

# Early postoperative bladder training in patients submitted to radical hysterectomy: is it still necessary? A randomized trial

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## Abstract

**Objectives** To evaluate the role of bladder training during postoperative hospital stay in patients submitted to nerve-sparing radical hysterectomy, and to identify any clinical or surgical factor associated with postoperative bladder dysfunction.

**Design, setting, and participants** Parallel group randomized single institution trial, on gynaecologic malignancies patients conducted in Catholic University of Sacred Heart Rome, between April 2009 and November 2011. Randomization was on 1:1, using a block randomized computer-generated list.

**Interventions** Patients underwent Querleu-Morrow type B2 or C1 radical hysterectomy. After 2 days from surgery, patients were randomized to perform or not bladder training (scheduled clamping and unclamping of the trans-urethral catheter every three hours). Main outcome measures Necessity and duration of clean intermittent self catheterization.

**Results** Randomized participants were 111 women (bladder training arm  $n = 55$ ; control arm  $n = 56$ ). A total of 22 women (19.8 %) required clean intermittent self

catheterization, equally distributed in the two arms. At univariate analysis, only the type of radical hysterectomy was significantly associated with need of clean intermittent self catheterization (type C1 vs. type B2;  $p = 0.013$ ). At univariate analysis, duration of clean intermittent self-catheterization was not associated with age, BMI, type of hysterectomy and of neo-adjuvant treatment.

**Conclusions** Functional bladder disfunctions are the most common long-term complications following radical hysterectomy. Systematic postoperative bladder training following nerve-sparing radical hysterectomy does not influence the rate of urinary retention or re-admission for bladder catheterization.

**Keywords** Bladder training · Radical hysterectomy · Gynaecologic cancer · Clean intermittent self catheterization

## Introduction

Radical hysterectomy (RH) is one of the most common pelvic surgery procedures. It is a technically demanding operation, typically performed by gynecologic oncology surgeons. The goal of this procedure is to obtain en bloc resection of the uterus and surrounding tissues, including the paracervix, upper vagina, and utero-sacral ligaments [1]. Although RH is associated with excellent oncologic outcomes, it may occasionally determine by substantial acute and/or chronic morbidity. In particular, in patients undergoing this type of surgery an increased risk of sexual, ano-rectal and bladder dysfunction has been reported by various authors [2, 3]. Bladder dysfunction, caused by the disruption of the pelvic autonomic nerves during paracervical resection, is the most common complication, reaching

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prevalence perhaps as high as 80 % [4]. Like the other well-known surgical complications, functional disorders of the bladder (i.e. voiding dysfunction) represent a large part of the surgery-related comorbidity that are negatively influencing the postoperative recovery and patients' quality of life.

Pelvic surgery has met the evolution of the surgical technique and of the perioperative management with an improvement of comorbidity rate. Furthermore, in the last two decades, nerve-sparing RH has been developed in an attempt to minimize complications [5]. As a result of this process, the standard of care of RH, i.e. extension and radicality of paracervical resection and lymph-node dissection based on tumor invasion, has been encompassing several procedures to preserve the neuroanatomical structures. The result of this surgical innovation is the use of a new classification that considers not only the laterality of the surgical dissection as well as its deepness. In fact, the latter is commonly associated with grade and severity of surgical-related complications [4, 6–9].

Moreover, to totally obtain the advantage of the new surgical technique in terms of postoperative outcomes, the early postoperative management is crucial in improving patient recovery. Several methods of bladder gymnastic were used trying to get a faster recovery of postoperative bladder function, even in the absence of a universal standardization. Thus, the primary endpoint of this prospective randomized study was to evaluate the role of one procedure of bladder training (BT) among those currently used during postoperative hospital stay in patients submitted who underwent nerve-sparing RH for gynecologic oncologic disease. Secondary endpoint of this study was to identify any clinical-surgical factor associated with postoperative bladder dysfunction in cervical cancer patients undergoing RH.

## Materials and methods

Between April 2009 and November 2011, women who underwent Querleu-Morrow class B2 and class C1 RH at the Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Catholic University of Sacred Heart, Rome, Italy, were enrolled in this randomized prospective study. All enrolled patients signed an informed consent. The Institutional Review Board and the Local Ethical Committee approved the study.

Patients were staged according to the International Federation of Gynecology and Obstetrics (FIGO 2009) staging system. As far as cervical cancer patients are concerned, only stages IB–IIB were enrolled. In this study, we enrolled also endometrial (FIGO stage II) patients in

which a type B2–C1 RH was required to obtain adequate surgical radicality.

