

Early Outcomes of Stereotactic Body Radiotherapy for Localized Prostate Cancer: A Retrospective Analysis

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Background: Prostate cancer is the most common cancer in US males. While conventional beam radiotherapy has been commonly used, there has been a shift toward hypofractionation, which involves using fewer higher-dose fractions over a shorter treatment course. Stereotactic body radiotherapy (SBRT) further condenses treatment to 5 fractions in < 2 weeks.

Methods: This was a retrospective chart review of a veteran population with localized prostate cancer who received SBRT between November 2014 and October 2024 at the Kansas City Veterans Affairs Medical Center. Androgen deprivation therapy (ADT) or pelvic nodal irradiation with ADT was administered where indicated. Patients were included and followed for at least 24 months to assess efficacy and genitourinary (GU) and gastrointestinal (GI) toxicity using Radiation Therapy Oncology Group (RTOG) criteria. Cone-beam computed tomography was exclusively used for image-guided radiotherapy without the use of fiducials or hydrogel spacers.

Results: A total of 174 patients met the inclusion criteria. The median age was 74 years, and the median prostate-specific antigen level was 11.9 ng/mL. Twenty-six patients had a Gleason score (GS) of 1, 77 had GS 2, 41 had GS 3, 18 had GS 4, and 12 had GS 5. Patients had a median follow-up of 45 months, and the disease-free survival and overall survival rates were 96.6% and 99.4%, respectively. There were 6 biochemical failures (3.4%), with 1 patient dying from metastatic cancer. The cumulative RTOG grade II and higher GU toxicity was 28.2% (26.4% grade II, 1.2% grade III, and 0.6% grade IV toxicity with rectovesical fistula requiring surgery). The cumulative RTOG grade II or higher GI toxicity rate was 3.4% with no grade III or IV complications.

Conclusions: This retrospective analysis indicates that a short course of SBRT for localized prostate cancer demonstrates acceptable toxicity and promising early efficacy, even without the use of fiducials or hydrogel spacers. Longer follow-up is warranted to confirm these findings.

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Prostate cancer is the most common cancer in US males, with an estimated 313,780 new cases and 35,770 deaths in 2025.¹ Several treatment options are available for localized prostate cancer that have similar outcomes, including active surveillance for low-risk cancers, surgery, or radiotherapy.^{2,3} Conventional fractionation radiotherapy (CFRT) with 40 to 45 fractions over 8 to 9 weeks has been used for decades. Over the past 2 decades, moderate hypofractionation schedules with 2.4 to 3.4 Gy per fraction over 20 to 28 fractions have become standard, as many noninferiority randomized clinical trials (RCTs) such as CHHiP (UK),⁴ PROFIT (Canada and Europe),⁵ NRG Oncology RTOG 0415 (US),⁶ HYPRO (Netherlands),^{7,8} and HYPO-RT-PC (Sweden and Denmark),⁹ have shown the noninferiority of moderately hypofractionated radiotherapy compared with CFRT. Notably, most of these noninferiority studies primarily included patients with low- or intermediate-risk prostate cancer, except for the HYPO-RT-PC trial,⁹ which also included patients with intermediate- and high-risk prostate cancer.

These noninferiority studies, along with technological advances in radiotherapy, such as intensity-modulated radiotherapy (IMRT), volumetric modulated arc therapy (VMAT), and image-guided radiotherapy (IGRT), paved the path to ultrahypofractionated stereotactic body radiotherapy (SBRT) that is delivered in 5 fractions of ≥ 6 Gy. This high dose per fraction may have a

radiobiologic advantage over conventional fractionation. The relatively low α/β ratio of prostate cancer, estimated to be between 1 and 2, suggests that tumor cells may be particularly sensitive to the high doses per fraction delivered in SBRT.¹⁰⁻¹³ Compared with CFRT, SBRT-induced tumor cell death may also be mediated through different pathways; this pathway appears to be generated in a dose-dependent manner, particularly with doses > 8 Gy per fraction.^{14,15} Additionally, the higher α/β ratio for the surrounding organs at risk, such as the bladder and rectum, theoretically allows for an improved therapeutic ratio window that maximizes tumor control while minimizing damage to healthy tissues.

