ACTAS UROLÓGICAS ESPAÑOLAS

www.elsevier.es/actasuro

Original – Voiding dysfunction

Three-years results of transvaginal cystocele repair with polypropylene mesh using a tension-free technique

Y. El Harrech, A. Ameur, A. Janane, K. Moufide, M. Ghadouane and M. Abbar*

Servicio de Urología, Hospital Militar Mohammed V, Rabat, Morocco

ARTICLE INFORMATION

Article history:
Received on 25 March 2009
Accepted on 23 July 2009

Keywords:
Cystocele
Synthetic mesh
Transvaginal approach
Tension free

A B S T R A C T

Objectives: To evaluate the long term efficacy and safety of transvaginal implantation of a non-resorbable synthetic prosthesis (Gynemesh®) for the treatment of cystocele using transvaginal free tension technique.

Materials and methods: Prospective study of patients that have been submitted to correction of cystocele between April 2004 and July 2007. A prolene mesh was cut to an appropriate size to cover the whole cystocele leaving two tabs on each side. The two tabs of the mesh were then placed in paravaginal spaces, tension free, without stitches. Mesh was used in 31 patients. All patients had a symptomatic cystocele ≥ 2 according to Baden-Walker halfway classification. Patients were reviewed initially at 1and 3 month and then every 6 months.

Results: The mean age of the patients was 58 years (range: 47–70 years). Mean parity was 5.8 (range 1-11), and mean weight was 75 kg (range 60-82Kg). All women were postmenopausal. The operation was combined with vaginal hysterectomy in 2 patients, Posterior colporraphy in 2 patients, Perineorrhaphy in 1 patient, Sacrospinous fixation in 2 patients, transobturator tape for stress urinary incontinence in 7 women. Average time of surgery was 23 minutes for cystocele. There were no major complications, such as trauma to the bladder, urethra, bowels, or large vessels in the patient group treated. There was no immediate postoperative complications (up to 7 days) recorded. No hematoma or infection was observed in the operative area. Mesh erosion was detected in one patient. It was treated by excision of the eroded part of the mesh.

Mean follow-up was 36.4 months (18 to 52 months). Using our definition of success based on both anatomic and functional outcomes, the overall cure rate was 74.19% (asymptomatic with no or grade 1 cystocele). The improvement rate (asymptomatic with a grade 2 cystocele) was 19.35% and the overall failure rate (symptomatic or with a grade 3 or 4 cystocele) was only 6.4% (2 women).

Discussion and conclusions: The interposition of a sub-vesical transversal tension-free polypropylene mesh by the vaginal route seems to be an excellent procedure in the definitive surgical treatment of anterior vaginalwall prolapse. This procedure is simple, mini-invasive, reproducible and efficient with low morbidity and good tolerance. The results seem to be stable after three years of follow up.

*Author for correspondence.
E-mail: ylg79@hotmail.com (Y. El Harrech).

Resultados a los tres años de la reparación de un cistocele transvaginal con malla de propileno usando una técnica sin tensión

Palabras clave:
Cistocele
Malla sintética
Abordaje transvaginal
Sin tensión

R E S U M E N

Objetivos: Evaluar la eficacia y la seguridad a largo plazo de la implantación transvaginal de una prótesis sintética no absorbible (Gynemesh®) para el tratamiento del cistocele mediante una técnica vaginal sin tensión.

Materiales y métodos: Estudio prospectivo de pacientes sometidas a corrección de un cistocele entre abril de 2004 y julio de 2007. Se cortaba una malla de propileno al tamaño adecuado para cubrir todo el cistocele, dejando dos lengüetas a cada lado. Las dos lengüetas de la malla se colocaban después en los espacios paravaginales sin tensión ni suturas. Se utilizó la malla en 31 pacientes. Todas ellas tenían un cistocele sintomático de grado ≥ 2, según la clasificación del punto medio de Baden-Walker. Se les revisaba inicialmente al cabo de uno y tres meses, y después cada 6 meses.

Resultados: La edad media de las pacientes era de 58 años (límites: 47-70 años). La paridad media era de 5,8 (límites: 1-11) y el peso medio de 75 kg (límites: 60-82 kg). Todas las mujeres eran posmenopáusicas. La operación se combinó con histerectomía vaginal en dos pacientes, colporrafia posterior en dos, perineorrafia en una, fijación sacroespinosa en dos y cinta transobturadora para incontinencia urinaria de esfuerzo en 7 mujeres. La duración media de la cirugía del cistocele fue de 23 minutos. En el grupo de pacientes tratadas no hubo complicaciones importantes como traumatismo de vejiga, uretra, intestino o grandes vasos. No se registraron complicaciones en el postoperatorio inmediato (hasta los 7 días). No se observó hematoma ni infección en la zona quirúrgica. En una paciente se detectó erosión de la malla, que se trató mediante extirpación de la parte erosionada de la misma.

