



Surgical and oncological outcomes of an improved nerve-sparing radical hysterectomy technique: 6 years of experience at two centres[☆]



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ABSTRACT

Objective: An improved nerve-sparing radical hysterectomy (NSRH), which is based on the paravesico-vaginal space, has been recently introduced in a phase II, prospective clinical trial by our team. This study aims to report the surgical and oncological outcomes of this improved NSRH.

Methods: One hundred seventy-seven consecutive patients were enrolled in our study and underwent the improved NSRH. The proportion of successful catheter removal and postvoid residual urine volume (PVR) of 50 mL or less at postoperative day 7 or day 4 was used to assess surgical outcomes. The local control rate (LCR), disease free survival (DFS), and overall survival (OS) were used to assess oncological outcomes.

Results: Postoperative 30-day complications occurred in 27/177 (15.3%) patients. The rate of successful catheter removal and PVR of 50 mL or less were 85.2% (23/27) and 66.7% (18/27) at postoperative day 7, and 73.3% (110/150) and 35.3% (53/150) at postoperative day 4. A total of 13 (7.9%) patients showed recurrence after a median follow-up time of 39.2 months (range 3.2–68.1 months). The estimated 2-year and 5-year DFS rates were 92.2% and 91.1%, respectively. Seven (4.2%) patients presented local recurrence, and five (3.0%) patients were dead at the end of the follow-up period. The estimated 5-year LCR and OS were 95.1% and 96.2%, respectively. In univariate analysis, International Federation of Gynecology and Obstetrics (FIGO) stage, lymphovascular space invasion (LVSI), and lymph node metastasis were found to be the prognostic risk factors of DFS. Patients with LVSI were associated with a worse DFS according to the multivariate analysis.

Conclusions: The improved NSRH in our study may provide better surgical outcomes without compromising the survival in patients with early cervical cancer.

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1. Introduction

Bladder dysfunction remains a major postoperative challenge for patients with early-stage cervical cancer. Female pelvic neuroanatomy has shown that damage to the hypogastric nerves, pelvic splanchnic nerves, and the inferior hypogastric plexus (IHP),

especially the bladder branch of the IHP, is the cause of impaired bladder function [1]. Preservation of the pelvic autonomic nerves can shorten the duration of postoperative catheterisation (DPC), thus improving the patients' quality of life.

Since the Japanese gynaecologist described the first nerve-sparing technique in radical hysterectomy [2], an increasing number of international investigators have reported their experience with preserving the autonomic nerves [3–5]. In 2008, Querleu and Morrow [6] described NSRH as type C1 in the new classification of surgery for early cervical cancer. However, with the development of nerve-sparing surgery, no consensus has been reached on the technique, especially the preservation of the bladder branch of the IHP, until now. Moreover, as more favourable surgical outcomes of NSRH have been reported compared with the conventional radical hysterectomy (CRH), the oncologic outcomes of NSRH received

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more attention by surgeons. Although several studies including some randomised controlled trials showed a similar rate of survival of NSRH compared with CRH, inadequate evidence addressing the oncological safety of nerve-sparing surgery have been collected due to the various techniques applied and the different study designs in previous reports [7–10].

We found a new clinical anatomy, the paravesico-vaginal space, in our practice of the NSRH since 2006 [11,12]. Radical hysterectomy was proved simpler when incorporating the paravesico-vaginal space into nerve-sparing procedures. In our prospective study (ClinicalTrials.gov Identifier: NCT02562729) [13], 49 patients were enrolled and received the improved NSRH between September 2015 and August 2016. The bladder catheter was routinely removed on postoperative day 4. Thirty-four (69.4%) patients had successful catheter removal on postoperative day 4, and 17 (34.7%) patients had a PVR less than 50 mL.

In this present cohort study, we aimed to report the surgical and oncological outcomes of the improved nerve-sparing technique in a large number of patients.

