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RESEARCH ARTICLE

Pelvic Floor Muscle Training for Voiding Dysfunction in Cervical Cancer Survivors with Radiation Cystitis: A Prospective Pilot Study

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Abstract

Introduction: The primary pathophysiology of radiation cystitis is the rupture and bleeding of telangiectatic blood vessels as a result of bladder distension. The objective of the study is to evaluate the effectiveness of pelvic floor exercises in improving pelvic floor muscle strength and thereby improving voiding dysfunction. **Materials and Methods:** We included 30 patients who presented to our Institute with radiation cystitis between January 2023 and December 2023. Participants were taught pelvic floor muscle (PFM) exercises to strengthen the pelvic floor muscles. Improvements to the Modified Oxford Scale (MOS) and Stop score for pelvic floor muscles and post void residual urine were tested after 4 weeks. The role of contributing factors for pelvic floor muscle dysfunction like voiding habit and uncontrolled blood sugars were also assessed. **Results:** The median score of the Modified Oxford Scale (MOS) improved from 2 to 3 post PFM exercises. [p-value < 0.001]. Similarly, the median Stop score of patients improved to 2 from 1.5 with PFM exercises. [p-value 0.006]. There was significant reduction in post void residual urine after one month of exercises. [p-value < 0.001] Around 37% of patients had uncontrolled diabetes at the presentation of radiation cystitis and 60% of patients had the habit of voiding urine in the standing position. **Conclusion:** Early initiation of pelvic floor exercises, patient education on proper voiding habits, can increase the pelvic muscle strength and significantly decrease post void residual urine. This might have a potential role in decreasing the radiation cystitis which needs to be validated in future randomised control studies with long term follow up.

Keywords: Radiation cystitis- Pelvic floor muscles- Kegel's exercises- Voiding technique- Modified Oxford Scale (MOS)

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Introduction

Radiation cystitis is a late complication of cervical cancer that affects 5-10% of women who received radical radiation therapy, which includes both external beam radiation and brachytherapy [1, 2]. Acute radiation cystitis happens during or shortly after pelvic radiation treatment, while chronic radiation cystitis is a problem that arises six months to twenty years following pelvic radiation [3]. There is a strong correlation between oxidative damage and chronic inflammation after radiation, and the neurological control of the irradiated bladder shifts from a cholinergic regulation influenced by interstitial cells to a purinergic regulation. Tissue rigidification also plays a role in issues with bladder contractility [4, 5]. This can result in bothersome lower urinary tract symptoms and a contracted poorly compliant bladder. Because of poor tissue repair, radiation oncologists and urologists have significant challenges in treating radiation-related urological problems. The best method is to avoid these issues as much as possible.

As patient survival rates increase, long-term survivorship issues become increasingly important, particularly radiation cystitis, which has a considerable

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influence on quality of life [6, 7]. When the bladder epithelium atrophies, the superficial telangiectatic blood vessels in the submucosa become visible. During hematuria, the poorly compliant bladder will undergo bladder outlet obstruction due to the formation of blood clots. This will lead to bladder distention, stretching and rupture of telangiectatic blood vessels, resulting in aggravation of hematuria [8]. The recurrence of radiation cystitis can be decreased by Pelvic floor muscle training, which will also enhance bladder voiding [9]. The objective of the study was to evaluate the effectiveness of pelvic floor exercises in improving pelvic floor muscle function and thereby combating voiding dysfunction.

Materials and Methods

Study Design and Patient Selection

This prospective single arm study was conducted from January 2023 to December 2023 in a quaternary cancer care centre. The study included 30 patients who presented with hematuria to the follow-up outpatient wing of the Division of Gynaecological Radiation Oncology. The study was performed in line with the principles of the Declaration of Helsinki and the study protocol was approved by the Institutional Ethics Committee. Informed consent was obtained from all study participants. Eligible patients were cervical cancer survivors who had been treated with radical radiation therapy, Eastern Cooperative Oncology Group (ECOG) performance status of 1–2, and were clinically disease free at the time of recruitment. Recurrence of malignancy was ruled out by clinical examination, contrast enhanced computed tomography (CT) scan of the abdomen and pelvis and cystoscopy.

