## ORIGINAL RESEARCH



# Lower incidence of sexual dysfunction associated with stereotactic radiosurgery using CyberKnife in prostate cancer patients: initial results

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#### **Abstract**

**Background:** Prostate cancer is among the most prevalent oncological diseases globally, and its management must prioritize both effectiveness and quality of life. Although advancements in prostatectomy techniques have improved outcomes, many patients still face a decline in sexual function post-surgery. The advent of early screening via prostate-specific antigen (PSA) testing and technological innovations in radiotherapy have introduced radiosurgery as a viable alternative for treating low- and intermediaterisk prostate cancer, with the added benefit of reduced toxicity. Methods: At our clinic, patients are treated with Stereotactic Body Radiation Therapy (SBRT) using the CyberKnife system, with a specific focus on preserving erectile function. The treatment protocol involves precise patient immobilization, anatomotopographic planning using Magnetic Resonance Imaging-Computed Tomography (MRI-CT) fusion imaging, a fixed radiation dose to the prostate, and strict adherence to dose limitations for surrounding critical structures. Results: Biochemical control is evaluated by monitoring PSA levels within one year post-treatment. In addition, patient-reported outcomes are assessed using the Expanded Prostate Cancer Index Composite (EPIC-26) questionnaire. This tool is administered prior to the first session and periodically during the year following treatment to track side effects and quality-of-life indicators, particularly in relation to sexual and urinary functions. Conclusions: CyberKnife-based SBRT represents an effective and patient-centered approach to prostate cancer treatment. It enables targeted tumor control while aiming to minimize adverse effects, especially those impacting sexual health. Early results indicate favorable biochemical control and tolerable side effects, supporting its use as an alternative to more invasive procedures for selected patients.

# **Keywords**

Prostate cancer; CyberKnife; Erectile function; EPIC-26 questionnaire; Quality of life

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# Menor incidencia de disfunción sexual asociada a la radiocirugía estereotáctica con CyberKnife en pacientes con cáncer de próstata: resultados iniciales

#### Resumen

Antecedentes: El cáncer de próstata es una de las enfermedades oncológicas más prevalentes a nivel mundial, y su tratamiento debe priorizar tanto la efectividad como la calidad de vida. Aunque los avances en las técnicas de prostatectomía han mejorado los resultados, muchos pacientes aún experimentan una disminución en la función sexual tras la cirugía. La introducción del cribado temprano mediante el antígeno prostático específico (PSA) y los avances tecnológicos en radioterapia han posicionado a la radiocirugía como una alternativa viable para el tratamiento del cáncer de próstata de bajo y riesgo intermedio, con el beneficio adicional de una menor toxicidad. Métodos: En nuestra clínica, los pacientes son tratados mediante Radioterapia Corporal Estereotáctica (SBRT) con el sistema CyberKnife, con un enfoque específico en la preservación de la función eréctil. El protocolo de tratamiento incluye una inmovilización precisa del paciente, planificación anatomotopográfica mediante fusión de imágenes de resonancia magnética nuclear (RMN) y tomografía computarizada (TC), una dosis fija administrada a la próstata, y un estricto cumplimiento de los límites de dosis a los órganos críticos circundantes. Resultados: El control bioquímico se evalúa mediante el seguimiento de los niveles de PSA durante el primer año posterior al tratamiento. Además, se analizan los resultados reportados por los pacientes mediante el cuestionario Expanded Prostate Cancer Index Composite (EPIC-26). Esta herramienta se aplica antes del inicio del tratamiento y periódicamente durante el año posterior, para valorar los efectos secundarios y los indicadores de calidad de vida, en especial aquellos relacionados con las funciones sexual y urinaria. Conclusiones: La SBRT con CyberKnife representa un enfoque eficaz y centrado en el paciente para el tratamiento del cáncer de próstata. Permite un control tumoral preciso y busca minimizar los efectos adversos, especialmente los que afectan la salud sexual. Los resultados preliminares muestran un control bioquímico favorable y efectos secundarios tolerables, respaldando su uso como alternativa a procedimientos más invasivos en pacientes seleccionados.

