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ORIGINAL RESEARCH

Use of vaginal dilators and effects on vaginal volume and quality of life: a randomized clinical trial

Uso de dilatadores vaginais e efeitos no volume vaginal e qualidade de vida: um ensaio clínico randomizado

Uso de dilatadores vaginales y efectos sobre el volumen vaginal y la calidad de vida: un ensayo clínico aleatorizado

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ABSTRACT | Although it is advised to use vaginal dilators following radiotherapy to prevent vaginal stenosis, compliance is frequently low. This study aimed to assess adherence to the use of vaginal dilators after brachytherapy and its effects in women who received phone call or texting apps guidance. A total of 30 women who previously underwent brachytherapy for cervical cancer were randomized into two groups using the R program: monitoring via phone calls and monitoring via text messages. They underwent gynecological examination with measurement of vaginal volume and answered the Functional Assessment of Cancer Therapy-Cervix Cancer (FACT-CX) questionnaire at the initial consultation and at the sixth month. No association was found between adherence and the types of follow-up (p=0.79). In the first month, 43.3% adhered to dilators, 36.6% did so in the third month, and 23% in the sixth month. The highest adherence group had higher difference in vaginal volume scores (16.81±10.45 cm^3) compared to the nonadherence group (10.45±9.55 cm^3) with a strong effect size (d=1.68). The difference between the initial and final vaginal volume was not associated with the FACT-CX scores (rho=−0.369; p=0.08. Although no differences were observed in adherence to dilators and type of follow-up, high adherence demonstrated a direct effect on increasing vaginal volume, showing the need to promote educational forms that encourage adherence.

Trial registration: Brazilian Registry of Clinical Trials (ReBEC), UTN Platform: U111111946547.

Keywords | Brachytherapy; Cervix Cancer; Vaginal Stenosis; Sexual Health; Treatment Adherence.

RESUMO | Embora seja aconselhado o uso de dilatadores vaginais após a radioterapia para prevenir a estenose vaginal, a adesão frequentemente é baixa. O objetivo deste estudo foi avaliar a adesão ao uso de dilatadores vaginais após a braquiterapia e seus efeitos em mulheres que receberam orientações por telefone ou aplicativos de mensagens de texto. Trinta mulheres previamente submetidas à braquiterapia para câncer cervical foram randomizadas por meio do programa R, em dois grupos: acompanhamento por telefone; e monitoramento via mensagens de texto. Todas realizaram exame ginecológico com aferição do volume vaginal e responderam ao questionário Functional Assessment of Cancer Therapy-Cervix Cancer (FACT-CX) na consulta inicial e no sexto mês. Não foi encontrada associação entre adesão e tipos de acompanhamento (p=0,79). No primeiro mês, 43,3% aderiram aos dilatadores, 36,6% no terceiro mês e 23% no sexto mês. O grupo de maior adesão teve maior diferença nos escores de volume vaginal (16,81±10,45 cm3) em comparação com o grupo de não adesão (10,45±9,55 cm3) com um tamanho de efeito forte

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(d=1,68). A diferença entre o volume vaginal inicial e final não apresentou relação com os escores do FACT-CX (rho=−0,369; p=0,08). Embora não tenham sido observadas diferenças na adesão aos dilatadores e no tipo de acompanhamento, a alta adesão demonstrou efeito direto no aumento do volume vaginal, mostrando a necessidade de promover formas educativas que estimulem a adesão.
Registro do ensaio: Registro Brasileiro de Ensaios Clínicos (ReBEC), Plataforma UTN: U111111946547.
Descritores | Braquiterapia; Câncer de Colo do Útero; Estenose Vaginal; Saúde Sexual; Adesão ao Tratamento.

RESUMEN | Aunque se recomienda el uso de dilatadores vaginales después de la radioterapia para prevenir la estenosis vaginal, su adherencia sigue siendo baja. El objetivo de este estudio fue evaluar la adherencia al uso de dilatadores vaginales después de la braquiterapia y sus efectos en mujeres que recibieron orientación por teléfono o aplicaciones de mensajería de texto. Treinta mujeres previamente sometidas a braquiterapia por cáncer de cuello uterino se dividieron aleatoriamente en el programa R en dos grupos: seguimiento telefónico; y seguimiento por mensajes de texto. Todas las participantes se sometieron a un examen ginecológico con medición del volumen vaginal y respondieron al cuestionario *Functional Assessment of Cancer Therapy-Cervix Cancer* (FACT-CX) al inicio del estudio y al sexto mes. No se encontró asociación entre la adherencia y los tipos de seguimiento (p=0,79). En el primer mes, el 43,3% de las participantes adhirieron a los dilatadores; el 36,6%, en el tercer mes; y el 23%, en el sexto mes. El grupo de mayor adherencia tuvo una mayor diferencia en las puntuaciones de volumen vaginal (16,81±10,45 cm3) en comparación con el grupo de no adherencia (10,45±9,55 cm3) con un tamaño de efecto fuerte (d=1,68). La diferencia entre el volumen vaginal inicial y el volumen vaginal final no se relacionó con las puntuaciones de FACT-CX (rho=-0,369; p=0,08). Aunque no se observaron diferencias en la adherencia a los dilatadores y en el tipo de seguimiento, la alta adherencia mostró un efecto directo sobre el aumento del volumen vaginal, lo cual revela la necesidad de promover medidas educativas que estimulen la adherencia.
Registro de ensayo: Registro Brasileño de Ensayos Clínicos (ReBEC), Plataforma UTN: U111111946547.
Palabras clave | Braquiterapia; Cáncer de Cuello Uterino; Estenosis Vaginal; Salud Sexual; Adherencia al Tratamiento.

