Trans-Obturator Approach and the Native Tissue in the Treatment of High Stage Prolapse of the Anterior Vaginal Wall: Midterm Results of a New Surgical Technique

Farzaneh Sharifiaghdas*

Purpose: Pelvic organ prolapse is a common condition as a consequence of the pelvic floor support weakness. This study evaluated the clinical results of treating the high stage prolapse of the anterior vaginal wall using a trans-obturator approach and the native vaginal wall tissue.

Methods: This was a prospective analysis of 94 patients with anterior vaginal wall prolapse stage ≥ III. They underwent surgery with the trans-obturator approach using the native vaginal wall tissue. The objective primary outcome was evaluated according to the pelvic organ prolapse staging system (POP-Q). The subjective primary outcome was evaluated with pelvic floor distress inventory (PFDI-20) and pelvic floor impact questionnaire (PFIQ-7) questionnaires. The secondary outcomes were post-surgery complications.

Results: Totally, 85 of 94 patients were followed up for a mean of 38.2 ± 4 months. The objective anatomical success rate was 90.58%. PDFI-20 and PFIQ-7 scores had improved ($P = 0.001$). The complications were minor (G1) according to the Clavien-Dindo classification (8.2 %). At one year follow up 3 out of 8 patients with clinical SUI underwent transvaginal repair with the Poly propylene mini sling mesh.

Conclusion: The midterm results of the surgical repair of the high stage anterior vaginal wall prolapse are promising with a new surgical technique by trans-obturator approach and native vaginal wall as the supportive layer

Keywords: high stage; anterior vaginal wall prolapse; trans Obturator

INTRODUCTION

Pelvic organ prolapse (POP) affects one third of the middle-aged and elderly women[1]. Its incidence is rising due to the increase of population age in many countries[2]. According to the population-based studies, the life-time risk of surgical intervention for POP is 11-19%[1]. The anterior vaginal wall prolapse (cystocele) is the most common type of POP[2].

Different surgical approaches have been introduced via the abdominal or vaginal cavity to treat POP. Anterior colporrhaphy was the procedure of choice in the treatment of cystocele with 80% to 100% success rates[3]. Other native tissue repair options include: abdominal or paravaginal repair, which was supported by White in 1912 with 67% to 100% success rates[4]. However, the high failure rate of anterior colporrhaphy at long term and major complications of the paravaginal repair were the key factors to popularize mesh-augmented repairs [5,6]. Although non-absorbable synthetic materials such as polypropylene mesh offer improved results, however there are associated with increased morbidity which has raised health related concerns[7,8].

In this prospective study, we report the midterm clinical results of repairing the high stage prolapse of the anterior vaginal wall with a new surgical technique using native tissue and trans-obturator approach to avoid the adverse effects of trans vaginal synthetic non-absorbable mesh products.

MATERIALS AND METHODS

In the past decade, use of mesh products has been limited in our medical center, especially because its costs were not totally covered by the healthcare insurances of our country. From June 2013 to February 2017, 94 patients who complained of sensing a lump in their vaginal cavity and prolapse of the anterior vaginal wall (cystocele) stage ≥ III were treated in our center. Their data is used in this prospective study.

The evaluations before surgery included: medical history, physical examination according to the pelvic organ prolapse staging system (POP-Q)[9], urinary ultrasound imaging (to determine the amount of post-void residual urine), urine analysis and culture, complete blood count and serum electrolyte levels. Patients with an associated bothersome lower urinary tract symptom underwent the conventional urodynamic study with POP reduction by gentle vaginal packing. The severity of POP and its impact on quality of life was evaluated with the pelvic floor distress inventory (PFDI-20) and pelvic floor impact questionnaire (PFIQ-7)[10].

All participants were informed about the type and steps of the procedure. They were referred to the anesthesiol-

Urology and Nephrology Research Center, Shahid Labbafinejad Medical Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

*Correspondence: Urology Nephrology Research Center, No. 103, 9th Boostan Street, Pasdaran Avenue, Tehran, Iran. Postal Code: 1666663111

Tel: +98 21 22567222. Fax: +98 21 22567282. Mobile: +98 9124339099. Email: f.sharifiaghdas@gmail.com.