#### **Palabras Clave**

Cáncer de próstata; CyberKnife; Función erectile; Cuestionario EPIC-26; Calidad de vida

### 1. Introduction

Prostate cancer (PC) is emerging as a leading cause of cancer-related deaths worldwide [1]. With advancements in early diagnosis through PSA screening, an increasing number of patients are diagnosed at a localized stage, where radical treatments such as prostatectomy or radiation therapy (RT) can be performed. Despite the historic breakthrough by Hugh Hampton Young in 1904—who was the first to perform surgical removal of the prostate at Johns Hopkins Hospital, and later advancements by Walsh and Docker with nerve-sparing prostatectomy, it became evident that while these procedures provided good therapeutic control, they did not significantly reduce treatment-related toxicity [2, 3]. The persistence of sexual dysfunction following radical prostate cancer therapy remains a major concern affecting patient satisfaction and overall quality of life [4].

Radiation therapy (RT) has emerged as a standard radical treatment for localized prostate cancer due to its comparable therapeutic efficacy with potentially lower toxicity. With technological advances in radiation oncology, a novel method called Stereotactic Body Radiation Therapy (SBRT) was developed. SBRT delivers high-dose radiation to the prostate in just a few fractions, enhancing treatment efficiency while minimizing exposure to surrounding healthy tissues. To assess its effectiveness, several single-institution prospective studies and multi-institutional phase I/II trials have been conducted, demonstrating excellent biochemical recurrence-free survival rates. These findings prompted the American Society for Therapeutic Radiology and Oncology (ASTRO) in 2013 to state: "SBRT could be considered an appropriate alternative for select patients with low- to intermediate-risk disease"

[5]. The following year, the National Comprehensive Cancer Network (NCCN) updated its recommendations, recognizing SBRT as a validated alternative to conventional fractionated RT for prostate cancer [6].

However, due to the anatomical proximity of the prostate to the rectum, bladder, and neurovascular structures critical to sexual function, side effects from SBRT remain a key concern. Complications such as urinary incontinence, irritative or obstructive urinary symptoms, bowel dysfunction, and sexual dysfunction can significantly impact patients' overall quality of life (QoL).

In 2013, King analyzed the QoL impact of SBRT in 864 patients with localized prostate cancer enrolled in multi-institutional phase I/II trials. The authors observed a temporary decline in urinary and bowel function within the first three months post-treatment, followed by a full and sustained recovery to baseline levels or even improvement within six months [7]. A decline in sexual function was also noted, peaking around nine months after SBRT.

Despite these findings, further evidence from larger studies is necessary to determine the long-term impact of SBRT on erectile function. For this reason, we initiated our trial with the following primary objectives:

- 1. To confirm that SBRT with CyberKnife achieves effective biochemical control with no evidence of recurrence.
- 2. To assess gastrointestinal and genitourinary toxicity following treatment.
- 3. To analyze the correlation between testosterone levels and sexual function scores using the Expanded Prostate Cancer Index Composite 26 (EPIC-26).

Our study aims to provide further insights into the benefits

of SBRT with CyberKnife, particularly in terms of oncological control, toxicity reduction, and preservation of quality of life.

### 2. Materials and methods

### 2.1 Design of the study

Since January 2023, our team has been collecting medical data on patients diagnosed with localized prostate cancer (PC) who underwent stereotactic body radiotherapy (SBRT) with CyberKnife. The study includes patients treated at the Clinic of Radiation Oncology, University Hospital "Sv. George" in Plovdiv, Bulgaria, and the Department of Clinical Oncology, Medical University of Plovdiv.

The primary cohort consists of patients who made a conscious and informed decision to choose SBRT over prostatectomy. Most cited concerns about the surgical option, particularly the risk of urinary disturbances and the potential need for long-term diaper use, as key factors in their decision. Notably, 70% of the patients reported that preserving sexual function during treatment was the decisive factor in selecting radiotherapy over surgery.

Another important point in choosing therapy for our patients is the price they pay, as thanks to the healthcare system in Bulgaria, this high-tech procedure is completely free for those with health insurance. The only additional payment they make is for the purchase of the necessary four fiducials, but their price does not exceed 200 euros.

