

Focal therapy versus radical prostatectomy: a propensity score-matched comparison of failure-free survival

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Abstract

Introduction

Focal therapy aims to treat clinically significant localized prostate cancer while preserving uninvolved tissue and adjacent structures, but direct comparisons with radical prostatectomy remain limited. The objective of this study was to compare failure-free survival (FFS) between patients undergoing focal cryotherapy or irreversible electroporation and those undergoing radical prostatectomy.

Materials and Methods

We retrospectively identified 274 focal-therapy and 2,000 prostatectomy patients treated in 2014–2026. Maximum-cardinality 1:1 matching used exact grade-group, calendar-period, and magnetic-resonance-imaging-stage strata plus propensity-score caliper, age, and balance restrictions. Among prespecified covariates, the maximum absolute standardized mean difference was 0.083 in 207 pairs. FFS was time to active treatment outside the index strategy or metastatic progression. Any adjuvant or salvage treatment after prostatectomy counted as failure; repeat focal ablation did not. Kaplan-Meier and pair-clustered robust Cox models were used.

Results

Median follow-up was 38.1 months (IQR 14.2–69.0) after focal therapy and 32.6 months (IQR 13.7–60.0) after prostatectomy. There were 39 versus 17 failures, including 37 versus 16 active post-index treatments and 2 versus 1 metastatic progression before treatment. Three-year FFS was 89% versus 92%; 5-year FFS was 79% versus 88%, (95% confidence interval [CI] – 19 to 0.2). The primary model favored prostatectomy (HR 1.99, 95% CI 1.13–3.51; $p = 0.017$).

Conclusions

Focal therapy had a higher rate of failure in the primary analysis. Nevertheless, approximately four in five focal-therapy patients remained free of radical treatment or metastasis at 5 years.

INTRODUCTION

Radical prostatectomy provides whole-gland treatment for localized prostate cancer but may impair urinary and sexual function. Focal therapy aims to ablate clinically significant tumor while preserving uninvolved prostate and adjacent structures. Contemporary guidance nevertheless recommends that focal high-intensity focused ultrasound or cryotherapy be delivered within prospective registries, with other ablative modalities restricted to well-designed trials, rather than treating focal therapy as a routine oncologic equivalent to standard radical treatment (1).

Evidence for focal cryotherapy and irreversible electroporation (IRE) has expanded, but it remains dominated by single-arm series with heterogeneous selection, surveillance, and failure definitions (2–5).

Direct propensity-score-based comparisons of focal or partial-gland therapy with prostatectomy remain few and heterogeneous in treatment modality, eligibility, outcome definition, and analytical approach, spanning oncologic and functional endpoints (6–10). More contemporary comparisons with transparent alignment of magnetic resonance imaging (MRI), biopsy burden, disease grade, and treatment era are therefore needed.

We compared FFS after an initial strategy of focal cryotherapy or IRE versus radical prostatectomy in a longitudinal institutional cohort. Exact and propensity-score matching were used to compare treatment-strategy outcomes among focal-therapy patients retained within observed common support, with prespecified sensitivity and exploratory subgroup analyses.

MATERIALS AND METHODS

Study design and patients. This retrospective cohort study used an ethics-approved prostate-cancer registry, with data integrated through a dedicated clinical data platform. The registry was approved in 2018 by the local research ethics committee (approval no. 2018-07). Individual informed consent was not obtained for this retrospective study. Reporting followed the STROBE recommendations (11). The data cutoff was August 3, 2026. Eligible patients received focal cryotherapy, focal IRE, or radical prostatectomy as their first active treatment between 2014 and 2026; prior active surveillance was permitted. We required baseline PSA, baseline ISUP grade group, no known nodal or metastatic disease before treatment, and post-treatment follow-up. Whole-gland or otherwise complete ablation was excluded. No upper PSA or ISUP restriction was imposed. No formal sample-size calculation was performed; all patients meeting the eligibility criteria were included.

Outcome. FFS was measured from index treatment to the earliest of active treatment outside the index strategy or documented metastatic progression. In the focal-therapy group, failure comprised radical prostatectomy, radiotherapy or brachytherapy, or systemic therapy after the index ablation; a second focal ablation remained within the organ-preserving strategy and was not a primary failure. In the prostatectomy group, any active postoperative treatment, including radiotherapy and/or systemic therapy, was counted as failure. Death without prior failure was not a failure event, and event-free patients were censored at their last longitudinal evidence.

