

Focal Versus Whole-Gland Cryoablation Therapy in High-Grade Prostate Cancer: A Single-Institution Retrospective Study

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Abstract

Background and objectives

High-grade prostate cancer carries substantial mortality risk, yet evidence supporting cryoablation in high-risk disease remains sparse. This study evaluates intermediate-term biochemical recurrence-free survival (bRFS) in patients with high-risk prostate cancer (PCa) undergoing primary focal (FC) or total gland cryoablation (TC), and assesses whether Gleason grade group predicts treatment failure.

Methods

In this single-center retrospective cohort study, 135 patients with D'Amico high-risk prostate cancer (GGG4, n = 85; GGG5, n = 50) underwent FC (n = 36) or TC (n = 99) from 2013 to 2024. Pathologic grade was confirmed by transrectal or transperineal saturation biopsy with histologic mapping; multiparametric MRI was used for lesion localization. Organ-confined disease was confirmed by staging with CT, bone scan, MRI, and PSMA PET. The primary endpoint was biochemical recurrence, defined per RTOG-ASTRO Phoenix criteria as a PSA rise of 2 ng/mL above nadir. Kaplan-Meier analysis with two-sided log-rank testing compared bRFS between grade groups within each cohort.

Key findings and limitations

Median follow-up was 36 months (IQR 19–58). At 48 months, bRFS was 69.8% and 50.0% for GGG4 and GGG5 in the FC cohort, and 71.6% and 55.0% in the TC cohort. No statistically significant difference in bRFS was identified between grade groups in either modality (FC p = 0.60; TC p = 0.23), though the study was underpowered for this comparison, particularly in the focal cohort, where only six patients had GGG5 disease. Further limitations include a single-center retrospective design, absence of a control arm, and reliance on PSA kinetics over post-operative biopsy in most patients.

Conclusions and clinical implications

Both FC and TC achieved meaningful intermediate-term disease control in selected high-risk PCa patients. Prospective multicenter trials with standardized protocols and extended follow-up are needed to formally establish cryoablation's role in this population.

Categories: Urology, Radiation Oncology, Oncology

Keywords: biochemical recurrence, cryoablation, focal therapy, high-risk prostate cancer, prostate cancer, salvage therapy, whole-gland therapy

Introduction

Prostate cancer remains the second leading cause of oncology-related death in the USA [1]. Patients with high-grade prostate cancer represent the most at-risk patients for prostate cancer-specific mortality (PCSM). Though accepted interventions, such as surgery and radiation with ADT, approved by the American Urological Association (AUA), lead to improved survival, high-grade prostate cancer (PCa) confers significant mortality and metastasis risk if not well controlled. Cryoablation of the prostate for focal therapy has gained popularity due to the use of multi-parametric MRI (mpMRI) [2]. The use of transrectal ultrasound-guided focal and whole-gland cryoablative therapies has been employed as a means to reduce tumor progression in a minimally invasive manner, with focal therapy (FC) being associated with better preservation of urinary continence and erectile function [3]. The use of nerve-sparing focal cryoablation as primary and salvage therapies with intermediate-risk prostate cancer and local recurrence is well documented, respectively [3–6].

However, there is little to no consensus around the efficacy of treatment of high-risk prostate cancer with

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cryoablation as a useful modality compared to radical prostatectomy, radiation, high-intensity focused ultrasound therapy (HIFU), with or without androgen deprivation therapy (ADT). Consequently, current literature on cryoablation (specifically focal) is sparse for this subgroup, and its application in patients with high-grade disease remains largely unexplored.

In this study, the outcomes from a cohort of 135 patients with D'Amico high-risk prostate cancer who underwent primary focal or total gland cryoablation are explored. To our knowledge, this is one of the largest analyses specifically evaluating primary cryotherapy in a uniformly high-grade prostate cancer population. The primary objective was to evaluate biochemical recurrence-free survival (bRFS) at 24, 36, 48, and 96 months (mo) following primary FC and TC in patients with GGG4-5 prostate cancer. The secondary objective was to assess whether Grade Group (GGG4 vs. GGG5) was associated with biochemical failure.

Materials And Methods

From 2013 to 2024, 135 patients with Grade Group (GGG) 4 (Gleason score 8) and Grade Group (GGG) 5 (Gleason scores 9-10) prostate cancer underwent focal (36 patients (26.7%)) or total (99 patients (73.3%)) gland cryoablation of the prostate at Nebraska Methodist Hospital, Omaha. These selected patients were offered FC or TC as an alternative to more aggressive treatments such as prostatectomy or radiation therapy.