# 2.2 Study criteria and restrictions

To be included in the study, patients had to meet the following criteria:

- 1. Adult males with histologically confirmed prostate cancer (PC).
  - 2. Imaging-based staging using MRI or CT. Exclusion criteria were established as follows:
  - 1. Locally advanced prostate cancer.
  - 2. Incomplete clinical data or follow-up.
- 3. Previous definitive treatment, including surgery or brachytherapy.
  - 4. Ongoing androgen deprivation therapy (ADT).

### 2.3 Study objectives

The primary objective of this trial is to evaluate the safety and effectiveness of SBRT with CyberKnife, specifically by assessing biochemical recurrence rates. To date, no enrolled patients have shown evidence of biochemical recurrence. Additionally, prostate cancer recurrence will be analyzed based on patient stratification across different PSA intervals.

A secondary objective is to assess the impact of radiosurgery on sexual function.

# 2.4 Evaluating toxicity and patient-reported outcomes

Traditionally, SBRT-related toxicity is assessed using physician-based evaluations, such as the Radiation Therapy Oncology Group (RTOG) scale for acute reactions. However, RTOG is a clinical assessment tool that may sometimes

underestimate the severity of radiation-induced side effects [8]. Studies suggest that this method carries a risk of underreporting toxicity levels [9, 10].

To address this limitation, patient-reported outcomes (PROs) have gained prominence as a more accurate method for long-term research on the lasting effects of radiation therapy. PROs provide a more direct and confidential record of patient experiences compared to physician assessments [11]. Additionally, PROs contribute valuable insights into symptom management and enhance patient-physician communication [12].

#### 2.5 Use of PROs tools in SBRT studies

Current trials are increasingly incorporating PROs tools to assess the real-world impact of prostate cancer therapies and to compare toxicity profiles when treatment effectiveness is similar [13]. Various validated questionnaires exist, such as:

- The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire.
  - The International Prostate Symptom Score (IPSS).

For this study, we selected the Expanded Prostate Cancer Index Composite-26 (EPIC-26), one of the most widely used PROs tools in SBRT trials. EPIC-26 is a validated questionnaire that quantifies patient-reported outcomes across five domains:

- Urinary function (three items) and urinary bother (six items).
  - Bowel bother (six items).
  - Sexual function (five items) and sexual bother (one item).
  - Hormonal bother (five items).

EPIC-26 scores are rescaled to a 0–100-point range, with higher scores indicating a better quality of life [14]. No validity or reliability issues have been identified in this tool [15].

### 2.6 Assessment of sexual function

Within EPIC-26, sexual function is evaluated through five specific questions. Three of these focus on the frequency and quality of erections, while the remaining questions assess the ability to engage in intercourse. Below, we highlight two key questions related to this domain:

- 1. How would you describe the FREQUENCY of your erections during the last 4 weeks?
  - (1) I NEVER had an erection when I wanted one.
- (2) I had an erection LESS THAN HALF the time I wanted one.
  - (3) I had an erection ABOUT HALF the time I wanted one.
- (4) I had an erection MORE THAN HALF the time I wanted one.
  - (5) I had an erection WHENEVER I wanted one.
- 2. During the last 4 weeks, how often did you have sexual intercourse?
  - (1) Not at all.
  - (2) Less than once a week.
  - (3) About once a week.
  - (4) Several times a week.
  - (5) Daily.

# 2.7 Patient-reported data collection and ethical considerations

Patients assess their experiences over the previous four weeks using a five-point scale in the EPIC-26 questionnaire. Depending on their responses, they receive scores of 0, 25, 50, 75 or 100 points for each item.

Notably, EPIC questionnaire completion rates in prostate cancer studies at the one-year mark are 82% for electronic records compared to only 36% for paper-based versions [16]. However, given the advanced age of our patient cohort and their limited familiarity with digital tools, we opted to use the paper format exclusively in our study. Additionally, we contributed to the field by developing the first official translation of EPIC-26 into Bulgarian.

Before starting treatment, patients complete the questionnaire for the first time, establishing a baseline for toxicity assessment following radiosurgery. At the same time, blood samples are collected to measure free and total PSA and testosterone levels. These evaluations are repeated at 1, 3, 6 and 12 months post-SBRT.

