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The Impact of a Rectal Spacer in VMAT Dosimetry in the Treatment of Prostate Cancer

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Abstract

Although the dosimetric advantages of rectal spacers in prostate cancer radiotherapy have been demonstrated in selected clinical trials, real-world data from routine clinical practice remain limited—particularly within the Portuguese healthcare system. This study offers a detailed dosimetric comparison of Volumetric Modulated Arc Therapy (VMAT), with and without rectal spacer use, in a real-world patient cohort, aiming to assess the clinical relevance of spacer insertion under standard treatment protocols. A retrospective dosimetric evaluation was performed on 80 prostate cancer patients treated at a radiotherapy centre in southern Portugal. Patients were equally divided into two matched groups (n = 40): one receiving VMAT alone, the other receiving VMAT with hydrogel rectal spacer placement. Dose-volume histograms (DVHs) were analysed for the planning target volume (PTV) and key organs at risk (OARs). Standard dosimetric metrics, such as V50–V75 for the rectum and bladder, V50 for femoral heads, and mean dose for the penile bulb, were assessed. PTV coverage was evaluated using conformity and homogeneity indices. Spacer use significantly decreased rectal dose exposure across all evaluated parameters without compromising PTV coverage or increasing dose to other OARs. These findings support routine rectal spacer applications to enhance treatment safety and patient outcomes.

Keywords: organs at risk; prostate cancer; rectal spacer; VMAT; clinical dosimetry; radiotherapy

1. Introduction

Prostate cancer is one of the most prevalent malignancies worldwide and accounts for a significant proportion of cancer-related mortality [1]. Management strategies range from active surveillance in low-risk cases to more aggressive interventions, such as radiotherapy (RT), radical prostatectomy, and hormonal therapy [2]. Given its high incidence and significant impact on patients' quality of life, prostate cancer has emerged as a major public health issue [2].

RT remains a cornerstone in the management of prostate cancer, aiming to deliver high doses to the tumour whilst sparing surrounding healthy tissues as much as possible [3].

Initially, prostate tumours were treated using the Three-Dimensional Conformal Radiotherapy (3DCRT) technique, employing static multileaf collimator (MLC). However, achieving improved local disease control required higher radiation doses, which were limited in 3DCRT by increased toxicity to organs at risk (OARs), potentially impairing their function [4–6].

Technological advances in linear accelerators enabled the development of Intensity-Modulated Radiotherapy (IMRT) and its evolution Volumetric Modulated Arc Therapy (VMAT). These techniques improve dose conformity, allowing for more precise tumour targeting and allowing for reduced planning target volume (PTV) [5]. The incorporation of dynamic MLCs allows continuous adaptation to gantry motion, further enhancing treatment accuracy. As a result, these innovations enable dose escalation with better disease control, and reduced toxicity to OARs [7].

Despite these advancements, rectal toxicity remains a significant concern, particularly in dose-escalated protocols. The introduction of perirectal spacers, especially polyethylene glycol (PEG) hydrogel, has shown promise in mitigating this risk. PEG hydrogel is of particular interest due to its stability throughout the course of fractionated RT and its high visibility on imaging. By creating anatomical separation between the prostate and rectum, the spacer displaces the anterior rectal wall from high-dose regions, significantly reducing radiation-induced rectal toxicity and enhancing treatment tolerability and quality of life [8–10].

In recent years, advanced techniques such as simultaneous integrated boost (SIB) have been explored, enabling the delivery of escalated doses to high-risk sub-volumes within the target area without increasing exposure to surrounding OARs [11,12]. Moreover, emerging strategies such as adaptive radiotherapy and the use of magnetic resonance-guided linear accelerators (MR-Linac) have garnered attention for their potential to enable real-time treatment adaptation based on anatomical and physiological changes [13]. These innovations reflect the growing trend towards precision and individualisation in prostate cancer radiotherapy [13,14].

1.1. Radiotherapy in the Treatment of Prostate Tumours

According to the World Health Organization (WHO), the global incidence of prostate cancer is rising, driven by increased life expectancy and advances in diagnostic imaging. It primarily affects elderly men and is associated high treatment success rates when diagnosed in localised stages. In External Beam Radiotherapy (EBRT), the prescribed dose depends on clinical parameters such as tumour stage, Gleason Score, and Prostate-Specific Antigen (PSA) levels [1,15].

The delivery of high radiation doses to the tumour necessitates precise planning and execution to ensure therapeutic efficacy while safeguarding organs at risk (OARs). A major challenge lies in balancing tumour dose escalation with the protection of OARs, as excessive radiation exposure may lead to functional impairments and significantly compromise patients' quality of life [16].

In this context, the therapeutic dose for prostate cancer is typically administered in a fractionated manner, i.e., the total radiation dose is divided into multiple fractions. Dose fractionation aims to maximise tumour control while minimising toxicity to surrounding healthy tissues [2]. Within this framework, a crucial parameter is the α/β ratio [17].

This ratio reflects the sensitivity of tissues to dose per fraction. Tumours with a high α/β ratio (>10 Gray (Gy)) tend to respond more effectively to smaller fraction sizes, whereas tumours characterised by a low α/β ratio—such as prostate cancer—are more sensitive to larger fraction sizes [17,18].

This concept is of relevance in prostate cancer due to its characteristically low α/β ratio (approximately 1.5 Gy), which renders the tumour more responsive to hypofractionated regimens. Consequently, hypofractionation presents a compelling therapeutic strategy in this setting. Notably, this approach does not appear to increase adverse effects in surrounding normal tissues, such as the rectum and bladder (with $\alpha/\beta \approx 3$–5 Gy), and is therefore regarded as a safe, effective, and advantageous treatment option [19,20].

1.2. The Volumetric Modulated Arc Therapy Dosimetric Technique Applied to Prostate Tumours

Among the various EBRT modalities, VMAT is widely favoured for its superior dose conformity, treatment efficiency, and enhanced sparing of organs at risk (OARs). VMAT, an advanced form of IMRT, delivers radiation through continuous arc rotations, enabling more complex, precise, and safer dose distributions [5,7,9,14,15].