Treatment allocation was determined by lesion distribution on template-saturation biopsy and multiparametric MRI. Patients with unifocal, organ-confined disease for whom preservation of erectile function and prevention of urinary incontinence were stated treatment goals were offered focal cryoablation; patients with multifocal but organ-confined disease were offered total gland cryoablation. All other inclusion requirements, including Gleason Grade Group 4 or 5 disease [7], confirmed organ-confined status, and negative metastatic staging, were identical between cohorts. All patients underwent transrectal or transperineal template-saturated biopsy, and all samples were submitted in their entirety for standard pathologic analysis and histological mapping to determine GGG and the exact location and distribution of cancer. The primary outcome was bRFS at 24, 36, 48, and 96 months following FC and TC, with biochemical recurrence (BCR) defined as described below. The secondary outcome was whether Grade Group (GGG4 vs. GGG5) predicted biochemical failure within each treatment modality, assessed by log-rank testing.

Biochemical recurrence was defined according to the RTOG-ASTRO Phoenix criteria as a rise in serum PSA of 2 ng/mL or more above the post-treatment nadir, with nadir defined as the lowest PSA value recorded following cryoablation [8]. We acknowledge that the Phoenix definition was developed and validated for radiotherapy rather than ablative therapy; no cryoablation-specific consensus definition currently exists, and Phoenix is the convention most widely applied in the focal therapy literature, permitting comparison with prior series. Patients were seen every three months during the first year to monitor serum PSA, with follow-up extended to every six months once PSA was stable for one year. Patients meeting criteria for biochemical recurrence underwent CT, bone scan, and PSMA PET at the discretion of the treating physician, most often when the primary tumor was poorly differentiated. Because imaging was not performed systematically in all patients with biochemical recurrence, the anatomic site of recurrence could not be reliably classified as local or distant, and no such classification is reported. If a salvage treatment was planned and the patient was not a candidate for radical prostatectomy, repeat cryoablation, or radiation, the patient was given ADT. Data on androgen deprivation therapy use, including neoadjuvant administration prior to cryoablation and salvage administration following biochemical recurrence, were not consistently available in the retrospective record and could not be reliably ascertained.

All analyses and visualizations were conducted in Python (v3.10) using the pandas, NumPy, and lifelines packages. 95% confidence intervals for Kaplan-Meier estimates were calculated using Greenwood's variance with a log-log transformation. Hazard ratios with 95% CIs were estimated using univariable Cox proportional hazards regression. First, patients who underwent focal and total cryoablation were stratified by GGG (Grade Group 4 and Grade Group 5). PSA failure in months was defined as the primary endpoint for each cohort and used to construct Kaplan-Meier survival curves for FC, global, and both methods of cryoablation. A risk table showing the number of patients at each risk level at each time point was calculated for each figure, as well as the disease-free survival probabilities at 24, 36, 48, and 96 months. Lastly, a two-sided log-rank test ($\alpha = 0.05$) was performed to determine if histological groups were predictive of recurrence between the different GGGs within each cohort and between them.

Results

The median age of patients who underwent cryoablation was 72 years (IQR 67.75 to 79; range 52 to 90), and the median pre-operative PSA was 7.42 ng/mL (IQR 5.55 to 11.54). The mean of 12.33 ng/mL reflects a right-skewed distribution driven by a small number of patients with markedly elevated PSA (range 0.648 to 71 ng/mL); median values are therefore reported throughout (Table 1). All 135 patients met D'Amico high-risk criteria on the basis of GGG4 and GGG5 disease. A total of 18 patients (13.3%) additionally met the criterion of pre-operative PSA greater than 20 ng/mL, of whom 17 were in the total gland cohort and one in the focal cohort; the remaining 117 patients (86.7%) qualified on grade alone with PSA of 20 ng/mL or less. Clinical T stage was not systematically recorded in the retrospective database and could not be used to classify risk.

Variable	IQR	Range	Median	Mean
Patient Characteristics				
Age (years)	67.75-79	52-90	72	74
Pre-operative PSA (ng/mL)	5.55-11.54	0.648-71	7.42	12.33
Post-operative PSA (ng/mL)	0.08-0.55	0.00-43	0.19	0.83
Follow-up (months)	19-58	-	36	-

TABLE 1: Baseline patient characteristics of high-risk prostate cancer patients undergoing primary focal or total gland cryoablation (2013-2024)
IQR, interquartile range; PSA, prostate-specific antigen.