# 3. SBRT treatment with Accuray CyberKnife® M6

All patients in this study will undergo stereotactic body radiotherapy (SBRT) using the Accuray CyberKnife® M6 system (Software version 10.6.0, Accuray, Inc., Sunnyvale, CA, USA)—the only fully robotic radiosurgery platform currently available. Its advanced mechanical design allows for real-time prostate tracking, actively adjusting beam focus to account for prostate movement or rotation during dose delivery [17].

The prostate gland can shift unpredictably throughout treatment, making precise tracking and compensation essential. Research has documented prostate motion of up to 10 mm within just 30 seconds, influenced by natural bodily functions such as bladder filling, intestinal gas or minor patient movements during the procedure [18].

# 3.1 Fiducial marker placement and imaging

Before anatomical-topographic planning begins, patients undergo implantation of three or four gold fiducial markers within the prostate. These markers enable the CyberKnife system to monitor and correct prostate movement in real-time during radiation delivery.

- Fiducial stabilization period: 10 days after implantation.
- First imaging step: Non-contrast CT scan with 1 mm slice thickness in an immobilized position.
- MRI fusion (if available): Patients with prior MRI scans undergo image fusion with their CT scan for more precise contouring of both tumor volume and surrounding critical structures (Fig. 1).
- Treatment Planning System (TPS): Treatment planning system MultiPlan® version 5.3.0 (Accuray, Inc., Sunnyvale, CA, USA) is used for image registration, planning, and dosimetry.

Fusion of magnetic resonance imaging (MRI) with computed tomography (CT) SOMATOM Definition AS20 Open (Siemens Healthcare GmbH, Erlangen, BY, Germany) is used

for precise delineation of the tumor volume and surrounding critical structures. The image presents combined anatomical information: the left half shows MRI, while the right half displays the corresponding CT. The colored contours represent:

- Red contour—total prostate volume
- Light blue contour—clinical target volume (CTV)
- Purple contour—rectum

# 3.2 Target volume definition

Due to the unique characteristics of SBRT, our protocol defines Gross Tumor Volume (GTV) and Clinical Target Volume (CTV) as identical, ensuring that only the prostate gland is included. The Planning Target Volume (PTV) is then constructed with a 1 mm margin around the GTV/CTV.

# 3.3 Dose prescription and hypofractionation strategy

Our study follows a strict hypofractionated dose regimen:

- Total dose: 36.25 Gy
- Fractionation: 7.25 Gy per fraction (5 fractions total)

Hypofractionation offers a superior therapeutic ratio by delivering higher doses per fraction, selectively targeting malignant cells while sparing surrounding healthy tissues. This approach is supported by prostate cancer's low  $\alpha/\beta$  ratio ( $\approx$ 1.5–2.0 Gy), which is lower than that of adjacent normal tissues [19, 20].

Using an  $\alpha/\beta$  of 1.5 Gy, the total dose of 36.25 Gy in five fractions corresponds to an equivalent dose at 2 Gy per fraction (EQD2) of 91 Gy, surpassing traditional fractionation regimens in effectiveness.

- Dose prescription: 78–86% isodose lines
- Coverage goal: 95% of the PTV volume

# 3.4 Critical organ contouring and dose constraints

To ensure treatment safety, we meticulously contour the following critical organs in each SBRT plan:

- Rectum
- Bladder + bladder wall
- Bulbous penis
- Testicles

One of the primary challenges in SBRT planning is adhering to dose constraints for these critical structures. Below, we outline the key dose limitations for a 36.25 Gy regimen (Table 1).

Regarding the urethra as a critical organ, we do not delineate it due to the high dose restrictions ( $\leq$ 42.8 Gy).

At the outset of our study, we planned to use Hydrogel Spacer Injection SpaceOAR, as previous research has shown its effectiveness in separating the prostate from the rectum, thereby reducing gastrointestinal toxicity. However, due to its high cost and the patients' financial constraints, we ultimately decided not to implement it in our treatment protocol.