As a prospective pilot study, no formal sample size calculation was performed. A convenience sample of 30 patients was considered adequate for preliminary feasibility assessment, to describe the distribution of outcomes, and to generate hypotheses for a future randomized controlled trial.

Treatment Protocol

All patients were hospitalised and managed conservatively. The initial treatment included antibiotics, analgesics, and anti-inflammatory drugs. Patients with haemoglobin levels below 8 g/dL received blood transfusions. If hematuria was persistent, bladder management involved cystoscopic removal of blood clots and placement of a three-way Foley catheter with continuous irrigation using normal saline. [10] If hematuria is not subsiding with continuous bladder irrigation, intravesical alum irrigation was administered. [11] For patients resistant to medical and irrigation therapy, cystoscopic intervention with laser fulguration or electrocoagulation of bleeding sites was performed. [12, 13] (Figure 1). After radiation cystitis was resolved, patients were evaluated for pelvic floor muscle strength using a Modified Oxford Scale (MOS). The score ranges from 0 to 5 (Table 1). Bladder sphincter control was measured using the Stop score, which was a test that determined whether urine could be halted midway. This

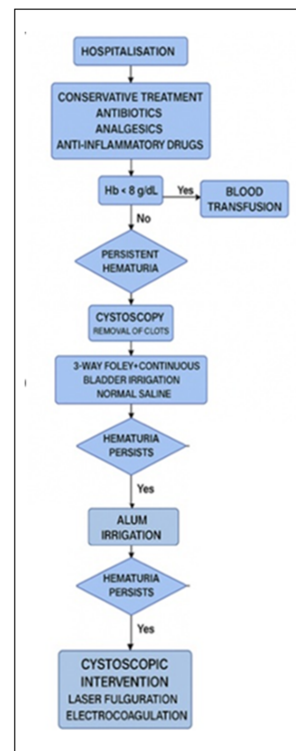

Figure 1. Management Protocol for Hematuria

was a novel scoring system created for this study. The score ranges from 1 to 5 (Table 2).

The Stop Score was assessed by a single trained physiotherapist [Mrs. Anitha Dharmaraj MPT] at baseline and 4-week follow-up to ensure consistency in scoring.

Pelvic Floor Muscle Training Protocol

Pelvic floor Muscle (PFM) exercises in this study consist of Modified Kegel's exercises and PFM core strengthening and toning exercises which were taught to patients as Pelvic Floor Muscle Training (PFMT) to help them improve their pelvic floor function. Pelvic floor exercises begin by emptying the bladder. They were asked to tighten the pelvic floor muscles and hold for 3–5 seconds. It was repeated three times a day with 25 repetitions each (total of 75 repetitions per day). The training was administered by a trained physiotherapist. The patients were instructed to maintain a dairy documenting the number of repetitions performed daily. Patient diaries were reviewed at weekly physiotherapy sessions to assess adherence to the prescribed exercise regimen. Participants who reported fewer than 75 repetitions on any given day were counselled regarding proper technique and motivation to increase compliance.

The repetitions were gradually increased to a maximum of 300 repetitions daily, divided into 100 repetitions each in the morning, afternoon and bed time. They were asked to increase 10 repetitions each time thereby increasing 30 repetitions per day, once in 3-4 days. Participants who experienced pelvic discomfort, pain, or fatigue during escalation were instructed to maintain their current repetition count and reassess tolerance at the following week. Escalation was resumed only if discomfort resolved. The minimum tolerated repetition

count was 75 and the maximum target was 300 per day, adjusted based on individual tolerance. The patients were specifically instructed not to tighten other muscles like the gluteus, thigh and abdominal muscles. [14] The pelvic and glute bridge exercises which help to strengthen the core and pelvic muscles were also taught and advised to do once daily. The pelvic floor muscle strength and bladder sphincter control were reassessed after 4 weeks of PFM exercises.

Important Safety Clarification: The Stop Score is an assessment tool used by clinicians only at baseline and 4-week follow-up visits to evaluate bladder sphincter function. Patients were NOT instructed to practice stopping urinary flow as a component of their daily pelvic floor exercises. All participants were advised to void completely without interruption during normal micturition, as repeated interruption of urinary flow is not recommended in the post-radiation setting due to the risk of urinary retention and infection.