Propensity-score matching. Covariates were selected a priori as factors associated with treatment selection and/or prognosis; outcomes were not used to specify the score or matching design. A nonpenalized logistic model estimated the probability of focal therapy from age, log-transformed PSA, an indicator for PSA > 20 ng/mL, treatment year, positive-core percentage, prior active surveillance, ASA class, and PI-RADS category. Missing age and positive-core percentage were median-imputed for model fitting and accompanied by missingness indicators; unavailable ASA and PI-RADS were explicit categories. ISUP grade group, treatment period (2014–2016, 2017–2019, 2020–2022, or 2023–2026), and MRI stage were reserved for exact matching and were not duplicated in the score.

Matching was 1:1 without replacement. Candidate pairs had identical exact-matching variables, a propensity-score-logit difference within 0.20 pooled standard deviations (12), and an age difference ≤ 10 years. Mixed-integer optimization first maximized cardinality subject to direct balance constraints, then minimized the sum of absolute propensity-score differences (13). Adequate balance was prespecified as an absolute SMD < 0.10 for every matching covariate (14, 15).

Statistical analysis. Continuous variables are reported as median and interquartile range (IQR), and categorical variables as number and percentage. Follow-up duration was summarized as median (IQR). Balance was assessed with SMDs, variance ratios, and graphical distributions before and after matching. FFS was estimated with Kaplan-Meier methods and 95% confidence intervals (CIs). Five-year absolute FFS differences and restricted mean failure-free time (RMST) through 5 years were estimated with 10,000 matched-pair bootstrap samples. The primary effect was a marginal Cox model with a robust sandwich variance clustered by matched pair (16). A Cox model stratified by pair and a model restricted to pairs with biopsy tissue-involvement measurements in both members were sensitivity analyses. Biopsy tissue involvement was calculated as $100 \times$ the total cancer length across all biopsy cores divided by total evaluable biopsy tissue length; it was treated as missing when either component was unavailable or the denominator was nonpositive, and missing values were not imputed. Proportional hazards were assessed using residuals. Each prespecified exploratory subgroup analysis fitted treatment, the binary subgroup indicator, and their interaction in the marginal pair-clustered Cox framework; category-specific treatment HRs and interaction p values were reported for ISUP grade group ≥ 2 , PSA ≥ 10 ng/mL, biopsy tissue involvement $\geq 5\%$, MRI-visible disease (PI-RADS 3–5), and age < 70 years.

RESULTS

Cohort construction. We assessed 307 patients for focal ablation and 2,221 patients for radical prostatectomy. After hierarchical exclusions, 274 focal-therapy and 2,000 prostatectomy patients were eligible (Fig. 1). The eligible focal cohort comprised 203 cryotherapy and 71 IRE treatments. Matching retained 207 focal patients (76%) and 207 prostatectomy patients. Sixty-seven clinically eligible focal patients could not be paired under all exact, caliper, age, and balance restrictions.

Balance and baseline characteristics. Propensity-score overlap improved substantially after matching (Fig. 2). Before matching, the largest imbalance involved positive-core percentage (absolute SMD 1.2); after matching, all prespecified propensity-score and exact-matching covariates were balanced, with a maximum absolute SMD of 0.083 (Table S1; Figure S1). Exact variables had SMDs of zero, and postmatching variance ratios for continuous score covariates ranged from 0.88 to 1.59 (Figure S2). The median absolute within-pair age difference was 4.5 years (IQR 2.4–7.1; maximum 9.9), and the median absolute propensity-score difference was 0.03. Matched clinical characteristics are summarized in Table 1. Five focal and four prostatectomy patients had PSA > 20 ng/mL, and each group included three ISUP grade-group 4 and two MRI cT3a patients; no matched patient had ISUP grade-group 5 or cT3b

disease. Compared with matched focal patients, the 67 unmatched focal patients were older, more often previously surveilled, and had lower positive-core percentages (Table S2).

Table 1
Baseline characteristics in the propensity-score-matched cohort.