# 4. Preliminary study results

Although we have not yet reached our target enrollment of 30 patients, we have successfully enrolled 27 patients over the

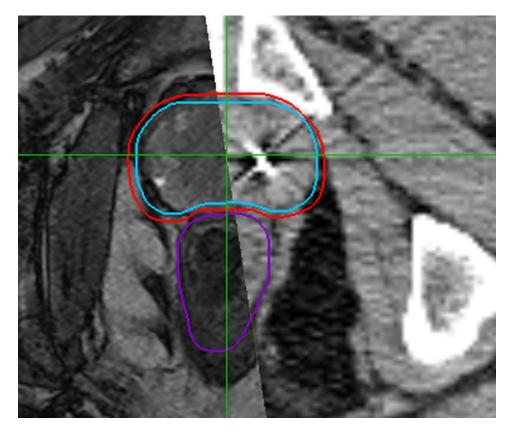


FIGURE 1. MRI-CT fusion for accurate contouring.

TABLE 1. Dose constraints for organs at risk in SBRT planning (36.25 Gy in 5 fractions).

planning (30.23 Gy in 3 if actions).					
Critical organs	Dose Coverage Criteria				
PTV	V (36.25 Gy) ≥95%				
CTV	V (36.25 Gy) ≥99%				
Bladder					
	V (37 Gy) <5 cc				
	V (100%) <10%				
	V (50%) <40%				
Rectum					
	V (36 Gy) <1 cc				
	V (100%) <5%				
	V (90%) <10%				
	V (80%) <20%				
	V (75%) <25%				
	V (50%) <40%				
Bulbous penis	V (29.5 Gy) <3 cc				
Testicles	D (20%) <2 G				

Table 1 from Stereotactic Body Radiation Therapy (SBRT) for clinically localized prostate cancer: The Georgetown University experience DOI: 10.1186/1748-717X-8-58.

PTV: Planning Target Volume; CTV: Clinical Target Volume.

past year, each at different stages of follow-up. In this report, we present data on our first 22 patients who have completed SBRT and have been closely monitored for one-year post-treatment.

### 4.1 Patient characteristics

Mean age: 74.8 ± 5.7 years
Histology: Adenocarcinoma
Median Gleason score: 6.8 ± 0.5

Baseline PSA levels: 8.913 ng/mL (mean)
Baseline testosterone levels: 6.09 ng/mL

All patients completed the EPIC-26 questionnaire before treatment, with the following baseline scores:

Sexual domain: 52.84Urinary domain: 97.15Bowel domain: 94.75

# **4.2 Early post-treatment results (1 month follow-up)**

Following SBRT with CyberKnife, where each patient received five fractions of 7.25 Gy per day over one week, we observed the first post-treatment results:

• Median PSA levels: 1.626 ng/mL

• Median testosterone levels: 5.64 ng/mL

• EPIC-26 follow-up score (sexual domain): 51.55

Figs. 2,3 illustrate the trends in average PSA and testosterone levels, as well as the median scores from the sexual, bowel and urinary domains over time.

In Table 2 we demonstrated our median and range results from Fig. 2.

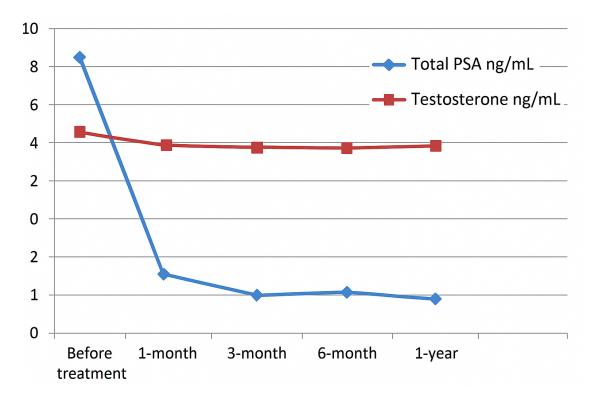


FIGURE 2. Graph illustration of the therapeutic changes after SBRT. PSA: prostate-specific antigen.