All patients with preoperative neurological and/or urinary dysfunctions were excluded from the study. Other exclusion criteria included previous or contemporary surgery of the lower urinary tract and presence of a psychiatric disease. Patient demographics, surgical and postoperative data were prospectively collected. Clinical and diagnostic information regarding actual disease was also noted.

According to an internal protocol, patients with locally advanced cervical cancer were submitted to neo-adjuvant platinum-based chemotherapy or chemo-radiation before performing RH [10, 11], whereas in the other patients RH was the first oncological procedure.

Postoperative bladder management consisted of Foley drainage for the first 2 days after RH. At the end of surgery, patients were randomized to perform (Group 1) or not (Group 2) BT that consists of a scheduled clamping and unclamping of the trans-urethral catheter every 3 h [13–15]. Randomization was on 1:1, using a block randomized computer-generated list. The patients of group 1 were submitted to passive bladder training during the third postoperative day, throughout the exercise the catheter remained closed for 3 h and open for 15 min during the entire day. After Foley removal at day 4, women are invited to spontaneous voiding every 3 h with a subsequent draining of the bladder with a ten French catheter to assess the residual urine volume. The above procedure was repeated every 3 h during the fourth and fifth postoperative days and continued until the residual urine volume was less than 100 ml [12, 14]. Patients were informed on how to perform home self-intermittent catheterization if they experienced voiding difficulty or urinary retention higher than 100 ml at the time of discharge. The voiding functionality was classified as follows: normal when spontaneous voiding and residual urine volume <100 ml was present in two consecutive measurements and abnormal when residual urine volume >100 ml was present and self-catheterization was necessary beyond the 1st month of follow-up. No antibiotics were prescribed to prevent urinary tract infections during catheterization. In regards to group 2, patients underwent removal Foley on day 3, and started draining the bladder every 3 h with the same procedure explained above, to assess the bladder voiding capacity.

## Statistical analysis

The primary hypothesis of this study was the non-inferiority of BT compared to non-BT nerve sparing radical hysterectomy in cervical cancer patients. The sample size calculation was based on the mean of early postoperative bladder dysfunction after nerve-sparing RH reported in the literature. On the basis of this threshold, 110 total events would be necessary for 80 % power with a two-sided type I error of

0.05. To face possible missing data or dropout in the follow-up, we aimed to recruit 55 patients per group, 110 in total. Subsequently, univariate analysis was conducted to verify any differences between the two groups (BT vs. non-BT). The Student's *t* test, Mann–Whitney test, Fisher's exact test, Chi-square analysis were performed where occurred. Probability (*p*) values were considered to be statistically significant at the <0.05 level. The SPSS® statistical software program (SPSS Inc., Chicago, IL) and STATA® Data 128 Analysis and Statistical Software, version 10 (StataCorp LP, College Station, Texas), were used.

## Results

During the study period, a total of 111 consecutive patients submitted to nerve sparing RH for gynecological cancer were enrolled in this trial. Clinical and pathological characteristics of the two study groups are resumed in Table 1. The two groups were superimposable for all parameters. Median age was 52 years (range 32–74 years) and 50 years

(range 27–81 years) for group 1 and group 2, respectively ( $p = 0.208$ ). Median BMI was 24.1 kg/m<sup>2</sup> (range 18.6–39.8) and 24 kg/m<sup>2</sup> (range 15.8–32.9) for group 1 and group 2, respectively ( $p = 0.639$ ). For the two groups, in this cohort, there was no statistically significant difference in terms of parity. In our study population, we enrolled 93 cervical cancer patients (83.8 %), 17 endometrial cancer patients (15 %), and 1 patient (0.9 %) affected by uterine sarcoma.

In the cervical cancer subgroup, 45 patients (48.4 %) were locally advanced (FIGO stage IB2–IIB). This group of patients underwent neo-adjuvant treatment followed by RH: 29 patients (26.1 %) and 16 patients (14.4 %) were treated with neo-adjuvant external platinum-based concomitant chemo radiation and with three cycles of platinum-based chemotherapy, respectively. The remaining 48 early stage patients (FIGO stage IB1–IIA1) were submitted directly to RH. Patients with other gynecological malignancies were at advanced stage (stage II–III endometrial cancer data not showed) and necessitated of RH to obtain radical oncological debulking.

RH was performed by laparoscopy in eight cases (7.3 %) and laparotomy in 103 cases (92.7 %). On the total, 27 (24.3 %) patients underwent type B2 and 84 (75.6 %) patients underwent type C1 RH. There was no statistically significant difference in RH type between the two groups ( $p = 0.867$ ) (Table 1). Median surgical time was 207 min (range 36–349) in Group 1 and 208 min (range 125–463) for the Group 2 ( $p = 0.642$ ). The number of patients submitted to neo-adjuvant treatment was similar in the two groups (36 vs. 39;  $p = 0.785$ ).