A substantial body of evidence from prospective studies and meta-analyses supports the use of SBRT for localized prostate cancer. HYPO-RT-PC, a significant phase 3 noninferiority study, enrolled 1200 patients with intermediate (89%) and high-risk (11%) prostate cancer randomized between 2 arms, including CFRT to 78 Gy in 39 fractions and SBRT to 42.7 Gy in 7 fractions, treated 3 days weekly. After a median follow-up of 60 months, the estimated 5-year biochemical relapse-free survival rate was 84% in both groups.⁹ This trial was notable because it was the first randomized study to demonstrate that SBRT was noninferior to CFRT in intermediate- and high-risk prostate cancer patients. Another pivotal phase 3 trial, the PACE-B study, enrolled 874 patients to compare SBRT (36.25 Gy to the prostate gland, with a secondary dose of 40 Gy

to the gross tumor volume where applicable, in 5 fractions) with CFRT (78 Gy in 39 fractions) and moderately hypofractionated radiotherapy (HFRT) (62 Gy in 20 fractions) in patients with low- or intermediate-risk prostate cancer. With a 74-month median follow-up, the study reported 5-year biochemical free rates of 94.6% for CFRT and 95.8% for SBRT, confirming the noninferiority of SBRT to CFRT.¹⁵

SBRT offers short, effective, and convenient treatment to many patients with localized prostate cancer. While previous guidelines were more restrictive, the March 2026 National Comprehensive Cancer Network (NCCN) guidelines now list SBRT as a preferred treatment modality for high-risk prostate cancer.¹⁶

Given the growing body of evidence supporting the efficacy and safety of SBRT, we implemented an SBRT program in 2014 at a tertiary care center for veterans. This retrospective study was undertaken to evaluate the early efficacy and toxicity of SBRT in patients with localized prostate cancer treated at our institution, including patients across all risk stratifications.

METHODS

We identified 242 patients diagnosed with prostate cancer who underwent SBRT treatment between November 2014 and October 2024 at Overland Park Veterans Affairs Radiation Oncology Clinic. For the final analysis, 46 patients with < 2 years of follow-up and 22 patients who died from causes other than prostate cancer were excluded, resulting in a cohort of 174 patients with ≥ 24-month follow-up.

Treatment

Patients eligible for staging underwent imaging according to NCCN guidelines, including computed tomography (CT) of the abdomen and pelvis, bone scintigraphy, or, in recent years, prostate-specific membrane antigen positron emission tomography, primarily used for unfavorable intermediate-risk (UIR) and high-risk (HR) cancers. Patients with a negative staging work-up for nodal or skeletal disease were included. Prior to planning the CT simulation, patients were given bowel preparation instructions, including a low-fiber and low-gas-producing diet, simethicone, and enemas, the night before and morning of the simulation. Patients were instructed to arrive with a comfortably full bladder, having not voided for 2 to 3 hours prior to the procedure. At Kansas City Veterans Affairs Medical Center (KCVAMC), SBRT treatment was generally restricted to patients with a baseline American Urological Association symptom

TABLE 1. Patient Characteristics (N = 174)

	Result
Age, y	
Range	51-88
Median	74
Prostate-specific antigen	
Median, range, ng/mL	11.9 (0.6-69.5)
Levels, No. (%)	
1-10 ng/mL	123 (70.7)
> 10-20 ng/mL	42 (24.1)
> 20-40 ng/mL	6 (3.5)
> 40 ng/mL	3 (1.7)
Cancer grade (Gleason score) class, No. (%) [Risk]	
1 (3 + 3)	26 (14.9) [LR]
2 (3 + 4)	77 (44.3) [FIR]
3 (4 + 3)	41 (23.6) [UIR]
4 (4 + 4; 5 + 3)	18 (10.3) [HR]
5 (9 -10)	12 (6.9) [HR]
Radiation therapy site, dose [No.]	
Pelvic nodes	25 Gy/5 fractions [51]
Prostate boost	37.5-40 Gy/5 fractions SBRT [51]
Prostate only	37.5-40 Gy/5 fractions SBRT [123]
Androgen deprivation therapy duration, No. (%)	93 (100)
6 mo	64 (68.8)
12 mo	0 (0.0)
18 mo	13 (14.0)
24 mo	16 (17.2)

Abbreviations: FIR, favorable intermediate risk; HR, high risk; LR, low risk; SBRT, stereotactic body radiotherapy; UIR, unfavorable intermediate risk.

