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Evaluation of pelvic floor muscle function(PFMF) in Cervical Cancer patients with Querleu-Morrow type C hysterectomy: A multicenter study

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Sha Wang, Shiyan Wang, Qing Wang, Tingting Cao and Huaxin Sun: Data collection.
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Shiyan Wang, Jianliu Wang and Xiuli Sun wrote the main manuscript.

All authors reviewed the manuscript.

Keywords Pelvic floor muscle strength(PFMS), pelvic floor muscle function(PFMF), Cervical cancer, QM-C hysterectomy, follow-up time

Brief summary The evaluation and analysis of PFMS were studied after Querleu-Morrow type C hysterectomy and the influencing factors were radiotherapy, chemotherapy and the follow-up.

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Abstract

Introduction and Hypothesis To evaluate the pelvic floor muscle function (PFMF) of cervical cancer patients after type QM-C hysterectomy and to explore the relationship between decreased PFMF and related factors..

Methods This was a multi-centered retrospective cohort study. 181 cervical cancer patients underwent type QM-C hysterectomy were enrolled from 9 tertiary hospitals. Strength of PFMF were measured by using neuromuscular apparatus (Phenix U8, French). Risk factors contributed to decreased PFMF was analyzed by univariate and multivariate ordinal ploytomous logistic regression.

Results Totally 181 patients were investigated in this study. 0-3 level of type I muscle fibre strength(MFSI) was 52.6%(95/181), 0-3 level of type IIA muscle fibre strength(MFSIIA) was 50%(91/181). Subjective stress urinary incontinence was 46%(84/181), urinary retention was 27.3%(50/181), dyschezia was 41.5%(75/181), fecal incontinence was 9%(18/181). ①MFSI : Multivariate ordinal ploytomous logistic regression shows that the follow-up time($p<0.05$), chemotherapy and radiotherapy ($p=0.038$) are independent risk factors of MFSI's reduction after type QM-C hysterectomy. ② MFSIIA: Multivariate ordinal ploytomous logistic regression shows that the follow-up time($p<0.05$) are independent risk factors of MFSIIA's reduction after type QM-C hysterectomy. The pelvic floor muscle strength(PFMS) increased after 9 months than in 9 months after operation, which showed that the PFMS could be recovered after operation.

Conclusions We advocate for more attention and emphasis on the PFMF of Chinese female patients with cervical cancer postoperation.

Contribution of the Paper The key messages of the article is that PFMF after QM-C hysterectomy have not been analyzed by current study. The new knowledge added by this study is that 3 months after radical hysterectomy patients' should do pelvic floor rehabilitation exercises.

Introduction

The morbidity of cervical cancer is still high but advanced technology enables more cervical cancers be detected at the early stage nowadays. With type QM-C hysterectomy plus pelvic lymphadenectomy, the rate of 5-year survival of cervical cancer patients could reach to 95%.^[1] However, evidences showed that type QM-C hysterectomy may seriously decrease the pelvic floor function of the patients, including mainly lower urinary tract syndrome,^[2,3] defecation disorders^[4,5] and sexual dysfunction.^[6] All of those problems would negatively affects the life quality of the patients for a long time. Dysfunction of the pelvic floor muscles (PFM) might result in urinary and faecal incontinence, pelvic organ prolapse (POP), sexual problems, and chronic pain.^[7] As PFM provides support and sphincteric functions to the pelvic organs, investigation to PFM function is crucial to shot the problems in individuals with pelvic floor disorders (PFD).^[8,9]

The PFM was mainly consisted of type I and type II muscle fibers.^[10] PFM plays an important role in maintaining vaginal constriction and the normal position of the organs in pelvis and, thus, further in keeping the normal function of urethral sphincter and rectal sphincter.^[11] Overactive bladder(OAB) and urinary incontinence(UI) are the two common courses that could have negative impacts on women's quality of life. PFM training is the most preferred treatment to increase PFM strength (PFMS) in women with stress urinary incontinence (SUI).^[12-16] The life quality of the patient will be improved if the elements affecting PFMS were analyzed and treated after type QM-C hysterectomy. However, there were only few studies focusing on the post QM-C hysterectomy PFMF. Our aim is to identify the elements resulting PFM weakness in patients who underwent QM-C hysterectomy for cervical cancer and to figure out a way to solve the problems.