Overall, ISC was needed in 22 patients (19.8 %). BT is not associated with lower risk of ISC (20.0 vs. 19.6 %;  $p = 0.962$ ). Pathological findings, age, BMI and parity were not associated with risk of ISC (Table 2).

At univariate analysis, the type of RH was significantly associated 157 with the need of ISC (25.0 % in type C1 vs. 1.0 % in type B2;  $p = 0.016$ ). In locally advanced cervical cancer patients submitted to neo-adjuvant treatment, no significant difference in ISC incidence was found between patients undergoing chemo-radiation in respect to those experiencing only chemotherapy ( $p = 0.1$ ) (Table 2). Median duration time of ISC was super-imposable for both groups, in particular 4 days in bladder training group (range 1–40 days) and 3 days in control group (range 1–30 days). At univariate analysis, ISC duration was not associated with age, BMI, type of hysterectomy and of neo-adjuvant treatment (Table 3).

About urinary infection, ten patients have shown mild urinary tract infections, five for each group. Only one patient still had voiding dysfunction after 1st month of follow-up. She has needed self-catheterization for 40 days before recovering a regular bladder voiding (data not showed).

**Table 1** Clinicopathological characteristics of the study population ( $N = 111$ )

Variables	Bladder training <i>N</i> (%)	No bladder training <i>N</i> (%)	<i>p</i> value
All cases	55 (49.5)	56 (50.5)	
Age median (years) (range)	52 (32–74)	50 (27–81)	0.208
BMI (kg/m <sup>2</sup> ) (range)	24.1 (18.6–39.8)	24.0 (15.8–32.9)	0.639
Parity	2 (0–10)	2 (0–6)	0.427
Pathological findings			
Cervical cancer	46 (83.6)	47 (83.9)	0.967
Other malignancies	9 (16.4)	9 (16.1)	
Surgical access			
Laparoscopy	2 (3.6)	6 (10.7)	0.149
Laparotomy	53 (96.4)	50 (89.3)	
Radical hysterectomy class*			
Type B2	13 (23.6)	14 (25.0)	0.867
Type C1	42 (76.4)	42 (75.0)	
Timing of surgery			
RH	31 (56.4)	34 (60.7)	0.895
NA-RT	15 (27.3)	14 (25.0)	
NA-CT	9 (16.3)	8 (14.3)	
Median ISC (days) (range)	4 (1–40)	3 (1–21)	0.733

BMI body mass index, RH radical hysterectomy, NART neo-adjuvant chemoradiotherapy, NACT neo-adjuvant chemotherapy, ISC intermittent self-catheterization

\* According to Querleu-Morrow's classification [7]

**Table 2** Univariate analysis of variables influencing clean intermittent self-catheterization (ISC)

Variables	ISC (N) (%)	<i>p</i> value
Age (years)		
≤51	13 (59.1)	0.417
>51	9 (40.9)	
BMI (kg/m <sup>2</sup> )		
≤25.0	14 (63.6)	0.476
>25.0	8 (36.4)	
Radical hysterectomy class		
Type B2	3 (4.5)	0.013
Type C1	21 (95.5)	
Type of NA treatment		
RT-CT	3 (37.5)	0.100
CT only	5 (62.5)	
Timing of surgery		
RH	14 (63.6)	0.637
NA-RH	8 (36.4)	
Bladder training		
Yes	11 (50.0)	0.962
No	11 (50.0)	

*BMI* body mass index, *RH* radical hysterectomy, *NA-RH* radical hysterectomy after neo-adjuvant treatment

**Table 3** Univariate analysis of variables influencing duration of clean intermittent self-catheterization (ISC)

Variables	Median ISC (days) (range)	<i>p</i> value
Age (years)		
≤51	4 (1–40)	0.964
>51	3 (1–21)	
BMI (kg/m <sup>2</sup> )		
≤25.0	4 (1–21)	0.780
>25.0	3 (1–40)	
Radical hysterectomy class		
Type B2	1 (1–2)	0.450
Type C1	4 (1–40)	
Type of neo-adjuvant treatment		
CT	3 (2–4)	0.575
RT-CT	2 (1–21)	