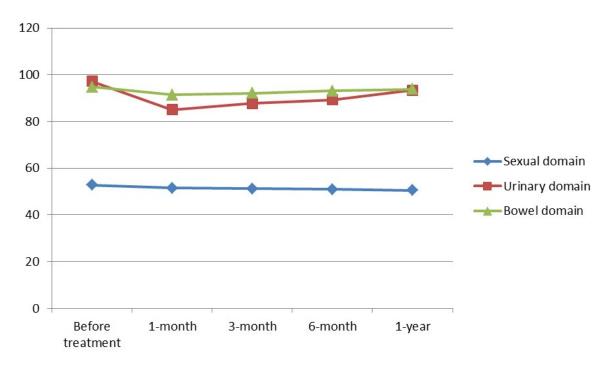


FIGURE 3. Graph illustration of the EPIC-26 score for each domain after SBRT.

TABLE 2. Median and range of prostate-specific antigen (PSA) levels following stereotactic body radiotherapy (SBRT).

	Total PSA (ng/mL)	Testosterone (ng/mL)	
Before treatment	$8.913 \pm 2.29$	$6.09 \pm 1.19$	
1-month	$1.626 \pm 0.55$	$5.64 \pm 1.07$	
3-month	$0.882\pm0.36$	$5.60\pm0.92$	
6-month	$0.992\pm0.38$	$5.58 \pm 0.84$	
1-year	$0.631 \pm 0.20$	$5.63\pm0.77$	

PSA: prostate-specific antigen.

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		Sexual domain	Urinary domain	Bowel domain			
	Before the treatment	$52.84 \pm 11.70$	$97.15 \pm 4.36$	$94.75 \pm 3.42$			
	1-month	$51.55 \pm 10.50$	$85.10 \pm 3.19$	$91.37 \pm 3.05$			
	3-month	$51.28 \pm 9.69$	$87.70\pm2.82$	$92.14 \pm 2.69$			
	6-month	$50.88 \pm 9.46$	$89.28 \pm 2.63$	$93.09 \pm 2.36$			
	1-year	$50.57 \pm 9.09$	$93.37 \pm 2.42$	$93.75 \pm 2.70$			

TABLE 3. Median and range of EPIC-26 domain scores following stereotactic body radiotherapy (SBRT).

In Table 3 we demonstrated our median and range results from Fig. 3.

Additionally, Figs. 4,5 showcase an intriguing case of excellent sexual function preservation one year after radical treatment, demonstrating the potential advantages of SBRT in maintaining quality of life.

It concerns a 72-year-old patient who was diagnosed in January 2023 with adenocarcinoma of the prostate—Gleason score 3 + 4 = 7. After the MRI was examined—PIRAD (Prostate Imaging-Reporting and Data System) 3 and negative bone scintigraphy, four fiducials were placed. The initial values of the total PSA—6.184 ng/mL and Testosterone—4.91 ng/mL. Before the SBRT the patient submit the EPIC-26 questionnaire and very high baseline result from the sexual domain was registered—88.46. He realized the intended five fractions of 7.25 Gy per day within one week, and apart from mild urinary complaints, the treatment was quite successful without serious side effects. One year after therapy, in addition to perfect tumor control, we monitored a minimal decline in the sexual domain from the baseline—84.4. In Fig. 5 we show information from Dose-volume histogram from his plan.

### 5. Discussion

Effective disease management remains the primary goal of prostate cancer treatment. Prostate-specific antigen (PSA) levels serve as a crucial biochemical marker to evaluate treatment response. Our study demonstrated a rapid initial PSA decline, followed by a gradual reduction over one year, aligning with prior research that reports a median PSA reduction of approximately 80% following SBRT [21, 22]. These findings reinforce the effectiveness of SBRT in achieving early biochemical control in patients with low- and intermediate-risk prostate cancer.

To enhance post-treatment monitoring, we considered incorporating Prostate-specific membrane antigen (PSMA)-directed positron emission tomography/computed tomography (PET/CT) imaging after the first year of follow-up. However, since none of our patients experienced a PSA rebound and the imaging modality was unavailable at our institution, we opted against referring patients to another city for this examination. Future studies with broader accessibility to PSMA PET/CT could help further refine follow-up strategies

# **5.1 Sexual function preservation**

Preservation of sexual function following SBRT is a critical concern. Existing studies, including large multicenter analyses, have reported varied outcomes, with some documenting declines in EPIC-26 sexual function scores of up to 40% [23]. In our cohort, we observed only a minimal decline in sexual function scores from baseline to the one-year follow-up, which appears more favorable than some prior reports. However, given our study's limited sample size and single-center design, caution is needed when generalizing these results.