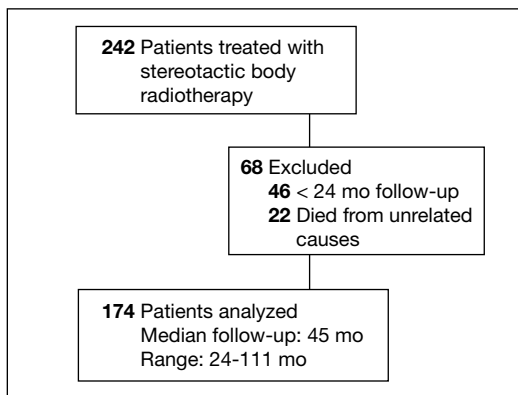


FIGURE. Patient Selection Flowchart

score of 15 to 20 out of 35 and a prostate gland size < 80 mL to minimize the risk of acute urinary toxicity. We did not use intraprostatic fiducials, hydrogel rectal spacers, or intravenous contrast agents for planning CT simulation.

Patients were placed in a supine position, and a vacuum bag was used for immobilization. Following the CT simulation, the images were transferred to the Eclipse treatment planning system. The clinical target volume (CTV) encompassed the prostate and the proximal 1.0 cm of the seminal vesicles for Gleason score (GS) 1 to 2, and the entire seminal vesicle was included

TABLE 2. Follow-up and Outcomes

Follow-up	Result
Range, mo	24-111
Median	45
Minimum	24
Patient outcome, No. (%)	
Biochemical recurrence	6 (3.4)
Died from metastatic disease	1 (0.6)
Patients living with diseases	5 (2.9)
Biochemical relapse-free survival	168 (96.6)
Disease-free survival	168 (96.6)
Overall survival	173 (99.4)

TABLE 3. Five-Year Outcomes by Risk Group

Risk group	No. (%)	5-Year DFS, %	5-Year OS, %
Low	26 (14.9)	100	100
Intermediate	118 (67.8)	97.2	99.1
High/very high	30 (17.2)	93.3	100

Abbreviations: DFS, disease-free survival; OS, overall survival.

for GS 3 to 5, which is consistent with KCVAMC practice and established safety protocols. The planning target volume (PTV) was created by uniformly expanding the CTV by 5 to 7 mm, except for the posterior margin, which was limited to 3 to 5 mm. When elective nodal radiotherapy was planned for HR prostate cancer, the pelvic field for CT simulation started at the L-2 upper border, with the lower border extending to the lesser trochanter. The pelvic nodes were delineated per Radiation Therapy Oncology Group (RTOG) guidelines.¹⁷ The CTV nodes (CTVn), including common iliac, external and internal iliac nodes, obturator, and presacral nodes, were created by uniformly expanding the CTVn by 2 to 3 mm. Slice-by-slice corrections were made to avoid bowel overlap in these patients.

The use of androgen deprivation therapy (ADT) for a duration of 6 to 24 months was prescribed for patients with UIR or HR prostate cancer per NCCN guidelines.¹⁶ The prescribed dose to the PTV was 36.25 to 40 Gy (40 Gy was mostly used as a boost to the dominant lesion) in 5 fractions, with each fraction ranging from 7.25 to 8 Gy. For elective nodal radiotherapy in patients at HR, the prescribed dose was 25 Gy in 5 fractions. All patients were planned for VMAT, which aims to deliver $\geq 95\%$ of the prescription dose to 95% of the PTV. Once the physician approved the treatment plan and physics quality assessment was completed, treatments commenced on an every-other-day schedule. Patients received the same bowel preparation instructions for each treatment as for the planning

CT simulation. Daily treatment accuracy was confirmed via daily 3-dimensional cone-beam CT (CBCT) for IGRT. No fiducials or hydrogel rectal spacers were used.

Follow-up Schedule and Toxicity Assessment

Follow-up assessments were conducted 4 to 6 weeks after radiation therapy and then repeated every 6 months for 2 to 5 years, and annually thereafter. At each follow-up visit, patients were evaluated for genitourinary (GU) and gastrointestinal (GI) toxicity, according to RTOG toxicity criteria. Prostate-specific antigen (PSA) levels were monitored; in patients receiving ADT, testosterone levels were also checked.