*BMI* body mass index, *CT* chemotherapy, *RT-CT* radio-chemotherapy

## Discussion

In the last decades, more and more gynecological cancer patients experienced have experienced both early and long-term pelvic floor symptoms after radical hysterectomy [10, 16]. In regards to the procedure of radical hysterectomy, a wide range of complications may arise: from storage and voiding dysfunctions of the bladder, to urinary or faecal

incontinence, and pelvic or rectal pain, presumably associated to the autonomic nerve damage during surgery. However, given the even greater accurate knowledge of autonomic nerve pathways, the nerve-sparing technique and the use of laparoscopy have recently permitted a tailored treatment with modulation of radicality, hesitating in a reduction of such symptoms [6, 11, 16–20]. The expected urinary dysfunction rate following RH is estimated to be in excess of 30 % [19–22]. Moreover, early postoperative bladder voiding dysfunction may request the self-catheterization with negatively impact on the patient's quality of life and could represent a problem for fast patient's discharge and a risk for readmission. In the clinical practice, the BT procedure is frequently used to improve bladder function recovery after surgery [21, 23], even if there are very few official descriptions among postoperative rehabilitation plans, and its real benefit on bladder postoperative recovery lacks authentic evidence. To our knowledge, this randomized study is the first to analyse the impact of BT on postoperative bladder function in gynecological oncology patients undergoing nerve-sparing RH. We observed no statistically significant difference in terms of rate of ISC between patients that underwent or not BT. Similarly, to other studies, we observed that patients undergoing type C1 RH showed higher rate of early postoperative bladder dysfunction compared to patients managed with type B2 RH. Thus, we confirmed that the radicality of the surgery performed, is likely to have an impact on the degree of early postoperative bladder dysfunction [2, 21–28]. Interestingly, we did not find any statistical differences in terms of bladder dysfunction between early cervical cancer patients who underwent upfront RH compared to locally advanced cervical cancer patients submitted to neo-adjuvant treatment followed by RH. In the latter group, we found no significant difference between patients who underwent neo-adjuvant chemotherapy when confronted with neo-adjuvant chemoradiation in regards to the risk of ISC. This result could confirm that, independently from the neoadjuvant treatment performed to reduce tumor volume, the major factor influencing urinary symptoms is the amount of the paracervix resection (C1 vs. B2), the tissue that contains autonomic nerve structure. Considering the relevance of this kind of surgery on the urinary system, even when accurately tailored, the correctly assessment and support of postoperative bladder function recovery appear crucial.

Among different proposed strategies, the benefits of ISC over supra-pubic catheterization have been identified in a variety of different clinical settings outside of gynecological oncology practice [29]. Naik et al. [18, 22] showed that cervical cancer patients submitted to RH prefer and are able to learn the ISC technique without difficulty, and, despite a greater urinary tract infection rate, the high incidence of supra-pubic catheterization site

problems can be avoided by the use of ISC. Although the nerve-sparing approach is believed to be associated with lower incidence of bladder and rectal dysfunction, the duration of bladder drainage still varies from 2.6 to 7 days [19–21]. Prolonged bladder drainage has been recommended by several authors to avoid postoperative urinary tract complications, although some others believe that prolonged catheterization may further worsen the bladder function due to chronic irritation produced by the presence of the catheter [30]. The duration of bladder drainage usually depends on the surgeon's preferences and experiences. Despite the trend towards a laparoscopic or robotic approach in performing RH resulting in a reduction of hospital stay, the length of postoperative bladder catheterization remains controversial among authors [28–30]. Chamberlain et al. [30] found that early removal of the indwelling catheter did not increase the risk of postoperative complications when compared to a historical cohort group (median duration of catheterization 6 vs. 30 days, respectively). Moreover, although some studies have shown a prolonged bladder catheterization, others demonstrated that a faster removal of urinary catheter on the second postoperative day following RH is feasible and not associated with increased incidence of urinary retention or re-admission for bladder catheterization [22, 28]. This latter observation is supported by the results of our study, which reported a bladder drainage of 3 days and showed a percentage of patients needing ISC for urinary residuals greater than 100 ml following catheter removal (19.8 % of our patients vs. 17.2 % of Turnbull et al.) [28]. In conclusion, we have shown that the systematic postoperative bladder training following nerve-sparing RH does not influence the rate of urinary retention or re-admission for bladder catheterization and accordingly this technique can safely be abandoned. Furthermore, our study confirms that the major influencing factor on bladder function in postoperative period remains the amount of paracervical resection expressed by the type of performed hysterectomy.

Thus, this manuscript supports the approach of early catheter removal both in classic laparotomic approach than to sustain and complement the introduction of laparoscopic and robot-assisted surgical techniques for surgical management of cervical cancer.

**Conflict of interest** The authors declare no conflict of interest.

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