




Article

The Role of Ultrasound-Based Monitoring of Bladder Volume in Patients with Prostate Cancer during CyberKnife Stereotactic Radiosurgery

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Featured Application: The conclusions of the study are pragmatic in terms of the implementation of prostate cancer radiotherapy using the CyberKnife system.



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Abstract: (1) Background: For patients irradiated due to prostate cancer, monitoring of bladder volume (BV) is crucial for accuracy of radiation delivery and minimizing exposure to surrounding healthy tissues. Due to the limited imaging capabilities of the CyberKnife system, ultrasound imaging plays a vital role in the monitoring of bladder filling. (2) Methods: A study was carried out in 142 prostate cancer patients treated with the CyberKnife system. Bladder ultrasound (US) was performed before each RTH session to assess real BV (rBV). The double US assessment of rBV was performed by two independent operators or a single operator during 177 and 495 RTH sessions, respectively, giving, in total, 1344 BV assessments. (3) Results: The mean BV in the first and second US assessment was 214.7 mL and 218.1 mL, respectively, while the mean planning bladder volume (pBV) was 340.8 mL. A pBV was significantly higher than an rBV. The mean difference between the US and CT assessment of BV was the smallest in the 100–349 mL group and the largest in the group above 349 mL. The Passing–Bablok regression results confirmed the reliability of the ultrasound (US) measurements. (4) Conclusions: The introduction of US-based BV assessment in patients irradiated due to prostate cancer using CyberKnife seems to be a crucial element in controlling the reproducibility of the treatment plan and should be a standard procedure. The pBV should be within the range of 200–300 mL. The US examination prior to CT scanning for planning is recommended to ensure the optimal range of BV for CT.

Keywords: CyberKnife; prostate cancer radiotherapy; ultrasound; bladder volume; radiation injury; bladder filling; ultrasound bladder monitoring; radiosurgery

1. Introduction

The CyberKnife[®] M6[™] Series (Accuray) system enables the delivery of highly precise radiation dose to the prostate [1–3]. Monitoring of bladder volume (BV) is crucial because changes in bladder size can alter the position of the target volume and other surrounding

normal organs [4,5]. Ensuring consistent BV helps maintain the correct positioning of the prostate and, thus, maximizes the accuracy of radiation delivery and minimizes exposure to surrounding normal tissues. Since this system has limited imaging capabilities, positioning of the prostate gland is performed using fiducial markers and two-dimensional X-ray images. This system does not have volumetric imaging capabilities; bladder and rectum filling cannot be monitored. Changes in BV during radiotherapy in patients with prostate cancer do not affect the position of the prostate as a target but may influence the position of the seminal vesicles. Significantly higher bladder toxicity is observed when the real BV (rBV) is less than the planned BV (pBV) [6]. Some studies have shown that BV less than 180 mL is correlated with a higher amount of bladder tissue within the higher dose range. In such cases, a trend toward prolonged acute genitourinary toxicity appears [6,7]. Due to this, rBV is monitored by cone beam CT (CBCT) prior to each RT session and matched as closely as possible to pBV (this refers to classical linacs). Volumetric imaging is not available for the CyberKnife system.

It has been observed that during radiation therapy (RTH), the time it takes for the patient to achieve a similar rBV is changing (increasing) [8,9]. Introducing ultrasound imaging instead of CBCT during CyberKnife stereotactic radiosurgery to monitor bladder filling seems to be accurate, fast, and comfortable for patients, consequently increasing the reproducibility of the pBV during RTH sessions.