Statistical Analysis

Biochemical failure was defined using the Phoenix definition (nadir PSA + 2 ng/mL). Differences between dose cohorts were assessed using the log-rank test for survival outcomes and χ^2 testing for categorical variables. GU and GI toxicities were summarized as cumulative incidences of RTOG grade \geq II events. Statistical significance was set at $P < .05$.

RESULTS

One hundred seventy-four patients were included in the retrospective review. Patients had a median follow-up of 45 months (range, 24-111) (Figure). The median age at treatment was 74 years (range, 51-88), and the median pre-treatment PSA level was 11.9 ng/mL (range, 0.6-69.5). Twenty-six patients (14.9%) had a GS 1, 77 (44.3%) had GS 2, 41 (23.6%) had GS 3, 18 (10.3%) had GS 4, and 12 (6.9%) had GS 5. Fifty-one patients (29.3%) received elective pelvic nodal radiotherapy, and 93 patients (53.4%) received ADT (Table 1).

At 24 months follow-up, 6 patients (3.4%) had biochemical failures. One patient died from metastatic prostate cancer, and 5 patients are living with biochemical failure (Table 2). The actuarial 5-year overall survival (OS) rate was 99.4%, and the 5-year disease-free survival (DFS) rate was 96.6%.

We performed a subanalysis comparing outcomes of the 36.25 Gy vs 40 Gy SBRT cohorts. There was no statistically significant difference in DFS, OS, or the cumulative incidence of grade II/III toxicity between patients treated with 40 Gy vs 36.25 Gy. Outcomes stratified by NCCN risk groups (low, intermediate, high/very high) are detailed in Table 3. As expected, DFS was slightly lower in the high-risk group, but overall disease control remained high across all stratifications.

The cumulative incidence of RTOG grade II and higher GU toxicity was 28.2% (Table 4). This included 46 patients (26.4%) with grade II GU toxicity and 2 patients (1.2%) who developed grade III GU complications (1 requiring self-catheterization and another a suprapubic catheter for urinary retention). One patient (0.6%) treated with a 40 Gy dose regimen experienced a grade IV GU complication in the form of a rectovesical fistula necessitating surgical intervention.

The cumulative incidence of RTOG grade II or higher GI toxicity was 3.4%, and no grade III or IV gastrointestinal toxicities were observed during the follow-up period. Importantly, intraprostatic fiducials, hydrogel rectal spacers, or intravenous contrast were not routinely used in this cohort of patients.

The high rates of actuarial 5-year DFS and OS observed suggest a favorable initial response to the SBRT regimen employed at KCVAMC. However, given the potential for late recurrence in patients with prostate cancer, longer follow-up is essential to determine the durability of these outcomes. The observed GU toxicity rate of 28.2% for grade II and higher events warrants careful consideration and compares with other published data on SBRT for prostate cancer.¹⁵ The occurrence of a grade IV rectovesical fistula, although rare, is a notable adverse event that warrants discussion in the context of the treatment approach. The low incidence of grade II or higher GI toxicity is an encouraging finding, particularly given that hydrogel rectal spacers are not routinely used to minimize rectal exposure.

DISCUSSION

The primary objective of this retrospective study was to evaluate the outcomes of SBRT for patients with localized prostate cancer treated at KCVAMC and to compare these results with those reported in the literature. Our findings demonstrate promising intermediate-term efficacy, with an estimated 5-year DFS of 96.6% and OS of 99.4% at a median follow-up of 45 months. Furthermore, the observed toxicity profile appears acceptable, with a cumulative grade II and higher GU toxicity rate of 28.2% and a grade II or higher GI toxicity rate of 3.4%. Notably, these outcomes were achieved without the routine use of intraprostatic fiducials or hydrogel rectal spacers.

Two pivotal randomized phase 3 trials have established the noninferiority of ultrahypofractionated radiotherapy (UHRT) with SBRT over conventional fractionation. The HYPO-RT-PC trial compared SBRT (42.7 Gy in 7 fractions) with

TABLE 4. Radiation Therapy Toxicity

RTOG grade	Genitourinary, No. (%)	Gastrointestinal, No. (%)
0	125 (71.8)	168 (96.6)
I	0 (0)	0 (0)
II	46 (26.4) ^a	6 (3.4)
III	2 (1.2)	0 (0)
IV	1 (0.6)	0 (0)

Abbreviation: RTOG, Radiotherapy Oncology Group.