A standard VMAT treatment plan typically involves two complete 360° gantry rotations around the patient. During delivery, the MLC dynamically adjusts to the shape of the PTV, while both dose rate and gantry speed are modulated in real time. These features contribute to reduced exposure of surrounding OARs. These technical improvements enable safer tumour dose escalation while reducing OAR toxicity, thereby improving disease control and patient outcomes [16].

The VMAT technique offers numerous advantages, including rapid treatment delivery (typically 1–2 min), which reduces the likelihood of patient movement during irradiation. It is also compatible with hypofractionated and ultra-hypofractionated regimens, which involve fewer treatment sessions with higher daily doses, without compromising disease control or increasing toxicity to OARs [6,17].

However, to maximise the success of this technique, it is essential that it be combined with Image-Guided Radiation Therapy (IGRT), allowing for daily verification of PTV and OAR positioning prior to each treatment session. This facilitates highly accurate, safe, and effective dose delivery [3].

1.3. Toxicity in Organs at Risk from External Beam Radiotherapy in Prostate Cancer Treatment

EBRT is a highly effective technique for treating prostate cancer, with well-established efficacy in achieving disease control [18]. However, as with any therapeutic intervention, EBRT is associated with potential adverse effects that vary in severity and onset. The severity and likelihood of these effects depend on several factors, including disease stage, total dose, treatment technique, and individual patient radiosensitivity. Acute toxicity usually occurs during or shortly after treatment, whereas late toxicity may manifest months to years after its completion [18,19].

The rectum is particularly vulnerable due to its radiosensitivity and anatomical proximity to the prostate. Acute rectal toxicity may present as loose stools or diarrhoea, rectal distension with cramping, and, in rarer cases, superficial ulceration accompanied by rectal bleeding [11]. Chronic complications may include radiation-induced damage to the rectal wall potentially resulting in faecal incontinence or stenosis [9,16,18].

The bladder is another organ at risk due to its close anatomical proximity to the prostate and its partial inclusion in the irradiation field. Acute bladder toxicity commonly manifests as radiation-induced cystitis, with symptoms such as urinary frequency, dysuria, and haematuria. Late effects may include persistent dysuria, decreased urinary flow, and, in severe cases, irreversible urinary incontinence [20,21].

Although not routinely contoured, the penile bulb is susceptible to radiation-induced damage. Studies indicate that doses exceeding 50 Gy significantly increase the risk of severe erectile dysfunction [22].

These radiation-induced toxicities can have a profound impact on patients' quality of life. Therefore, meticulous dosimetric planning is crucial to minimize radiation exposure to OAR while ensuring adequate coverage of the PTV [8,23,24].

Given the central role of radiotherapy in prostate cancer treatment recent advancements in dosimetric techniques, this study aims to assess the impact of VMAT on dose distribution and treatment-related toxicity. Specifically compares the dosimetric outcomes between two patient cohort—those treated with a rectal spacer and those without—by analysing radiation doses to the PTV and key OAR, including the rectum, bladder, femoral heads, and penile bulb.

2. Materials and Methods

This retrospective cohort study was conducted in 2023 at a radiotherapy centre in southern Portugal, in accordance with the ethical principles of the Declaration of Helsinki, ensuring the protection of participants' rights and well-being. Written informed consent was obtained from all participants. Data were processed in full compliance with the General Data Protection Regulation (GDPR), ensuring confidentiality and privacy of patient information throughout the research process.

The study included 80 prostate cancer patients who were eligible for curative treatment and met the inclusion criteria. The clinical characteristics of the patient cohort were analysed to ensure adequate representation and homogeneity between treatment groups:

- The mean age of the patients was 70.4 years (±4.9), with a median of 71.0 years.
- Tumour staging was predominantly distributed among cT2cN0M0 (n = 27), T2bN0M0 (n = 23), and T2N0M0 (n = 19), with a smaller subset of patients presenting other classifications [25,26].
- Gleason scores were distributed as follows: 6 (3 + 3) in 15 patients, 7 (3 + 4) in 21 patients, 7 (4 + 3) in 19 patients, and 8 (4 + 4) in 13 patients. Less frequent combinations included 8 (3 + 5) in 3 cases, 8 (5 + 3) in 2, 9 (5 + 4) in 3, 9 (4 + 5) in 2, and 10 (5 + 5) in 2 patients.
- Serum prostate-specific antigen (PSA) values at diagnosis ranged from 0.9 to 90.0 ng/mL, with a mean of 16.3 ng/mL (±16.0).

These data confirm a clinically representative sample of patients with localised prostate cancer undergoing VMAT, with or without the use of a rectal spacer. The cohort comprised 40 patients treated with VMAT alone and 40 who received rectal spacer insertion prior to radiotherapy. All patients were treated with curative intent between 2020 and 2021, according to predefined inclusion and exclusion criteria (Table 1).

Table 1. The inclusion and exclusion criteria defined for the study participants.

Inclusion Criteria	Exclusion Criteria
Patients who underwent VMAT dosimetry, planned in three phases:	Exclusion criteria included patients with metastatic or recurrent disease, as their treatment planning was not consistent with primary prostate cancer protocols.
• First phase: irradiation of the prostate, seminal vesicles, and nodal areas.	
• Second phase: irradiation of the prostate and vesicles.	
• Third phase: irradiation of the prostate only.	

The prescribed doses were 50 Gy for phase 1, 14 Gy for phase 2, and 16 Gy for phase 3. Each treatment plan employed two full 360° arcs with dynamic MLCs and 10 MV photon beams. In arc 1, the gantry rotated clockwise from 179° to 181°, while in arc 2, it rotated counter-clockwise from 181° back to 179°.

To provide a clearer understanding of the clinical workflow, a brief overview of each treatment stage is presented below.

The process begins with an initial consultation with the radiation oncologist. During this consultation, the oncologist reviews the patient's medical history, defines the most appropriate treatment strategy based on the tumour stage, and prescribes the total dose and treatment schedule. The potential side effects of treatment are also discussed with the patient at this stage.

In patients undergoing VMAT with a rectal spacer, a minimally invasive procedure is performed to insert the spacer between the prostate (outlined in red) and the rectum (in green). This spacer serves to reduce rectal radiation exposure during treatment (see Figure 1).