El seguimiento medio fue de 36,4 meses (de 18 a 52). Según nuestra definición de éxito, basada en los resultados anatómico y funcional, la tasa de curación global fue del 74,19% (asintomática sin cistocele o con cistocele de grado 1). La tasa de pacientes con mejoría (asintomáticas con cistocele de grado 2) fue del 19,35% y la de fracasos globales (sintomáticas o con cistocele de grado 3 o 4) de sólo el 6,4% (dos mujeres).

Comentario y conclusiones: La interposición de una malla de polipropileno subvesical transversal, sin tensión, por la vía vaginal, parece ser un procedimiento excelente para el tratamiento quirúrgico definitivo del prolapso de la pared vaginal anterior. Se trata de un procedimiento simple, poco invasivo, reproducible y eficiente con baja morbilidad y bien tolerado. Los resultados parecen mantenerse estables a los tres años de seguimiento.

Introduction

Pelvic organ prolapse is caused by a defect in pelvic floor support, including active support by the trapezius muscles of the anus and passive support provided by the endopelvic fascia.

Despite improved understanding of the pathophysiology of pelvic prolapse, its surgical treatment is one of the most controversial problems in reconstructive surgery of the pelvis, and although various surgical techniques continue to be proposed, success rates are still unsatisfactory.

Traditional prolapse repairs using the patient's native supporting tissue are often associated with high failure rates of up to 58%[1]. To improve the success of anterior compartment repair, various types of prostheses have been used. The central argument for the use of vaginal mesh has always been to reduce surgical anatomical failures and noncomparative studies suggest that the use of nonabsorbable synthetic mesh may reduce failure rates to 4-20%[2,3].

Therefore, the objective of our study was to determine the safety and efficacy of transvaginal cystocele repair with a macroporous monofilament polypropylene mesh using a tension-free technique.

Materials and methods

This prospective study was conducted in the Department of Urology of Rabat Military Hospital (Morocco) on patients submitted to cystocele repair between April 2004 and July 2007. Classification of cystoceles was based on the Bridge-Walker halfway classification. Eligible patients were women with symptomatic cystocele ≥ grade 2. Patients with asymptomatic prolapse were excluded.

Gynemesh* Gynecare nonabsorbable synthetic mesh (Ethicon, Johnson & Johnson, France) was placed using a transvaginal tension-free technique as reinforcement for correction of the cystocele.

Figure 1 – Polypropylene mesh with a central oval body and two lateral wings.

Table 1 – Patient characteristics (n = 31)

Characteristics	Value
Age	58 years (range 47-70 years)
Mean weight	75 kg (range 60-82 kg)
Mean parity	5.8 (range 1-11)
No. of menopausal women	31 (100%)
No. of women with HRT	2 (6.4%)
No. of women with prior cystocele repair	1 (3.2%)

HRT: hormone replacement therapy.

Surgical procedure

All procedures were performed with patients under spinal anesthesia and in the dorsal lithotomy position.

A mixture of 1% xylocaine with epinephrine was injected at the site of the incision. An incision was made in the anterior vaginal wall 1 cm below the urethra and the bladder was dissected off the vagina by bloody dissection with a pair of scissors. A deep and narrow paravaginal canal was created by blunt dissection with the index finger.

A propylene mesh was cut to an adequate size to cover the whole cystocele, leaving two tabs on each side (fig. 1). The two tabs of the mesh were then placed in the paravaginal spaces, tension-free, without sutures. Subsequently, the central part of the mesh was sutured with 2-0 Vicryl ITM (braided absorbable polyglactin 910 suture, manufactured by Ethicon, Johnson & Johnson) at the 4 corners to the perivesical tissues for anchoring.

Hemostasis was assessed again, a minimum clipping of the vaginal skin was made and the skin was sutured using continuous stitches of 2-0 Vicryl ITM suture (braided absorbable polyglactin 910 suture, manufactured by Ethicon, Johnson & Johnson), followed by placement of a vaginal plug in all cases.

Any coexisting significant rectocele or uterovaginal or vaginal vault prolapse was repaired at the time of surgery.

A single intravenous dose of 2 g of cefazolin was administered during surgery as antibiotic prophylaxis.