The role of contributing factors for pelvic floor muscle dysfunction like voiding habit and uncontrolled blood sugars were also assessed. The participants were taught correct voiding techniques. The women were asked to sit properly in the toilet seat with their feet supported. Leaning forward during and after urination helps to empty the bladder fully. It is important to give enough time to empty the bladder. After finishing urinating it was instructed to wait for few more minutes and try to void some more urine. It is very important not to strain during the entire process. The post void residual urine was also recorded pre PFM exercises and was reassessed after 4 weeks of exercises.

The statistical analysis was performed using SPSS software, version 15.0. The Wilcoxon signed-rank test was used to assess whether the change is significant.

Results

The median age of onset of symptoms was 59 years. Two-thirds of patients developed symptoms of radiation cystitis five years after completion of radiation treatment.

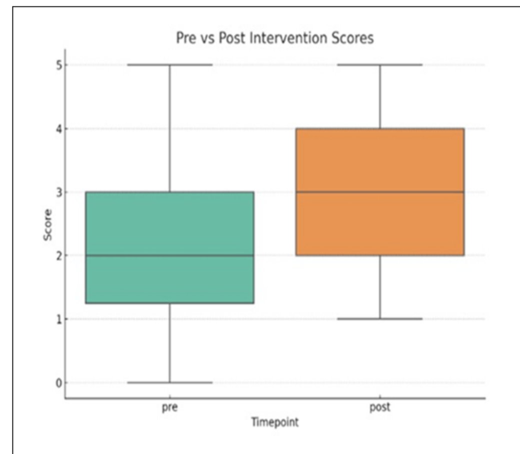

Figure 2. The Modified Oxford Scale (MOS) Pre and Post Pelvic Floor Muscle Exercises

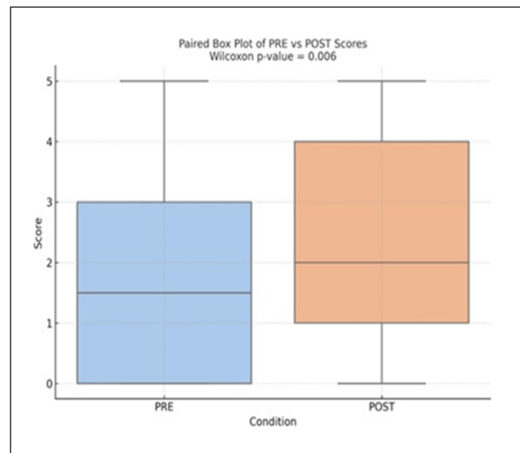

Figure 3. The STOP Score Pre and Post Pelvic Floor Muscle Exercises

The patient demographics are given in Table 3. Twenty four patients had grade 1-2 radiation cystitis, while six patients had grade 3-4 radiation cystitis. The Radiation Therapy Oncology Group [RTOG] grading of cystitis is given in Table 4. Twenty-four patients received a cumulative bladder dose within the bladder tolerance of

Table 1. Modified Oxford Scale (MOS)

0	None	No visible or palpable contraction
1	Flicker	Slight contraction is felt
2	Weak	Weak contraction, but not sustained
3	Moderate	Moderate contraction, sustained
4	Good	Good contraction, with a lift felt on the pelvic floor
5	Strong	Strong contraction with a visible lift felt on the pelvic floor

Table 2. Stop Score

0	None	No visible or palpable contraction
1	Flicker	Slight contraction is felt
2	Weak	Weak contraction, but not sustained
3	Moderate	Moderate contraction, sustained
4	Good	Good contraction, with a lift felt on the pelvic floor
5	Strong	Strong contraction with a visible lift felt on the pelvic floor

Table 3. Baseline Patient Characteristics

Patient characteristics	Number (%)
	30 (100)
Median Age	59 [42 – 72] years
ECOG PS	
I	24 [80]
II	6 [20]
Histology	
Squamous	26 (87)
Non-squamous	4 (13)
FIGO STAGE	
I	4 (13.3)
II	16 (53.3)
III	10 (33.3)
Uncontrolled Diabetes Mellitus	11 (37)

EQD2 [Equivalent Dose of 2 Gy per fraction] 80 Gy, while six patients received a cumulative bladder dose more than EQD2 80 Gy. During treatment, eight patients required continuous bladder irrigation, three patients underwent clot evacuation under general anaesthesia, one patient required alum irrigation, and two patients underwent laser fulguration due to persistent hematuria.