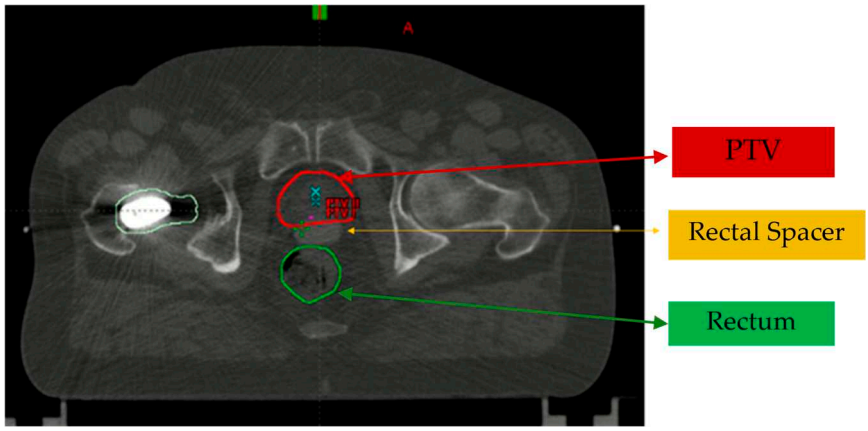

Figure 1. Axial pelvic slice showing the location of the rectal spacer in Eclipse Planning System version 15.6 by Varian Medical Systems.

The rectal spacer is inserted approximately 1 month prior to the planning CT scan. The device is cylindrical in shape and composed of hydrogel. According to recent studies, the hydrogel maintains the created anatomical separation for approximately 3 months and is gradually absorbed by the body within 6 months of placement [27].

All subsequent stages were identified for both groups, regardless of spacer use. The planning CT scan was conducted following a standard protocol: patients were instructed to empty their bladder and drink 0.5 L of water and wait 30 min to ensure consistent bladder filling. The rectum was also required to be empty. This protocol was maintained throughout

the treatment course to minimise OAR dose and ensure reproducibility of organ position and volume. During the planning CT scan, the patient's positioning and immobilization devices were defined to ensure treatment accuracy, and the acquired images were used for dosimetric planning.

Clinical dosimetry followed, during which the radiation oncologist delineated the target volumes, identified OARs, and prescribed the appropriate dose. Based on this input, the dosimetrist planned the optimal beam arrangement to deliver the prescribed dose to the target whilst maximizing the protection of adjacent critical organs. After approval of the dosimetric plan, the patient is scheduled to begin treatment.

2.1. Rectal Spacer Placement: Indications, Contraindications, and Procedural Protocol

The principal indication for rectal spacer placement is the diagnosis of prostate cancer, particularly in patients at increased risk of rectal toxicity associated with radiotherapy.

Contraindications include the presence of active infection in proximity to the treatment area and a known history of inflammatory bowel disease [9,10].

Procedural Protocol

The rectal spacer placement procedure at radiotherapy centre is conducted as follows [28]:

1. Patient Preparation
    - The procedure is generally performed on an outpatient basis under mild sedation or local/regional anaesthesia.
    - The patient is positioned in the lithotomy position, as is standard practice for prostate examinations or transrectal biopsies.
    - The perineal region is cleansed and disinfected using standard aseptic techniques.
2. Image Guidance—Transrectal Ultrasound (TRUS)
    - A TRUS probe is utilised to provide real-time imaging throughout the procedure.
    - The prostate and rectum are clearly visualised to enable accurate guidance and placement.
3. Access and Initial Insertion
    - Using a guiding needle, the clinician accesses the space between the prostate and the anterior rectal wall (posterior periprostatic space).
    - A dilator or a proprietary device (e.g., from Spacer/BioProtect) is then employed to create adequate separation between the two anatomical structures.
4. Insertion of the Spacer
    - The spacer balloon is introduced into the prepared space and inflated with a biocompatible hydrogel.
    - The device maintains an average separation of at least 1 cm between the prostate and rectum.
    - Correct positioning is confirmed via transrectal ultrasound.
5. Completion and Follow-up
    - Once in place, the spacer remains stable throughout the course of radiotherapy, typically spanning several weeks.
    - The hydrogel is fully biodegradable and is naturally reabsorbed by the body within approximately 6 months, thereby obviating the need for surgical removal.

2.2. Data Collection and Analysis

For this study, quantitative data were extracted from each dose distribution (VMAT without spacer and VMAT with rectal spacer). The data were obtained from Dose Volume Histogram (DVH) using the Eclipse Planning System, version 15.6 (Varian Medical Systems, Palo Alto, CA, USA).

Quantitative parameters for the PTV and OARs were evaluated according to institutional criteria derived from the QUANTEC guidelines [23]. The OARs evaluated included the rectum, the bladder, the penile bulb, and the femoral heads. For the rectum, the volume percentages receiving 50 Gy (V50), 60 Gy (V60), 65 Gy (V65), 70 Gy (V70), and 75 Gy (V75) were analysed. For the bladder, the volume percentages receiving 65 Gy (V65), 70 Gy (V70), 75 Gy (V75), and 80 Gy (V80) were assessed.

The mean dose to the penile bulb was calculated, and for the femoral heads, the percentage volume receiving a dose of 50 Gy (V50) was evaluated.

For the PTV, the parameters analysed included D98% (dose received by 98% of the volume), D2% (dose received by 2% of the volume), and V95% (volume receiving 95% of the prescribed dose). These parameters were used to calculate the homogeneity index (HI) and conformity index (CI) for the PTV, according to the Radiation Therapy Oncology Group (RTOG) formulas [29]. HI was calculated using the following formula: lower values indicate a more homogeneous dose distribution with an ideal value approaching zero [30]:

$$HI = \frac{D_{2\%} - D_{98\%}}{Prescribed\ Dose}$$

CI was used to assess the conformity of the dose distribution to the 95% isodose line, with a value approaching 1 indicating optimal conformity [29]. The formula is as follows:

$$CI = \frac{V_{95\%}}{VPTV}$$

where V_{PTV} is the Total PTV volume.