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Table 1. Demographic data of patients

Parameter	Value
Age ,years old	
mean(range)	63.7 (46-77)
Parity mean(range)	4.1 (1-9)
Body mass index (kg/m^2) mean(range)	27.09 (21-34)
Menopause mean (%)	78 (91.7%)
Prior hysterectomy mean (%)	27 (31.76%)
Prior Ant vaginal wall prolapse repair mean (%)	38 (44.70%)
Prior anti-incontinence surgery mean (%)	21 (24.70%)

ogy and cardiology departments to evaluate the overall risk of surgery and get permission for the operation. They all signed an informed consent before undergoing the surgery.

The inclusion criterion was having a cystocele stage III-IV (point Ba $\geq +1$)[9]. The exclusion criteria were having: 1) a history or evidence of urogenital malignancies, 2) history of pelvic radiotherapy, 3) uncontrolled diabetes mellitus, 4) history of anterior compartment surgery with mesh products, vaginal vault or uterine prolapse (Point C $\geq +1$)[9] (such cases were scheduled for a simultaneous apical and anterior vaginal wall repair via transvaginal sacrospinous fixation with polypropylene mesh). In case of any active vaginal or urinary tract infection, the patient was treated promptly and then scheduled for a surgery after it.

All surgeries were done by one surgeon (the author) at one hospital. The local ethics committee of our center approved the study protocol. All investigations were carried out according to the principles of the Declaration of Helsinki.

The procedure was done under general or spinal anesthesia. Preoperative antibiotic prophylaxis was administered to all patients. The patients were placed in the exaggerated lithotomy position and an indwelling 16-F urethral catheter was inserted and left in place.

The surgical procedure

The anterior vaginal wall epithelium and its underlying connective tissue were incised longitudinally from the cervix or vaginal cuff to 1 cm cephalad to the bladder neck. Dissection was carried out widely up to the pubic rami in both sides (**Figure 1**). The stab skin incisions were created unilaterally (according to the right dominant hand of the surgeon, left side of the patient). The distal stab skin incision was made at the level of clitoris, the proximal stab skin incision was 2 cm lateral and 3 cm inferior to the distal one.

The obturator fossa was entered only at one side (left side) with the aid of helical needles and out-in approach (**Figure 2**). The most proximal and distal points of the dissected right half of the vaginal wall mucosa and sub-mucosa (contralateral to the left stab skin incisions) were sutured by two separate 1-0 Vicryl at the cephalad and caudal parts. The free ends of the Vicryl material were passed into the open hole of helical needle and brought out through the proximal and distal stab skin incisions by a reverse rotation of the helical needle (**Figure 3**).

By putting gentle traction on the Vicryl arms, the dissected right half of the vaginal wall mucosa and sub-mucosa covered all the space underneath the bladder base, pushing it to a higher level as much as possible. To create a reliable anchoring point for the Vicryl sutures, the third stab skin incision was made halfway of the first two (**Figure 4**). The final knots were made by tying the free ends of both Vicryl sutures (**Figure 5**). To obtain a symmetric position of the bladder base, the remaining dissected half of the vaginal wall (usually the left side) was brought to the opposite side of the vaginal cavity (right side) and sutured to the former half which was beneath in an overlying manner by 0-2 Vicryl sutures in a separate order. Urethra and bladder neck were checked and readjusted for inadvertent overcorrection. Vaginal packing and the urethral catheter were left in place for 12 hours. The patients were advised to to avoid vaginal intercourse during the first 3 months post operation.

The patients were examined at the first week, one, three and six months after the surgery and every six months thereafter. The PFDI-20 and PFIQ-7 were completed again at the second year after surgery and an independent physician re-examined the patients. The primary end points were objective anatomical success (Ant. vaginal wall prolapse $\leq$ stage 1) (Ba ≤ -1) and subjective improvement in bothersome symptoms (change in the scores of the PFDI-20 and PFIQ-7 Questionnaires). The secondary end points were post-operative adverse effects.

The local ethics committee of the Urology and Nephrology Research Center of Shahid Beheshti University of Medical Sciences approved the study protocol. All investigations were carried out according to the principles of the Declaration of Helsinki. All patients had signed an informed consent before undergoing the surgery.

Statistical analysis

The data were analyzed with the statistical package for social sciences (SPSS) software version 19. Numeric data were expressed as mean ± standard deviation and categorical data were reported as number and percentage. After doing the normality test, the paired t-test or Wilcoxon were used for comparing the data before and after surgery. *P* value less than 0.05 was considered significant.