The incidence of cervical cancer was high, and it was one of the common malignant tumors in gynecology. The annual incidence of new cases in China accounted for about 1/3 of the new cases of cervical cancer in the world^[17]. The standard treatments for invasive cervical cancer was surgical treatment and radiotherapy supplemented by chemotherapy. Annually, about 83.9% of cervical cancer patients in China undergo surgical treatment with the main procedure to be QM-C hysterectomy and pelvic lymphadenectomy^[18]. With the improvement of cervical cancer screening in recent years, the trend of rejuvenation was obvious and the 5-year survival rate of patients with early stage of cervical cancers has raised high^[19]. Patients with early stage of

cervical cancer could survive or even "cure" after treatment. However, due to the large scope of surgery, the preoperative removal of para-uterine tissue in QM-C hysterectomy procedures would also damage the pelvic floor nerves, muscles and fascia, and radiotherapy and chemotherapy would lead to pelvic tissue fibrosis, low ovarian function and even failure, resulting in postoperative PFD, which seriously affects the life quality of patients. At present, there was still a lack of large-scale study on the incidence of pelvic floor dysfunction and related factors in patients with cervical cancer treated with surgery as the main treatment. This study performed retrospective analyses PFMS measurement and other methods to assess the PFMS of 181 patients with cervical cancer after QM-C hysterectomy.

The PFM plays an important role in supporting the pelvic and abdominal organs and controlling urinary and fecal continence in addition to their role in the sexual function^[20]. The types of PFMF included: MFSI belonged to the pelvic and abdominal cavity support system, accounting for 70% of the pubic vaginal and puborectalis muscles, 90% of the pubis caudal muscles, and 68% of the sacral and posterior tibial muscles. The function was characterized by tonic contraction, long contraction time and long-lasting, and it was not easy to fatigue. MFSIIA belonged to the pelvic and abdominal cavity movement system, and their functions were staged contraction, rapid and short-lived, and were easy to fatigue.^[21] Why was PFMS important for female patients? Decreased PFMS could cause LUTS, defecation disorders, and sexual dysfunction.^[22] It would seriously affect the quality of patients' life.

The fact that cervical cancer patients had the above three PFD diseases might be related to the reduction of PFMS.

According to reports, for women who demonstrated SUI during pregnancy and delivery, postpartum SUI was mostly linked to weakening of PFM^[23]. After being comprehensively and accurately assessed, PFM rehabilitation was able to enhance PFM strength and muscle tone, which gave rise to improvement of SUI^[24-25]. The most popular assessment methods in China for assessing the condition of PFM in postpartum female patients were the digital palpation and EMG evaluation because of easy access to relevant equipments and low cost^[28]. EMG was mostly utilized to identify muscle activity, measure intramuscular force ratio and record PFM dysfunction^[29]. As a result, we chose EMG as the evaluation method to record the pelvic muscle strength. Pelvic floor exercise and biofeedback for patients with cervical cancer surgery, and pelvic floor rehabilitation for patients with PFD could improve the life quality of patients. However, there was no retrospective study for systematic examination and analysis, and PFMS was not being measured in patients with cervical cancer.

Materials and Methods

1. Patient recruitment:

The patients will be recruited from the cervical cancer patients who had been underwent QM-C hysterectomy participating hospitals during January 2012 to March 2015. Patients will be included if they were 1) ≥ 18 years of age, 2) underwent QM-C hysterectomy for cervical cancer for 3-24 months, and 3) consent to participation by signing the informed consent form. Patient will be excluded if they 1) experienced preoperative adjuvant radiotherapy, 2) had received pelvic floor rehabilitation after surgery, 3) had less than 3cm of main sacral ligament resection and /or less than 3cm of vaginal resection, and 4) could not completed questionnaires or PFMS evaluation. As the first step of patient enrolment, eligible patients would be examined by two experienced gynecologic oncologists at the participating hospitals for pelvic floor function, and were staged according to the patient's medical history and clinical manifestations following the clinical staging criteria of cervical cancer revised by FIGO in 2009.

1) Patients who met the inclusive criteria would be contacted and invited by the investigators to participate the study via explaining the study in detail. An informed consent prior approved by the Institutional

Review Board (IRB) of Peking University People's Hospital would be signed by the patient and the doctor when the patients agreed to participate the study with all her questions about the study fairly answered and understood. Patients who had died by the study contacting were not included into the analysis.

