Natural Orifice Uterine Suspension: an easier way to treat advanced uterine prolapse in elderly patients (IDEAL Phase 2a) (#615)

Chi Zhang, Liao Peng, Yuanzhuo Chen, Hong Shen, Deyi Luo

Department of Urology, West China Hospital, Sichuan University, Chengdu, Sichuan, P.R. China

Introduction

Pelvic organ prolapse (POP) is a common clinical condition that detrimentally impact on patient's quality of life. With the aging global population, the prevalence of symptomatic POP is predicted to increase by 50% by 2050[1].

While surgical treatments for anterior and posterior prolapse have become relatively standardized, addressing uterine prolapse, especially in advanced cases, remains challenging. Abdominal sacrocolpopexy (ASC) is considered the "gold standard" for apical POP due to its low recurrence rate and significant effectiveness[2]. Nonetheless, even with the development of laparoscopic sacrocolpopexy to reduce incision-related morbidity, the risks of complications, including enterotomy, ureteral injury, rare but life-threatening presacral space hemorrhage and the technical complexities have stimulated the exploration for technically simple, safe, and effective alternative techniques[3].

Therefore, we introduced a novel uterine-preserving technique, the **Natural Orifice Uterine Suspension (NOUS) technique**, designed to address **apical POP in elderly patients**. Here we describe the NOUS procedure and present the initial experiences with this technique following the Innovation, Development, Exploration, Assessment, and Long-term (IDEAL) 2a framework[4].

Methods and Materials

Study design

This prospective study design was consistent with the phase 2a study described in the IDEAL framework.

Inclusion Criteria

a. Inclusion criteria Age > 65 years;
b. Patients with atrophic postmenopausal uterus;
c. Patients with advanced uterine prolapse seeking surgical correction (pelvic organ prolapse-quantification (POP-Q) > II stage);
d. Patients without known gynecological malignancy, pathology (e.g., fibroids, endometriosis, abnormal uterine bleeding and cervical dysplasia);
e. Patients without pelvic radiotherapy and any contraindication to laparoscopic surgery.

Outcome measures

The follow-up schedule consisted of physical examination and administration of questionnaires at 1, 3, and 12 months after surgery and every 12 months thereafter.

The primary outcomes:

- Objective success (defining as the absence of recurrent uterine prolapse beyond the hymen, according to the C point)
- Point C value
- Complications associated with the NOUS procedure.

The secondary outcomes:

- The POP-Q score
- The functional outcomes (including the PFDI-20 and the PFIQ-7 scores),
- Surgical parameters
- Postoperative pain assessed by the Visual Analog Scale (VAS).

Surgical procedure

(a) Identification of port points

The intersection of the midline of the abdominal wall and a horizontal line located two centimeters above the pubic symphysis is identified as prosthesis fixation point (Figure 1-B). The point above the umbilicus is identified for laparoscopic trocar placement (Figure 1-A).

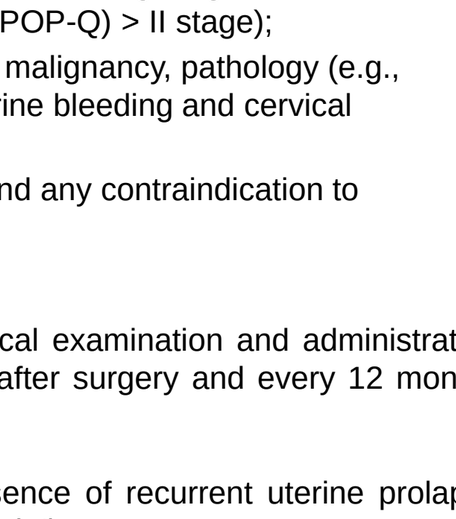

Figure 1. Identification of port points.

(b) Patient positioning and preoperative preparation

After general anaesthesia, the patient was placed in the lithotomy-Trendelenburg position. After skin preparation and sterile draping, a urinary catheter was applied for drainage. The pneumoperitoneum was then established.