^aMany patients were on α blockers for pre-existing lower urinary symptoms prior to starting radiotherapy.

conventional fractionation (78 Gy in 39 fractions) in intermediate- and high-risk patients with prostate cancer and reported a 5-year biochemical relapse-free survival of 84% in both arms.⁹ The PACE-B trial, which included patients at low- and intermediate-risk, compared SBRT (36.25 Gy in 5 fractions) with conventional or moderate HFRT and reported a 5-year biochemical control rate of 95.8% in the SBRT arm and 94.6% in the control arm.¹⁵

A comprehensive review and meta-analysis of 7 phase 3 studies involving 6795 patients compared different radiotherapy regimens, namely, UHRT, HFRT, and CFRT, and reported that after 5 years, the DFS rates were 85.1% for CFRT, 86% for HFRT, and 85% for UHRT, with no significant difference in toxicity among the 3 different treatment approaches.¹⁸ This suggests that shorter, more intense radiotherapy schedules (UHRT and HFRT) may be as effective and safe as traditional, longer courses of radiation.

There are multiple published nonrandomized prospective trials in which thousands of patients with extreme hypofractionation have been treated with different doses, fractions, and techniques. While heterogeneity and limited long-term follow-up in the existing evidence are acknowledged, these data suggest that prostate SBRT provides appropriate biochemical control with few high-grade toxicities, supporting its ongoing global use and justifying further prospective investigations. Comparative data are shown in Table 5. Several ongoing studies are evaluating noninferiority, superiority, and cost-effectiveness using different methodologies (Table 6).^{9,15,19-24}

This study's efficacy outcomes, particularly the high DFS rate, are consistent with the findings from these landmark trials, suggesting that the SBRT regimen used at KCVAMC is effective in achieving early disease control despite 17.2% of patients having high-risk disease. The GU toxicity observed in this study,

TABLE 5. Prostate SBRT Radiotherapy Study Comparison

Study	Risk group (No. patients)	RT design	bRFS, % (follow-up, y)	RTOG (toxicity) grade \geq III	
				Genitourinary, %	Gastrointestinal, %
Zelevsky et al ²⁴	LR, IR (136)	5 x 6.5-8 Gy	NR	0.7	0
Meier et al ²²	IR (309)	5 x 8 Gy	97.1 (5)	1.3	0
Fuller et al ²⁰	LR, IR (259)	4 x 9.5 Gy	100 LR; 88.5 IR (5)	1.9	0
Quon et al ²³	LR, IR (152)	5 x 8 Gy	95.7 (5)	NR	NR
Widmark et al ⁹	IR, HR (589)	7 x 6.1 Gy	84.0 (5)	5.1	1.0
Jackson et al ²¹	LR, IR, HR; (6116)	5 x 6.25-8 Gy	95.3 (5)	2.0	1.0
van As et al ¹⁵	LR, IR (355)	5 x 7.25 Gy	95.8 (5)	26.9	10.7 (> II)
De Cooman et al ¹⁹	All risks (267)	5 x 7.25-8 Gy	98.5 (3)	27 (> II)	2.0
Reddy et al (present study)	All risks (174)	5 x 7.25-8 Gy	96.6 (3.8)	1.7	0

Abbreviations: bRFS, biochemical relapse-free survival; HR, high risk; IR, intermediate risk; LR, low risk; NR, not reported; RTOG, Radiotherapy Oncology Group; SBRT, stereotactic body radiotherapy.

TABLE 6. Ongoing Large Stereotactic Body Radiotherapy Trials

Study (No. patients)	Study arms	Primary objectives
NCT01584258 (1716)	Prostatectomy vs SBRT (PACE-B) IMRT for ineligible for surgery vs SBRT (PACE-C)	bRFS
NCT01766492 (622)	SBRT 36.5 Gy/5 fractions vs IMRT to 70 Gy/28 fractions	Superiority of SBRT relating to GU/GI toxicity
NCT03830788 (240)	SBRT vs low dose rate brachytherapy	Cost-effectiveness analysis
NCT05946213 (301)	SBRT (ultra-hypofractionation) vs conventional or moderate hypofractionation	Comparing metastasis-free survival