INTRODUCTION

Radiotherapy plays a crucial role in the treatment of gynecological malignancies; however, accumulated radiation in pelvic organs can lead to intestinal, bladder, and genital toxicity[1]. Vaginal stenosis stands out as one of the adverse genital effects of radiotherapy affecting up to 50%–60% of women undergoing radiotherapy, although such prevalence is highly variable[1,2].

Numerous studies recommend the regular use of vaginal dilators to prevent or treat vaginal stenosis[2,3], despite the lack of reliable scientific evidence to support this indication[4]. However, observational data indicates an association between the use of vaginal dilators and reduced rates of self-reported vaginal stenosis[4-6].

Although the use of vaginal dilators after combined pelvic radiation therapy and brachytherapy is recommended to prevent vaginal stenosis, adherence to this treatment is often low. Some studies show the success of interventions to encourage the use of vaginal dilators, leading to increased adherence[7]. Patient reports of the consequences of vaginal stenosis on quality of life and sexual function may be important but are rarely reported[8].

In vaginal stenosis, follow-up feedback can be an adherence facilitator. Therefore, this study aimed to assess adherence to the use of vaginal dilators in women who received guidance via monthly teleconsultations. As a secondary outcome, the effect of the use of dilators on vaginal volume and quality of life.

METHODOLOGY

Study design

This is a randomized clinical trial.

Population

Women who underwent brachytherapy for cervical cancer.

Sample definition

The sample size was estimated by the calculations suggested by Dupont and Plummer[9], with a 5% alpha error and 80% detection power, based on the comparison of the studies by Cerentini et al. and Brand[10,11]. The estimation suggested 30 cases.

Participants were selected in order of appearance for consultation according to their convenient accessibility and desire to participate in the study and were randomized, using the R program, into the following two groups: a group in which patients were instructed to perform vaginal dilation three times per week for 10 min/day and monitoring was done via monthly phone calls; and the second group in which participants were instructed to perform vaginal dilation three times per week for 10 min/day and monitoring was done via monthly messaging using texting apps such as WhatsApp®. Participants and researchers knew which intervention was being adopted, and participants were aware of the other allocation option.

Location

This trial was carried out at the cervical pathology outpatient clinic of Pedro Ernesto University Hospital, from December 2019 to December 2021.

Selection criteria

Women aged over 18 years who previously underwent brachytherapy for cervical cancer were included in the study. Women with vaginal fistulas or with excessive mucosal bleeding at the initial evaluation were excluded.

Data collection

Kits with six dilators, lubricants, and an instruction manual prepared by the researchers were provided to each participant. Participants were instructed to perform vaginal dilation three times per week for 10 min/day. Patients were evaluated and oriented about female sexual anatomy, use of dilators, and pelvic floor exercises. They were monitored for six months and received monthly orientation via texts and/or phone calls.

A disposable speculum (Vagispec®, São Paulo, Brazil) made of polystyrene, a 245 mm disposable polystyrene Cheron forceps consisting of 2 rods with 4 locking levels (Vagispec®, São Paulo, Brazil), and an endocervical brush with 16 cm cylindrical plastic rod (Kolplast®, São Paulo, Brazil) were used to measure vaginal volume.

Vaginal volume was calculated considering the vaginal anatomy represented by a three-dimensional rectangle based on our previous research, which demonstrated good reproducibility with the method[12]. Each patient was placed in a lithotomic position. After the speculum was inserted, it was opened to the first sensation of discomfort reported by the patient. The anteroposterior diameter was measured by inserting and opening the Cheron forceps in the sagittal plane (midline), oriented toward the anus. The lateral diameter was measured by opening the Cheron forceps in the transverse plane supported on the posterior flap of the speculum. The distance between the end-to-end locking rods was measured in millimeters; after removal, the corresponding measure of the opening of the Cheron forceps was made in its outer portions. Using the endocervical brush cable, total vaginal length was measured from the left posterior fornix to the mucocutaneous junction of the left lower vaginal wall by marking the brush cable with a permanent pen, removing it from the vagina and measuring the distance from the end to the mark. Vaginal volume was obtained in cm^3 by calculating the product of the following three parameters: anteroposterior diameter, lateral diameter, and length.

