

Laparoscopic radical hysterectomy with the use of SNAIL Tenaculum™. A simplified uterine manipulator for the management of early cervical cancer

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ABSTRACT

Objective: To evaluate safety and efficacy of the SNAIL Tenaculum™ uterine manipulator (Simple Nebs Arising Incision Landmark) for total laparoscopic radical hysterectomy in early cervical cancer.

Material and Methods: SNAIL Tenaculum™ uterine manipulator origin by a surgical reusable instrument named Uterine Tenaculum Forceps, model Schroder (code 32-622-25 of Martin catalogue). It is modified adding two or four nebs 1-2 cm of distance from the tips of the instrument. We grasped the cervix with SNAIL Tenaculum™ and in order to preserve an adequate pneumoperitoneum during colpotomy surgical gloves are placed in vagina.

Results: Twenty patients with early cervical cancer underwent total laparoscopic radical hysterectomy used SNAIL Tenaculum™ uterine manipulator. During surgery the nebs were always under vision and the median length of vagina removed was 21 mm. (range 10-40mm). None intra-operative complications were registered.

Conclusion: We found SNAIL Tenaculum™ to be a safe and efficient tool with lowest cost so far recorded. It eliminated risks of perforation and LVS involvement, maintaining good uterine mobility. Also the nebs allow surgeon to choose the length of vaginal wall to be removed.

Keywords: Simple Nebs Arising Incision Landmark; SNAIL Tenaculum uterine manipulator; laparoscopic radical hysterectomy; early cervical cancer

INTRODUCTION

The advantages of minimally invasive gynecologic surgery have been described more recently even for oncologic cases such endometrial and cervical cancer^(1,4). In a review by the SGO Clinical Practice Endometrial Cancer Working Group for the Society of Gynecologic Oncology Clinical Practice Committee⁽⁵⁾ it refers in recommendations : "...laparoscopy should be embraced as the standard surgical approach for comprehensive surgical staging in women with endometrial cancer (level of evidence: A)." Also in cervical cancer FIGO stage IB1,IB2,IIB, multiple studies and trials support the advantages of laparoscopic approach^(6,8). The procedure of Total Laparoscopic Radical Hysterectomy (TLRH) performed in these cases assume using of uterine manipulator.

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SOMMARIO

Obiettivi: Valutare la sicurezza e l'efficacia della pinza da presa SNAIL Tenaculum™ come manipolatore uterino per l'isterectomia radicale laparoscopica nel trattamento del cancro cervicale iniziale.

Materiali e metodi: Lo SNAIL Tenaculum™ origina da uno strumento chirurgico riutilizzabile denominato Uterine Tenaculum Forceps, modello Schroder (codice 32-622-25 del catalogo Martin degli strumenti chirurgici). Questa pinza fu modificata aggiungendo due o quattro rebbi, di 0.8 - 1cm di lunghezza, a 1 o 2 cm di distanza dall'estremità dello strumento. Prima dell'intervento chirurgico, la cervice fu pinzata e chiusa con lo SNAIL Tenaculum™ e il pneumoperitoneo, durante la colpotomia circolare, fu mantenuto inserendo alcuni guanti chirurgici nella vagina.

Risultati: 20 pazienti furono sottoposte a isterectomia radicale laparoscopica con l'utilizzo dello SNAIL Tenaculum™. Durante l'intervento chirurgico i rebbi furono sempre evidenziati attraverso la parete vaginale anche nelle pazienti obese. La vagina rimossa fu mediamente di 21 mm (range, tra 10 e 40 cm) e nessuna complicazione intraoperatoria si verificò. **Conclusioni:** Lo SNAIL Tenaculum™ si rivelò un manipolatore uterino sicuro, valido e di basso costo eliminando i rischi di perforazione uterina e di coinvolgimento neoplastico degli spazi linfovascolari, mantenendo una buona mobilità uterina e permettendo al chirurgo di scegliere la lunghezza di vagina da asportare.

At present there is no standard recommendation for use of manipulators in the surgical treatment of endometrial and cervical cancer. Risk of perforation, LVS involvement and positive peritoneal cytology by uterine manipulation is still debated. Should also be considered the costs of uterine manipulators both reusable and disposable.

We evaluate safety and efficacy of a modified tenaculum called SNAIL Tenaculum™ (Simple Nebs Arising Incision Landmark) for laparoscopic radical hysterectomy in early cervical cancer.