All statistical analyses were conducted using IBM SPSS Statistics (version 30). Prior to group comparisons, the distribution of each continuous variable was assessed for normality using the Shapiro–Wilk test, which is appropriate for the sample size of each group (n = 40). Several dose-volume metrics did not satisfy the assumptions of normality, and visual inspection of histograms and Q–Q plots further corroborated the presence of non-normal distributions. Accordingly, the Mann–Whitney U test was employed to compare dosimetric parameters between the VMAT without spacer and VMAT with rectal spacer techniques. This non-parametric test is suitable for independent samples and is robust against non-normal distributions and outliers. A two-tailed significance threshold of $p < 0.05$ was adopted for all tests.

In addition to the mean and standard deviation, percentiles (25th, 50th, and 75th) were included in the descriptive analysis to provide a more comprehensive representation of the data distribution. Given the use of non-parametric statistical tests and the presence of variables with non-normal distributions, percentile values offer robust, distribution-free measures of central tendency and spread. The 50th percentile (median) is less influenced by outliers and skewness than the mean and is therefore a more appropriate indicator of central tendency in this context. The 25th and 75th percentiles further characterise the interquartile range, allowing for the assessment of data dispersion and symmetry within and between groups.

3. Results

Following analysis of the study sample quantitative results are presented below, organised by OARs, and PTV. For the rectum, Table 2 show the mean volume percentage and corresponding standard deviation (SD) for each evaluated parameter (V50, V60, V65, V70, and V75) comparing the two treatment groups. Across all evaluated dose thresholds, patients treated with VMAT and a rectal spacer exhibited significantly lower irradiated rectal volumes.

Table 2. Values obtained in the two groups for the rectum.

Technique	V50 < 50%		V60 < 35%		V65 < 25%		V70 < 20%		V75 < 15%	
	Average	SD	Average	SD	Average	SD	Average	SD	Average	SD
VMAT without rectal spacer	18.9	8.02	11.6	5.05	9.03	3.96	6.8	3.15	4.6	2.28
VMAT with rectal spacer	6.08	4.40	2.35	2.50	1.50	1.80	0.87	1.30	0.43	0.81

Additionally, Tables 3 and 4 present the 25th, 50th (median), and 75th percentiles for each dosimetric parameter, providing further insight into the distribution of dose exposure and inter-patient variability within each group.

Table 3. Descriptive statistics (25th, 50th, and 75th percentiles) of rectal dose-volume parameters (V50, V60, V65) for patients treated with VMAT, with and without a rectal spacer.

Technique	V50 < 50%			V60 < 35%			V65 < 25%		
	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3
VMAT without rectal spacer	13.58	17.75	22.28	8.05	11.35	14.18	6.33	8.95	11.83
VMAT with rectal spacer	2.15	5.85	8.95	0.13	1.65	4.03	0.03	0.09	2.20

Table 4. Descriptive statistics (25th, 50th, and 75th percentiles) of rectal dose-volume parameters (V70, V75) for patients treated with VMAT, with and without a rectal spacer.

Technique	V70 < 20%			V70 < 15%		
	Q1	Q2	Q3	Q1	Q2	Q3
VMAT without rectal spacer	4.15	7.05	9.48	2.83	5.00	6.73
VMAT with rectal spacer	0.00	0.15	1.30	0.00	0.00	0.38

To further assess the dosimetric impact of rectal spacer use, a comparative analysis of dose-volume parameters was conducted between patients treated with VMAT alone and those treated with VMAT combined with a rectal spacer (VMAT_S). This analysis focused on the percentage of rectal volume receiving predefined dose thresholds (V50, V60, V65, V70, and V75). The results are summarised in both graphical (Figure 2) and (Table 5) formats. Statistical comparisons were performed using the Mann–Whitney U test to evaluate differences between the two groups.

Bladder dose parameters (V65 to V80) for both groups are summarised in Table 6. A slight reduction in bladder dose was noted in the group treated with VMAT and a rectal spacer.

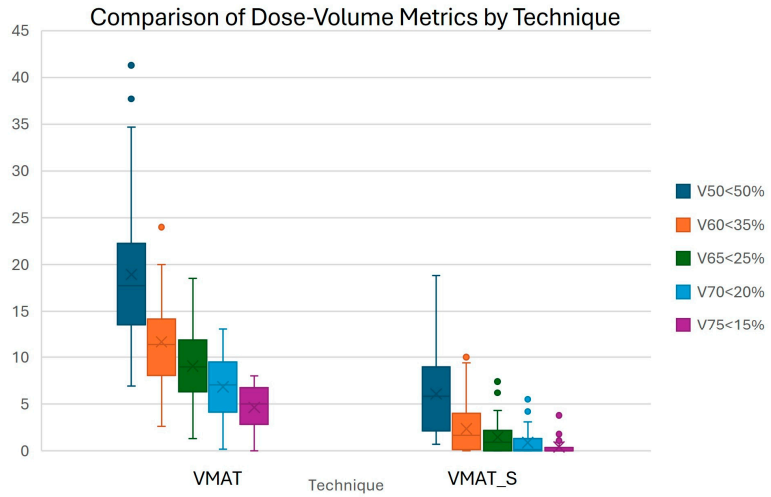

Figure 2. Boxplot comparison of rectal dose-volume parameters (V50–V75) between VMAT and VMAT_S. The Mann–Whitney U test was employed for statistical comparison.

Table 5. Comparison of dose-volume metrics between VMAT and VMAT_S techniques for the rectum. Mann–Whitney U test was used for statistical comparison.

Variable	Technique	*n*	Mean Rank	U	Z	*p*-Value
V50 < 50%	VMAT	40	58.23	91.000	−6.823	0.001
	VMAT_S	40	22.78			
V60 < 35%	VMAT	40	58.88	65.000	−7.075	0.001
	VMAT_S	40	22.13			
V65 < 25%	VMAT	40	59.20	52.000	−7.206	0.001
	VMAT_S	40	21.80			
V70 < 20%	VMAT	40	59.00	60.000	−7.150	0.001
	VMAT_S	40	22.00			
V75 < 15%	VMAT	40	58.81	67.500	−7.125	0.001
	VMAT_S	40	22.19			

Note: All *p*-values refer to two-tailed asymptotic significance.