Ultrasound imaging plays a significant role in the assessment of bladder volume, particularly in medical fields such as urology and radiation therapy. There are two main types of ultrasound techniques for bladder evaluation: transabdominal ultrasound (TAUS) and transrectal ultrasound (TRUS). These methods differ in terms of their approach and utility, especially when it comes to precision and patient comfort. Transabdominal ultrasound (TAUS) is a non-invasive and widely used method for bladder volume assessment. The probe is placed on the abdomen, and the bladder is visualized in two dimensions, which allows for the calculation of its volume. TAUS is generally sufficient for routine measurements of bladder volume, particularly when high precision is not critical, as it provides a fast, painless, and effective way to estimate bladder content. This makes it a practical choice in daily clinical settings, including radiotherapy, where consistent bladder filling is important for precise targeting. In contrast, transrectal ultrasound (TRUS) offers a more detailed and accurate view of the bladder and surrounding tissues. By inserting the probe into the rectum, the TRUS provides visualization closer proximity to the bladder, making it suitable for detecting abnormalities and providing more precise volume measurements. However, this method is more invasive and less comfortable for the patient, limiting its use primarily to specialized diagnostic situations [10,11].

When comparing ultrasound with computed tomography (CT) and magnetic resonance imaging (MRI), it is clear that ultrasound offers several advantages. It is noninvasive, portable, and does not expose patients to ionizing radiation, which is a concern with CT scans. Magnetic resonance imaging, while offering highly detailed images, is time consuming and expensive, making it less practical for frequent bladder volume assessments. However, both CT and MRI provide more precise volumetric data, especially in cases where the shape or position of the bladder needs to be considered in greater detail [12].

The main objectives of this study were to evaluate the utility of a bladder ultrasound (US) scanner to assess rBV during CyberKnife stereotactic radiosurgery in patients with prostate cancer and to compare US-assessed rBV with pBV. Regarding the quantity of scientific publications on this topic, there appears to be a growing body of research addressing bladder volume control during radiotherapy, especially regarding ultrasound use as a noninvasive and practical solution. However, ultrasound-based studies specifically within the context of the CyberKnife system are still relatively novel. This suggests that, while there are studies on bladder volume management in radiotherapy, more research is emerging focusing on CyberKnife and ultrasound integration, making this study a valuable contribution to the specific niche. The authors are not aware of any radiotherapy center

where BV measurements are performed as a standard. The results of this study may suggest a change in approach in this regard.

2. Materials and Methods

A group of 142 patients with prostate cancer treated with the CyberKnife® M6™ Series system was included in the study. The patients were irradiated with a fractional dose of 7.25 Gy to a total dose of 36.25 Gy, administered every two days. All patients treated with the CyberKnife system for prostate cancer from January 2022 to August 2023 were included in the study. No exclusion criteria were applied, as the reproducibility of bladder volume is clinically significant and there were no contraindications to performing ultrasound examinations. Although ultrasound examinations can be routinely performed during radiotherapy, approval was obtained from the bioethics committee to conduct the study.

2.1. Ultrasound Assessment of Bladder Volume

For each patient, radiation therapy technologists (RTT) performed a BV measurement study prior to each RTH session to automatically calculate its volume (Figure 1). For 177 RTH sessions, two independent operators performed double US assessment. For 495 sessions, a single operator performed double US assessment. A total of 1344 rBV assessments were performed. The US-based rBV was compared to the reference CT-based pBV.

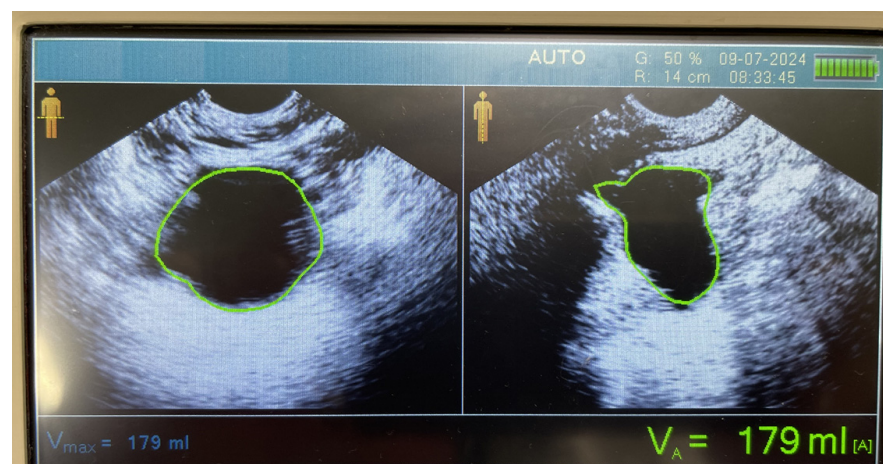


Figure 1. An example of automatic bladder volume measurement (PINIT, Echo-Son).