All 30 enrolled participants completed the 4-week intervention and post-intervention assessments. There were no dropouts or lost to follow-up cases.

The median score of the Modified Oxford Scale (MOS) pre-PFM exercises was 2. The median score of MOS after PFM exercises was 3. [p-value < 0.001] (Figure 2). Similarly, the median Stop score of patients before PFM exercises was 1.5. The median Stop score post-PFM exercises was 2. [p-value 0.006] (Figure 3) 29 out of 30 patients had post void residual urine more than 50 ml pre intervention. Post interventional strategies only 11 out of 30 patients had post void residual urine more than 50 ml. There was significant reduction in post void residual urine after one month of exercises. [p-value < 0.001] (Figure 4). Around 37% of patients had uncontrolled diabetes at the presentation of radiation cystitis, and 60% of patients had the habit of voiding urine in the standing position. The median post-void residual urine reduction for diabetic patients (n=11) was 72 mL and for non diabetic patients (n = 19) was 65 mL. There was no statistically significant difference in the magnitude of post void residual urine reduction between diabetic and non-diabetic patients (p value - 0.813). The details are given in Table 5.

Tolerance Distribution

Participants demonstrated heterogeneous tolerance to exercise escalation. At the 4-week follow-up, the distribution was as follows: 12 patients (40%) remained at the baseline dose of 75 repetitions/day [25 × 3 sessions] because they experienced mild pelvic discomfort upon attempting escalation; 8 patients (27%) escalated to 150 repetitions/day [50 × 3 sessions]; 6 patients (20%) escalated to 210 repetitions/day [75 × 3 sessions]; and 4 patients (13%) achieved the target of 300 repetitions/day [100 × 3 sessions]. No participant was forced to escalate beyond their comfort level; all escalations remained voluntary and symptom-limited.

Adverse Events

No serious adverse events were recorded. Specifically, there were zero cases of symptomatic urinary retention, acute urinary tract infection, new-onset dysuria, or moderate-to-severe pelvic pain during the 4-week intervention period. The mild pelvic discomfort experienced by 12 patients resolved with dosing adjustments and did not result in any participant discontinuing the exercise program.

Discussion

The incidence of radiation cystitis is influenced by both reversible and irreversible risk factors. Among the irreversible factors, the cumulative radiation dose

Table 4. RTOG Grading of Radiation Cystitis

Grade 0	Normal
Grade I	Microscopic hematuria, mild telengiectasia, and little epithelial atrophy
Grade II	Intermittent macroscopic hematuria, generalized telengiectasia, and moderate frequency
Grade III	Severe generalized telengiectasia with petechiae, severe frequency and dysuria, and decreased bladder capacity (<150cc)
Grade IV	Necrosis, severe hemorrhagic cystitis, and a bladder that is contracted less than 100 cm

Table 5. Stratified Analysis of Post-void Residual Urine (PVR) before and after Kegel Exercises by Diabetic Status

Diabetic status	n	Median Pre-Kegel PVR (mL)	Median Post-Kegel PVR (mL)	Median PVR reduction (mL)	P value
Diabetic	11	119 (108–137)	27 (10–54)	72	0.001
Non Diabetic	19	102 (87–137)	32 (18–60)	65	<0.001
Group comparison of Median reduction in PVR					0.813
Mann–Whitney U test (two-tailed)					