MATERIAL AND METHODS

We prospectively collected data from patients with cancer of the uterine cervix in FIGO stage IB1. All patients underwent a type C1 laparoscopic radical hysterectomy plus pelvic

lymphadenectomy, with the use of SNAIL Tenaculum™ like uterine manipulator.

This invention origin by a surgical reusable instrument named Uterine Tenaculum Forceps, model Schroder, code 32-622-25 of Martin catalogue. This tenaculum is modified adding two or four nebs 1-2 cm of distance from the tips of the instrument. The nebs are 0,8-1 cm each and widen with a 90 degrees angle between them. They can be perpendicular to main axis of instrument or forming with latter 45-60 degrees angle bent forward (Figure 1). In order to preserve an adequate pneumoperitoneum during colpotomy surgical gloves are placed in vagina.

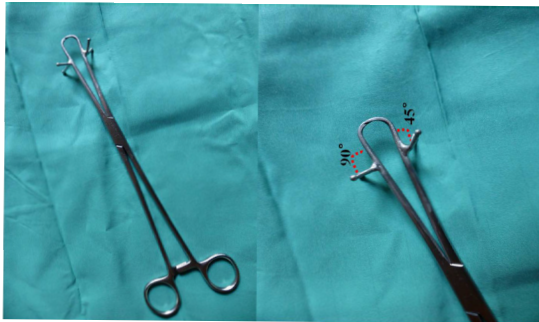


Figure 1: Simple Nebs Arising Incision Landmark (SNAIL) uterine manipulator

Inclusion criteria were: good general condition, tumor size < 3 cm, no evidence of lymph node metastases in imaging study (MRI and/or CT and/or PET). BMI was not a considered an exclusion criterion. All patients were staged according the most recent FIGO clinical staging system⁽⁹⁾. All patients received a bowel preparation preoperatively, and antithrombotic prophylaxis with subcutaneous low-molecular weight heparin. Approval to conduct the study was obtained independently from an internal review board at each participating institution.

Clinical patient characteristics included age, body mass index (BMI), histopathological subtype, and tumour grade. Intraoperative parameters evaluation included operative time, complications, and blood loss. Blood transfusions were administrated if Hb value was ≤ 7 g/L. Postoperative parameters included short-term (within 30 days of the procedure), and long-term complications (more than 30 days after the procedure); moreover, status of the surgical margins, status and number of pelvic lymph nodes removed, length of dissected vagina, width of bilateral parametrium were evaluated, along with length of hospitalization, time to recovery of normal bladder function.

Surgical technique

No uterus manipulator devices were used, but the cervix were grasped with a SNAIL (Figure 2) and a iodine gauze with some gloves, depending by width of the vagina, were emplaced in vagina in order to preserve an adequate pneumoperitoneum during colpotomy .

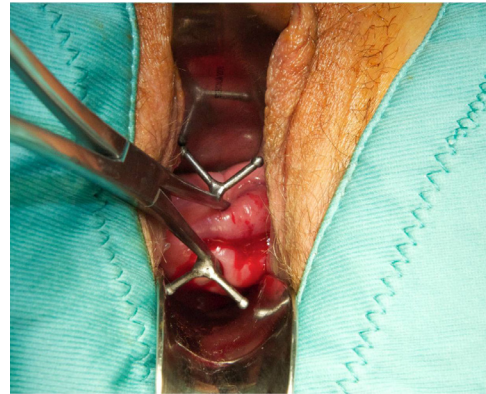


Figure 2: Cervix is grasped with a SNAIL Tenaculum™

The first step of our technique consist of open the all retroperitoneal spaces according to the following sequence: paravesical space, pararectal lateral space (Latzko), pararectal medial space (Okabayashi), rectovaginal space and vesicovaginal space.

The second step is the “en bloc” level 1 and level 2 pelvic lymphadenectomy according to Queleu and Morrow classification⁽¹⁰⁾. Para-aortic lymphadenectomy is not routinely performed unless suspicious pelvic lymph nodes are confirmed to have metastatic disease on frozen section evaluation in order to determine the field of postoperative radiation.

Afterwards, type C1 radical hysterectomy was performed as described by Querleu and Morrow. During surgery, we used an advanced multifunctional ultrasounds instrument (Ethicon Harmonic Ace curved shears[®]) to dissect, cut and coagulate.

In young patients whose ovarian function needs to be preserved, the ovaries are transposed laterally to the para-colic gutters and fixed securely to the abdominal wall, or else the ovaries are moved from the infundibulopelvic vessels with a caution of the ureter.