2. Study Methods

The PFMS and the life quality of the patients were evaluated and the relevant influencing factors were investigated in a stratification of deferent post-surgery periods as 3-6 months, 7-9 months, 10-12 months, 13-18months, 19-24 months. Eligible patients would went through the procedures as shown in Figure 1 and described as the follows:

- 2) Demographic data collection: Demographic data was collected through interviewing the eligible patients in a private room, and by an investigator who did not perform treatment on the patient and was blind of the patient's history. Data that was collected includes the age, body mass index (BMI), preoperative comorbidities, number and mode of deliveries, clinical staging, and type of hysterectomy, etc..
- 3) Clinical Record Review: Clinical record on the QM-C hysterectomy was checked to confirm the resected part of the Main sacral ligament was ≥ 3 cm and that of the vagina was ≥ 3 cm. Treatment information would be also collected for analysis.
- 4) Clinic Examination: Detailed physical examination would be conducted by trained investigators and results recorded, followed by laboratory examination and test as described below.

3. PFMS Examination

Our PFMS examination is followed by relevant guidelines and regulations from a book which is written by academician Jinghe Lang^[21].

Instruments: Phenix USB8 biofeedback system (Electron-IC Concept Lignon Innovation Co., France), the same equipment as used in Navarro Brazález B's study^[16], was used to test the PFMS of the patients. The manometer was interfaced with the biofeedback system that was installed in an IBM compatible personal computer. A vaginal pressure probe of 115 mm in length (Foshan Shanshan Datang Medical Technology Co., Ltd. China) inside of an airbag was linked with the manometry. The 41mm-long airbag was used for enlarging the vagina through inflating it to be oval-sized with air. Manometry and dynamometry were more reliable than vaginal palpation for the assessment of PFM strength in women with PFD, especially when different raters were involved^[16].

PFM Fibers categorization The PFM fibers were categorized into two types: type I and type II fibers. Type I fibers, also called sustained contraction muscles, is featured to have long lasting contraction and is not easy to fatigue. Most of type II fibers commonly distribute in the levator ani muscle. Type II fibers, also called as rapid contraction muscles, provide quick contraction that lasts very short and are easy to fatigue. They mostly distribute in the superficial layer of the pelvic floor. PFMS measurement mainly oriented to the strength of the muscle contraction, the ability of the muscle to resist resistance, the duration, symmetry and fatigue of the muscle contraction, the ability of the muscle in repeat contractions, and the rapid contraction times. Research evidence showed that changes of these basic electrophysiological indicators are usually detectable earlier than pelvic floor dysfunction appears and could be used as an evaluative index for early detection of pelvic floor dysfunction and the treatment outcomes. Comparing the postoperative PFMS of the two groups of patients could objectively evaluate the functional status of the pelvic floor.

Measurement of PFMS. The baseline pressure was set to 0cm H₂O. Patients were asked to contract their PFM for measurement of type I muscle fibers strength (MFS-I) by squeezing maximum for 5 times. The total width of **Figure 1** represents 10 seconds in time and the width of the yellow module represents 6 seconds. When the patient's MFS-I contraction called the sustained contraction made the red curve reach 40% of the yellow module height, the patient would be instructed to contract her vagina with maximum power for three times to obtain the maximum and minimum vaginal manometry values. The peaks of the yellow module in **Figure 1** represents the

maximum value of the vaginal manometry, while level 0 to level 5 represent the duration of the muscle strength (MSD) from 0s to 5s, respectively. **Figure 2** shows the muscle strength rapid contraction levels when the type IIA PFM contraction made the red curve reach to 70% - 90% of the yellow module height (referring to **Figure 2**).

Comparing of the MFS. To identify the factors that impact the MFS of the enrolled patients, they were categorized into 3 groups according to the therapies they underwent. Patients who underwent surgery only were referred as Group-S; patients who underwent surgery plus radiotherapy were referred as Group-SR; patients who underwent surgery and chemotherapy were referred as Group-SC; and those who were treated with surgery followed by radiotherapy and chemotherapy were referred as Group-SRC. MFS-I and IIA will be compared among those groups.

4. Statistical Analysis

Statistical analysis was performed using R software programming. Ordinal ploytomous logistic regression was used to analyze the influencing factors of MFS of type I and IIA after QM-C hysterectomy. The PFMS was categorized into three groups according to the measured duration levels, with which group A refers to patients with 0 level MSD, group B refers to those with 1-3 level MSD, while group C refers to those with 4-5 level of MSD. A p values of < 0.05 was considered statistically significant in comparison of the PFMS in different periods after QM-C hysterectomy, excluding the confounding factors, and analyzing the influencing factors of the postoperative PFMS in patients with cervical cancer..