Abbreviations: bRFS, biochemical relapse-free survival; GI, gastrointestinal; GU, genitourinary; IMRT, intensity-modulated radiation therapy; NCT, national clinical trial; PACE, Prostate Advances in Comparative Evidence; SBRT, stereotactic body radiotherapy.

with a 28.2% rate of grade II or higher events, is also comparable with the 26.9% reported in the 5-fraction SBRT arm of the PACE-B trial, which had a longer median follow-up of 74 months.¹⁵ It is important to note that a portion of these grade II events occurred in patients who were already on α blockers for pre-existing lower urinary tract symptoms before starting radiotherapy, which may inflate the observed cumulative acute toxicity score.

A critical comparison is how SBRT toxicity aligns with moderate hypofractionation (eg, 60 Gy in 20 fractions or 70 Gy in 28 fractions as reported by others).^{4,6} Our observed grade III and higher GU toxicity rate (1.7%) and grade III and higher GI toxicity rate (0%) are highly favorable when compared with historical moderate hypofractionation data, which typically report grade III GU toxicity in the range of 2% to 3% and grade III GI toxicity around 1% to 2%. This suggests that despite the higher dose per fraction, SBRT

does not necessarily lead to increased severe acute toxicity, potentially offering a superior therapeutic ratio for GI and GU sparing.

However, the occurrence of a grade IV rectovesical fistula in 1 patient (0.6%)—who received the 40 Gy dose—was a serious complication that warrants careful consideration. This rare, but severe, complication in the higher dose cohort underscores the potential for increased organ-at-risk toxicity, particularly in the absence of a hydrogel rectal spacer, which is designed to mitigate high-dose rectal exposure. While the overall rate of significant GU toxicity remains low, this event highlights the potential risks associated with SBRT. Hydrogel rectal spacers are designed to increase the distance between the prostate and the rectum, which can reduce the rectal radiation dose and potentially mitigate the risk of such fistulas. The low rate of grade II or worse GI toxicity (3.4%) in our study is noteworthy, especially considering that hydrogel spacers were not routinely used. This finding aligns with the 2.5%

GI toxicity rate reported in the SBRT arm of the PACE-B trial, suggesting that careful treatment planning and delivery techniques, such as VMAT-IMRT and daily CBCT for IGRT, may contribute to minimizing GI toxicity even without the use of rectal spacers.¹⁵ The exclusive use of 3-dimensional CBCT for IGRT in our study, without the use of fiducial markers, suggests that accurate target localization can be achieved with this approach, contributing to the observed efficacy and reduced toxicity.

Strengths and Limitations

This study's retrospective, single-center design may have introduced selection bias. The median follow-up of 45 months, while substantial, is still relatively short for assessing very late toxicities and long-term oncologic outcomes in prostate cancer, which is known for late recurrences. Additionally, the lack of a direct comparison group within KCVAMC limits the ability to definitively attribute the observed outcomes solely to SBRT treatment. However, the strengths of this study include the inclusion of a consecutive series of veteran patients with localized prostate cancer across all risk categories, providing a real-world perspective on SBRT outcomes in a diverse patient population. Furthermore, the detailed assessment of efficacy and toxicity via standardized RTOG criteria enhances the comparability of our findings with those of other published prospective studies, despite the retrospective nature of the data.

CONCLUSIONS

This single-institution retrospective analysis revealed that short-term SBRT (36.25 to 40 Gy in 5 fractions), with a minimum follow-up of 24 months and a median follow-up of 45 months, for localized prostate cancer, including patients at HR, is associated with promising early efficacy and acceptable toxicity, even in the absence of routine fiducial or hydrogel spacer use. The favorable actuarial 5-year DFS and OS rates, coupled with a manageable toxicity profile, suggest that SBRT is a safe and convenient treatment option for many patients with localized prostate cancer. However, a longer follow-up is necessary to confirm these findings and fully characterize the long-term efficacy and toxicity of this SBRT regimen. Nevertheless, the results contribute to the growing body of evidence suggesting that SBRT is a safe and convenient treatment option for many patients with localized prostate cancer.

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Disclaimer

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Ethics and consent

The Kansas City Veterans Affairs Medical Center Research and Development Committee and Institutional Review Board reviewed and approved the study (IRBNet ID#1578727).

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