Total Prolift System surgery for treatment posthysterectomy vaginal vault prolapse – do we treat both anatomy and function?

Total Prolift System w leczeniu chirurgicznym wypadania kikuta pochwy po histerektomii – czy korekta anatomiczna likwiduje także zaburzenia czynnościowe?

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Summary

Objectives: *To assess clinical efficacy of Total Prolift System® surgery kit in the treatment of post hysterectomy vaginal vault prolapse.*

Material and methods: *Study group consisted of 27 women (mean age 60.3±10.3 years) who between February 2006 and September 2007 underwent vaginal cuff prolapse surgery with Total Prolift System®. Nineteen patients had vaginal cuff prolapse POP-Q stage IV and 8 patients – POP-Q stage III with subjective feeling of prolapse. Seventeen patients were sexually active and among them twelve suffered from dyspareunia. Three patients had stress urinary incontinence and four OAB symptoms. Bladder emptying difficulty were present in seven and chronic constipation in four patients.*

Results: *Twenty one patients (77.8%) were available for follow up visits after 12 months. Only 3 out of 21 patients had recurrence of cystocoele but to a much less extent that (POP-Q stage II). This gives an efficacy of 85.7% in terms of anatomical restoration. SUI de novo occurred in two patients and OAB symptoms intensified in three women (in one case symptoms markedly decreased). Out of twenty one patients available on follow up visits thirteen (61.9%) were sexually active. Four women complained about dyspareunia, whereas women who complained for sexual dysfunction before operation were cured. Three patients were not completely satisfied with the effect of surgery due to occasional but severe pelvic pain causing difficulty with walking and moving.*

Conclusions: *Gynecare Total Prolift System® surgical kit enables simple and highly effective treatment of the vaginal vault prolapse, however there are some discrepancies between anatomical and functional results.*

Key words: **vaginal prolapse** / **Total Prolift System®** / **surgery** /

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Otrzymano: **25.10.2008**
Zaakceptowano do druku: **25.11.2008**

Ginekol Pol. 2008, 79, 835-839

Streszczenie

Cel pracy: *Ocena klinicznej efektywności systemu Total Prolift System® w leczeniu wypadania kikuta pochwy.*

Materiał i metodyka: *Grupę badaną stanowiło 27 kobiet (średnia wieku 60,3±10,3 lat) u których pomiędzy lutym 2006 a wrześniem 2007 wykonano operacyjną korekcję wypadania kikuta pochwy stosując Total Prolift System®. U 19 pacjentek wypadanie było kompletne (POP-Q IV), zaś u 8 kobiet stwierdzono stopień III. Wszystkie operowane miały subiektywne objawy związane z wypadaniem. Spośród 17 aktywnych seksualnie kobiet aż 12 uskarżało się na dyspareunię. Dodatkowo u 3 stwierdzono WNM, a u 4 operowanych objawy OAB. U 7 kobiet występowały istotne problemy z opróżnianiem pęcherza, a chroniczne zaparcia stwierdzono u 4.*

Wyniki: *Dwadzieścia jeden kobiet (77,8%) zgłosiło się do kontroli po 12 miesiącach. Tylko u 3 stwierdzono nawrót cystocoele ale w znacznie mniejszym stopniu zaawansowania (POP-Q II). Pełną korektę anatomiczną defektu odnotowano u 18 kobiet (85,7%). WNM de novo wystąpiło u 2 pacjentek, a objawy OAB nasiliły się u 3 (w 1 przypadku objawy zmniejszyły się). Spośród 13 pacjentek (61,9%) aktywnych seksualnie u 4 wystąpiła de novo dyspareunia, ale u wszystkich ankietowanych, które miały problemy z bolesnym współżyciem przed operacją objawy ustąpiły. Trzy pacjentki nie były kompletnie usatysfakcjonowane z przeprowadzonego leczenia z powodu okresowych dolegliwości bólowych występujących przy chodzeniu.*

Wnioski: *Gynecare Total Prolift System® pozwala na skuteczną anatomiczną korekcję wypadania kikuta pochwy, ale nie likwiduje wszystkich objawów czynnościowych występujących u pacjentek z zaburzeniami statyki dna miednicy.*

Słowa kluczowe: **wypadanie pochwy** / **korekcja chirurgiczna** / / **Total Prolift System®** /

Pelvic Organ Prolapse (POP) represents a significant health as well as economical problem worldwide and may have a deleterious impact on a woman's quality of life. It is estimated that 25% of women older than 60 years suffer from some degree of POP, and more than 300,000 operations for Pelvic Organ Prolapse are performed annually in the USA only. The incidence of prolapse and incontinence surgery was reported in a retrospective cohort study [1, 2].