Biopsy types varied in these patient cohorts, with 58 patients undergoing transrectal prostate biopsy and the other 77 undergoing transperineal-mapping biopsy. Our entire cohort was 135 patients with D'Amico high-risk prostate cancer, with 85 (63.0%) being GGG4 and 50 (37.0%) being GGG5 patients. One month after FC, a 93% reduction in PSA resulted in a median post-operative PSA of 0.19 ng/mL (IQR: 0.08-0.55 ng/mL). The median follow-up time from the initial procedure was 36 mo (IQR: 19-58).

At 48 mo, our clinical data on focal cryoablation yielded biochemical disease-free survival rates of 69.8% (95% CI: 46.5-84.5) and 50.0% (95% CI: 11.1-80.4) for GGG4 and GGG5, respectively (Table 2). Additionally, at 48 mo, our clinical data on the TC cohort showed BCR of 28.4% and 45.0% for GGG4 and GGG5, respectively, leading to a post-operative TC biochemical disease-free survival rate of 71.6% (95% CI: 55.1-83.0) and 55.0% (95% CI: 35.2-70.9) for GGG4 and GGG5, respectively. The anatomic site of recurrence was not systematically determined, and these figures therefore reflect biochemical failure irrespective of whether disease was local or distant. The focal GGG5 subgroup comprised six patients, with three remaining at risk at 36 months and two at 96 months; estimates beyond 36 months in this subgroup are imprecise, and the apparent convergence of the focal curves at later time points should not be interpreted as a grade effect. bRFS did not differ significantly between grade groups within the FC cohort (log-rank p = 0.60), within the TC cohort (p = 0.23), or across both modalities (p = 0.53).

Cohort	Months	GGG4 bRFS % (95% CI)	GGG4 at risk	GGG5 bRFS % (95% CI)	GGG5 at risk
FC	24	79.8 (57.9-91.1)	19	83.3 (27.3-97.5)	5
FC	36	79.8 (57.9-91.1)	16	50.0 (11.1-80.4)	3
FC	48	69.8 (46.5-84.5)	10	50.0 (11.1-80.4)	3
FC	96	36.6 (13.0-61.0)	3	50.0 (11.1-80.4)	2
TC	24	87.5 (74.3-94.2)	36	86.9 (71.3-94.4)	31
TC	36	74.5 (58.3-85.1)	28	74.2 (56.0-85.8)	22
TC	48	71.6 (55.1-83.0)	24	55.0 (35.2-70.9)	13
TC	96	57.5 (37.6-73.2)	6	45.8 (26.4-63.3)	1

TABLE 2: Biochemical recurrence-free survival (bRFS) at specified time points following focal or total gland cryoablation, stratified by GGG.
bRFS, biochemical recurrence-free survival; FC, focal cryoablation; TC, total gland cryoablation; GGG4, Gleason Grade Group 4 (Gleason sum 8); GGG5, Gleason Grade Group 5 (Gleason sum 9-10); mo, months.

Table with 6 columns: Cohort, n GGG4 (events), n GGG5 (events), HR GGG5 vs GGG4 (95% CI), Cox p, Log-rank p. It compares FC and TC cohorts for GGG4 and GGG5 events, hazard ratios, and p-values.

TABLE 3: Comparison of biochemical recurrence-free survival between Gleason Grade Group 4 and Grade Group 5 within each cryoablation cohort

bRFS, biochemical recurrence-free survival; CI, confidence interval; FC, focal cryoablation; GGG4, Gleason Grade Group 4 (Gleason sum 8); GGG5, Gleason Grade Group 5 (Gleason sum 9-10); HR, hazard ratio; TC, total gland cryoablation.