Table 6. Values obtained in the two groups for the bladder.

Technique	V65 < 50%		V70 < 35%		V75 < 25%		V80 < 15%	
	Average	SD	Average	SD	Average	SD	Average	SD
VMAT without rectal spacer	10.10	10.90	6.60	3.90	4.60	2.90	2.10	1.60
VMAT with rectal spacer	7.22	4.90	5.32	3.70	3.68	2.80	1.73	1.50

Furthermore, Table 7 presents the 25th, 50th (median), and 75th percentiles for each bladder dose parameter, providing further insight into the distribution and variability of bladder dose exposure between the two treatment techniques.

To further assess the dosimetric impact of rectal spacer use, a comparative analysis of dose-volume parameters was conducted between patients treated with VMAT alone and those treated with VMAT combined with a rectal spacer (VMAT_S). This analysis focused on the percentage of bladder volume receiving predefined dose thresholds (V65, V70, V75, and V80). The results are summarised in both graphical (Figure 3) and tabular

(Table 8) formats. Statistical comparisons were performed using the Mann–Whitney U test to evaluate differences between the two groups.

Table 7. Descriptive statistics (25th, 50th, and 75th percentiles) of bladder dose-volume parameters (V65, V70, V75, V80) for patients treated with VMAT, with and without a rectal spacer.

Technique	V65 < 50%			V70 < 35%			V75 < 25%			V80 < 15%		
	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3
VMAT without rectal spacer	4.40	7.75	12.63	3.43	6.00	9.68	2.30	4.15	6.68	0.90	1.80	3.20
VMAT with rectal spacer	3.43	6.55	8.83	2.53	4.85	6.85	1.80	3.05	4.95	0.80	1.40	2.30

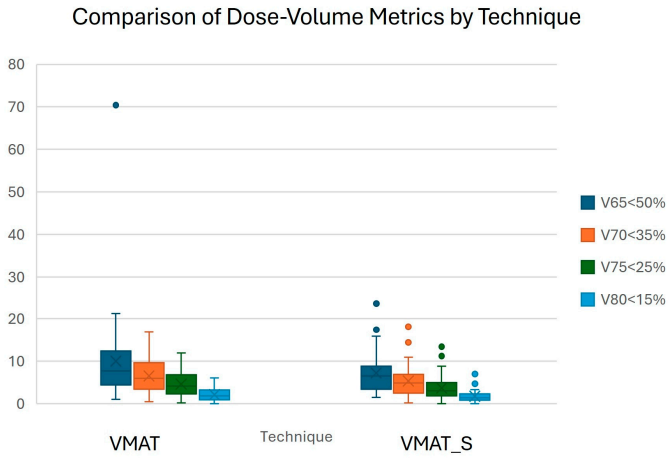

Figure 3. Boxplot comparison of bladder dose-volume parameters (V65–V80) between VMAT and VMAT_S. The Mann–Whitney U test was employed for statistical comparison.

Table 8. Comparison of dose-volume metrics between VMAT and VMAT_S techniques for the bladder. Mann–Whitney U test was used for statistical comparison.

Variable	Technique	*n*	Mean Rank	U	Z	*p*-Value
V65 < 50%	VMAT	40	44.28	649.0	−1.453	0.146
	VMAT_S	40	36.73			
V70 < 35%	VMAT	40	44.54	638.5	−1.554	0.120
	VMAT_S	40	36.46			
V75 < 25%	VMAT	40	44.70	632.0	−1.617	0.106
	VMAT_S	40	36.30			
V80 < 15%	VMAT	40	43.23	654.0	−1.237	0.216
	VMAT_S	40	36.85			

Note: All *p*-values refer to two-tailed asymptotic significance.

Table 9 displays the V50 values for the right and left femoral heads in both groups. In both groups, the V50 for the femoral heads remained well below tolerance limits, with slightly lower values in the rectal spacer group. For this OAR, no differences were observed in the 25th, 50th, and 75th percentiles between the two techniques.

To further evaluate the dosimetric impact on the femoral heads, a comparative analysis of the V50 parameter was undertaken between patients treated with VMAT alone and those treated with VMAT in conjunction with a rectal spacer (VMAT_S). This analysis assessed the percentage volume of both the left and right femoral heads receiving a dose of 50 Gy. The results are presented in both graphical format (Figure 4) and tabular form

(Table 10). Statistical comparisons between the two treatment groups were performed using the Mann–Whitney U test.

Table 9. Values obtained for the femoral heads in both groups.

Technique	Right Femoral Head		Left Femoral Head	
	V50 < 10%		V50 < 10%	
	Average	SD	Average	SD
VMAT without rectal spacer	0.24	1.50	0.27	1.50
VMAT with rectal spacer	0.05	0.30	0.05	0.30

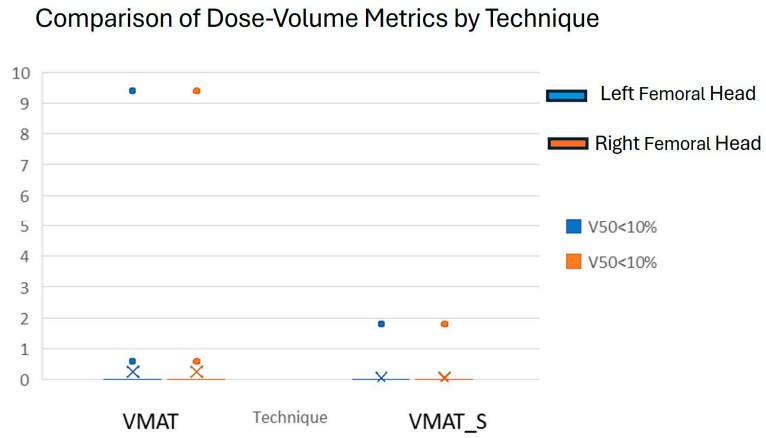

Figure 4. Boxplot comparison of the V50 dose-volume parameter for the femoral heads between VMAT and VMAT_S. The Mann–Whitney U test was employed for statistical comparison.