2. Methods

2.1. Patients

A multicentre, exploratory study was conducted in Zhongshan Hospital and Cancer Hospital, Fudan University between November 2011 and August 2016. A total of 177 patients were included, with 115 patients undergoing the improved NSRH between November 2011 and May 2014 in Fudan University Cancer Hospital, and 62 patients undergoing the improved NSRH in Zhongshan Hospital, Fudan University, in which 49 patients were enrolled in a prospective study (ClinicalTrials.gov Identifier: NCT02562729) [13]. Patients who were diagnosed with International Federation of Gynecology and Obstetrics (FIGO) stage Ib1 or IIa1 cervical cancer, and who were aged between 18 and 70 years and with no neo-adjuvant chemotherapy, were included. A flowchart of patient population was shown in Fig. 1. Adjuvant concurrent chemoradiotherapy (CCRT) or CCRT followed by chemotherapy using cisplatin was administered to patients with more than two intermediate-risk factors including pathological tumour size greater than 4 cm, stromal invasion of 50% or higher and lymphovascular space invasion (LVSI); or more than one high-risk factor including lymph node metastasis, parametrial invasion and positive resection margin. In individual cases, adjuvant radiotherapy or chemotherapy alone was offered. All the patients signed informed consent.

2.2. Surgical techniques

Radical hysterectomy with or without salpingo-oophorectomy following pelvic lymphadenectomy was performed in all the patients. Procedures of hypogastric nerve preservation in our improved NSRH were the same as in the conventional NSRH. Surgical procedures to identify the paravesico-vaginal space were performed in three steps as reported in our previously published paper [13] and Supplementary Fig. 1. The cardinal ligament was dissected using Ligasure after we connected the paravesico-vaginal space with the para-rectal space by blunt or sharp dissection (Supplementary Fig. 2).

2.3. Assessment of postoperative bladder function

In the initial period of performing the improved NSRH (11/11/2011–04/18/2012), we removed the catheter at postoperative day 7. The results were beyond expectation; thus, we were able to remove

the catheter at postoperative day 4 in the second part of our study (04/24/2012–8/23/2016). The proportion of successful catheter removal and postvoid residual urine volume (PVR) of 50 mL or less at postoperative day 7 or day 4 was calculated to assess the postoperative bladder function. The PVR was measured by ultrasound after spontaneous voiding. Patients who were unable to void spontaneously or voided with difficulty underwent re-catheterisation, and we would attempt to remove the catheter again on postoperative day 14.

2.4. Data collection and follow-up

Radicality and survival were evaluated by LCR, DFS, and OS. Disease local control was defined as patients who survived without any signs of vaginal or pelvic recurrence according to the regular gynaecological examination and imaging scans. For each patient, medical records were abstracted for age at surgery, body mass index (BMI), FIGO stage, histology, operative time, estimated blood loss, pathology, postoperative 30-day morbidity and mortality, adjuvant therapy, DPC, PVR, LCR, DFS, and OS. BMI values were classified according to the World Health Organization (WHO) criteria [14]. All patients were followed up every 3 months after the surgery for the first 2 years and every half year thereafter with a physical gynaecological examination, tumour marker (squamous cell carcinoma antigen) tests, and abdominal-pelvic ultrasound imaging. Vaginal cytology, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET)-CT would also be performed if indicated. The follow-up period ended on August 16, 2017.

2.5. Statistical analysis

Statistical analysis was performed using the SPSS software package for Windows (Statistical Package for the Social Sciences 19.0, SPSS Inc, Chicago, IL). The LCR, DFS, and OS rates were evaluated using the Kaplan-Meier method. Prognostic factors associated with the DFS were determined using the log-rank test and the Cox proportional hazards regression model. A *P*-value of <0.05 was considered to be statistically significant.

3. Results

3.1. Baseline and patient characteristics

A total of 177 consecutive patients were evaluable for this study. The patient characteristics are shown in Table 1. The median patient age was 48 years (range 25–70 y). Fourteen patients were categorised as underweight (BMI < 18.5); 121 patients were normal weight (BMI: 18.5–24.9); 37 patients were obese class I (BMI: 25–29.9); and 5 patients were obese class II (BMI ≥ 30). One hundred forty-five (82.0%) patients were diagnosed with stage Ib1, and 32 (18.0%) with stage IIa1 cervical cancer. Histology results showed 152 (85.9%) cases of squamous cell carcinoma, 14 (7.9%) cases of adenocarcinoma, and 8 (4.5%) cases of adenosquamous carcinoma.

3.2. Surgical outcomes

The median operative time was 76 min (range 32–340 min), and the median blood loss was 200 mL (range 50–2200 mL). For the postoperative pathology, 25 (14.1%) patients presented large tumour size (>4 cm). Seventy-eight (44.1%) and 87 (49.2%) patients were diagnosed with LVSI and deep stroma invasion, respectively. Thirty-five (19.8%) patients presented lymph node metastasis, and both positive surgical margin and parametrial invasion were found in two (1.1%) patients, respectively.

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