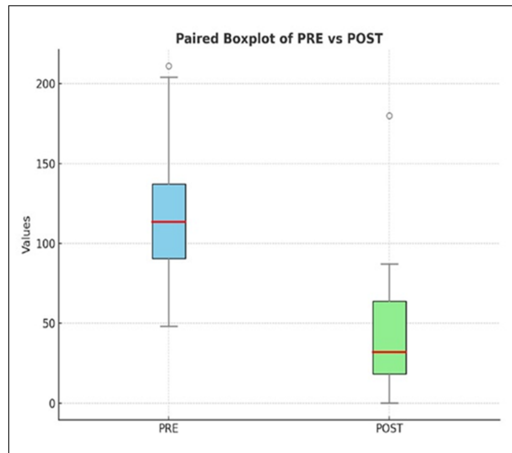

Figure 4. The Post Void Residual Pre and Post Pelvic Floor Muscle Exercises

received by the bladder plays a significant role. The risk of developing radiation cystitis increases with higher mean bladder doses from approximately 3% in patients receiving < 50 Gy to around 12% in those receiving > 80 Gy [1]. However, numerous reversible risk factors also contribute to the development and severity of this condition. In our study, the majority of patients (24 out of 30) had a cumulative bladder dose within the tolerance limits. This underscores the critical importance of identifying and modifying reversible risk factors in order to mitigate the incidence and progression of radiation cystitis.

Pelvic floor muscle dysfunction is the primary initiator of the pathophysiological cascade leading to radiation cystitis. This has been shown in Figure 5. The pelvic floor comprises a complex network of muscles and fascia anchored to the bony pelvis. The deep layer of the pelvic floor includes the levator ani muscle group of muscles namely the pubococcygeus, iliococcygeus, ischiococcygeus, and puborectalis which play a pivotal role in supporting pelvic organs and maintaining continence especially when there is raised intra abdominal pressure. [15, 16]. These muscles operate under the regulation of both autonomic and somatic nervous systems, allowing coordination of contraction and relaxation to preserve urinary continence [17]. A high prevalence of pelvic floor dysfunction with symptoms such as urinary incontinence and urgency has been reported among patients undergoing pelvic radiotherapy [18].

To enhance treatment strategies for pelvic floor dysfunctions, a detailed understanding of radiation induced muscle tissue changes is essential. A study by Gervaz et al. [19] presented a case study followed over four years post radiation therapy. Histopathological examination revealed significantly higher immunoreactivity for transforming growth factor β1 (TGF-β1) and connective tissue growth factor (CTGF) in anal sphincter muscle strips from an irradiated patient compared to a non-irradiated control particularly within the smooth muscle cells. These findings indicate sustained radiation induced fibrosis in muscle tissue especially in the smooth muscle layers. This supports the hypothesis that radiation leads to structural alterations in pelvic floor muscles through progressive fibrotic changes which may persist even years after treatment. Furthermore, Coakley et al. [20] utilized MRI to demonstrate that 97.1% of subjects exhibited radiation induced changes in the levator ani muscles evidenced by increased signal intensity. In addition 80.0% showed similar changes in the urogenital diaphragm muscles following brachytherapy. These imaging findings corroborate the ongoing long term impact of radiation on the pelvic floor muscles. In our study as well 18 out of 30 patients demonstrated poor scores on the Modified Oxford Scale (MOS) and 23 out of 30 had poor STOP scores supporting the previously reported findings. These results reinforce the evidence that pelvic floor muscle dysfunction manifested through impaired strength is a common and measurable consequence of pelvic radiation therapy.

This pelvic floor muscle dysfunction coupled with improper voiding technique will lead to increased post void residual urine. The study by Turkmen et al [21] showed increased post void residual urine in standing position compared to sitting position. There are various other studies which showed voiding in standing position did not increase post void residual urine [22]. But these are done in normal healthy women. In women with post radiotherapy pelvic floor muscle dysfunction, there is a high probability that voiding in standing position can lead to significant post void residual urine. In our study also 29 out of 30 patients had significant post void residual urine.