Table 10. Comparison of dose-volume metrics between VMAT and VMAT_S techniques for the femoral heads. Mann–Whitney U test was used for statistical comparison.

Variable	Technique	*n*	Mean Rank	U	Z	*p*-Value
V50 < 10% (Left Femoral Head)	VMAT	40	41.49	760.5	−1.006	0.314
	VMAT_S	40	39.51			
V50 < 10% (Right Femoral Head)	VMAT	40	40.51	799.5	−0.018	0.986
	VMAT_S	40	40.49			

Note: All *p*-values refer to two-tailed asymptotic significance.

Mean dose to the penile bulb is shown in Table 11 for both treatment groups. The mean dose to the penile bulb was lower in the group treated with VMAT and a rectal spacer.

Table 11. Values obtained for the penile bulb in both groups.

Technique	Mean Dose < 50 Gy	
	Average	SD
VMAT without rectal spacer	18.30	12.40
VMAT with rectal spacer	11.50	8.00

Furthermore, Table 12 presents the 25th, 50th (median), and 75th percentiles for the V50 parameter in the penile bulb, thereby offering a more detailed understanding of the distribution and variability of dose exposure within this anatomical structure. This percentile-based analysis enhances the characterisation of individual variability and potential differences in treatment response between the two techniques.

Table 12. Descriptive statistics (25th, 50th, and 75th percentiles) of the mean dose (Dmean < 50 Gy) to the penile bulb in patients treated with VMAT, with and without a rectal spacer.

Technique	Mean Dose < 50 Gy		
	Q1	Q2	Q3
VMAT without rectal spacer	8.33	15.30	28.28
VMAT with rectal spacer	5.00	7.90	17.15

To further assess the dosimetric impact on the penile bulb, a comparative analysis of the mean dose (Dmean < 50 Gy) was undertaken between patients treated with VMAT alone and those treated with VMAT in combination with a rectal spacer (VMAT_S). This analysis evaluated the mean dose delivered to the penile bulb, with particular focus on values below 50 Gy. The results are presented in both graphical format (Figure 5) and tabular form (Table 13). Statistical comparisons between the two treatment groups were performed using the Mann–Whitney U test.

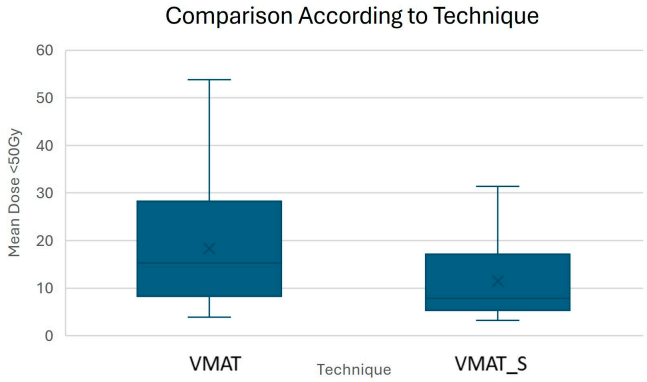

Figure 5. Boxplot comparison of the mean dose (Dmean < 50 Gy) to the penile bulb between VMAT and VMAT_S. Statistical comparison was performed using the Mann–Whitney U test.

Table 13. Comparison of dose-volume metrics between VMAT and VMAT_S techniques for the penile bulb. Mann–Whitney U test was used for statistical comparison.

Variable	Technique	*n*	Mean Rank	U	Z	*p*-Value
Mean dose <50 Gy	VMAT	40	46.16	453.5	−2.922	0.003
	VMAT_S	40	31.26			

Note: All *p*-values refer to two-tailed asymptotic significance.

PTV results based on homogeneity index (HI) and conformity index (CI) are summarised in Table 14. No statistically significant differences were observed between the two groups in terms of HI or CI.

Table 14. Values obtained for the PTV in both groups.

	HI		CI	
	Average	SD	Average	SD
VMAT without rectal spacer	0.032	0.010	0.996	0.010
VMAT with rectal spacer	0.034	0.010	0.999	0.002

Furthermore, Table 15 presents the 25th, 50th (median), and 75th percentiles for the HI and IC within the PTV, thereby providing a more detailed understanding of the distribution

and variability of these dosimetric indicators. This percentile-based analysis enhances the characterisation of treatment quality and supports the evaluation of potential differences in dose uniformity and target coverage between the two techniques.

Table 15. Descriptive statistics (25th, 50th, and 75th percentiles) of HI and IC within the PTV in patients treated with VMAT, with and without a rectal spacer.

Technique	HI			CI		
	Q1	Q2	Q3	Q1	Q2	Q3
VMAT without rectal spacer	0.03	0.03	0.03	0.999	0.999	1.00
VMAT with rectal spacer	0.03	0.03	0.04	0.999	1.00	1.00

To further evaluate the dosimetric characteristics of the PTV, a comparative analysis of HI and IC was undertaken between patients treated with VMAT alone and those treated with VMAT in combination with a rectal spacer (VMAT_S). This analysis assessed treatment quality in terms of dose homogeneity and conformity within the PTV. The results are presented in both graphical format (Figure 6) and tabular form (Table 16). Statistical comparisons between the two treatment groups were performed using the Mann–Whitney U test.

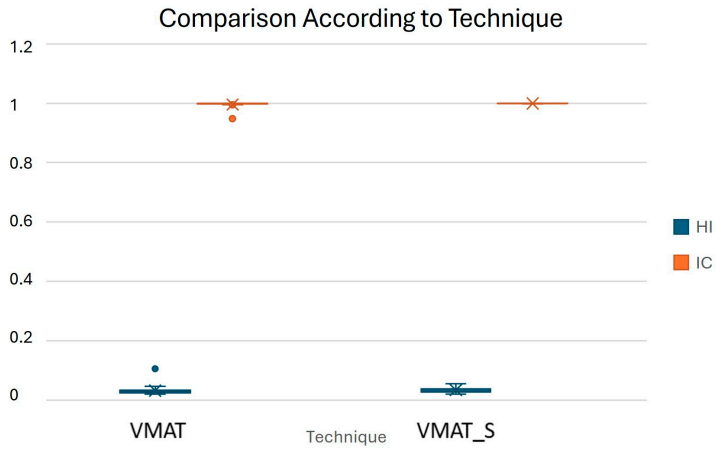

Figure 6. Boxplot comparison of HI and IC within the PTV between VMAT and VMAT_S. Statistical comparison was conducted using the Mann–Whitney U test.