All women underwent gynecological examination with measurement of vaginal volume and answered a Functional Assessment of Cancer Therapy questionnaire (FACT-CX) at baseline and at the sixth-month consultation. The FACT-CX assesses functioning and condition of women with cervical cancer, using the last seven days as a temporal reference. The questionnaire consists of 42 items with score ranging from zero to 168.

Nonadherence was defined as the absence of dilation for a period of 6 months; low adherence to dilation was defined as the absence of dilation for a period of 1 to 2 months; moderate adherence to dilation as the absence of dilation for 3 to 4 months; and high adherence to dilation as the performance of dilation three times per week for more than 5 months.

Data analysis

The analysis of covariance (ANCOVA) test was carried out to evaluate the difference in final vaginal volume between the four degrees of adherence, as follows: nonadherence, low, moderate, and high, final scores of

sexual function according to the degree of adhesion, and final scores of quality of life. Cohen's d was used for pairwise comparisons using the following interpretive norms: no effect (between 0.00 and 0.10); weak effect (between 0.11 and 0.29); moderate effect (between 0.30 and 0.49) and strong effect (>0.50).

A Chi-square test of independence (2×2) was also carried out to investigate the association between adherence to dilators (yes–no) and two types of follow-ups (telephone monitoring and text message). Repeated measures of Student's *t*-test were carried out to investigate the extent to which the intervention was able to increase the sample's vaginal volume. The normality assumption was evaluated using the Shapiro Wilk test, and Cohen's d was used to measure the effect size. Spearman and Pearson correlation analysis were used to assess the difference in initial and final vaginal volume, and the difference in the initial and final scores of the quality-of-life index. The analysis was performed using SPSS software for Windows version 23.

RESULTS

In total, 30 participants were randomly enrolled into the monitoring by phone call or text message groups. (Figure 1).

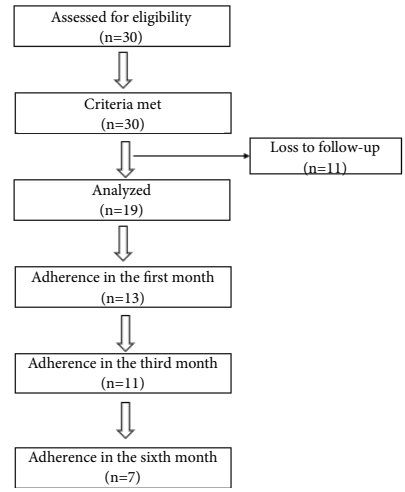

Figure 1. Flow diagram of a parallel randomized trial involving two groups of women: one monitored via phone calls, the other via a texting app

Intervention

Table 1 shows the clinical and sociodemographic characteristics of women in relation to follow-up. No significant association was found between adherence to dilators and the types of follow-up (p=0.80).

There was also no difference between initial and final vaginal volume and FACT-CX scores between those who received guidance via telephone call and those who received it via text messages.

Table 1. Clinical and sociodemographic characteristics and type of follow-up

	Messages (N=17)			Phone calls (N=13)			p-value
Age (mean±SD)	47.64±10.6			44.77±11.14			p=0.83
BMI (mean±SD)	28±7.14			28±5.31			p=0.99
Education	Illiterate	0	(0%)	Illiterate	1	(7.7%)	p=0.21
	Middle school	12	(70.6%)	Middle school	5	(38.5%)	
	High school	5	(29.4%)	High school	6	(46.1%)	
	Higher education	0	(0%)	Higher education	1	(7.7%)	
Smoking	Never	11	(64.7%)	Never	8	(61.5%)	p=0.87
	Ever	4	(23.5%)	Ever	4	(30.8%)	
Parity (mean ±SD)	2.6±1.68			2.33 ± 0.98			p=0.06
Radiotherapy dose	4861.18±380.29			4656.92±245.2			p=0.12
Brachytherapy dose	2252.94±433.18			2181.82±517.34			p=0.50
Interval from brachytherapy to dilation (months)	17±24.71			22±23.05			p=0.82
Adherence to dilators	Yes	7		Yes	6		p=0.80
	No	10		No	7		

p = statistical significance level.

Adherence to dilators

Of the 30 women who initially participated in the study, nine (30%) did not return to the final consultation and abandoned the use of dilators. There were 19 women remaining in the study at the end of six months.

Among those who completed the study, 13 women adhered to the use of dilators (43.3%) in the first month. Adherence dropped from the third month onwards, with 11 women (36.6%) adhering to dilators in the third month and by late sixth month, only seven (23%) women continued using the dilators.