In another study by Olsen et al. lifetime risk of undergoing at least one such surgery was estimated to be as high as 11.1%, and in two thirds of such cases the indication for surgery was advanced degree of POP. However the most discouraging finding presented in this study was that one third of the women who underwent surgery needed repeat surgery due to recurrence of preoperative symptoms [3]. There is no doubt that reasons leading to POP are multifactorial, but main underlying condition is weakness of the pelvic support, including musculature, ligaments, and fascia. There is a common believe that in adults, the condition usually results from obstetrical trauma and lacerations sustained during labour and delivery, although genetical background is also considered [4, 5].

Weakening of the vaginal vault and of the suspending ligaments causes prolapse of the uterus (uterocele), or - in patients after removal of the uterus - it causes prolapse of the vaginal vault itself. In the worst cases, the entire vagina and surrounding organs (urinary bladder and rectum) protrude through the vaginal opening causing significant discomfort to patients as it is often associated with urinary incontinence, voiding difficulty culminating in urinary retention, constipation, local discomfort, and discomfort during sexual intercourse, etc. [6, 7].

As the hysterectomy itself either abdominal or vaginal is a risk factor for POP suspension of the vaginal apex to the uterosacral ligaments (McCall culdoplasty) or to the sacrospinous ligaments at the time of vaginal hysterectomy is the mainstay for prevention of post hysterectomy vaginal vault prolapse [8]. Presently, surgery is the only effective treatment for POP and can be performed by an abdominal or vaginal approach. The vaginal approach, while less invasive, is less efficient and still demands significant surgical skills as well as regional or general anesthesia and – in the majority of cases – hospitalization of at least 1-3 days [9].

During last ten years, many new, potentially more effective, treatments are being developed mainly based on introduction artificial polypropylene as well as xenogenic prostheses in order to reinforce connective tissue support of female pelvic organs [10]. Moreover this new type of surgery, besides being less invasive, pays much more attention not only on anatomical but also functional outcome of the procedure especially in terms of bladder and bowel functions as well as vaginal coital capacity.

Aim

The aims of this present study were to evaluate safety and performance of Total Prolift System® surgical kit used to treat a complete vaginal cuff prolapse (POP-Q IV) among patients who previously underwent total hysterectomy.

An interim analysis of twenty seven patients who underwent this minimally-invasive surgical procedure for vaginal vault prolapse is reported.

Table I. Functional outcome of Total Prolift System® surgery due to vaginal vault prolapse.

SYMPTOMS	BEFORE SURGERY		AFTER SURERY		*p* value
	No of patients	%	No of patients	%	
Urinary incontinence	**3**	**11.1%**	**5**	**23.8%**	0.43
Overactive bladder symptoms	**4**	**14.8 %**	**3**	**14.3%**	0.96
Dyspareunia	**12**	**44.4%**	**4**	**19.0%**	0.06
Difficulty in bladder emptying	**7**	**25.9%**	**0**	**0**	**0.012**
Constipation	**4**	**14.8%**	**0**	**0**	0.065
Pelvic pain	**0**	**0%**	**3**	**14.3%**	**0.043**
Subjective prolapse feeling	**27**	**100%**	**3**	**14.3%**	**<0.0001**