Results

A total of 689 patients who underwent QM-C hysterectomy for cervical cancer at the referral center between January 2012 and March 2015 and met the enrollment criteria were approached for the study, among which 181 patients consented for participation by signing the Informed Consent Form and being enrolled for pelvic floor function screening. Of the 181 patients, 170 have complete data of pelvic floor function examinations for both type I and type IIA MFS (see Fig 3) .

Table 1 describes the age, body mass index, parity, mode of baby production, FIGO staging, treatment type, and the postoperative follow-up time of the enrolled patients (see Table 1).

Of the 181 enrolled patients, 22.1% (40) were detected as level 0, 30.5% (55) as level 1-3, and 47.4% (86) as level 4-5 of type I MFS, while 15.3% (28) of them were detected as level 0, 34.7% (63) as level 1-3, and 50% (90) as level 4-5 of type IIA MFS. The interviewing to those patients shows that 46% (83) of them had SUI, 27.3% (49) had UR, 41.5% (75) had Dyschezia, and 9% (16) suffered fecal incontinence; 77.5% of the patients were not satisfied with their sexual life. All those data suggest that the therapy of cervical cancer they were underwent have significant negative influences on patients' pelvic function, and PFMS is an important pelvic floor function indicator to assess that influences (See Table 2).

Univariate analyses to the risk factors of the 181 enrolled patients showed that the type I muscle fiber strength (MFS-I) of Group SR was significantly worse than Group-S (Group-SR vs Group-S, est 0.203, 95% CI 0.071-0.577, $p=0.003$), and that MFS-I of the patients who were 18-24 months after operations was significantly better than that of the patients who were 3-6 months after surgery (18-24months vs 3-6months, est 2.539, 95% CI 1.077-5.987, $p=0.033$); the type IIA muscle fiber strength (MFS-IIA) of the patients in Group-SR was significantly worse than those in Group-S (Group-SR vs Group-S, est 0.333, 95% CI 0.119-0.931, $p=0.036$) (Table 3). Results from univariate analyses suggests that multiple therapies have negative impact on MFS-I and MFS-IIA and recovery time helps in MFS recovery.

We also performed multivariate regression analysis on each of the factors as: postoperative period and treatment methods. After excluding confounding factors, we found that MFS-I of Group-SR were significantly worse than that of Group-S (Group-SR vs Group-S, est 0.230, 95% CI 0.072-0.738, $p=0.013$); and the muscle strength of patients in Group-SRC was significantly worse than that of the patients in Group-S (Group-SRC vs

Group-S, est 0.428, 95% CI 0.192-0.954, $p=0.038$). Muscle strength in Group SC was different with that of Group-S but not statistically significant (Group SC vs Group-S, est 0.602, 95% CI 0.388-1.731, $P=0.602$). Results from multivariate regressive analyses also suggests the negative impacts of multiple therapies on MFS-I and MFS-IIA recovery.

In comparing the MFS of the patients with different post-treatment periods (PTP), patients with PTP of 18-24 months, 12-18 months and 9-12 months are all significantly worse than patients with a PTP of 3-6 months (18-24 mths vs 3-6m, est 3.126, 95% CI 1.278-7.647, $p=0.013$; 12-18mths vs 3-6m, est 3.194, 95% CI 1.339-7.617, $p=0.009$; and 9-12 mths vs 3-6 mths, est 3.816, 95% CI 1.095-13.302, $p=0.036$, respectively). However, patients with a PTP of 6-9 months is not significantly worse and those with a PTP of 3-6 (6-9m vs 3-6m, est 1.592, 95% CI 0.641-3.954, $p=0.316$). This result suggests a time-base trends of MFS that the longer the PTP is, the worse the MSF is.

The results also shows that MFS-IIA of the patients in Group-SR was better than that of patients in Group-S with no statistical significance (Group-SR vs Group-S, est 0.318, 95% CI 0.100-1.009, $p=0.052$), although the P value is close to 0.05. It was suggested that radiotherapy might be a risk factor for type II pelvic floor muscle fibers (SQ-this conclusion is far-fetched and should not be concluded).

When comparing MSF-IIA of the patients with different PTPs, patients with a PTP of 18-24mths, 12-18mths, 9-12mths, and 6-9mths are all better than patients with PTP of 3-6mths, but significant differences only shows in the comparisons between patients with PTP of 12-18mths and those with PTP of 3-6mths (12-18m vs 3-6m, est 2.385, 95% CI 1.007-5.649, $p=0.048$) and that between patients with a PTP of 9-12mths and those with PTP of 3-6mths (9-12m vs 3-6m, est 5.178, 95% CI 1.454-18.445, $p=0.011$), with no difference shows in comparisons between patients with PTP of 18-24 and those with PTP of 3-6 (18-24m vs 3-6m, est 1.981, 95% CI 0.815-4.815, $p=0.131$) and that between patients with PTP of 6-9 and those with PTP of 3-6 (6-9m vs 3-6m, est 1.257, 95% CI 0.505-3.126, $p=0.623$) (See Table 4). Those results suggest that most of the MFS-IIA recovery may took place in 9-12 months of PTP.