The repeated measures of Student's *t*-test did not show significant differences in the initial vaginal volume of the sample (85.96±47.33) when compared with final vaginal volume (83.14±54.91); (p = 0.593). The effect size of the difference tested was low (Cohen's d = –0.12).

The longer interval between brachytherapy and the start of dilation was shown to be associated with higher adherence (30±19.8 months in those who adhered versus 3±2.3 months in those who did not adhere, p<0.001).

Vaginal dilator adherence and vaginal volume

The degree of adherence had a significant effect on the vaginal volume (p = 0.03). Table 2 presents the results of an a posteriori analysis (Bonferroni's post-hoc test). The high adherence group showed a greater difference in vaginal volume scores (M = 16.81; SD = 10.45) compared to the nonadherence group (M = 10.45; SD = 9.55), with a strong effect size (d = 1.68). Although the other pairwise comparisons did not show significant differences, they had a high effect size, except for the comparison between the low and moderate adherence groups, which showed a weak effect size.

Table 2. Descriptive data and post-hoc Bonferroni test results of final vaginal volume between four degrees of adherence

Degree of adhesion	Mean difference between the initial and final vaginal volume	Pairwise comparison	p-value	d
High	16.81 ± 11.35	High-low	1.00	0.81
Low	16.30 ± 18.8	High-moderate	1.00	0.98
Moderate	13.85 ± 15.34	High – none	0.02*	1.68
None	10.45 ± 9.55	Low – Moderate	1.00	0.16
		Low – None	1.00	0.87
		Moderate–No adherence	1.00	0.70

p-value = statistical significance level; *p<0.05; d = Cohen's d.

Vaginal volume and quality of life

A correlation analysis was carried out between the difference in the initial and final vaginal volume and the difference in the initial and final scores of the quality of life index. The difference between the initial and final vaginal volumes did not show a significant relationship with the quality of life scores (rho = –0.369; p = 0.83, correlation coefficient=0.13).

DISCUSSION

Vaginal stenosis is a frequent adverse event after treatment of cervical cancer with brachytherapy. The micro and macroscopic changes that occur in irradiated tissues lead to tissue adaptations, which culminate in structural and functional changes in the organ, resulting in vaginal stenosis. In the long term, these physical changes can result in sexual dysfunction, in addition to compromising the pelvic examination for follow-up and surveillance of disease recurrence[4].

Vaginal dilator therapy increases vaginal length and width in patients with vaginal narrowing and treats or prevents stricture following vaginal surgery, radiation, or vulvovaginal dystrophy. However, its use is limited due to several issues[13]. Different methods can be used to improve patient adherence to treatment[13,14]. Some studies have already demonstrated improved adherence to medication treatment by using text messages and phone calls for patients with mental disorders and other chronic diseases[14,15].

Our results regarding adherence to the use of dilators showed adherence of 43.3% in the first month, 36.6% in

the third month, and 23% at the end of the sixth months. No difference was noted between types of follow-up.

Few studies show adherence above 50% in the follow-up period[16-18], and even studies that showed high adherence demonstrate a significant decrease over time[5,6,13-15].Hanlon et al.[19] evaluated 42 women on two occasions. After six weeks, adherence was 64%, dropping to 15% at six months. Friedman et al.[20] found 33% adherence in the first month of treatment, dropping to 14% from the second to the fourth month.

In our study, we used an objective method to calculate the vaginal volume, which can be useful for self-monitoring so that women can have a concrete perception of improvement or worsening. The results showed a direct relationship between high adherence to dilators and increased vaginal volume. Additionally, it was shown that increased adherence was associated with a longer delay between brachytherapy and the beginning of dilation, which may be connected to a higher perception of the usefulness of the procedure.

Optimal dilator practice remains controversial, with previous research showing wide variations in the recommended use of vaginal dilators[21]. The use of an objective method to assess vaginal volume and the comparative analysis of two adherence monitoring techniques are the main strengths of our study. The main limitation was the small sample size at the end of the study, which reduced the confidence level.

Additional prospective studies with a large sample size, excluding participants who interrupt sexual activity during the study, and with longer follow-ups are required to confirm the effect of dilation adherence on vaginal volume. Such studies should also demonstrate how this adherence directly affects sexual function.

CONCLUSIONS

Although no differences were observed regarding adherence to dilators in relation to the type of follow-up, higher adherence was associated with a longer time between brachytherapy and the beginning of dilation and had a direct impact on increasing vaginal volume. This highlights the need to promote educational support that encourage adherence. Furthermore, future studies are needed to determine the aspects of telemonitoring that could increase adherence to the use of dilators, including information about changes in vaginal volume for both adherent and nonadherent women.

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