RESULTS

A number of 94 patients underwent surgical repair of the anterior vaginal wall prolapse by the above-mentioned technique in our center. Nine of them were ex-

Table 2. Quality of life assessment at two years follow up time. Values are presented as mean ± standard deviation.

Questionnaire	Before surgery	2 years follow up	Paired difference	*P*-value
PFDI- 20	42.3 ± 6.6	8.3 ± 6.4	33.1 ±7.7	< 0.001
PFIQ- 7 POPIQ	76.6 ± 6.9	21.9 ± 11.1	51.3 ± 12.1	< 0.001
UIQ	80.1 ± 11.9	22.8 ± 11.6	52.2 ± 16.9	< 0.001
CRAIQ	20.5 ± 11.6	10.9 ± 9.6	9.3 ± 7.1	< 0.001
Sum Score	172 ± 25.4	53.9 ± 24.6	116 ± 25.9	< 0.001

Abbreviations: PFDI-20, Pelvic Floor Distress Inventory; PFIQ-7, Pelvic Floor Impact Questionnaire short form; POPIQ, Pelvic Organ Prolapse Impact Questionnaire; UIQ, Urinary Impact Questionnaire; CRAIQ, Colorectal- Anal Impact Questionnaire.

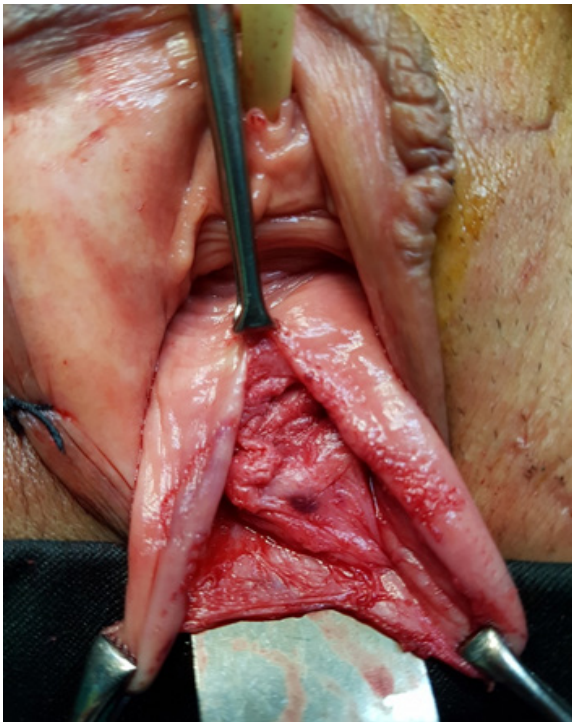

Figure 1. The anterior vaginal wall longitudinally incised from the vaginal apex up to the bladder neck.

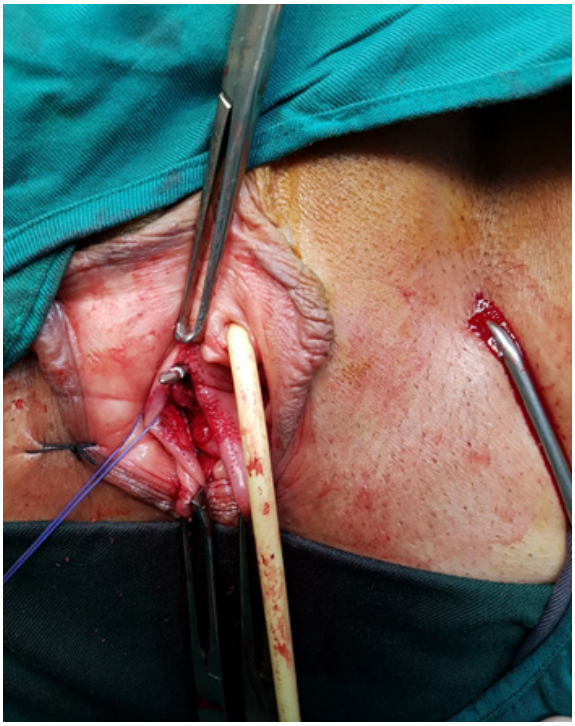

Figure 2. The distal stab skin is incised and the helical needle is passed through the obturator space entering the vaginal cavity with an out-in maneuver. The distal point of the right half of dissected vaginal wall is sutured by Vicryl.

cluded from the final analysis because they had not cooperated until the end of follow-up. Their short-term follow-up was good until three months after surgery. So, the data of 85 patients were analyzed (**Table 1**). Mean age was 63.7 (range 46- 77) years.