Materials and methods

The study was conducted on a group of 27 women who underwent vaginal cuff prolapse surgery with Total Prolift System® in Our Department between February 2006 and September 2007. During this period we performed 290 Prolift surgeries including anterior and posterior vaginal wall repair, so patients with complete vaginal cuff prolapse accounted for 9.3% of all women operated with this technique. Before surgery patients were classified according to Pelvic Organ Prolapse Quantification. Nineteen patients had vaginal cuff prolapse POP-Q stage IV and 8 patient had both cystocoele – POP-Q stage III and rectocoele – POP-Q stage II. Mean age at the time of surgery was 60.3±10.3 years (mean ±SD). All women were after vaginal deliveries and mean parity was 2.3±1.0 (mean ±SD). Eight patients in the past underwent vaginal hysterectomy while nineteen patients had previously total abdominal hysterectomy with or without bilateral salpingoophorectomy. Three patients had additional Burch colposuspension performed during previous procedure. Three other patients underwent colporrhaphy before the hysterectomy. Average time of Total Prolift System® surgery was 67±10min. (mean ±SD). The only intraoperative complication was bladder perforation which was successfully sutured and patient was catheterized for 6 days after the surgery. Before Total Prolift System® surgery seventeen patients were sexually active, while ten patients were not due to other causes than pelvic organ prolapse. Among the seventeen sexually active patients twelve suffered from dyspareunia before surgery. Three patients suffered from stress urinary incontinence and four from overactive bladder symptoms before surgery. Additionally seven patients had difficulty in bladder emptying and four complained for chronic constipation. All of them had a subjective feeling of prolapse. Twenty one patients (77.8%) were available for follow up visits after 6 and 12 months. During follow up visits patients were gynecologicaly examined and checked for pelvic static according to POP-Q scale. Additionally cough test was performed with bladder filled with 250ml of saline in order to check continency.

Uroflowmetry and ultrasonography was used to check the bladder outflow and post-void residual. Fisher exact test was used to evaluate the outcome of surgery and p value <0.05 was considered as statistically significant.

Results

After twelve months only 3 out of 21 patients had recurrence of cystocoele but to a much less extent that before primary repair (POP-Q stage II A). It should be mentioned that these three patients were blue collar workers. In the remaining 18 women from our study group the POP-Q stage after 6 and 12 months of follow up was 0 in 13 and stage I in 5 patients. This gives us an efficacy of 85.7% in terms of anatomical restoration, however it should be stressed that during the observation time there was no real recurrence of vaginal vault prolapse (we considered these 3 patients with stage IIA prolapse of anterior vaginal wall as recurrence of POP). Mean vaginal length as measured after twelve months was 8cm (VC = - 8±1.0cm). We observed two mesh erosions in the apex of the vaginal vault on second follow up visit – after twelve months. The eroded mesh fragments were excised and vagina was sutured again without necessity for removing the whole mesh. Stress urinary incontinence *de novo* occurred in two patients and overactive bladder symptoms intensified in three women but in one case symptoms markedly decreased.

Out of twenty one patients available on follow up visits thirteen (61.9%) were sexually active. Four women complained about dyspareunia, however this was found after the operation whereas women who complained for sexual dysfunction before operation were cured. None of patients had problems with constipation and defecation after surgery as confirmed by Subjective Bowel Function Questionnaire. We did not observed significant outflow obstruction and post-void residual on follow up visits. Three patients were not completely satisfied with the effect of surgery due to occasional but severe pelvic pain causing difficulty with walking and moving.

Discussion

Besides all prophylactic measures performed at the time of hysterectomy which include routine reattachement of the vaginal vault to the cardinal-uterosacral ligament complex, routine use of culdoplasty sutures and cul-de-sac obliteration or enterocele excision after removal of the uterus, post-hysterectomy vaginal vault prolapse still remains a common disorder (between 0.5% to 1.8% of all hysterectomized patients and may increase to 11.6% in women who have undergone hysterectomy for the indication of uterovaginal prolapse) [11].

Additional risk factors for this condition include vaginal deliveries and obesity, although genetic predisposition leading to reduced connective tissue and muscle strength may also play a role. The high recurrence rate of pelvic organ prolapse (POP) of up to 30% after classical pelvic reconstructive surgery makes a more refined surgery imperative, as well as calls for either biological or synthetic prostheses as adjuvant treatment [12]. Surgical correction of this disorder can be performed through either the abdominal or transvaginal approaches [8]. Nowadays, the use of surgical mesh in pelvic floor surgery has become increasingly popular due to the high incidence of recurrence with primary repairs and no surrogate material. Despite the lack of various ideal characteristics, the type I monofilament, macroporous polypropylene, has been suggested to have the lowest incidence of infection and erosion among the nonabsorbable prostheses [10, 12].