(c) Creation of the suspension passage and placement of the Strip

The trocar was withdrawn after a suture fixed to its tip. And then, the suture on the cervix side was fixed to one end of the strip. Subsequently, the strip was pulled upward into the uterine cavity by pulling the free end of the suture on the abdominal side.

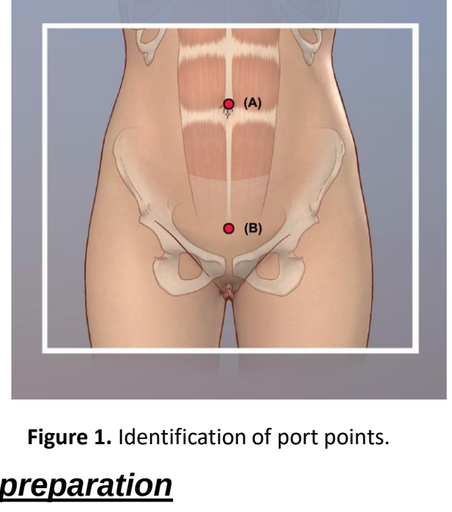

Figure 2. Creation of uterine suspension passage.

(d) Fixation of the Strip

A transverse incision was made at the external cervical orifice. The end of the prosthetic strip on the cervix side was cut into a Y shape and was secured to the cervix with non-absorbable 2-0 sutures bilaterally (Figure 3). Then, the cervical transverse incision was closed using an interrupted suture with non-absorbable 2-0 sutures that pass through the embedded prosthesis.

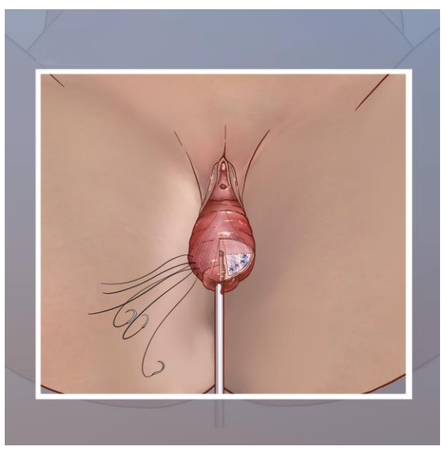

Figure 3. Fixation of the Strip to the cervix.

A 2-cm longitudinal midline skin incision was performed across the predetermined abdominal suspension site. Subsequently, the subcutaneous tissue was bluntly dissected layer by layer until the fascia was exposed. After releasing the pneumoperitoneum, the cervix was then elevated cephalad with fingers placed in the vagina, until to or slightly beyond its usual anatomic position. The free end of the strip was trimmed to a Y shape and secured to the rectus sheath with bilaterally non-absorbable 4-0 sutures (Figure 4). Figure 5 shows the overview of the Natural Orifice Uterine Suspension procedure.

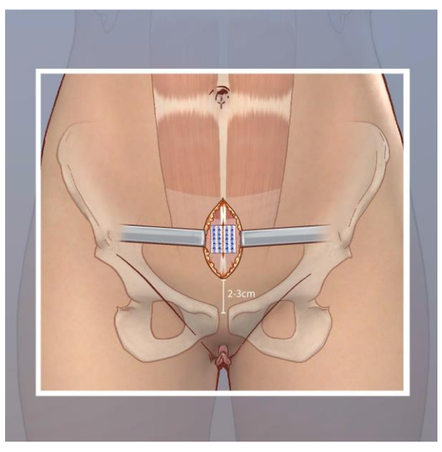

Figure 4. Fixation of the Strip to the abdominal wall.