The patients' most common symptoms and signs before surgery were as following: sensation of a lump in the vagina (93.2%). Obstructive urinary symptoms (68.3%), urinary urge incontinence (62.7%), clinical stress urinary incontinence (9.41%), occult stress urinary incontinence (17.64%) and recurrent urinary tract infections (25.5%). Anterior vaginal wall prolapse was at stage IV in 28% of the patients.

There were no major intraoperative complications such as massive bleeding according to Clavien-Dindo classification. The mean of surgery time was 45 ± 10 minutes .The duration of hospital stay was 26±5 hours. The mean of follow up time was 38.2 ± 4 months (range of 25 to 57 months). The anatomical success rate was 90.58% (77 out of 85). The PFDI- 20 and PFIQ- 7 scores improvement were 42.3 ± 6.6 to 8.3 ± 6.4 and 172. ± 25.4 to 53.9±24.6 respectively, after the surgery which were statistically significant ($P < 0.001$) (**Table 2**).

Totally, 9.3% of the patients complained of pelvic and thigh pain which resolved gradually until one month after the surgery. 6.5% complained of mild induration of stab skin incision over the place of Vicryl knot which resolved one month after surgery. 4.6% of the patients who refused sexual abstinence through vaginal cavity during the first 3 months post –operative, complained of de novo mild dyspareunia which did not interfere seriously with their sexual life. The rate of urinary urge incontinence decreased to 21% post-operation. ($P = 005$). Seven (8.2%) patients complained of de novo frequency and urgency which resolved after two months. At one year follow up, 3 out of 8 patients with pre-op clinical and bothersome SUI requested surgical treatment and underwent trans vaginal repair with mini-sling poly- propylene mesh tape. The vaginal mucosa over the mid-urethra was longitudinally incised for 1 cm and the mini-tape was positioned and secured in the surgical plane. The procedure was fast and uneventful, as the incisional site was far enough from the previous surgical scars. SUI was mild in another 7 cases (including 2 with de novo SUI) , managed by pelvic floor physiotherapy and regular kegel exercise with no request from the patients` side for invasive treatment.

DISCUSSION

Many surgical techniques have been introduced to correct high stage anterior vaginal wall prolapse. In 2015 we reported our results with trans-obturator four arm polypropylene mesh in the treatment of high stage anterior vaginal wall prolapse. In that group of patients, we did not trim the excess vaginal wall tissue and covered the polypropylene mesh with over sewn bilayer vaginal wall tissue to decrease the rate of post-operative vaginal mesh extrusion. There was no complication regarding the over sewn vaginal tissues which became the basis of the present study[11].

The high failure rate of anterior colporrhaphy and major complications with the paravaginal repair were the key factors to popularize mesh-augmented repairs[12,13]. Parker placed the Marlex Mesh in the vaginal cavity during the surgical treatment of rectocele for the first time in 1993[14].

Reviews in the Cochrane database regarding the surgi-

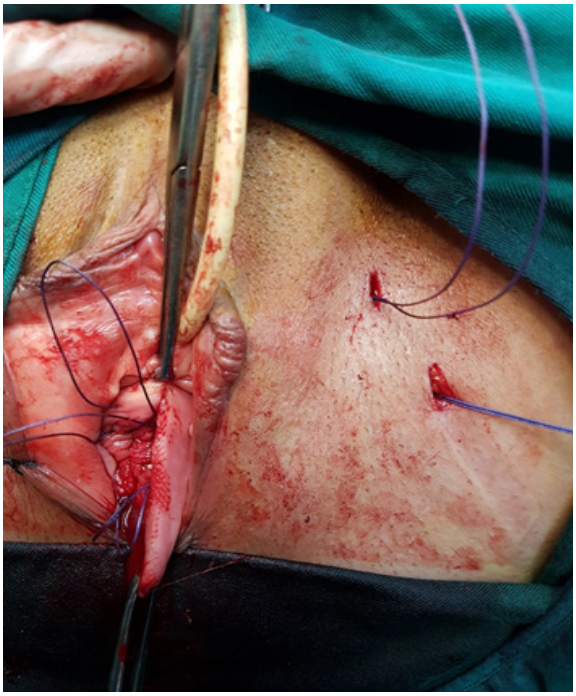

Figure 3.The proximal stab skin incision is made and the proximal point of the vaginal wall flap is sutured by vicryl.