After a careful control of blood loss, to minimize the risk of port site metastases, the vagina prior to removal of the ports and all the ports sites are irrigated with 5% povidine-iodine solution prior to completion of the surgery. In all patients the urine catheter is removed 3 days after

operation and an intermittent self catheter is used for voiding until the residual urine volume is less than 100 ml.

RESULTS

From January 2013 to December 2014, twenty patients were included into the study. The median age was 46 years (range, 25 - 65), median BMI was 24 kg/m² (range, 15 - 49 kg/m²). There were not conversion to abdominal surgery and all patients underwent total laparoscopic radical hysterectomy (type C1) and pelvic lymphadenectomy (Table I).

Table I: Clinical characteristics of the 20 women with early cervical cancer underwent TLRH with pelvic lymphadenectomy with use of SNAIL manipulator

Characteristics	Patients
Median Age (years)	44 (19-72)
Median BMI (kg/m ²)	24 (16-34)
Median tumour size (mm)	15 (10-30)
Previous abdominal surgery	10 (50%)
Histology	
Squamous	13 (65%)
Adenocarcinoma	7 (35%)
Grading	
G1	1 (5%)
G2	8 (10%)
G3	11 (55%)

The surgical outcomes are summarized in Table II. The median operating time was 188 minutes (range, 140-280 minutes) with no limitation of BMI. The median blood loss was 240 ml (range, 30-480 ml); none of the patients required intraoperative blood transfusion, while two patients had a postoperative blood transfusion. The median number of removed pelvic lymph nodes was 21 (range, 10-37). Five squamous cell carcinoma and one adenocarcinoma patients had a total of 9 positive pelvic nodes at frozen section. In these patients, lymphadenectomy was extended to the para-aortic nodes, with negative specimens. The superior border of the dissection in the para-aortic lymphadenectomy was the inferior mesenteric artery and the median number of removed para-aortic lymph nodes was 7 (range, 5-11). The median length of dissected vagina was 21 mm (range, 15-45 mm). The median width of parametrium was 24 mm on the right side (range, 10-50 mm) and 25 mm on the left side (range, 15-50). The surgical margins were free of disease in all cases.

Table II: Surgical outcome of the 20 patients with early cervical cancer operated by TLRH with pelvic lymphadenectomy with use of SNAIL manipulator

Characteristics	TRRH
Median operative time (min)	188 (140 - 280)
Median blood loss (mL)	240 (30 - 480)
Median pelvic lymph nodes	21 (10 - 37)
Median width right parametrium (mm)	24 (10 - 50)
Median width left parametrium (mm)	25 (15 - 50)
Median length vaginal cuff (mm)	21 (15 - 45)
Major intraoperative complications	1 (5%)
Major early postoperative complications	2 (10%)
Major late postoperative complications	9 (25%)
Blood transfusion	2 (10%)
Conversion to laparotomy	0
Reoperation	0
Median hospital stay (days)	4 (2 - 10)

There was one intra-operative complication: one patient had injury of the left hypogastric vein and promptly repaired during the same laparoscopic surgery with a total blood loss of 480 ml. She needed a post operative of blood transfusion. There were two postoperative short term complications: in one case postoperative pelvic bleeding was successfully recovered by drainage; the other woman suffered from lymphocyst on the 10th day post-operation. The median hospital stay was 4 days (range, 3 - 10 days). The self catheter commenced postoperatively from day 3. The time to resumption of normal bladder function ranged from 10 days to 3 months. Four patients treated with radiation therapy and three with chemoradiation plus brachytherapy showed a worsening in condition.

Long term complications were: 2 patients suffered urinary incontinence; 2 patients had constipation, while other 1 patient had dyspareunia. Of these 5 patients, 3 patients had undergone further radiotherapy.

Adjuvant therapy was administrated in 10 patients. Six patients, with pelvic lymph nodes metastasis, underwent adjuvant radiochemotherapy. Four patients underwent adjuvant radiotherapy for lymph-vascular space invasion (LVSI) and high grade lesion.

The median follow-up was 12 months (range, 3 – 27) and although our median follow-up is still less than 3 years of survival, all patients are alive without disease.

DISCUSSION

Most gynecologic surgeons appreciate the advantages of uterine manipulation during hysterectomy procedures because of the improved visualization of key anatomic structures throughout the dissection. However there have been concerns that uterine cancer pathology may be altered (increased LVSI) from uterine manipulators^(11,13) and some investigators choose not to use manipulators in cervical cancer^(14,16) without mentioning the risk of perforation and positive peritoneal cytology.

