



Introducing nerve-sparing approach during minimally invasive radical hysterectomy for locally-advanced cervical cancer: A multi-institutional experience

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Abstract

Objective: To evaluate the impact of nerve-sparing (NS) approach on outcomes of patients undergoing minimally invasive radical hysterectomy (MRH) for locally advanced stage cervical cancer (LACC).

Methods: Data of consecutive patients undergoing minimally invasive surgery for LACC were retrospectively retrieved in a multi-institutional setting from 2009 to 2016. All patients included had minimally invasive class III radical hysterectomy (MRH or NS-MRH). Propensity matching algorithm was used to decrease possible allocation bias when comparing outcomes between groups.

Results: Overall, 83 patients were included. The prevalence of patients undergoing NS approach increased over the study period (from 7% in the year 2009–2010 to 97% in the year 2015–2016; p-for-trend < 0.001). NS-MRH and MRH were performed in 47 (57%) and 36 (43%) patients, respectively. After the application of the propensity-matching algorithm, we compared 35 patients' pair (total 70 patients). Postoperative complications rate was similar between groups. Patients undergoing NS-LRH experienced shorter hospital stay than patients undergoing LRH (3.6 vs. 5.0 days). 60-day pelvic floor dysfunction rates, including voiding, fecal and sexual alterations, were lower in the NS group in comparison to control group (p = 0.02). Five-year disease-free (p = 0.77) and overall (p = 0.36) survivals were similar comparing NS-MRH with MRH.

Conclusions: The implementation of NS approach in the setting of LACC improves patients' outcomes, minimizing pelvic dysfunction rates. NS approach has not detrimental effects on survival outcomes.

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Introduction

In the recent years minimally-invasive surgery has emerged as the gold standard for the management of several gynecological malignancies [1–3]. Accumulating data

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support laparoscopic and robotic-assisted approaches as safe and feasible treatments for organ-confined gynecological cancers [2–4]. In particular, randomized trials suggested laparoscopy to be superior to open surgery for the management of endometrial cancer [4,5]. Moreover, a growing body of the literature is showing minimally invasive surgery to improve outcomes in early stage cervical cancer patients as well [3,6]. However, only few data on the utilization of minimally invasive surgery for patients with locally advanced cervical cancer (LACC) are available, up to now [7–14].

In fact, no consensus exists about the preferred treatment modality of LACC. Although chemo-radiation represents the mainstay of treatment of LACC, accumulating evidence supports neoadjuvant chemotherapy (NACT) followed by radical surgery as valuable option in this setting [15–19]. NACT might reduce tumor volume, thus allowing the radical extirpation of the tumor and avoiding the long-term sequelae of radiotherapy [7–17].

Similarly, several attempts were done to improve outcomes of patients undergoing radical surgery in the recent years. The introduction of nerve sparing (NS) approach has dramatically reduced the occurrence of postoperative pelvic dysfunctions related to the injuries of the pelvic splanchnic nerves [20,21].

Data about the role of NS approach executed via minimally-invasive surgery in LACC patients are scant. The present study aimed to evaluate whether the introduction of NS approach is improving peri-operative outcomes of patients undergoing surgery via minimally invasive surgery for LACC. As secondary endpoint we intended to audit the results of a large multi-institutional experience about the utilization of minimally invasive radical hysterectomy (MRH) following NACT administration.

Materials and methods

Data of all consecutive women undergoing minimally invasive surgery at four Italian Gynecologic Oncology Units were retrospectively evaluated. The institutions included were: (1) IRCCS National Cancer Institute of Milan (Milan), (2) University of Pavia (Pavia); (3) University of Insubria - Ospedale di Circolo - Fondazione Macchi (Varese), and (4) University of Genoa (Genoa). Ethics committee approval was obtained, and all women included in the study gave written informed consent for data collection for research purpose.

Inclusion criteria were: (1) age \geq 18 years old, (2) type C radical hysterectomy executed via minimally invasive surgery (3) clinical follow-up $>$ 60 days, (4) diagnosis of LACC, (5) the execution of NACT.

In all centers, patients were thoroughly counseled about the different possible choices of treatment. In particular, in case of stage IB2-III disease, they were informed about concomitant chemo-radiation was indicated as standard treatment for LACC, and that NACT + MRH represented

an experimental option. Therefore, the choice of treatment was based on.

As primary outcome we evaluated the impact of NS approach of peri-operative outcomes in women undergoing MRH. For this reason, patients undergoing NACT followed by NS-MRH were matched with patients undergoing MRH. For every patient undergoing NACT plus NS-MRH one control was selected using a propensity score model. Propensity score for an individual is defined as the probability of having been treated with an intervention based on different covariates (detailed description of propensity-matched comparison is reported below in the statistical method section) [22].

NACT consisted of carboplatin and paclitaxel or cisplatin chemotherapy with the addition of ifosfamide and paclitaxel or topotecan (in case of squamous cells tumors) or adriamycin and paclitaxel (in case of endocervical adenocarcinoma). Response to NACT was defined according to the Response Evaluation Criteria in Solid Tumors [23,24].

There were no significant differences in the facilities available for patient care and in the referral patterns within departments. Teams of skilled laparoscopic surgeons performed all surgical operations in every institution following the same standardized surgical steps. Detailed description of the surgical technique for NS-MRH and MRH and pelvic lymphadenectomy is presented elsewhere [22–27]. Briefly, the main steps of NS-MRH are:

Step 1: Preserving the caudal part of the inferior hypogastric plexus (IHP) and bladder branches. After dissecting the posterior part of vesicovaginal ligament, the nerve fibers (bladder branches) that run along the lateral vaginal wall are identified and detached from the vaginal wall. Step 2: Preserving the parasympathetic fibers and the middle part of the IHP. All of the vessels are cut, and the loose connective tissues of the cardinal ligament (CL) and the paracolpium attached to the pelvic side wall are radically freed, with preservation of all parasympathetic fibers but the fibers that run in the dorsomedial part of the CL. Step 3: Preserving the inferior hypogastric nerve and the proximal part of the IHP. The medial uterosacral ligaments are separated from the lateral nervous fibers. The medial ligaments are resected, whereas the lateral parts are saved. Step 4: Separating the parametrium and paracolpium from the uterus and vagina. The CLs and paracolpium are pulled up, maintaining slight tension on it to uncover the fibers that run from the IHP to the base of the bladder. MRH does not involve nerve preservation and, therefore, the paracervix is transected completely, including the part caudal to the deep uterine vein.

Over the study period, surgical therapy consisted in performing a type C radical hysterectomy, with or without oophorectomy plus systematic pelvic lymphadenectomy; para-aortic lymphadenectomy was limited to patients with bulky nodes or it was performed in case of suspicious lesions in the para-aortic area detected at preoperative

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