Postoperative analgesia consisted of 100 mg of ketoprofen and 1 g of acetaminophen administered intravenously every 8 hours on the first day only. On Day 2, oral analgesia with acetaminophen was used.

The vaginal plug and urethral catheter were removed on the first and second postoperative days, respectively.

A database was created for prospective follow-up.

The mesh supplier was not informed of conduct of the study in order to maintain this experience in our patients free from the contributions of mesh manufacturers.

After surgery, patients were initially reviewed at 1 and 3 months and then every 6 months. The procedure was considered a success in women who were asymptomatic with grade 1 cystocele (descent halfway to the hymen) or no cystocele. Women were considered to have improved if they remained asymptomatic with a grade 2 cystocele (descent to the hymen).

Surgery was considered to have failed in women who were symptomatic or with a grade 3 or 4 cystocele (descent halfway past the hymen or maximum possible descent, respectively) in the follow-up.

The study was approved by our hospital's ethics committee and all patients were informed about surgical procedure they would be submitted to and its potential complications.

Results

From April 2004 to July 2007, we inserted 31 tension-free anterior vaginal meshes. The mean age of the patients was 58 years (range: 47-70 years).

Demographic and clinical characteristics are presented in Table 1.

Mean parity was 5.8 (range: 1-11) and mean weight was 75 kg (range: 60-82 kg). All women were postmenopausal. Two patients had undergone prior hysterectomy and surgery for pelvic organ prolapse.

Preoperatively, 12 patients (41.9%) had grade 2 prolapse, 17 (54.8%) had grade 3 prolapse and two (3.3%) had grade 4 prolapse of the anterior wall.

The operation was combined with vaginal hysterectomy in 2 patients, posterior colporrhaphy in 2 patients, perineorrhaphy in 1 patient, and sacrospinous fixation in 2 patients.

Seven women were diagnosed with stress urinary incontinence and were submitted to a concomitant antiincontinence procedure (TOT technique) (Table 2).

Mean duration of cystocele surgery was 23 minutes.

There were no major complications, such as trauma to the bladder, urethra, bowels, or large vessels, in the patient group treated.

No immediate postoperative complications (up to 7 days) were recorded. No hematoma or infection was observed in the operative area.

There were also no TOT related complications in 7 cases in which this technique was used, nor any related to the anesthesia used.

No additional drug therapy to that originally planned was required to control postoperative pain.

All patients left the hospital at 72 hours of surgery.

To date, after a follow-up of 18 to 52 months, the overall failure rate is 6.4% (two women), using our definition for determining success. Recurrence of grade 3 central cystocele occurred at 2 and 28 months. During the vaginal examination of one of these women, a fold in the mesh was identified (fig. 2). These 2 patients were operated on again using the TVM technique.

Of the 29 women with satisfactory cystocele repair, 23 were healed (asymptomatic with no or grade 1 cystocele) and 6 had improved results (asymptomatic with grade 2 cystocele).

In all patients with a heavy or bulging sensation before surgery these symptoms disappeared. No patient had dyspareunia or vaginal discharge again after the procedure. Patients who had sexual relations before surgery were able to continue them without changes after it.

Mesh erosion was detected in one patient. It was treated by excision of the eroded part of the mesh. To date, this women has not had any recurrent mesh exposure in the follow-up.

Table 2 – Operations performed in women (n = 31)

Operations performed	No. (%)
Anterior repair using mesh	31 (100.0)
Posterior repair	2 (6.4)
Vaginal hysterectomy	2 (6.4)
Transobturator tape	7 (22.5)
Richter	2 (6.4)
Perineorrhaphy	1 (3.2)

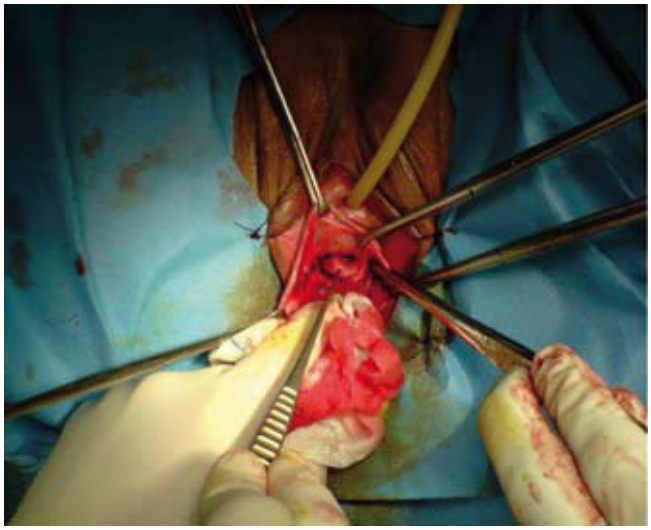

Figure 2 – Identification of a fold in the mesh after recurrence of a cystocele.