For all patients, ultrasound BV evaluation was performed in the therapeutic position prior to the RTH session. A vacuum mattress and a special knee pad were used as stabilizers. RTH was not performed if the bladder filling difference (the difference between rBV and pBV) exceeded 100 mL. In such cases, the US assessment was repeated (after correction of bladder filling). Only the result of the first US assessment of the day was included in the analysis. Each patient was prepared for the RT session according to the bladder filling protocol. According to this procedure, after voiding, the patient was instructed to drink 0.5 L of still water in 15 min and then wait for 1.5 h. After this period, the US was performed to assess BV.

Measurement of bladder volume was performed using ultrasound imaging. The patient was lying on his back during the examination, with the abdomen exposed, allowing easy access to the lower abdomen. Ultrasound gel is applied to the patient's lower abdomen to ensure better contact between the transducer and the skin, eliminating air bubbles that could interfere with image quality. The ultrasound transducer is placed above the pubic symphysis, in the lower part of the abdomen, directly over the bladder. The transducer is slowly moved and rotated in different directions to obtain appropriate cross sections of

the bladder (in both longitudinal and transverse planes). Appropriate cross sections are those in which, in the operator's assessment, the bladder appears largest. At this point, the operator saves the images, and the system automatically analyzes them, identifies the boundaries of the bladder, and calculates the volume based on the surface area in two planes. The result of the bladder volume measurement, expressed in milliliters (mL), appears on the device screen.

2.2. Ultrasound Device

In the study, a PINIT device (Echo-Son SA, Puławy, Poland) was used. This device is intended for non-invasive basic imaging and measurement of organs of the urinary system, specifically dedicated to measuring BV and assisting urodynamic examinations. According to the ultrasound device specification for the BV measurement, the tolerable measurement error for the method was $\pm 15\%$. The assessment of BV took from few to several seconds, and the results can be stored as a digital or printed version. The S225B ultrasound probe allows the bladder to be scanned in both transverse and longitudinal projections. The scanner was used in the automatic BV measurement mode, in which the bladder boundaries are automatically outlined in two planes, followed by an immediate calculation of the BV (Figure 1). The operating frequency range of the ultrasound probe was 2.5–5.0 MHz. The scanning angle is 120, with a scanning depth range of 12–20 cm. The measurement range for the BV in automatic mode was 0–999 mL. The PINIT device adheres to the What You See Is What You Get (WYSIWYG) principle. This means that the measurement obtained is closely tied to the image, so that the accuracy and repeatability of the measurement results depend on the operator's anatomical knowledge and experience.

2.3. Radiological Assessment of Bladder Volume

The planned bladder volume (pBV), also known as the reference bladder volume, was determined using computed tomography (CT) images obtained for radiotherapy planning purposes. Since the bladder is an organ at risk (OAR) in prostate cancer radiotherapy, a radiation oncologist delineated the contours of the organ for each patient on CT images. The contour was drawn along the outer surface of the bladder wall, and a contouring system (Eclipse™ treatment planning system, Varian) automatically calculated the volume of the organ. Each patient was prepared for the CT scan according to the bladder filling protocol, which was the same as that used for the RT session (see Section 2.1).

