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Application of portable vaginal irrigator in patients with cervical cancer undergoing external irradiation combined with intracavitary brachytherapy

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► ***Original article***

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ABSTRACT

***Background*:** To probe the impact of portable vaginal irrigator in patients with cervical cancer undergoing radiotherapy. ***Materials and Methods*:** A total of 100 patients with advanced cervical cancer who received radiotherapy in our hospital from January 2021 to December 2022 were chosen and separated into control group (CG, n=50) and research group (RG, n=50). After radiotherapy, patients in the CG control group adopted extrusion balloon irrigator for vaginal irrigation, while patients in the RG adopted portable vaginal irrigator for vaginal irrigation. The cleanliness, vaginal length, vaginal width, comfort ratio, patient satisfaction, and occurrence of complications in both groups were compared. ***Results*:** The number of patients with a white blood cell count of 15-30 in the RG was less than that of the CG (P<0.05). The number of patients in cleanliness degree I in the RG was higher relative to the CG (P<0.05), while the number of patients in cleanliness degree III in the RG was lower compared to the CG (P<0.05). Three months after radiotherapy, the vaginal length and vaginal width of the RG were higher relative to the CG (P<0.05). The comfort ratio and satisfaction of patients in the RG was higher compared to the CG (P<0.05). The occurrence of complications in the RG was declined compared to the CG (P<0.05). ***Conclusion*:** The use of portable vaginal irrigation device realizes the comfortable feeling of patients in the process of use, improves the effect of vaginal irrigation, reduces the occurrence of complications after radiotherapy, which is worthy of clinical promotion.

INTRODUCTION

Cervical cancer belongs to the most common female malignant tumor in our country [1, 2]. Due to the increase of certain high-risk factors, such as the first sexual life in advance, frequent sexual life and induced abortion, the incidence of tumor is high all the year around [3, 4]. In recent years, with the popularization of follow-up cervical cancer cell smear examination, the detection rate of the disease has increased, and some patients have received timely treatment in the early stage of the disease [5]. However, there are still some patients with cervical cancer who come to the hospital for treatment in the middle and late stage and have lost the best opportunity for surgery [6]. At present, radiotherapy is a common method for patients with advanced cervical cancer, often using external irradiation plus intracavity brachytherapy [7]. External irradiation is the use of linear accelerator generated X-ray accurately hit cervical cancer pelvic spread and metastasis area [8]. Internal irradiation is to take advantage of the natural favorable conditions of cervical cancer and put radioactive sources into the natural lumen of human body to irradiate the primary area of cervical cancer at close range [9]. However, such patients often have complications, such as increased vaginal exudate, loss of necrotic tissue, peculiar smell, vaginal infection, stenosis, and vaginal adhesion, which brings a lot of inconvenience to their lives, seriously affects the self-confidence of patients, and is very unfavorable to the recovery of the disease [10].

At present, the appliance of vaginal irrigation for patients by themselves belongs to the extrusion balloon irrigation device, which has simple structure [11]. On the one hand, the corresponding cleaning head is connected with the corresponding elastic extrusion balloon in a straight line. If the force is not uniform in the use process, the liquid will be used up at one time, resulting in waste of cleaning liquid or too small force to maintain the continuous outflow of cleaning liquid, which cannot reach the best cleaning results [12]. On the other hand, in the process of extrusion cleaning, the cleaning fluid is easy to flow back into the balloon, resulting in the contamination of the cleaning fluid. At the same time, the arm of the cleaner must be extended long enough to place the flushing device at the flushing site, which is difficult to be carried out at home, which brings great inconvenience to the patient [13].

In order to improve the compliance of patients

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with vaginal irrigation, reduce the complications of radiotherapy, and make patients feel comfortable and convenient, our department designed a portable vaginal irrigator, and probed its effect on patients with cervical cancer undergoing radiotherapy. Our study indicated that the use of portable vaginal irrigator could improve the effect of vaginal irrigation, reduce the occurrence of complications of patients with cervical cancer after radiotherapy.

