



## Vaginal extension improves sexual function in patients receiving laparoscopic radical hysterectomy☆



Hongyuan Jiang<sup>a,1</sup>, Jing Zhu<sup>a,1</sup>, Sun-Wei Guo<sup>a,b,\*</sup>, Xishi Liu<sup>a,b,\*\*</sup>

<sup>a</sup> Shanghai OB/GYN Hospital, Fudan University, Shanghai 200011, China

<sup>b</sup> Shanghai Key Laboratory of Female Reproductive Endocrine-Related Diseases, Fudan University, Shanghai, China

### HIGHLIGHTS

- The sexual function of women receiving radical hysterectomy is reduced substantially.
- Vaginal extension, however, significantly attenuates this reduction.
- More ovarian reserve also contributes to this attenuation.
- Joint vaginal extension and ovarian preservation further ameliorate this reduction.

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### ABSTRACT

**Objective.** To investigate as to whether vaginal extension (VX) following laparoscopic radical hysterectomy (LRH) improves sexual function in patients with early-stage cervical cancer patients.

**Methods.** A total of 216 patients with stage Ia1–IIa2 cervical cancer were recruited, 115 of them received LRH concurrently with VX (group VX) and the other 101, LRH only (group C). Demographic, clinicopathological, and peri-operative data were collected. The Female Sexual Function Index (FSFI) questionnaire was administered before and one year after surgery. Serum estrogen and follicle-stimulating hormone levels were also measured one year after surgery. The total and domain-wise FSFI scores before and after surgery were compared.

**Results.** Irrespective VX or not, all 6 domains of the FSFI scores in women with early-stage cervical cancer were significantly reduced one year after LRH. VX, however, significantly attenuated this reduction and improved all 6 FSFI domain scores, at the only cost of <20 min longer operating time. In addition, more ovarian reserve and better pre-operational sexual function also contributed to the attenuation. The ovarian reserve was improved if ovarian preservation procedure was performed during LRH.

**Conclusions.** While the sexual function in patients receiving VX procedure does not fully achieve the pre-operational level, the improvement is nonetheless global and significant. Ovarian preservation procedure during LRH may also help improve the sexual function. Therefore, VX and ovarian preservation may be desirable for patients with early-stage cervical cancer who undergo RH.

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### 1. Introduction

Cervical cancer is the second most common female-specific cancer after breast cancer, accounting for ~8% of both total cancer cases and total cancer deaths in women [1]. While the incidences of new cases

and mortality of cervical cancer are both gradually decreasing in the US and many parts of the world [2], the number of newly diagnosed cases appears to be increasing in the coastal regions of China [3,4]. More disturbingly, most incident cases are in the age group of 15–44 years [4], that is, the most productive and sexually most active period in a woman's life.

Most newly diagnosed cervical cancers are early stage ones, and radical hysterectomy (RH) with pelvic lymphadenectomy has been the standard care. While the prognosis is encouraging, RH has been well documented to result in considerable changes in anatomy, including vaginal shortening and decreased elasticity of the vaginal wall [5–9]. After parametrial resection, the nerve supply to the vaginal wall could be damaged, yielding inadequate relaxation of the smooth muscle of the vaginal arterio-venous plexus and insufficient vasocongestion and

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\* Correspondence to: Sun-Wei Guo, Shanghai Obstetrics and Gynecology Hospital, Fudan University, 419 Fangxie Road, Shanghai 200011, China.

\*\* Correspondence to: Xishi Liu, Shanghai Obstetrics and Gynecology Hospital, Fudan University, 419 Fangxie Road, Shanghai 200011, China.

E-mail addresses: [hoxa10@outlook.com](mailto:hoxa10@outlook.com) (S.-W. Guo), [lxdoc@hotmail.com](mailto:lxdoc@hotmail.com) (X. Liu).

<sup>1</sup> These two authors contributed equally to this work.

vaginal lubrication when sexually aroused [10]. Oophorectomy also contributes potentially to the pathophysiological mechanism of sexual dysfunction [9]. Consequently, RH results in sexual morbidity, manifested as reduced sexual desire, arousal, and lubrication, and increased dyspareunia, risk of orgasmic disorders, and reduced sexual satisfaction [9,11]. Unfortunately, the restoration of sexual function or minimizing the risk of sexual morbidity for cervical cancer survivors after RH is still an unmet medical need that begs for solution.

To consummate a sexual intercourse and to achieve satisfying sexual experience, a vagina of proper length is one important prerequisite. Yet a shortened vagina following RH is a nagging complaint among cervical cancer survivors [5–7,12,13]. To combat this problem, a vaginal extension procedure (VX) has been proposed over half a century ago [14], and VX with posterior peritoneal flap sutured to posterior vaginal wall also has been proposed for patients with cervical cancer after RH [15]. Unfortunately, it is unclear as whether these VX procedures truly improve sexual function or at least attenuate the negative impact resulting from RH.

Ye et al. reported a procedure for VX following RH for patients with FIGO stage Ib1–Ib2 cervical cancer but found no improvement in sex-related dimensions despite extended vaginal length [16]. However, the lack of statistical difference may likely be attributable to its moderate sample sizes. In addition, the psychometric instrument used may not be adequate enough to capture the changes resulting from the VX procedure rendered.