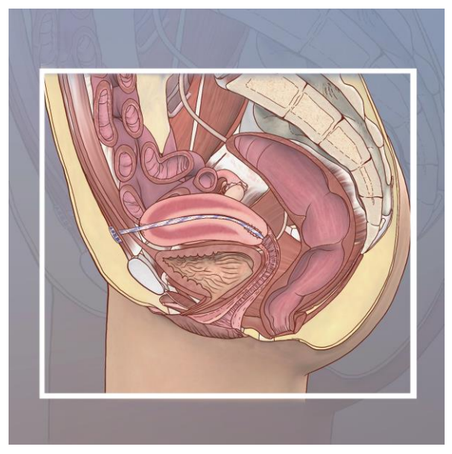

Figure 5. Overview of the NOUS procedure.

Results

Twenty patients with advanced uterine prolapse met the inclusion criteria and underwent the NOUS procedure. The mean age of participants was 76.0 ± 6.0 years, with a mean body mass index (BMI) of 24.7 ± 4.2 kg/m^2. In one case, concomitant laparoscopic bilateral adnexectomy was performed. All included patients completed 12 months follow-ups.

- **No conversions to alternative procedures were necessary.**
- **The objective success rate was 100% at the 12-month follow-up**.
- **The point C value significantly decreased from 5.2 ± 1.5 to -8.2 ± 1.8 ($p < 0.001$) three months after discharge and remained stable with a median of -8.0 (IQR, -9.0 - -6.3) ($p < 0.001$) during the 12-month follow-up.**
- **No intraoperative complications were observed. No complications classified as Clavien grade 3 or greater were recorded during the follow-up period.** Mild urgency, slight pulling sensation at the abdominal fixation point, and increased vaginal discharge were reported in several patients. Most of complications were disappeared within 1 month.

The median operative duration and estimated intraoperative blood loss were 51.0 (IQR, 42.5-60.0) min and 10.0 (IQR, 10.0-15.0) ml, respectively. The overall median length of stay after surgery was 3.0 (IQR, 3.0-4.0) days.

The patient satisfaction rate was 100%. The VAS score decreased from 3 (IQR, 3 - 4) to 0 (IQR, 0 - 0) at the 1-month follow-up and was maintained consistently. Two patients developed anterior vaginal prolapse without symptomatic uterine prolapse at 4 and 5 months postoperatively, respectively. One of these patients was initially treated with the Transvaginal Mesh (TVM) procedure, while the other patient preferred observation to surgery.

Table 1. Anatomical and functional outcomes.

Variable	Result [a]			p value	
	Baseline	3 months	12 months	3 months	12 months
Aa	0.5 (0.0 - 2.0)	-3.0 (-3.0 - -2.0)	-2.0 (-2.0 - -2.0)	<.001	<.001
Ba	4.4 ± 1.7 [b]	-3.0 (-3.0 - -2.0)	-2.0 (-2.0 - -2.0)	<.001	<.001
C	5.2 ± 1.5 [b]	-8.2 ± 1.8 [b]	**-8.0 (-9 - -6.3)**	<.001	<.001
D	3.6 ± 1.5 [b]	-10.0 (-11.0 - -9.0)	-10.0 (-10.0 - -6.5)	<.001	<.001
Ap	1.0 (-1.0 - 1.0)	-3.0 (-3.0 - -2.0)	-3.0 (-3.0 - -2.0)	<.001	<.001
Bp	3.6 ± 1.5 [b]	-3.0 (-3.0 - -2.0)	-3.0 (-3.0 - -2.0)	<.001	<.001
PFIQ-7	100.0 (95.2 - 109.5)	0.0 (0.0 - 8.3)	0.0 (0.0 - 0.0)	<.001	<.001
PFDI-20	95.8 (88.0 -116.1)	0.0 (0.0 - 8.3)	0.0 (0.0 - 0.0)	<.001	<.001

[a] Values are given as mean ± SD; [b] Values are given as median (IQR)

Conclusions

This IDEAL phase 2a study demonstrated that the NOUS technique is a **technically simple**, **feasible**, **safe**, and **effective** approach for treating advanced uterine prolapse in elderly patients. However, further prospective and comparative studies of this technique are warranted to validate and strengthen our findings.

References

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