Several factors may have contributed to the relatively preserved sexual function in our study. The age distribution of patients is a key determinant, as erectile dysfunction rates naturally increase between 60 and 70 years [24]. Furthermore, external social and medical factors influence sexual function outcomes. Some patients reported an ability to achieve an erection but were unable to engage in sexual activity due to the loss of a partner or their partner's medical condition. These considerations must be acknowledged when interpreting EPIC-26 scores.

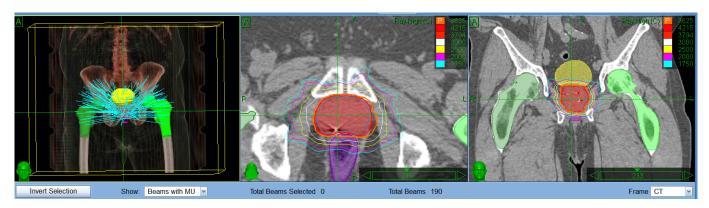
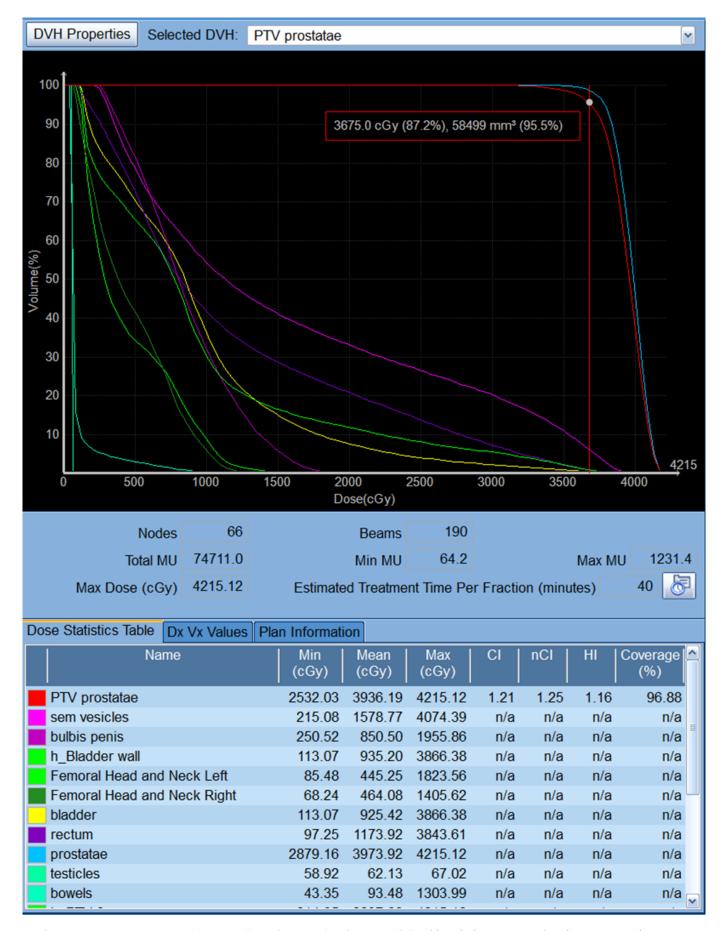


FIGURE 4. Beam delivery to the PTV through Cyberknife. CT: computed tomography; MU: Monitor Units.



**FIGURE 5. Dose-volume histogram from SBRT with Cyberknife?** Abbreviations: PTV: Planning Target Volume; DVH: Dose-Volume Histogram; CI: Conformity Index; nCI: Normalized Conformity Index; HI: Homogeneity Index.

### 5.2 Urinary function

Our data indicate an initial decline in the EPIC-26 urinary domain score within the first month post-treatment, corresponding with a transient increase in urinary toxicity. Patients commonly reported dysuria and urinary discomfort during the first post-treatment week. However, as reflected in Table 3, urinary function gradually improved over time, with scores returning close to baseline within one year. Notably, none of our patients required the use of incontinence pads, supporting the conclusion that SBRT with CyberKnife does not lead to significant long-term urinary dysfunction. These findings align with previous studies reporting favorable urinary toxicity profiles following SBRT [25].