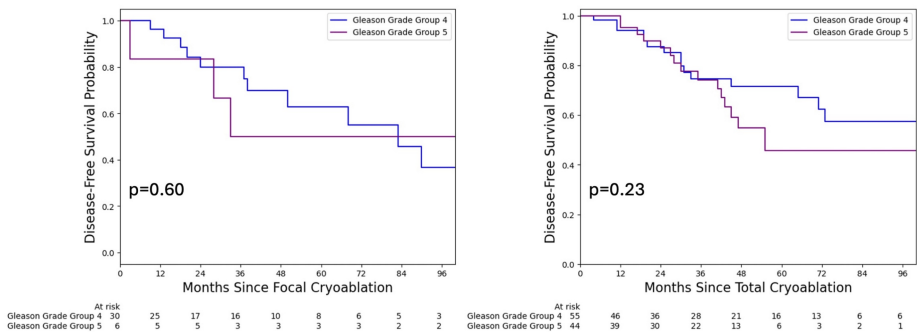


FIGURE 1: a-b. Kaplan-Meier estimates of bRFS following focal and total cryoablation stratified by GGG

GGG, Gleason Grade Group; bRFS, biochemical recurrence-free survival

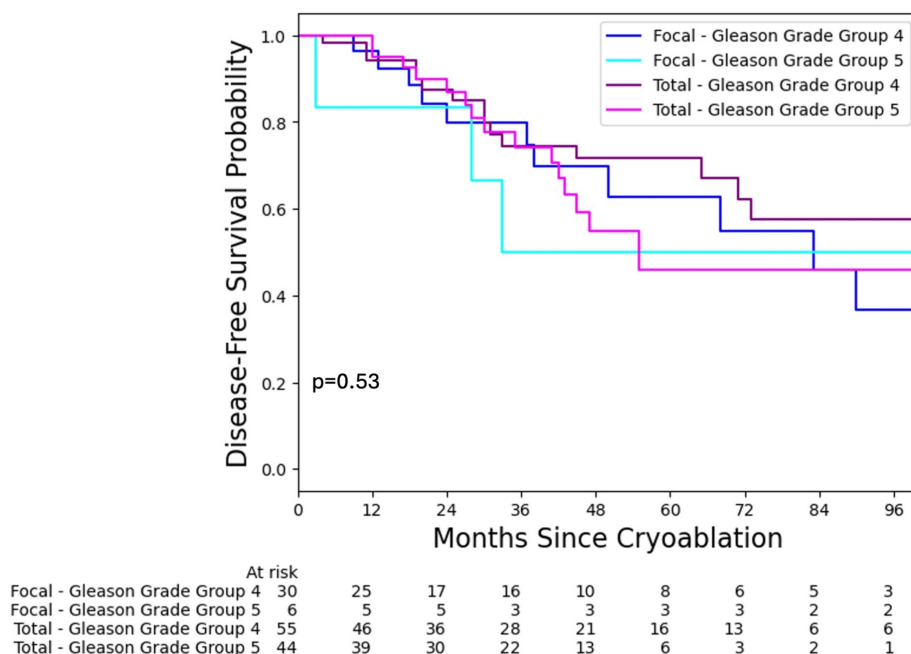


FIGURE 2: Kaplan-Meier estimates of bRFS for both focal and total cryoablation stratified by GGG.

GGG, Gleason Grade Group; bRFS, biochemical recurrence-free survival

Discussion

This retrospective cohort study presents one of the largest analyses to date on the use of primary FC and TC in patients with D'Amico high-risk prostate cancer. This population has historically been underrepresented in the literature on focal therapy. Within this cohort, our results demonstrate promising, though cautiously interpreted, bRFS outcomes in both GGG4 and GGG5 patients, with our 48-month bRFS of 69.8% and 50% in the FC cohort and 71.6% and 55.0% in the TC group, respectively. These findings contribute to a growing body of evidence suggesting that FC may hold therapeutic value in select patients with high-grade prostate cancer.

Current AUA/ASTRO guidelines describe focal ablation as investigational for low- and intermediate-risk disease and advise against its use in high-risk disease outside of a clinical trial [9]. This recommendation stems from concerns regarding occult metastases alongside a lack of robust, long-term outcomes data in high-risk cohorts. Despite these apprehensions, our study, among others, provides data that challenge the notion that cryoablation is categorically unsuitable for high-grade disease.

Jones and Rewcastle (2008) previously reported a five-year biochemical disease-free survival rate of 64.4% in patients with GGG4 and GGG5 grade cancers [10]. Similarly, Oishi et al. (2019) documented a 5-year biochemical failure-free rate of 75% for high-grade patients undergoing hemi-gland cryoablation [11]. A retrospective series of 191 patients with localized high-risk PCa, defined by Gleason sum 8-10, stage T3a or greater, or PSA above 20 ng/mL, reported a 5-year BCR-free rate of 66.7% [12]. Our study yields a slightly lower but comparable 48-month bRFS, particularly in GGG5 disease, suggesting that cryotherapy may offer meaningful disease control in appropriately selected high-risk cases. For reference, Greenberger et al. (2020) reported bRFS rates between 60% and 85% in high-risk patients treated with prostatectomy or radiation plus ADT [13]. In this context, our outcomes, especially in the GGG4 cohort, indicate that both TC and FC may offer a less morbid alternative with meaningful disease control in select patients. Additionally, emerging evidence suggests that the efficacy of cryoablation may be independent of tumor grade or cellular differentiation, further encouraging its exploration in high-grade disease [14].