MATERIALS AND METHODS

General data

A total of 100 patients with advanced cervical cancer who received radiotherapy in our hospital from January 2021 to December 2022 were chosen and separated into control group (CG, n=50) and research group (RG, n=50). No significant difference was discovered in general information between the two groups (P>0.05, table 1), which was comparable. This study was carried out with the approval of the ethics committee of Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine (Registration No. SHL002019A-L, December, 2020).

Inclusion criteria: (1) Diagnosed with cervical cancer and the tumor stage was intermediate and advanced. (2) All patients needed radical radiotherapy. (3) The patient's family voluntarily signed an informed consent form. (4) Normal intelligence and communication.

Exclusion criteria: (1) Mental illness. (2) Severe liver, heart and kidney dysfunction. (3) Coagulopathy, cardiovascular and cerebrovascular diseases.

Table 1. Comparison of general information of patients in both groups.

Items		Control group (n=50)	Research group (n=50)	P value
Age (years)		52.38±10.62	52.41±10.73	>0.05
Pathological types	Cervical squamous carcinoma	42	43	>0.05
	Cervical adenocarcinoma	8	9	
Stages	II a	4	5	>0.05
	II b	15	14	
	III a	6	7	
	III b	23	24	
	IV	2	1	

METHODS

Radiotherapy method

The treatment plan of the two groups was the same, which was as follows: external irradiation combined with intracavitary brachytherapy. External irradiation was implemented by 6 MV X-ray linear accelerator (Varian, China). The median dose of pelvic cavity was 45 ~ 50 Gy, 1.8 ~ 2.0 Gy/f, 5 times/week, and three-dimensional conformal radiotherapy was added 10 ~ 16 Gy in positive lymph nodes. While intensity modulated radiation therapy was synchronously increased to 60 Gy. When the external irradiation dose reached 45 Gy, intracavitary brachytherapy was performed at 6 ~ 7 Gy/f, 1 ~ 2 times per week, for 4 ~ 6 times in a row.

Vaginal irrigation method

After radiotherapy every day, patients in the CG control group adopted extrusion balloon irrigator (Cofoe, China) for vaginal irrigation, while patients in the RG were treated with portable vaginal irrigator (LFcare, China) for vaginal irrigation, and the process was as follows: According to the need, the required vaginal irrigation solution was aspirated into the injection cylinder, and at the same time, the cleaning head was filled to connect the cleaning head and the injection cylinder. The patient took a comfortable squat position to completely place the cleaning head into the vagina, and pushed the piston rod to make the washing liquid flow out of the small hole in the cleaning head to lubricate the vaginal wall. As the silicone brush on the surface of the piston cleaning head rotates with the cleaning head, so as to achieve the purpose of thoroughly cleaning the vagina.

Observation indicators

(1) Patients in both groups underwent vaginal discharge examination 1 week after radiotherapy. Vaginal cleanliness was divided into degree I, degree II, degree III as well as degree IV using microscope (Olympus, Japan). Degree I: bacteria in the vagina were mainly lactobacillus, a lot of vaginal epithelial cells could be seen, cocci and other miscellaneous bacteria could not be seen. At high power, there were no more than 5 pus cells in one field of vision. Degree II: vaginal bacteria were only partially Lactobacillus and partially vaginal epithelial cells. At high power, the number of pus cells in a field of vision was more than 5 and less than 15. Degree III: only a small amount of lactobacillus and vaginal epithelial cells could be seen, on the contrary, the number of miscellaneous bacteria increased; there were 15 ~ 30 pus cells in a high magnification field. Grade IV: almost no lactobacillus and vaginal epithelial cells could be seen, the visual field was all miscellaneous bacteria, more than 30 pus cells.

(2) Gynecological examination was performed 3 months after radiotherapy, and the vaginal length and vaginal width after different irrigation methods were recorded.

(3) According to the visual analogue scale score, the comfort ratio was calculated: 0-2 points indicated comfort, 3-4 points indicated mild discomfort, 5-6 points indicated moderate discomfort, 7-8 points indicated severe discomfort, and 9-10 points indicated extremely severe discomfort.