Discussion

In the last century, numerous surgical procedures were proposed to correct all types of anterior vaginal wall defects (central, paravaginal and combined) using an abdominal or vaginal approach. Despite improved knowledge of pelvic anatomy and organ function and progress in surgical techniques, the long-term success rate is still variable.

The ideal method for surgical reconstruction of cystocele should include repair of bladder herniation, correction of coexisting stress urinary incontinence without causing obstruction, and retention or improvement of vaginal depth and axis. However, relocation of the bladder base may cause weakening of posterior and lateral pelvic support. Pubocervical fasciae and other ligaments may be damaged by prior surgery, complicated deliveries, or progressive connective tissue disease, or may be naturally weak.

Attempts to use these anatomical tissues as surgical support may cause relapse or occurrence of a new herniation. With the different surgical procedures for anterior vaginal prolapse, recurrence rates of 3%[4] to 20%[5] have been reported after simple anterior colporrhaphy, from 22%[6] to 92%[7] if anterior colporrhaphy is combined with other procedures (sacrospinous ligament suspension), from 2%[8] to 59%[9] after 4-corner suspension and from 5%[10] to 50%[11] after paravaginal repair. The use of mesh is attractive because it avoids the major risk of dependence on the ligaments and fasciae that were responsible for previous prolapse due to an intrinsic or acquired deficiency.

Based on these concepts, some authors concluded that correct vaginal reconstruction is best accomplished with techniques that are not based only on the patient's native tissue for support, and that this is often achieved with substitution by synthetic mesh or tissue graft[12].

A tension-free mesh placed against the bladder wall supports the viscera only at times of increased intraabdominal pressure and has been stated to provides safe, long-lasting and constant plane of support to the bladder base, neck and lateral wall[13].

Our technique did not cause perioperative complications. There were no blood transfusions, bladder or rectal wounds or infections. Thus, the complication rate was similar or lower than that reported in other studies where a tension-free technique was used[14,15]. A multivariate analysis showed that prior hysterectomy increases the risk of bleeding or bladder and rectal wounds by 3[16]. These complications are more common when dissection is difficult and are not directly attributable to the prosthesis itself.

Our study has a number of limitations, such as the small number of patients and the lack of a control group. Therefore, it is not indicated whether use of a graft improves outcomes compared with a conventional cystocele repair without a graft.

Nevertheless, this prospective cohort study shows that surgery with transvaginal tension-free mesh for pelvic organ prolapse is accompanied by satisfactory subjective and objective clinical results. Using our definition of success, based on both anatomical and functional results, the overall cure rate was 74.19% (asymptomatic with no or grade 1 cystocele), with persistence of pelvic organ support for 18 to 52 months of follow-up. The improvement rate (asymptomatic a

grade 2 cystocele) was 19,35%, and the overall failure rate was only 6.4% (2 women).

Our cure rates are higher than those previously reported with traditional anterior repair[1,17].

Several recent studies reported excellent results and low erosion rates after transvaginal implantation of a polypropylene mesh for correction of anterior vaginal wall prolapse[18-21]. Mesh erosion rates ranged from 0% to 6.9%, but not all these patients required surgery. Hoenil et al[18] and Deffieux et al[22] used tension-free Gynemesh for transvaginal repair of cystocele. In the first study, no mesh erosion was found[18]. Deffieux et al[22] reported vaginal erosions in 20% of patients, erosion rates with use of Gynemesh and Gynemesh-soft did not differ significantly. The high erosion rates could be explained by vertical vaginal incision during the surgical procedure and total hysterectomy. Age over 70 years was identified as an independent predictor factor for vaginal erosions. Whenever possible, total hysterectomy and vertical vaginal incision should be avoided. At 6 months of the procedure, the anatomical cure rate was 95%.

Natale et al[23] described a "tension-free" technique for the mesh placement following a prior colporrhaphy in women with recurrent cystocele. A double-wing shaped polypropylene mesh was placed between the pubocervical fascia and the vaginal wall without sutures. At18 months of follow-up of 138 women, a recurrence rate of 2.2% was found.

In conclusion, despite the lack of well-designed prospective randomized studies, there is growing evidence suggesting that the synthetic meshes placed in the vagina have a place in cystocele repair.