Based on a larger sample size and using the Female Sexual Function Index (FSFI) as a psychometric instrument, Chen et al. reported more recently that peritoneal vaginoplasty following laparoscopic RH (LRH) improved sexual function in patients with early-stage cervical cancer [17]. They report that VX yielded a slight 2.3%, albeit statistically significant, improvement in the total FSFI scores over non-VX group. Given this nearly minute improvement, the statement that VX improves sexual function seems somewhat tenuous at best. After all, a *statistically significant* event is not necessarily a *clinically meaningful* one.

Aside from these ambiguities and uncertainties, there is also a question as whether there are other factors, besides vaginal length, are responsible for the sexual function after RH as objectively measured by instruments such as FSFI. Faced with such ambiguities, uncertainties and unknowns, we undertook this study to investigate the effect of VX on sexual function after RH. We hypothesized that VX, in conjunction with ovarian preservation during RH, may improve sexual function in women undergone RH. We compared sexual functions between early-stage cervical patients with and without VX following LRH, assessed before as well as one year after surgery using FSFI based on larger sample sizes. We measured circulating follicle-stimulating hormone (FSH) level, a proxy for ovarian reserve, and attempted to identify factors potentially contributed to the total FSFI scores in addition to vaginal length. We also compared the intra-operative parameters of the two groups.

## 2. Materials and methods

### 2.1. Patient recruitment and data collection

One hundred and fifteen patients with FIGO stage Ia1 (with positive margins)–Ia2 cervical cancer who received LRH concurrently with VX procedure using peritoneum at Shanghai OB/GYN Hospital, Fudan University, between January 2011 and December 2013, were recruited to this study after informed consent. The criteria for recruitment and inclusion were: 1) younger than 45 years; 2) regularly cycling; 3) sexually active and intended to be so after recovery from surgery; 4) negative history of previous gynecologic operation, and the absence of pelvic adhesion as confirmed during operation; and 5) negative vaginal margins by intra-operative frozen pathological evaluation. All eligible patients were given detailed explanation regarding the surgical procedure, and possible risks and benefits of VX. It was the patient herself who made

the final decision as whether or not to have VX. Informed consent was obtained prior to the operation.

For comparison, an additional 101 stage-matched and married patients (Group C), who received LRH of the same radicality as the VX group, were selected randomly from the pool of 1191 eligible patients in the same hospital during the same time period were recruited to this study after informed consent. They received the same standard of care except no VX procedure was made during surgery. For all patients, the diagnosis was made by pre-operative pathological biopsies and confirmed by post-operative histology. None of them received any neo-adjuvant chemotherapy or radiotherapy prior to the surgery.

Following the National Comprehensive Cancer Network (NCCN) guidelines [18], when the patient was younger than 45 years and the pre-operative imaging examination showed no ovarian involvement, ovarian preservation was suggested to her before surgery and performed if consented and if gross ovarian biopsy was found to be negative during LRH. In addition, to minimize the impact of postoperative pelvic radiotherapy on ovarian reserve, ovarian transposition was performed who received ovarian preservation. Two patients, one aged 35 and staged Ib2, and the other, aged 39 and staged Ib1, neither with ovarian involvement, still requested bilateral oophorectomy out of concern for possible metastasis, and their wishes were granted.

As with other cervical patients in our hospital, both groups of patients were followed up regularly: if no post-operative adjuvant chemotherapy or radiotherapy was taken, the first follow-up one month after surgery, then every 3 months for the first and second years after surgery, and every 6 months thereafter. If post-operative chemotherapy/radiotherapy was administered, monthly follow-up was carried for the first 6 months after surgery. Follow-up assessments included pelvic exams, pelvic ultrasonography, vaginal cytology, and serum squamous cell carcinoma antigen test. Computerized tomography or other imaging procedures were also used when deemed necessary.

For both VX and C groups, FSFI questionnaire [19], as a main outcome measurement, was administered after informed consent within one week before surgery and one year after, as reported previously [20]. FSFI is a well-validated, self-report multiple choice questionnaire for assessing key dimensions or domains of sexual function and quality of life for women. It consists of 6 domains: genital desire, arousal, lubrication, orgasm, sexual satisfaction, and pain. We have used this instrument before [20] and its Chinese version has been validated [21]. In addition, clinical and surgical data were retrieved and recorded, and the information regarding time to resume sexual activity after surgery was also queried and recorded.

Following the NCCN guidelines [18] and the hospital's guidelines, postoperative adjuvant chemotherapy, radiotherapy or both were recommended to patients deemed to have high risks of metastasis. Following the same guidelines [18], pelvic radiotherapy plus concurrent cisplatin-containing chemotherapy with or without vaginal brachytherapy were advised given the surgical findings of positive pelvic nodes and/or positive surgical margin and/or positive parametrium. Since no patient had positive vaginal mucosal margins, no patient received brachytherapy in this study.

Before and one year after surgery, all recruited patients were interviewed vis-à-vis by a well-trained staff in an isolated room, free from any distraction, and were asked to finish the FSFI questionnaires themselves. The interviewer was blinded to the group assignment. After interview, a gynecologic oncologist evaluated the patient by pelvic examination and measured the vaginal length. After dilating the vagina by a two-bladed speculum, it was examined for any signs of vault dehiscence. To measure vaginal length, a sterile, calibrated glass vaginal stent, wrapped with a condom and properly lubricated, was gently inserted into the vagina down to the vaginal apex and the vaginal length was measured without any stretching [20] and recorded according to the calibration marked on the stent.

All recruited patients were requested for the evaluation of their circulating FSH, E<sub>2</sub>, and progesterone (P<sub>4</sub>) levels one year after RH. Due to

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