(4) The self-designed satisfaction questionnaire after vaginal irrigation was used to score and

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calculate patient satisfaction.

(5) The occurrence of complications such as vaginitis, pelvic infection, vaginal wall injury, bleeding, and vaginal adhesion was evaluated.

Statistical analysis

SPSS 16.0 software (International Business Machines Corporation, USA) was adopted to analyze the data. t test was applied for measurement data, and χ^2 test was applied for enumeration data, and P<0.05 was significance.

RESULTS

Cleanliness in both groups

It was displayed in table 2 that, the number of patients with a white blood cell count of 15-30 in the RG was less than that of the CG (P<0.05). However, no difference was seen in the white blood cell count of 0-5 and 15-30 between both groups (P>0.05).

No difference was discovered in bacterial vaginosis of patients in both groups (P>0.05, table 3).

It was displayed in Table 4 that, the number of patients in cleanliness degree I in the RG was higher relative to the CG (P<0.05), while the number of patients in cleanliness degree III in the RG was reduced relative to the CG (P<0.05). Meanwhile, no difference was discovered in cleanliness degree II and degree IV between both groups (P>0.05).

Table 2. Comparison of white blood cell count of patients after vaginal irrigation in both groups (n, %).

Groups	N	White blood cell count of 0-5 (10^9/L)	White blood cell count of 5-15 (10^9/L)	White blood cell count of 15-30 (10^9/L)
Research group	50	9	30	11
Control group	50	8	21	21
χ^2		0.07	3.24	4.60
P		>0.05	>0.05	<0.05

Note: N: number. P values were obtained by t test. P values were obtained by chi-square test.

Table 3. Comparison of bacterial vaginosis of patients after vaginal irrigation in both groups (n, %).

Groups	N	Bacterial vaginosis (-)	Bacterial vaginosis (+)	Bacterial vaginosis (±)
Research group	50	45	0	5
Control group	50	42	2	6
χ^2		0.80	2.04	0.10
P		>0.05	>0.05	>0.05

Note: N: number. P values were obtained by t test. P values were obtained by chi-square test.

Table 4. Comparison of cleanliness of patients after vaginal irrigation in both groups (n, %).

Groups	N	Degree I	Degree II	Degree III	Degree IV
Research group	50	10	23	17	0
Control group	50	1	16	31	2
χ^2		8.27	2.06	7.85	2.04
P		<0.05	>0.05	<0.05	>0.05

Note: N: number. P values were obtained by chi-square test.

Vaginal length and vaginal width in both groups

Three months after radiotherapy, the vaginal length and vaginal width of patients after vaginal irrigation in the RG were elevated relative to the CG (P<0.05, figure 1A-1B).

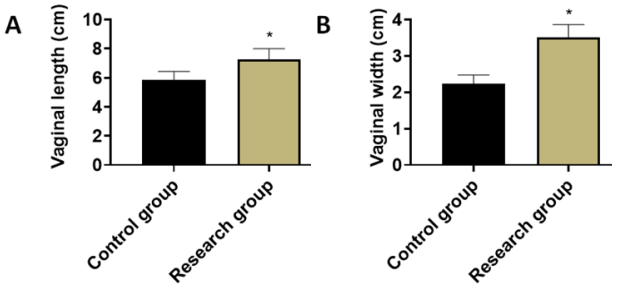


Figure 1. Comparison of vaginal length and vaginal width of patients after vaginal irrigation in both groups. **(A)** Vaginal length of patients after vaginal irrigation in both groups. **(B)** Vaginal width of patients after vaginal irrigation in both groups. *P<0.05. P values were obtained by t-test.

Comfort ratio in both groups

The comfort ratio of patients in the RG was 70.00%, which was higher compared to 48.00% in the CG (P<0.05, table 5).

Table 2. Comparison of white blood cell count of patients after vaginal irrigation in both groups (n, %).

Groups	N	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort	Extremely severe discomfort	Comfort ratio (%)
Research group	50	35	10	5	0	0	70.00%
Control group	50	24	16	10	0	0	48.00%
χ^2		5.00					
P		<0.05					

Note: N: number. P values were obtained by chi-square test.