### 5.3 Bowel function

Similar to urinary function, bowel function showed a slight decrease in EPIC-26 scores during the first month post-treatment, followed by rapid recovery. These results suggest that gastrointestinal toxicity is not a major concern following SBRT, which is consistent with prior research demonstrating minimal long-term bowel dysfunction after CyberKnife-based treatment. However, further studies with larger patient populations and longer follow-up durations are necessary to confirm these observations.

### 5.4 Testosterone levels and sexual health

Testosterone plays a crucial role in maintaining sexual function. In our study, testosterone levels remained relatively stable throughout the follow-up period, with only a slight decrease from baseline. This stability may have contributed to the preservation of sexual function observed in our patients. While our findings are encouraging, larger studies with extended follow-up periods are needed to assess long-term hormonal effects of SBRT.

### 5.5 Study limitations and strengths

While our study provides valuable insights into the functional outcomes following SBRT with CyberKnife, several limitations must be acknowledged. The single-center design and small sample size limit the generalizability of our results. Additionally, the absence of PSMA PET/CT imaging for post-treatment monitoring may have constrained our ability to detect subclinical disease recurrence. Furthermore, our follow-up period is relatively short, and longer-term data are needed to assess the durability of treatment effects.

Despite these limitations, our study has notable strengths. The use of EPIC-26 for functional assessment allows for a detailed evaluation of patient-reported quality of life outcomes. Additionally, our findings contribute to the growing body of evidence supporting the role of SBRT in preserving urinary, bowel and sexual function in prostate cancer patients. We believe these outcomes could significantly enhance patients' quality of life, making this treatment approach a valuable option in prostate cancer care.

### 6. Conclusions

Our initial findings from this comprehensive study highlight that SBRT using the CyberKnife system is not only an effective method for treating prostate cancer but also demonstrates a high safety profile with reduced toxicity. These promising results suggest that SBRT offers a viable alternative for patients, potentially leading to better outcomes and fewer side effects.

Moreover, we are particularly encouraged by the early successes related to the preservation of sexual function in our patients. This aspect is crucial, as it significantly impacts the overall quality of life and post-treatment satisfaction among prostate cancer survivors. As we continue to monitor and follow up with our next cohort of patients, we remain hopeful that these positive trends will persist, thereby confirming the long-term benefits of this treatment approach.

Additionally, our study underscores the importance of patient selection in determining the most suitable radical treatment method. We believe that our research is vital in providing deeper insights into how the choice of treatment impacts patients' quality of life. This knowledge is essential for health-care professionals as they strive to personalize treatment plans and optimize outcomes for individuals diagnosed with prostate cancer.

In conclusion, the preliminary success of SBRT with CyberKnife in terms of efficacy, safety, and quality of life enhancements offers a promising outlook for prostate cancer treatment. Future research and follow-up studies will be crucial in solidifying these findings and further guiding clinical practices to improve patient care and treatment experiences.

### **AVAILABILITY OF DATA AND MATERIALS**

The data presented in this study are available on reasonable request from the corresponding author.

#### **AUTHOR CONTRIBUTIONS**

SP and VP—designed the research study; wrote the manuscript. SP, GS and VP—performed the research. PA—provided help and advice on urological part. SP and GS—analyzed the data. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

# ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Prior to initiating patient observations, this study received approval from the Scientific and Ethical Commission at the Medical University of Plovdiv (2023\_0CAF692B0B\_request-No4/04.05.2023), ensuring compliance with all Bulgarian regulations governing clinical research involving human participants.

All participants were fully informed about the purpose, procedures and scope of the study. Written informed consent was obtained from each patient prior to enrollment. Participation was voluntary, and individuals were assured that they could

withdraw at any time without affecting their medical care.

The study collects and analyzes anonymized medical data with full transparency and adheres to the ethical principles outlined in the Declaration of Helsinki (June 1964, and its subsequent amendments), ensuring the highest standards of ethical conduct in human research.

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### **CONFLICT OF INTEREST**

The authors declare that there are no conflicts of interest relevant to the content of this study. No financial, personal or professional affiliations have influenced the research, analysis or conclusions presented in this work.

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