2.4. Statistical Analysis

Data were analyzed using nonparametric methods due to the lack of normal distribution in the data ($p < 0.001$). Normality of the distribution was tested with the Shapiro–Wilk test. Differences between two groups were determined using the Wilcoxon rank sum test with continuity correction or, in the case of dependent samples, using the Wilcoxon signed rank test. The equivalence of two measurement methods between US and CT was examined using Bland–Altman plots and Passing–Bablok regression. The strength of the correlation between the results from both methods was expressed by Spearman's rank correlation coefficient (R).

3. Results

3.1. Bladder Volume

The mean rBV evaluated during the first ultrasound examination (rUS1) and the second ultrasound examination (rUS2) was 214.7 mL and 218.1 mL, respectively. Both series had similar results in terms of mean value, median, and standard deviation. The mean pBV based on computed tomography (CTplan) for planning purposes was 340.8 mL and was significantly higher than rBV (rUS1 and rUS2) (Table 1). The Shapiro–Wilk test indicates that the data distribution for the three variables is not normal (Table 1). Interestingly, despite the fact that the entire treatment lasted less than two weeks, both the mean and median rBV decreased with each subsequent fraction of RTH (Table 2).

Table 1. Bladder volume measured by ultrasound (US) and computed tomography (CT).

BV	N	Mean	Median	Min	Max	SD	p-Value
CTplan	142	340.8	320.0	89.0	930.0	173.4	<0.001
rUS1	672	214.7	199.0	70.0	483.0	81.9	<0.001
rUS2	672	218.1	204.0	61.0	505.0	83.0	<0.001

Table 2. Variation in real bladder volume during subsequent treatment fractions.

Fraction	N	Mean	Median	Min	Max	SD
1	116	227.4	219.0	74.0	462.0	83.9
2	116	224.1	204.0	93.0	472.0	84.6
3	116	211.8	198.0	74.0	453.0	75.8
4	116	210.7	198.5	84.0	428.0	75.8
5	116	208.7	189.0	77.0	483.0	87.9
Overall	580	216.5	200.5	74.0	483.0	81.8

3.2. Reliability and Repeatability of US Assessment

The results of the Passing–Bablok regression indicate that the rUS1 and rUS2 assessments are equivalent in terms of linearity and slope. A slope coefficient close to 1 and the lack of a significant difference from 1 confirm that both measurements yield similar results. This allows the conclusion that the US assessments are repeatable and, therefore, their results are reliable (Table 3). This applies to measurements performed by the same operator as well as by two different operators.

Table 3. Repeatability of ultrasound assessment of bladder volume (results of Passing–Bablok regression).

BV	Slope Coefficient	95% CI (Slope)	Intercept	95% CI (Intercept)	Linear Dependence	Linearity p-Value
Overall	1.013	0.987–1.045	0.408	−5.865–5.671	Yes	0.4716
2 operators	0.971	0.905–1.055	4.661	−8.62–16.28	Yes	1
1 operator	1.018	0.989–1.052	0.109	−6.79–5.74	Yes	0.481

For repeatability analysis, 177 ultrasound assessments performed by two independent operators were included. The BV assessments performed by two different operators were consistent and equivalent, according to both the Wilcoxon statistical test ($p = 0.932$) and the Bland–Altman plot analysis (Figure 2). Furthermore, the results of the Passing–Bablok regression indicate that the slope coefficient is close to 1, which means that there is a high agreement between the two assessment methods (Table 3). The mean difference between the assessments was very small (0.76 mL) and most of them were in the range between −66.06 mL and 67.58 mL, being consistent and reliable (Table 4).

Furthermore, the consistency of the rBV assessment performed by the same operator was verified on the basis of 495 paired ultrasound assessments. The rBV assessments performed by the same operator are consistent and equivalent. The result of the Passing–Bablok regression indicates that the slope coefficient is close to 1, which means that there is high agreement between the two measurement methods. The confidence interval includes the value 1, which indicates that there are no significant differences (Table 3). This is also confirmed by the agreement intervals for the Bland–Altman plot (Figure 3).