Table 16. Comparison of dose-volume metrics between VMAT and VMAT_S techniques for the PTV. Mann–Whitney U test was used for statistical comparison.

Variable	Technique	*n*	Mean Rank	U	Z	*p*-Value
HI	VMAT	40	37.10	664.0	−1.314	0.189
	VMAT_S	40	43.90			
IC	VMAT	40	34.31	552.5	−2.591	0.010
	VMAT_S	40	46.69			

Note: All *p*-values refer to two-tailed asymptotic significance.

4. Discussion

This study evaluated the impact of rectal spacer insertion in the treatment of localised prostate cancer using two radiotherapy techniques: VMAT without a spacer and VMAT with a rectal spacer, by comparing the dosimetric outcomes between these approaches

The results demonstrate that the spacer significantly reduces radiation exposure to critical organs at risk (OARs), particularly the rectum and penile bulb, whilst enhancing dose conformity without compromising dose homogeneity [8–10].

These findings are consistent with existing literature, confirming that the insertion of a rectal spacer between the rectum and the prostate significantly reduces the radiation exposure to organs at risk, most notably the rectum, which is highly radiosensitive [5].

In the non-spacer group, rectal dose parameters V50 to V75 were 18.9%, 11.6%, 9.0%, 6.8%, and 4.6%. Corresponding values in the spacer group were significantly lower: 6.8%, 2.4%, 1.5%, 0.9%, and 0.4%. This reduction is attributable to the spacer's ability to increase anatomical separation between the prostate and rectum, thereby decreasing rectal dose and minimising radiation-induced toxicity [5,31,32].

The statistical analysis supported this assertion, as the rectum consistently demonstrated significantly lower Vx values (V50 to V75) in the VMAT_S (with rectal spacer) group ($p < 0.001$), thereby confirming the efficacy of the rectal spacer in reducing rectal irradiation. This finding is of clinical relevance as rectal sparing is associated with a decreased risk of gastrointestinal toxicity [8,31].

Bladder dose values were low across both groups, in line with previous studies. This outcome reflects VMAT's superior dose conformity, which enables effective protection of adjacent OARs [33]. However, unlike the rectum, the bladder showed only minor dose reductions with spacer use. This can be explained by the spacer's anatomical placement, which primarily displaces the rectum without significantly affecting bladder proximity [32]. In both groups, bladder dose metrics remained below tolerance levels, helping preserve bladder function and minimise the risk of acute or late toxicity [22].

The statistical analysis demonstrated a trend towards reduced radiation exposure with spacer utilisation; however, these differences did not reach statistical significance. Nevertheless, the consistent directional trend in mean ranks suggests a potential clinical benefit, warranting further investigation in larger patient cohorts.

This result is also supported by the clinic's preparation protocol, which requires patients to empty their bladder and then drink 0.5 L of water 30 min prior treatment. This process ensures bladder filling, causing it to expand like a "balloon", thereby reducing the portion of the bladder near the prostate [34].

For the femoral heads, the V50 values remained very low in both groups, well below tolerance thresholds. This is due to the precise dose conformity achieved with the VMAT technique [22]. The lateral anatomical position of the femoral heads relative to the centrally located prostate, together with the conformal isodose shaping, accounts for the minimal radiation exposure observed.

Statistical analysis did not reveal any statistically significant differences between the groups in terms of femoral head dose parameters. This further supports the notion that both techniques offer equally effective sparing of these structures.

Regarding the penile bulb, the results indicate a difference between the group treated with VMAT without a rectal spacer and the group treated with a rectal spacer, with the average dose received by this organ being 18.3 Gy and 11.5 Gy, respectively. Both values remained well below the accepted dose constraint of 50 Gy. This reduction may be clinically relevant in the preservation of sexual function, as higher doses to the penile bulb are associated with increased risk of erectile dysfunction [35].

Statistical analysis confirmed the significance of this finding, with a markedly lower mean dose observed in the VMAT_S (with rectal spacer) group ($p = 0.003$).

As with the bladder, the spacer's anatomical positioning limits its protective effect to the rectum, with only minimal impact on other pelvic structures.

Regarding the PTV, both groups met the ICRU recommendations, with no significant differences observed in HI or CI, indicating adequate dose coverage of the PTV. These findings reinforce the advantages of VMAT, which combines dynamic multileaf collimation with arc-based delivery to achieve superior dose conformity to the PTV [7]. Moreover, VMAT effectively reduces radiation exposure to OARs and this reduction is particularly significant for the rectum, when a rectal spacer is employed, as demonstrated in the present study [36].

Statistical analysis further confirmed these observations with respect to overall treatment plan quality. The HI did not differ significantly between the techniques ($p = 0.189$), suggesting that uniform target coverage is maintained regardless of spacer use. However, the CI was significantly improved in the VMATCS (with spacer) group ($p = 0.010$), indicating enhanced dose conformity around the target volume when a rectal spacer is utilised.

Treatment time constitutes another critical factor: VMAT significantly reduces session time, often delivering the prescribed dose in under 1 minute. This reduction minimises the likelihood of intrafractional motion, thereby enhancing treatment reproducibility—an essential principle in radiotherapy. However, a known limitation of arc-based techniques such as VMAT is the so-called "low-dose bath" to surrounding tissues, typically amounting to approximately 5–10% of the prescribed dose [32]. Although generally considered clinically insignificant, this low-dose exposure should be carefully monitored and optimised, particularly in dose-escalated protocols [21].

The findings of this study also support the implementation of hypofractionated dose protocols. These protocols aim to employ fraction doses exceeding 2 Gy, maintaining equivalent disease control optimisation without significant alterations in toxicity OARs [15,17,37].