However the increasing variety of available materials and techniques, combined with a lack of well conducted clinical trials, make the choice of repair to use difficult. Innumerable techniques have been described for vaginal vault prolapse and enterocele repair including abdominal (open, laparoscopic, and robotic) and vaginal techniques [8]. Recently several transvaginal minimal access techniques, utilizing synthetic or biological adjuvant grafts for vaginal vault suspension, have been introduced into clinical reality [13]. These techniques have been associated with high success rates in terms of anatomical reconstruction albeit substantial graft complications such as erosion, contraction and dyspareunia. The Gynecare Total Prolift System® for pelvic floor repair comprises a synthetic meshes placed via a transvaginal, transobturator and ischiorectal approach [14]. The biggest up to day published retrospective multicentered study evaluating clinical efficacy of Prolift system comprised 684 patients who underwent surgery at seven French centers between October 2002 and December 2004. All patients had a genital prolapse ≥3 according to ICS classification. In peri-surgical complications, (2%) were five bladder wounds (0.7%), one rectal wound (0.15%) and seven hemorrhages greater that 200mL (1%). Among early post-surgical complications (during the first month after surgery) (2.8%) were two pelvic abscesses (0.29%), 13 pelvic hematomas (1.9%), one pelvic cellulitis (0.15%), two vesicovaginal fistulas and one rectovaginal fistula (0.15%). Among late post-surgical complications (33.6%) there were 77 granulomas or prosthetic expositions (11.3% [6.7% in the vaginal anterior wall, 2.1% in the vaginal posterior wall and 4.8% in the fornix]), 80 prosthetic retractions (11.7%), 36 relapse of prolapse (6.9%) and 37 SUI *de novo* (5.4%).

Multivaried analysis shows that previous history of hysterectomy or placing of an isolated anterior prosthesis increase the risk of peri-surgical complication; preserved uterus and isolated posterior prosthesis lessen the risk of granulomas and prosthetic retractions; and association of a Richter's intervention increases the rate of prosthetic retractions. Authors conclude that the cure rate of genital prolapse with synthetic prostheses interposed by vaginal route is now reliable and can be reproduced with a low rate of peri- and early post-surgical complications [15]. On the other hand Lucioni et al. presented 6 months follow-up on 12 patients who underwent anterior or total vault prolapse surgery with Prolift System®. Similary to our results they also did not observe major perioperative complications but with no incidence of mesh erosion or sexual dysfunction. Ours two erosions were found during check-up after 12 months and were no present half year after surgery. *De novo* enterocele development was seen in just one patient without any other incidence of recurrence in 42 weeks observation time [16]. The group of French surgeons evaluated the results of surgical insertion of a polypropylene mesh via the vaginal route in 20 young women (less than 50 years old; 19 sexually active) presenting genital prolapse with mean post-surgery follow-up 21 months (range 6 to 52 months). In this group vaginal erosion of the mesh occurred in 2 women (10%) and cystocele recurred in one woman among the 17 patients who had an anterior polypropylene mesh (5%). Among 19 post-operatively sexually active women, 5 (26%) reported alteration of sexual activity after surgery (with dyspareunia in 4 cases (21%), and 14 women (74%) reported no changes or improvement in sexual activity [17].

All above discussed papers present very similar outcome to ours observations however follow-up period (at least 12 months) is much longer in our material. There is no doubt that long-term observations are necessary in order to obtain firm and reliable conclusions. It should be stressed that in recently published Cochrane review concerning surgical management of pelvic organ prolapse, in terms of evidence based medicine, sacrocolpopexy is still considered the best surgical option for long term effect.

Based on literature review Authors agreed that abdominal sacrocolpopexy is associated with a lower rate of recurrent vault prolapse and dyspareunia than the vaginal sacrospinous colpopexy however these benefits must be balanced against longer operating time, longer time to return to activities of daily living and increased cost of the abdominal approach. Panel of experts stated that the use of mesh or graft inlays at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele and the addition of a continence procedure to a prolapse repair operation may reduce the incidence of postoperative urinary incontinence, but this benefit needs to be balanced against possible differences in costs and adverse effects [18].

The best surgical approach to vaginal vault prolapse still remains unknown. Surgeon comfort and preference as well as proper patient selection remain critical. However the use of graft materials in pelvic floor reconstruction open a new field in surgical strategy in terms of pelvic floor disorders.

Definitely there is a need for well powered, controlled, long-term, randomized studies with patient generated quality-of-life questionnaires comparing the short and long-term outcomes of these techniques.

Conclusions

Total Gynecare Prolift surgical kit enables simple and highly effective treatment of the vaginal vault prolapse, however there are some discrepancies between anatomical and functional results.

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