Patient satisfaction in both groups

The patient satisfaction in the RG was 96.00%, which was higher compared to 78.00% in the CG (P<0.05, table 6).

Table 6. Comparison of patient satisfaction after vaginal irrigation in both groups (n, %).

Groups	N	Satisfied	Generally satisfied	Unsatisfied	Satisfaction rate (%)
Research group	50	36	12	2	48 (96.00%)
Control group	50	25	14	11	39 (78.00%)
χ^2		7.16			
P		<0.05			

Note: N: number. P values were obtained by chi-square test.

Occurrence of complications in both groups

The occurrence of complications in the RG was 18.00%, which was declined compared to 40.00% in the CG (P<0.05, table 7).

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Table 7. Comparison of occurrence of complications after vaginal in both groups (n, %).

Groups	N	Vaginitis	Pelvic infection	Vaginal wall injury	Bleeding	Vaginal adhesion	Total incidence rate (%)
Research group	50	5	1	2	1	0	9 (18.00%)
Control group	50	8	3	4	3	2	20 (40.00%)
χ^2		5.88					
P		<0.05					

Note: N: number. P values were obtained by chi-square test.

DISCUSSION

Patients with cervical cancer treated with radiotherapy are mostly in the middle and late stages of the disease [14, 15]. Due to tumor rupture and invasion of surrounding tissues and blood vessels, there are varying degrees of vaginal bleeding and serous secretions, accompanied by infection and malodor [16]. During radiotherapy, the involvement of the upper part of the vagina and the cervix is high, which can cause radioactive reaction of the vaginal mucosa, make the tumor tissue necrosis and fall off, gather in the vagina, easily cause a large amount of secretion accumulation, and aggravate bacterial infection [17]. If the irrigation is not timely, it is easy to cause retrograde infection, resulting in uterine effusion and cervical mouth adhesion, affecting the smooth progress of radiotherapy [18]. It also leads to decreased radiosensitivity of tumor cells [12]. Therefore, effective and thorough vaginal irrigation is of great significance for patients with cervical cancer undergoing radiotherapy.

Vaginal irrigation can effectively remove necrotic exfoliated cancer tissue, prevent infection, promote epithelial healing, avoid adhesion, increase radiosensitivity, and reduce radiation response [19]. In our study, the cleaning head of the portable vaginal irrigation was elliptical spherical design, which can fully expand the vagina. The cleaning head was tubaeform, which was conducive to the full discharge of the cleaning solution, and it was convenient to thoroughly rinse the cervical mouth and the vaginal dome, without any dirt remaining. The use of piston type liquid storage device could reduce the pollution caused by the reflux of liquid medicine. The curved tube was connected with the cleaning head and the injection cylinder to meet the physiological curve, which was convenient for patients to operate at home.

In our study, the outcomes indicated that the number of patients with a white blood cell count of 15-30 in the RG was less than that of the CG. The number of patients in cleanliness degree I in the RG was higher relative to the CG, while the number of patients in cleanliness degree III in the RG was lower relative to the CG. The vaginal length and vaginal width of the RG were higher compared to the CG. The comfort ratio and satisfaction of patients in the RG were higher compared to the CG. The occurrence of complications in the RG was declined compared to the CG. All these data implied that portable vaginal irrigation could promote cleanliness, reduce the incidence of radiotherapy complications, so as to promote the comfort and satisfaction of patients, which was consistent with former studies [20].

In summary, portable vaginal irrigation device promotes the comfortable feeling of use, improves the effect of vaginal irrigation, reduces the occurrence of complications after radiotherapy, which is worthy of clinical promotion.

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***Conflict of interest*:** The authors confirm they have no conflicts of interest to declare.

***Ethical consideration*:** This study was carried out with the approval of the ethics committee of Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine (Registration No. SHL002019A-L, December, 2020).

***Author contribution*:** H.Z. and J.Q. participated in the study design and the literature search. H.Z. and J. L. collected the data and wrote the manuscript. All authors revised, read and approved the final manuscript.

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