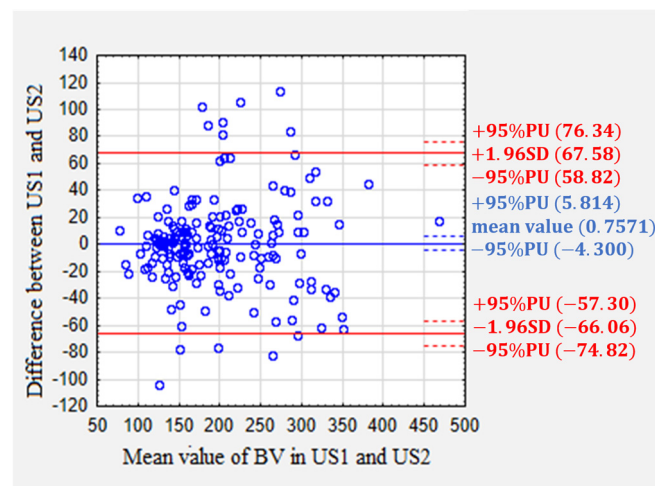


Figure 2. Bland–Altman plot for ultrasound measurements performed by two independent operators.

Table 4. Differences in bladder volume measurements taken by two independent operators (rUS1 and rUS2).

N	Mean Difference (mL)	Confidence −95%	Confidence +95%	SD	Lower Agreement Limit	Upper Agreement Limit
177	0.76	−4.30	5.81	34.09	−66.06	67.58

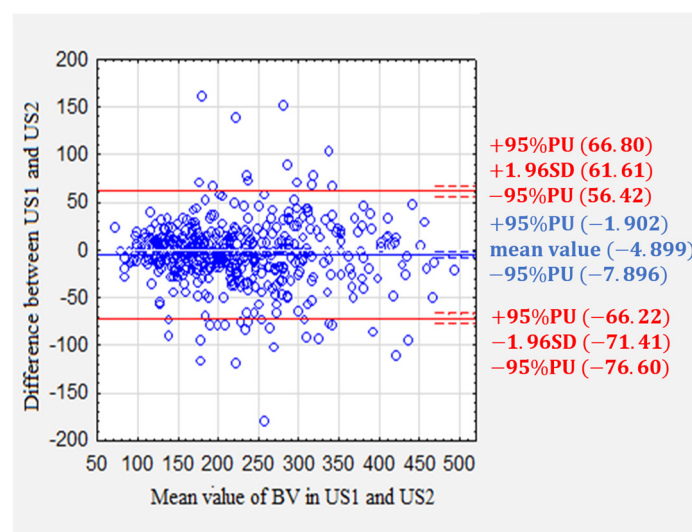


Figure 3. Bland–Altman plot of ultrasound measurements performed by the same operator.

3.3. The Impact of pBV on rBV Reproducibility during RTH

The compatibility of rBV was inversely proportional to that of pBV. The results indicated that the best reproducibility was obtained for pBV in the range of 100–349 mL. The mean difference in pBV and rBV was 41.56 mL, 171.2 mL, and 333.33 mL for pBV in the range of 100–349 mL, 350–499 mL, and 500–800 mL, respectively (Table 5). It is worth noting that pBV in the range of 100–349 mL represented almost 60% of all evaluations (the highest percentage of patients in the studied group). The Spearman test showed a correlation between rBV and pBV in the 100–349 mL and 500–800 mL groups of bladder volume (Table 6).

Table 5. Statistical data on bladder volume differences (pBV versus rBV) in each group, including the mean of US measurements.

pBV	Type of Measurement	N	Mean (mL)	Median (mL)	Min (mL)	Max (mL)	SD
100–349	CT-US *	386	41.56	41.50	−176.0	200.5	79.18
	CT (pBV)	386	226.37	224.00	100.0	349.0	75.25
	US	386	184.80	172.00	72.5	411.5	63.38
350–499	CT-US *	168	171.32	178.25	−82.0	325.0	75.63
	CT (pBV)	168	405.30	391.00	352.0	483.0	38.41
	US	168	233.98	220.75	124.0	469.0	69.65
500–800	CT-US *	108	333.33	324.50	144.5	533.5	84.26
	CT (pBV)	108	633.79	627.00	505.0	788.0	70.39
	US	108	300.45	295.25	108.0	494.0	78.79

* US = rUS1 + rUS2/2.