In our study, surgical correction of medium or high grade anterior vaginal wall prolapse using a polypropylene mesh applied with a tension-free technique was a safe and effective method. Our long-term follow-up showed good anatomical and functional correction, no negative impact on anorectal function, and a low intra- or perioperative complications rate.

Conclusion

Transvaginal cystocele repair using a tension-free polypropylene mesh seems to be a good approach. The technique is simple, safe and easy to perform, and is associated with low rates of failure and morbidity.

REFERENCES

1. Whiteside JL, Weber AM, Meyn LA, Walters MD. Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol. 2004;191:1533-8.
2. Hinoul P, Ombelet WU, Burger MP, Roovers JP. A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh kit (Prolift anterior) for symptomatic cystocele repair. J Minim Invasive Gynecol. 2008;15:615-20.
3. Letouzey V, de Tayrac R, Deffieux X, Fernández H. Long-term results after trans-vaginal cystocele repair using tension-free polypropylene mesh. J Minim Invasive Gynecol. 2008; 15:S28.
4. Porges RF, Smilen SW. Long-term analysis of the surgical management of pelvic support defects. Am J Obstet Gynecol. 1994;171(6):1518-26.
5. Flood CG, Drutz HP, Waja L. Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles. Int Urogynecol J Pelvic Floor Dysfunct. 1998;9(4):200-4.
6. Morley GW, DeLancey JO. Sacrospinous ligament fixation for eversion of the vagina. Am J Obstet Gynecol. 1988;158(4):872-81.
7. Holley RL, Varner RE, Gleason BP, Apffel LA, Scott S. Recurrent pelvic support defects after sacrospinous ligament fixation for vaginal vault prolapse. J Am Coll Surg. 1995;180(4):444-8.
8. Raz S, Klutke CG, Golomb J. Four-corner bladder and urethral suspension for moderate cystocele. J Urol. 1989;142(3):712-5.
9. Miyazaki FS, Miyazaki DW. Raz four-corner suspension for severe cystocele: Poor results. Int Urol. 1994;5:94-7.
10. Richardson AC, Edmonds PB, Williams NL. Treatment of stress urinary incontinence due to paravaginal fascial defect. Obstet Gynecol. 1981;57(3):357-62.
11. Benson JT. Female pelvic floor disorders. New York: Norton; 1992.
12. Barber MD, Visco AG, Weidner AC, Amundsen CL, Bump RC. Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse. Am J Obstet Gynecol. 2000;183(6):1402-10.
13. Migliari R, Usai E. Treatment results using a mixed fiber mesh in patients with grade IV cystocele. J Urol. 1999;161(4):1255-8.
14. Sola V, Pardo J, Ricci P, Guiloff E. Tension free monofilament macropore polypropylene mesh (Gynemesh PS) in female genital prolapse repair. Int Braz J Urol. 2006;32(4):410-4.
15. Cervigni M, Natale F, La Penna C, Panei M, Mako A. Transvaginal cystocele repair with polypropylene mesh using a tension-free technique. Int Urogynecol J Pelvic Floor Dysfunct. 2008;19(4):489-96.
16. Caquant F, Collinet P, Debodinance P, Berrocal J, Garbin O, Rosenthal C, et al. Safety of Trans Vaginal Mesh procedure: retrospective study of 684 patients. J Obstet Gynaecol Res. 2008;34(4):449-56.
17. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol. 2008;111(4):891-8.
18. Jo H, Kim JW, Park NH, Kang SB, Lee HP, Song YS. Efficacy and outcome of anterior vaginal wall repair using polypropylene mesh (Gynemesh). J Obstet Gynaecol Res. 2007;33(5):700-4.
19. Amrute KV, Eisenberg ER, Rastinehad AR, Kushner L, Badlani GH. Analysis of outcomes of single polypropylene mesh in total pelvic floor reconstruction. Neurourol Urodyn. 2007;26(1):53-8.
20. Gauruder-Burmester A, Koutouzidou P, Rohne J, Gronewold M, Tunn R. Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(9):1059-64.
21. Fatton B, Amblard J, Debodinance P, Cosson M, Jacquetin B. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)--a case series multicentric study. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(7):743-52.
22. Deffieux X, de Tayrac R, Huel C, Bottero J, Gervaise A, Bonnet K, et al. Vaginal mesh erosion after transvaginal

repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(1): 73-9.

23. Natale F, Marziali S, Cervigni M. Tension-free cystocele repair (TCR): long-term follow-up. Proceedings of the 25th annual meeting of the International Urogynecological Association; 2000. p. 22-5.