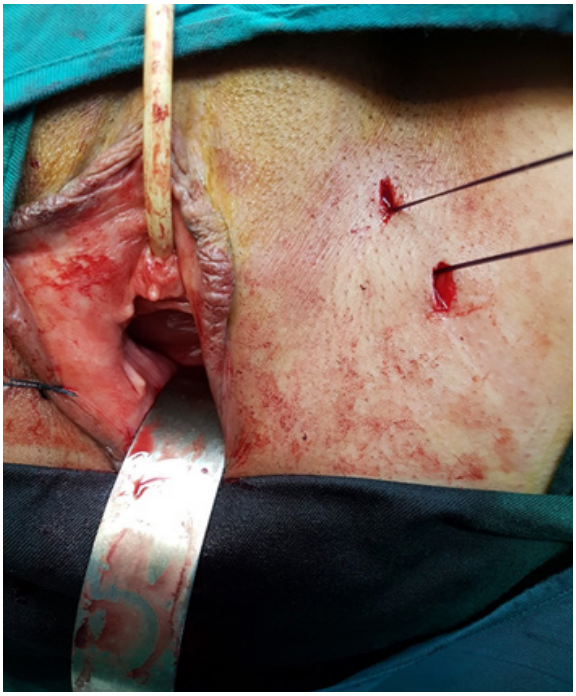

Figure 4. Both free ends of the vicryl sutures have been passed through the obturator fossa and brought from the skin.

cal management of POP in women revealed that the risk of anterior vaginal wall prolapse recurrence is reduced by placing polypropylene mesh[15]. However, there are specific complications (pain, vaginal extrusion, shrinkage of mesh, dyspareunia) related to mesh repairs as well as longer surgery time[16]. Barski stated that use of light-weight mesh results in fewer complications after surgery[17].

In the past decades, vaginal wall flap was introduced as a suspensory tissue. Raz et al proposed vaginal wall as

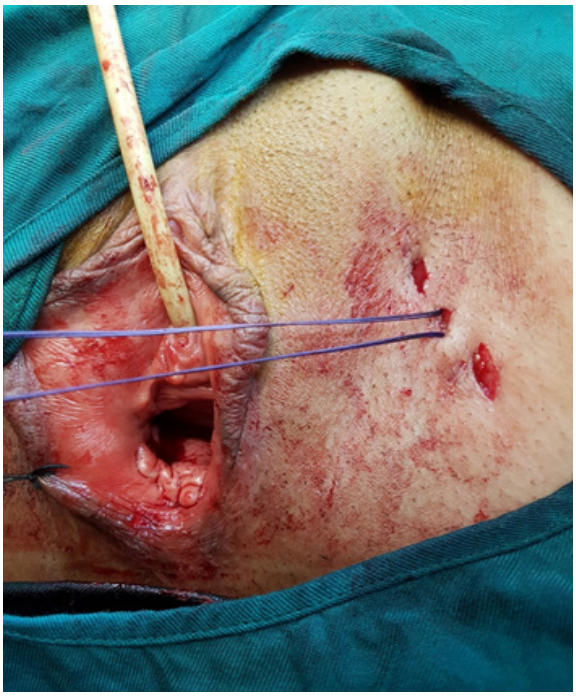

Figure 5. The third stab skin incision is made half way the proximal and distal stab skin incisions. the free ends of both vicryl suture material are passed sub cutaneously and brought out from the middle stab skin incision.

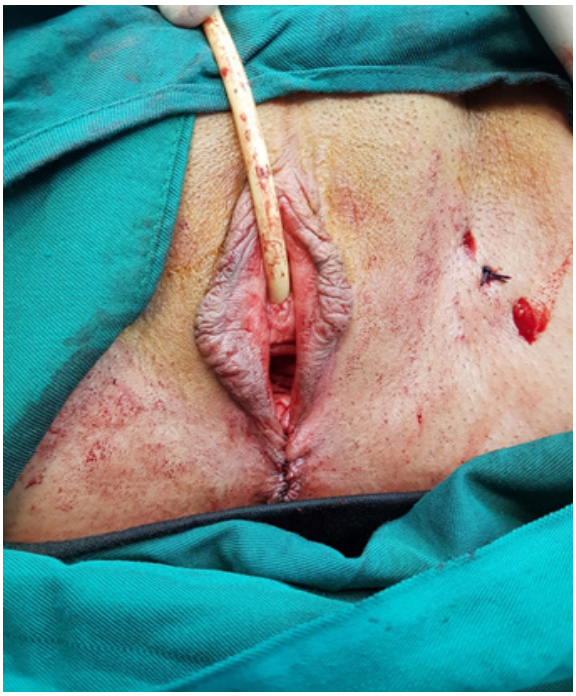

Figure 6. The anchoring knot has been made by suturing the vicryl materials to each other. The anterior vaginal wall prolapse has been repaired.