Table 6. Correlation of BV for US and CT measurements (pBV and rBV) in each group (Spearman test).

pBV	N	R	T(N-2)	p-Value
100–349	386	0.376	7.942	<0.001
350–499	168	0.138	1.799	0.074
500–800	108	0.419	4.748	<0.001
overall	662	0.577	18.147	<0.001

4. Discussion

The results of the present study showed the repeatability of the US-based rBV assessment, confirming the reliability of the method. In this study, due to the lack of volumetric imaging capability of the CyberKnife system, US-based BV assessment was not correlated with radiologically based rBV (e.g., CBCT). Therefore, the consistency of the results of two independent assessment methods cannot be confirmed. However, the data available in the literature indicate the consistency of US-based results with those based on radiologically. Poncylusz et al. compared bladder filling before RTH assessed with the PINIT ultrasound (AUTO mode) and with CBCT and reported comparable results. However, the study did not specify the difference between pBV and rBV [13]. In a phase III randomized study, Mullaney et al. compared BV using a BladderScan BVI 6100 device and computed tomography (CT) in 190 patients treated for prostate cancer. The radiation oncologist performed three US assessments (considering the average and maximum readings) of the BV immediately before CT, followed by a CT-based BV assessment. There was shown to be a strong positive correlation between both results. A slight underestimate of the US-based rBV was observed [14]. Other authors reported similar results. Bai et al. conclude that the bladder scanner provides an acceptable indicator for monitoring bladder volume in pelvic radiotherapy patients [15]. Ohira states that the use of the portable ultrasound bladder scanner in mode A significantly improved the reproducibility of BV [16]. Chauha concluded that US was accurate in measuring bladder volume and can be used for daily monitoring in prostate cancer radiotherapy [17]. Kuo observed that the measurement of BV caused a relative reduction in the failure rate with an odds ratio of 0.44 and an absolute reduction of 9.1% [18].

The results indicate that the planning of radiotherapy for patients should not involve bladder fillings greater than 350 mL, as it is difficult to reproduce it in rBV. Our data showed that during RTH, patients found it difficult to achieve rBV close to pBV. This finding is consistent with data from the literature. Issues related to bladder anatomy and physiology suggest that the need to urinate generally occurs at a BV between 250 and 300 mL, while at 400 mL, the urge is strong, making refraining from urination difficult [19]. This would explain the large differences in rBV in the group of patients with pBV greater than 349 mL. Grun et al. analyzed BV changes during high-dose IMRT in relation to acute genitourinary

toxicity in 193 patients treated for prostate cancer. rBV was maintained between 200 and 300 mL. The results showed that rBV greater than 180 mL allowed for the reduction in the acute toxicity ratio [20]. Thus, it seems reasonable for such patients to maintain the pBV within the range of 200–300 mL, both due to the reduction in potential toxicity and the urgency sensation, which can improve patient comfort and the reproducibility of the treatment plan. To ensure that CT scanning for planning is performed in the optimal range of BV, the US-based rBV assessment is recommended before CT (such an approach reduces the radiation dose for the patient and saves time in the CT scan room). The US-based rBV assessment should be introduced as a standard procedure prior to each fraction of CyberKnife stereotactic radiosurgery in prostate cancer patients and prior to CBCT in preparation for the radiotherapy session.