In a prospective randomized clinical trial about effects of uterine manipulation on surgical outcomes in laparoscopic management of endometrial cancer⁽¹⁷⁾ the authors did not find an increase rate of positive peritoneal cytology or lymphovascular space invasion after using of a uterine manipulator. Subsequently on International Journal of Gynecological Cancer appeared a comment⁽¹⁸⁾ on Lee paper showing some limitations of the study. Between them the uterine manipulator was inserted after ligation of both the fallopian tubes so one would not expect to find endometrial cancer cell spillage. Moreover the risk of perforation when using a uterine manipulator in endometrial cancer patients was not mentioned. This may reflect publication bias of relatively rare complications. In patients with deep myometrial invasion this may be important. Since that over 70% of the included patients have less than 50% myometrial invasion, this study may be underpowered to detect differences in recurrence.

Larger series are necessary to confirm the findings as well as the risks of perforation on outcome. At present there is no standard recommendation for use of uterine manipulators in the surgical treatment of endometrial and cervical cancer. The influence on both surgical and oncological outcome using the already known uterine devices is unclear. The risk of perforation, lympho-vascular spaces (LVS) involvement and positive peritoneal cytology by uterine manipulation is still debated. A uterine manipulator performs the following functions: manipulates the uterus stretching the side being operated upon and brings the uterus closer to the surgical laparoscopic instruments facilitating the procedure; increases the distance between the

uterus and bladder, ureters, rectum thus reducing the chance of injury; facilitates identification of the vaginal cuff just below the cervical attachment; pulls the uterus vaginally after its complete detachment and maintains the pneumoperitoneum following colpotomy.

An ideal uterine manipulator to perform TLRH in endometrial or cervical cancer should have the following characteristics: easy to assemble, inexpensive, does not fragment or break down into pieces during the procedure, none risk of perforation, has a good range of mobility and mobilizes the uterus in anteversion, retroversion and lateral movements, should close external uterine orifice to avoid endometrial cells leakage in vagina, facilitates identification of the vaginal cuff choose the length of vaginal wall to be removed modulating, proximally or distally, the incision line.

There are many uterine manipulators available; some manipulators are reusable (ideal), some are disposable and some are partially disposable and partially reusable such that the tips are disposable but the handle is reusable. Complications attributable to the use of uterine manipulators include cervical lacerations, uterine perforation, laceration of the uterine vessels, retroperitoneal or intraperitoneal bleeding, perforation of the bowel, rectum or bladder, ascending infection, interruption of unsuspected intrauterine pregnancy and retention of part of the manipulator as a foreign body. In oncologic cases we were looking for something which doesn't stress the inner surface of the uterus, without any pushing or squeezing the endometrium and the cervical canal, which are the sites of neoplasm, and without any possible leakage of neoplastic cells in vagina. So the solution for our needs was close our eyes.

We did a simple modification of an instrument very familiar and used by gynecologists worldwide: a surgical reusable instrument named Uterine Tenaculum Forceps, model Schroder, code 32-622-25 of Martin catalogue. This tenaculum is modified adding two or four nebs 1-2 cm of distance from the tips of the instrument. The nebs are 0,8-1 cm each and widen with a 90 degrees angle between them. They can be perpendicular to main axis of instrument or forming with latter 45-60 degrees angle bent forward in order to respect the different angle of the posterior fornix, despite the anterior, with the vagina. The nebs expose very clearly the vagina for colpotomy and allow surgeon to choose the length of vaginal wall to be removed modulating, proximally or distally

to them, the incision line. In some patients, not included in the study, the SNAIL Tenaculum™ has poor chances to fix the uterus since the disappearance of the cervix after amputation or radiochemotherapy (RTCT).

We found SNAIL Tenaculum™ to be a safe and efficient tool for patients who undergoing TLRH since it eliminates risks of perforation, LVS involvement and positivization of peritoneal cytology, maintaining good chances of uterine mobility. Also the nebs allow surgeon to choose

the length of vaginal wall to be removed. Last, but not least, must be said SNAIL Tenaculum™ combines the ease of use of a very familiar instrument to gynecologists, widespread at all latitudes, with the lowest cost so far recorded.

COMPETING INTERESTS

The authors report no conflicts of interest. The authors are responsible for the content and writing of the paper.

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