Urinary tract infections [UTI] are more common and severe in patients with Type II Diabetes Mellitus. Various factors like poor immune function, disordered metabolism and incomplete bladder emptying due to autonomic neuropathy contribute to this. In our study also, 37% of patients had uncontrolled diabetes mellitus. It is

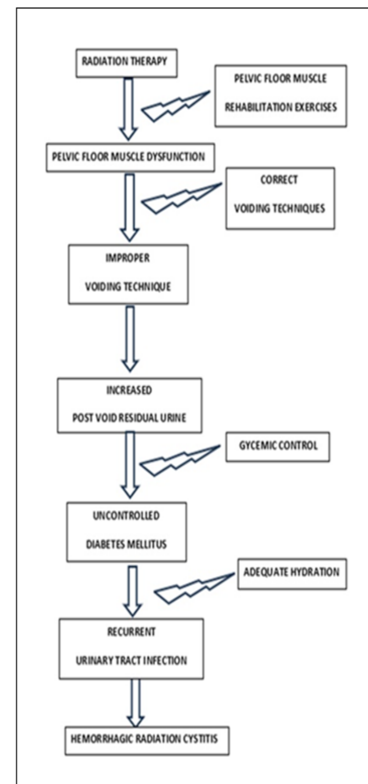

Figure 5. Pelvic Floor Muscle Dysfunction

this infection most commonly triggers radiation cystitis in post pelvic radiation therapy cervical cancer survivors. To prevent recurrent UTI, it is important to have good glycemic control along with adequate hydration.

Limitations

37% of the patients had uncontrolled diabetes mellitus at presentation. This is a potential confounder since diabetes increases infection risk, which may trigger or exacerbate cystitis. Diabetes is a potential effect modifier too, since diabetic neuropathy may impair the neuronal response to PFMT. This study conducted a subgroup analysis stratified by diabetes status, but the sample size was not adequately powered to detect any meaningful difference.

All patients received medical management before the exercise program. This can be a confounding factor in the reduction in symptoms and hematuria. The role of pelvic floor training in the reduction of radiation cystitis needs to be validated in future prospective randomised control trials.

Another significant limitation of this study is the short follow-up period of 4 weeks. While improvements in pelvic floor muscle strength and post-void residual urine were demonstrated, longer-term follow-up data (minimum 6-12 months) are needed to assess the sustainability of these improvements and their impact on hematuria recurrence rates. The outcomes measured in this study are surrogate markers; future studies should directly assess hematuria resolution and time to recurrence as primary outcomes

In conclusion, radiation cystitis is a debilitating complication that significantly impairs the quality of life in cervical cancer survivors. Despite advances in cancer treatment managing radiation cystitis remains a considerable challenge. While the cumulative bladder dose is a non-modifiable risk factor, several modifiable risk factors can be addressed to reduce the risk and severity of this condition. Pelvic floor muscle dysfunction, improper voiding techniques, poor glycemic and inadequate hydration are among the reversible risk factors that play a crucial role in the development and recurrence of radiation cystitis. Early initiation of pelvic floor exercises, patient education on proper voiding habits, can increase the pelvic muscle strength and significantly decrease post void residual urine. This might have a potential role in decreasing the radiation cystitis which needs to be validated in future randomised control studies with long term follow up. Clinicians must take a proactive approach in identifying at risk survivors and implementing preventive strategies to minimize the burden of radiation cystitis.

Declarations

Funding

This study was fully funded by the Cancer Institute (WIA), Chennai.

Clinical trial registration

Not applicable

Conflicts of interest/Competing interests

Authors declare that they have no conflicts of interest.

Availability of data and material

The data sets used and/or analyzed during the current study are available from the corresponding author per reasonable request.

Code availability

The custom code was used.

Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Sundara vadhana, Anitha Dharmaraj, Madhavan Sasidharan Satish and Ram Madhavan. The first draft of the manuscript was written by Ram Madhavan and all authors commented on previous versions of the manuscript. All authors approved the final version for submission.

Ethics approval

This study was approved by Ethics Committee of the Cancer Institute (WIA), Chennai.

Consent to participate

Written informed consent was obtained from all study participants prior to enrollment. The study was conducted in accordance with the Declaration of Helsinki and ethical principles of good clinical practice.

Consent for publication

All participants provided informed consent for the publication of de-identified data and results. Patient anonymity and confidentiality have been maintained throughout the manuscript.

Originality Declaration for Figures

All figures included in this manuscript are original and have been created by the authors specifically for the purposes of this study. No previously published or copyrighted images have been used. The authors confirm that all graphical elements, illustrations, and visual materials were generated from the data obtained in the course of this research or designed uniquely for this manuscript.

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