Discussion

Our study conducted a postoperative questionnaire survey of 689 patients and performed PFMS examination in 181 patients. From our analyses, PFMS is likely at a low level within 9 months after treatments and can be recovering after 9 months after surgery. Therefore, it pelvic-floor-function rehabilitative treatment might have a certain protective effect on the pelvic floor function of patients with cervical cancer if it can be started in 3 month post the treatments. There currently is no literature to examine and analyze the muscle strength of patients with cervical cancer. As a clinical registered study, this study not only investigated the MFSI and MFS II A of patients with cervical cancer surgery, but also taps into the risk factors for the reduction of PFMS.

The results of this study showed that significant attenuation of MFS-I is directly related with radiotherapy as a single factor and multivariate analysis showed radiotherapy to be an independent risk factor on attenuation of MFS-I ($P<0.05$). The fact that MFSI radiotherapy would lead to the formation of tissue scars in muscles and ligaments maybe a fair explanation for the weakness of Type I fibers after radiotherapy. Our results also showed that MFS-I remained at a poor level within 9 months after treatment and MFS-I recovered and maintained at a certain level that is lower than the normality in 9-24 months after treatments, demonstrating that the muscle strength recovered gradually long with the prolonging of PTP, which could be an evidence to recommend muscle fibers exercise within 3 months after surgery.

Multivariate regression analysis showed that radiotherapy was also an independent risk factor for MFS-IIA ($P<0.05$), which could result in significant weakness of type IIA muscle fibers. However, multivariate analysis

showed that MFS-IIA of the patients with PTP of 9-18 months had been significantly improved in comparing with patients with a PTP of six months, but that of the patients with a PTP of 6-9 months and 18-24 months had not been significantly bettered, although they are getting little better. This indicates that the improvement of MFS-IIA can be improved along with the PTP prolonging but the obvious improvement happens during 9-18 month after the treatments (See Fig 4) . Our long-term follow-up on some of the patients showed that, MFS-IIA could be significantly improved after one and a half years of PTP.

As a retrospective analyses, the study has limitation on the enrollment of patients, who are with different months of PTPs. Perspective study would be designed and conducted if we need to collect data of patients with a PTP of same time to demonstrate the exact impacts of the risk factors on the MFS. In our study, it was very difficult to get the specific and objective parameters of PFMS of 181 cervical cancer patients. However, the results of our study provided valuable evidences to indicate how and when the doctors should have such patients to exercise pelvic floor muscle after operation.

Therefore, we concluded that Radiotherapy is an independent factor to have negative impact on the recovery of both type I and IIA pelvic floor muscle fibers; Weakness of PFMF can be improved along with the time going of post treatment period, and most of the recovery taking place during 9-12months of PTP. Pelvic floor muscle exercise should be prescribed to the patients with 3 months after the treatments.

Ethical Approval This was a multi-centered and retrospective cohort study, the research protocol was approved by the Institutional Review Board(IRB) .(IRB number 2015PHB021-04).

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Conflict of interest

None.

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Figures

Figure 1

Type I muscle strength of grade 5

Figure 2

Type II muscle strength of grade 5

Figure 3

Flowchart of this study. PFE: pelvic floor examination; Q: questionnaire; PFEmF: pelvic floor electromyography function; PFTF: pelvic floor tension function; PFUF: pelvic floor urinary control function; PFSF: pelvic floor sexual function; PFNIM: pelvic floor nerve injury measurement

Figure 4

Comparison of muscle strength half a year after operation with that of 3-6 months after operation. For type I muscle fiber, 6-9 months, 9-12 months, 12-18 months, 18-24 months after operation was 1.592 times ($P>0.05$), 3.816 times ($P<0.05$), 3.194 times ($P<0.05$), 3.126 times ($P<0.05$) than 3-6 months after operation. For type II muscle fiber, 6-9 months, 9-12 months, 12-18 months, 18-24 months after operation was 1.257 times ($P>0.05$), 5.178 times ($P<0.05$), 2.385 times ($P<0.05$), 1.981 times ($P>0.05$) than 3-6 months after operation.

Supplementary Files

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