This outcome is largely attributable to the distinctive radiobiological properties of prostate cancer, particularly its low α/β ratio (approximately 1.4–1.5 Gy), which contrasts with the higher α/β ratios of adjacent organs at risk (3–5 Gy). This disparity supports the use of fractionation schedules with higher doses per fraction [18,19].

Hypofractionated and ultra-hypofractionated regimens offer practical advantages for both patients and healthcare systems. Fewer treatment sessions improve the efficiency of linear accelerator usage and increase departmental capacity, aiding in the management of waiting lists [17,38,39].

For patients, reduced hospital visits lower transport costs and time commitment, offering a favourable cost-benefit ration. Treatment regimen selection should be individualised, taking into account clinical status, prostate anatomy, toxicity risk, and the available technological and human resources [17,19,39].

The implementation of a rectal spacer represents a valuable advancement in the delivery of hypofractionated and ultra-hypofractionated radiotherapy regimens for prostate cancer, offering enhanced protection to the rectum—the most radiosensitive OAR [40].

By significantly reducing the rectal dose, the spacer contributes to lowering the risk of gastrointestinal toxicity, which is particularly important in high-dose-per-fraction schedules [11,12].

The device consists of a biodegradable hydrogel that is safely absorbed by the body within a few months, with no reported adverse systemic effects or long-term complications. Its biocompatibility and transitory nature make it an ideal option for temporary anatomical separation during treatment. Moreover, the insertion procedure is minimally invasive, typically performed under local or light sedation, and is generally well tolerated by patients [8,28].

Crucially, once placed, the spacer maintains a stable position throughout the entire course of radiotherapy, ensuring consistent anatomical geometry. This stability supports one of the core principles of radiotherapy—daily reproducibility—which is essential for

accurate dose delivery and treatment efficacy. As such, the integration of a rectal spacer not only enhances the therapeutic ratio by improving organ-at-risk sparing, but also reinforces the precision and safety of advanced radiotherapy techniques such as VMAT.

In summary, the statistical findings underscore the clinical and dosimetric advantages of incorporating a rectal spacer in VMAT for pelvic irradiation. Notably, its use improves rectal and penile bulb sparing and enhances dose conformity to the target volume, all whilst maintaining dose homogeneity.

Limitations

The principal objective of this study was to conduct a retrospective dosimetric evaluation of the impact of rectal spacer insertion in patients with localised prostate cancer treated with VMAT, with specific emphasis on quantifying dose reduction to organs at risk, particularly the rectum.

Whilst we acknowledge that therapeutic efficacy, radiation-induced toxicity, and patient-reported quality-of-life outcomes represent essential dimensions for a comprehensive clinical assessment, the retrospective and exclusively dosimetric nature of this study precluded the collection of standardised follow-up data regarding clinical outcomes and functional parameters.

The absence of longitudinal clinical follow-up constitutes a relevant limitation, as it prevents direct correlation between dosimetric benefits and actual patient outcomes. Future research should therefore prioritise prospective study designs that integrate clinical, dosimetric, and patient-reported endpoints. Such approaches would enable more robust validation of the advantages associated with rectal spacer use, particularly within hypofractionated treatment regimens and anatomically heterogeneous patient populations.

5. Conclusions

This study supports and reinforces existing evidence that the use of a rectal spacer in conjunction with volumetric modulated arc therapy (VMAT) results in favourable dosimetric outcomes, particularly by significantly reducing rectal radiation dose and thereby lowering both acute and late toxicity risks. In contrast to most previous studies conducted in controlled or trial-based settings, this work provides real-world evidence from routine clinical practice, confirming the feasibility and benefit of spacer use under standard treatment conditions. VMAT facilitates the safe administration of high therapeutic doses whilst preserving the function of critical OARs, including the rectum, bladder, penile bulb, and femoral heads.

The utilisation of a rectal spacer in VMAT significantly reduces radiation dose to critical pelvic structures, particularly the rectum and penile bulb, whilst enhancing dose conformity. Although no statistically significant improvements were observed in bladder or femoral head sparing, the overall dosimetric profile supports the use of a spacer. These findings advocate for the integration of spacer techniques into routine radiotherapy planning for prostate cancer, in order to improve protection of organs at risk and to optimise overall treatment quality.

Furthermore, these results support further investigation into the incorporation of rectal spacers within VMAT protocols for eligible patients, particularly in the context of dose escalation to 84 Gy. Escalation to this dose level, alongside the implementation of hypofractionated and ultra-hypofractionated regimens, may enhance local tumour control, as indicated by previous studies. However, it remains imperative to evaluate the impact of such dose escalation on both acute and late toxicity to OARs, as well as patient survival and local disease control, with meticulous monitoring throughout treatment and follow-up.

Future research should also address potential displacement of the rectal spacer during EBRT and evaluate whether the hydrogel material may induce any adverse effects that could limit its clinical applicability.

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Institutional Review Board Statement: The study was approved by the Director of Joaquim Chaves Saúde—Radiotherapy Clinic of Faro, who granted ethical clearance for its conduct (Date: 26 July 2022). All procedures were performed in accordance with the Declaration of Helsinki and applicable national regulations.

Informed Consent Statement: Written informed consent was obtained from all participants prior to their enrolment in the study.

Data Availability Statement: The original contributions presented in this study are included in the article. Further enquiries can be directed to the corresponding authors.

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Conflicts of Interest: The authors declare no conflict of interest.

Abbreviations

The following abbreviations are used in this manuscript:

3DCRT	3D conformal radiotherapy
CI	Conformity index
DVHs	Dose-volume histograms
EBRT	External beam radiotherapy
GDPR	General Data Protection Regulation
HI	Homogeneity Index
IGRT	Image guided radiation therapy
ICRU	International Commission on Radiation Units and Measurements
IMRT	Intensity-modulated radiotherapy
MLC	Multileaf collimator
OARs	Organs at risk
PTV	Planning target volume
PEG	Polyethylene glicol
PSA	Prostate-specific antigen
RTOG	Radiation Therapy Oncology Group
RT	Radiotherapy
SIB	Simultaneous integrated boost
TRUS	Transrectal ultrasound
VMAT	Volumetric Modulated Arc Therapy
WHO	World Health Organization

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