four corner bladder and urethral suspension in the treatment of stress urinary incontinence and moderate cystocele[18]. Ferrari and Frigerio created a triangular vaginal patch sling for the stress-related urinary incontinence and hypermobile urethra. They covered the intact vaginal mucosa patch by the remaining vaginal wall without adverse events related to buried intact vaginal wall mucosa[19]. In 2001, Cosson et al reported 93% success rate for an autologous vaginal patch measuring 6-8 cm in length and 4 cm in width suspended from the tendinous arcus of the pelvic fascia[20]. There has been no longer follow up reported by the authors.

Nevertheless, the use of non-absorbable mesh kits is controversial based on FDA safety communications [21] In a prospective randomized controlled trial, Minasian et al reported two years follow-up results of an anterior colporrhaphy plus a polyglactin mesh (vaginal approach) compared to a paravaginal defect repair (abdominal approach). Women with symptomatic anterior vaginal wall prolapse were enrolled in both groups. The results were 32% and 40% objective failure rates for their vaginal and abdominal groups, respectively. Subjective failure rates were lower and similar in both groups[22].

Balzarro et al. showed the long term (more than five years) results of 109 patients retrospectively. Their patients were allocated to the three groups of anterior colporrhaphy alone, anterior colporrhaphy reinforced by porcine xenograft and, transvaginal anterior repair with polypropylene mesh[23]. They concluded that using mesh and xenograft does not significantly improve objective and subjective outcomes. Instead prosthetic device led to higher rates of complications. In a systematic review about the surgical treatment of anterior compartment vaginal prolapse, Durnea et al concluded that clinical trials often neglect to report important safety outcomes[24]. Some recent reports are in favor of native tissue repair. Lavelle et al reported an institution's outcomes for native tissue repair with a mean follow up of 5.8 years. There was 7.4% rate of recurrent isolated anterior compartment prolapse, but only 3.3% of them required a second procedure[25]. In a review article on suture-based repairs for anterior compartment vaginal prolapse, Amin and Lee conclude that native tissue repair is the most common procedure, whether done solely or concomitantly with other prolapse surgeries. It is safe for women and has symptom relief[26].

In our study, subjective and objective success rates of using native vaginal wall tissue have shown to be promising at midterm follow-up with more than 90% objective response. The surgery time was short and there were no major complications according to the Clavien-Dindo classification. Among 23 patients with SUI,8 suffered from clinical SUI. Concomitant POP and SUI surgical repair is not the policy of our medical center, nor it is an obligation and depends on the physician-patient preferences and agreements .Three out of 8 patients with pre-op clinical SUI underwent correction of SUI by transvaginal approach and mini sling synthetic tapes. The other 7 cases (including 2 with de-novo SUI) were managed non-invasively which emphasizes in step by step management in this special group of patients, as overall 22 (including 2 with de-novo mild SUI) escaped from an additional intervention.

Despite medical advice to avoid vaginal intercourse during the first 3 months post-operation, some refused and complained of dyspareunia , however the symptom was mild and temporary and there was no sexual dysfunction related to native tissue that limited sexual intimacy at midterm, perhaps as there has been no foreign material in the place.

According to our knowledge, this is the first clinical report of a new surgical technique by trans-Obturator approach with a native vaginal wall tissue as a supportive layer to repair high stage prolapse of the anterior vaginal wall. Some of the limitations of this study were the small number of patients, and lack of long term follow-up.

CONCLUSIONS

The midterm clinical results of a new surgical technique with trans-obturator approach and native vaginal wall tissue as a supportive layer is promising in the treatment of high stage prolapse of anterior vaginal wall. The complications are minor and insignificant. However, long-term data in multi-centered studies with large number of patients is needed to confirm the efficacy of this new surgical approach.

CONFLICT OF INTEREST

The author declares that she has no conflict of interest.

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