسلفا" تراوحت من ٢٠-٦٠ سم مياه بمتوسط قدره ٥٠.٠٥ ± ١١.٢ سم مياه ووسيط قدره ٥٣.٥٠ سم مياه. وكان اختبار السعال إيجابيا لجميع نساء الدراسة ، ولقد شكلت النساء اللاتي يعانين من فرط حركة مجري البول ٤٥٪ (٩ نساء) بينما لم يعاني باقي النساء (٥٥٪) من ذلك الداء.

انخفض الحد الأقصى لمعدل التدفق البولي انخفاضا طفيفا من ٢٢.٢ ± ٣.٥ إلى ٢١.٤ ± ٣.٥ بعد شهر واحد ولكن هذا الانخفاض لم يكن ذو دلالة إحصائية جوهرية ($P = 0.001$) ، حدث تسرب بولي لثلاث مرضى خاضعين للدراسة كما أوضحت الدراسة الديناميكية للتبول خلال فترة المتابعة بعد شهر و ٦ أشهر و تم اجراء تعديل للغرز الجراحية لمريضة واحدة.

لم يلاحظ أي تغيير ملموس للحد الأقصى لمعدل التدفق بدون قسطرة خلال فترة المتابعة. وأظهر الضغط الأقصى للنافصة عن انخفاض طفيف لكن لم يكن ذو دلالة إحصائية جوهرية. واستخدم هذين المؤشرين للكشف عن انسداد المسالك البولية باستخدام الرسم التخطيطي لانسداد مخرج المثانة البولية ، حيث عانت أربع نساء (٢٠٪) من إعاقة بولية خفيفة عند الشهر الأول من المتابعة ، وانخفض هذا العدد إلى اثنين فقط (١٠٪) بعد ٦ أشهر من المتابعة.

لوحظ احتباس البول العابر لدى ٢٥% من النساء بعد العلمية مباشرة (خلال الأسبوع الأول) ، في حين لم تعانى أي امرأة من مثل تلك الأعراض بعد شهر أو ٦ أشهر من المتابعة، كما ظهر التهاب المثانة فى ثلاث حالات فقط (١٥٪). ولوحظ سلس البول بين ثلاث حالات (١٥٪) على الفور بعد العمل الجراحي وحالتين (١٠٪) بعد شهر واحد من المتابعة، ولقد أجرى تعديل الغرز الجراحية لحالة واحدة فقط لتصحيح سلس البول.

وقد استخدمت المشاورة الدولية لاستبيان سلس البول النموذج القصير (ICIQ-UI) لقياس جودة الحياة قبل الجراحة ثم أعيدت بعد شهر و ٦ أشهر بعد التدخل الجراحي ، ولقد انخفض متوسط نقاط المقياس من ٧٣.٥٧ ± ١٢.٠١٥٪ (قبل الجراحة) الى ٢.٦٢±٨.٠٩% بعد ٦ أشهر من المتابعة، بما يفيد تحسن جودة حياة النساء اللاتي أجرين العملية ، كما لوحظ تسريب بولي لمرة واحد أسبوعيا أثناء ممارسة النشاط البدني أو الرياضي لدى ١٠٪ فقط بعد شهر من المتابعة بينما استمر نفس معدل التسرب بعد ستة أشهر من المتابعة.

في نهاية هذه الدراسة فإننا استنتجنا أن عملية السدلة المهبلية المقواة هي تقنية آمنة وفعالة في علاج الإناث الذين يشكون من السلس البولي الاجهادى بسبب خلل الصمام الداخلي مع إيواء مضاعفات قليله خلال فترة متابعة قصيرة مكونه من ٦ أشهر.

الملخص العربى

لجنة الإشراف

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تقييم السدلة المهبلية المقواه لاصلاح السلس البولى الاجهادى عند النساء الذين يعانون من خلل الصمام الداخلي

مقدمة من

هيثم محمد إبراهيم كامل
بكالوريوس الطب والجراحة - جامعة الإسكندرية، ٢٠٠٨

للحصول على درجة

الماجستير

فى

جراحة المسالك البولية والتناسلية

لجنة المناقشة والحكم على الرسالة	**موافقون**
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رسالة

مقدمة لكلية الطب – جامعة الإسكندرية

إستيفاء للدراسات المقررة للحصول على درجة

الماجستير

فى

جراحة المسالك البولية والتناسلية

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