US monitoring of bladder filling during RTH is also important due to the fact that the obtained results, as well as other published studies, indicate variability in bladder filling during the course of RTH. Studies in which daily or weekly bladder ultrasound was performed showed a decrease in BV of 16–50% compared to its initial value [6]. According to some studies, the time required to fill the bladder to the same volumes also changes during the course of RTH (with increasing RT treatment time, the time needed to fill the bladder to the same volume also increases). The bladder filling time in the seventh week of RT may even increase by up to 40 min compared to the time needed in the first week. This requires individual modifications to the patient's preparation protocol for each subsequent RT session and is time-consuming [7]. According to Grun et al., the greater the difference in bladder filling compared to the treatment plan, specifically in terms of decreased BV, the greater the probability of increased toxicity of treatment [6].

In this study, the conformity between ultrasound measurement and radiological measurement was not assessed. While the study compares bladder volume measured by ultrasound (PINIT), no direct volumetric imaging (e.g., CBCT, CT) was used during treatment to validate ultrasound measurements against real-time CT or CBCT-based measurements. This is a significant limitation because the ultrasound device used for bladder volume assessment has a tolerable measurement error of $\pm 15\%$, which may introduce variability, particularly in cases where precise bladder volume control is critical to the treatment plan.

Although the study found a high degree of reliability in US measurements between different operators, there is still the possibility of operator-dependent variability, particularly with less experienced operators, which could affect the accuracy of BV assessments. Despite the consistency of both measurements, it is possible that both independent operators performed the ultrasound examination incorrectly. This means that both measurements, despite their consistency, may indicate an incorrect bladder volume.

In this study, the time between the ultrasound measurement and the start of the radiotherapy session was also not checked. It was assumed that the treatment took place immediately after the ultrasound, in accordance with the protocol. Changes in bladder filling during the radiotherapy session were also not monitored. Since one session lasts more than half an hour, in some cases, the BV may have changed significantly.

There are several potential future research directions in the area of monitoring bladder volume during ultrasound-based radiotherapy, particularly with the CyberKnife system. Since the CyberKnife system lacks volumetric imaging capabilities, future research could focus on comparing the accuracy of ultrasound (US) measurements with more advanced imaging techniques such as cone beam computed tomography (CBCT). This would help determine discrepancies between these methods and improve the precision of the bladder volume assessment. Future research could aim to refine and personalize bladder filling protocols to improve consistency between real bladder volume (rBV) and pBV, ensuring more precise treatment delivery. In addition, further studies could explore how to monitor and adjust bladder filling protocols as treatment progresses to maintain consistency and improve treatment outcomes. Finally, next research could explore the connection between bladder volume and genitourinary toxicity in greater detail to assess how precise bladder volume control can reduce treatment-related side effects and improve patient outcomes. It

is also worth considering the possibility of ultrasound evaluation of rectal filling, which could significantly streamline work on a therapeutic device and likely reduce the patient's exposure to additional radiation from repeated CBCT imaging.

In summary, due to the lack of other imaging methods for bladder filling in the CyberKnife system, US-based BV assessment appears to be a safe, quick, effective, and recommended solution.

5. Conclusions

The introduction of US-based BV assessment in patients irradiated due to prostate cancer using CyberKnife technology seems to be a crucial element in controlling the reproducibility of the treatment plan and should be a standard procedure.

The planned bladder volume (pBV) should be within the range of 200–300 mL. To achieve this, it is recommended to perform a US-based bladder volume assessment beforehand, ensuring that CT scanning for planning occurs within the optimal BV range.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data supporting reported results are available by email: dawid.bodusz@gliwice.nio.gov.pl.

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

Abbreviations

Abbreviation	Full Meaning
BV	Bladder volume
CBCT	Cone beam computed tomography
CT	Computed tomography
IMRT	Intensity-modulated radiotherapy
MRI	Magnetic resonance imaging
OAR	Organ at risk
pBV	Planned bladder volume
PINIT	Portable non-invasive imaging tool (Echo-Son SA Poland)
rBV	Real bladder volume
RTH	Radiotherapy
RTT	Radiation therapy technologists
TAUS	Transabdominal ultrasound
TRUS	Transrectal ultrasound
US	Ultrasound

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