The FALCON Delphi consensus project established a structured international framework to standardize the clinical application of partial gland ablation for localized prostate cancer [15]. Drawing from a panel of 79 experts across 16 countries, the consensus defined standards for patient selection, biopsy protocols, imaging modalities, and follow-up care. Notably, while the consensus did not recommend focal therapy as standard care for high-risk disease, it did identify a small subset of high-risk patients, specifically those with solitary, organ-confined, and MRI-visible index lesions, as potential candidates for focal treatment when combined with rigorous staging and close surveillance. Our study closely aligns with these recommendations,

specifically targeting GGG4 and GGG5 patients with localized, histologically confirmed disease, and utilizing transperineal or transrectal saturation biopsies in conjunction with mpMRI mapping. This methodological alignment with FALCON's criteria enhances the translational relevance of our findings in the high-risk setting.

This study has several limitations. It represents a single-center, single-physician experience, which limits generalizability and lacks a control group for direct comparison with other treatment modalities. Functional outcomes such as erectile function and urinary continence were not systematically assessed. While the median follow-up of 36 mo provides meaningful intermediate-term data, longer observation is necessary to evaluate metastasis-free and cancer-specific survival. Only a limited proportion of the cohort underwent post-operative biopsy; thus, recurrence assessments relied primarily on PSA kinetics. A recent comprehensive review in JAMA (2025) and the 2024 AUA/ASTRO guideline summary both emphasize that serial PSA measurement, not routine early biopsy, is the primary means of post-radiotherapy surveillance, and that biopsy should be reserved for select cases with clinical or biochemical suspicion of recurrence [16,17]. Although post-treatment biopsy at 24-36 mo is ideal for confirming local control, most patients declined a repeat biopsy in favor of serial PSA monitoring at three-month intervals [18]. Further, the Phoenix definition of biochemical recurrence was developed and validated for radiotherapy rather than ablative therapy, and no cryoablation-specific consensus definition currently exists. The study is underpowered to detect differences in bRFS between grade groups, particularly within the focal cohort, where only six patients had GGG5 disease.

Our finding of no statistically significant difference should be interpreted as an absence of evidence rather than evidence of equivalence. Estimates beyond 36 months in the smaller subgroups rest on two to three patients at risk and are correspondingly imprecise, as reflected in the width of the associated confidence intervals. Clinical T stage was not systematically recorded and could not be used to characterize the full distribution of D'Amico risk features. Androgen deprivation therapy use, including neoadjuvant administration prior to cryoablation and salvage administration following biochemical recurrence, was not analyzed in this study. Finally, attrition due to loss to follow-up or death from unrelated comorbid conditions may have affected longitudinal outcome tracking. These limitations underscore the need for prospective, multicenter studies with standardized protocols and extended follow-up. Notably, the absence of a statistically significant difference between grade groups across both modalities raises the possibility that Gleason grade alone may not reliably predict cryotherapy failure in organ-confined disease, a preliminary signal that warrants validation in larger cohorts.

Conclusions

This study represents one of the largest single-institution analyses of primary focal and total gland cryoablation in a uniformly high-grade prostate cancer population. Our findings demonstrate that both FC and TC can achieve meaningful intermediate-term biochemical disease-free survival in carefully selected GGG4 and GGG5 patients. Prospective, multicenter trials with standardized selection criteria, functional outcome assessment, and extended follow-up are needed to establish cryoablation's role in this population.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Anwar Khan, Ansar U. Khan, Michael Feloney

Drafting of the manuscript: Anwar Khan, Jacob Shawwa, Alan Ho

Critical review of the manuscript for important intellectual content: Anwar Khan, Jacob Shawwa, Alan Ho, Dominic Coletta, Aryan Dalal, Ansar U. Khan, Michael Feloney

Acquisition, analysis, or interpretation of data: Jacob Shawwa, Alan Ho, Dominic Coletta, Aryan Dalal

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Disclosures

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