Characteristic	Focal therapy (n = 207)	Radical prostatectomy (n = 207)	SMD
Age, years	67.4 (61.7–72.3)	66.7 (62.7–71.0)	0.028
PSA, ng/mL	6.10 (4.51–8.39)	6.05 (4.87–8.48)	0.033†
PSA > 20 ng/mL	5 (2.4)	4 (1.9)	0.033
Treatment year	2022 (2019–2024)	2021 (2019–2024)	0.036
ISUP grade group 1	73 (35.3)	73 (35.3)	0.000
ISUP grade group 2	103 (49.8)	103 (49.8)	0.000
ISUP grade group 3	28 (13.5)	28 (13.5)	0.000
ISUP grade group 4	3 (1.4)	3 (1.4)	0.000
Positive biopsy cores, n	3 (2–4)	3 (2–4)	0.054
Positive biopsy cores, n: missing	2 (1.0)	3 (1.4)	0.044
Positive biopsy cores, %	13.5 (8.7–18.2)	13.6 (8.3–19.6)	0.083
Positive biopsy cores, %: missing	3 (1.4)	4 (1.9)	0.037
Evaluable biopsy cores, n‡	23 (22–31)	23 (15–30)	0.333
Evaluable biopsy cores, n: missing	3 (1.4)	4 (1.9)	0.037
Total positive biopsy length, mm‡	11 (7–19)	13 (6–20)	0.119
Total positive biopsy length, mm: missing	8 (3.9)	61 (29.5)	0.732
Prior active surveillance	58 (28.0)	60 (29.0)	0.021
ASA I	9 (4.3)	10 (4.8)	0.023
ASA II	110 (53.1)	111 (53.6)	0.010
ASA III	13 (6.3)	13 (6.3)	0.000
Values are median (IQR) or n (% of the full treatment group). †SMD calculated on log-transformed PSA. Positive-core percentage was a propensity-score covariate; its SMD uses observed values, with missingness reported separately. ‡Descriptive biopsy variables not used for matching; differing sampling and missingness account for residual imbalance. MRI-unavailable and PI-RADS-unavailable counts overlap and should not be summed. No patient in either group had matched ISUP grade group 5 or MRI cT3b disease. ASA, American Society of Anesthesiologists; IQR, interquartile range; ISUP, International Society of Urological Pathology; MRI, magnetic resonance imaging; PI-RADS, Prostate Imaging Reporting and Data System; PSA, prostate-specific antigen; SMD, standardized mean difference.			

Characteristic	Focal therapy (n = 207)	Radical prostatectomy (n = 207)	SMD
ASA unavailable/other	75 (36.2)	73 (35.3)	0.020
MRI stage cT1–2	174 (84.1)	174 (84.1)	0.000
MRI stage cT3a	2 (1.0)	2 (1.0)	0.000
MRI unavailable	31 (15.0)	31 (15.0)	0.000
PI-RADS 1–2/no lesion	39 (18.8)	40 (19.3)	0.012
PI-RADS 3	35 (16.9)	34 (16.4)	0.013
PI-RADS 4–5	101 (48.8)	99 (47.8)	0.019
PI-RADS unavailable	32 (15.5)	34 (16.4)	0.026
Values are median (IQR) or n (% of the full treatment group). †SMD calculated on log-transformed PSA. Positive-core percentage was a propensity-score covariate; its SMD uses observed values, with missingness reported separately. ‡Descriptive biopsy variables not used for matching; differing sampling and missingness account for residual imbalance. MRI-unavailable and PI-RADS-unavailable counts overlap and should not be summed. No patient in either group had matched ISUP grade group 5 or MRI cT3b disease. ASA, American Society of Anesthesiologists; IQR, interquartile range; ISUP, International Society of Urological Pathology; MRI, magnetic resonance imaging; PI-RADS, Prostate Imaging Reporting and Data System; PSA, prostate-specific antigen; SMD, standardized mean difference.			

Follow-up and failures. Median follow-up was 38 months (IQR 14–69) after focal therapy and 33 months (IQR 14–60) after prostatectomy. Failure occurred in 39/207 focal-therapy patients (19%) and 17/207 prostatectomy patients (8%). Active post-index treatment was the first event in 37/207 (18%) and 16/207 (7.7%), whereas metastatic progression before such treatment was the first event in 2/207 (1%) and 1/207 (0.5%), respectively (Table 2; Table S3). A second focal ablation was performed in 20/207 patients (9.7%); four later experienced a primary failure and none underwent a third focal ablation. Among 40 focal-therapy patients with a positive post-treatment biopsy but no primary failure, 14 underwent a second focal ablation and 26 received no active retreatment. One focal-therapy and five prostatectomy patients died without prior failure, all from other causes.

Table 2
Follow-up and failure-free survival in the matched cohort

Outcome	Focal therapy (n = 207)	Radical prostatectomy (n = 207)	Comparison
Median follow-up, months	38.1 (14.2–69.0)	32.6 (13.7–60.0)	—
Follow-up < 12 months	43 (20.8)	41 (19.8)	—
Failures	39/207 (18.8)	17/207 (8.2)	—
Active post-index treatment as first event	37/207 (17.9)	16/207 (7.7)	—
Metastatic progression before post-index treatment	2/207 (1.0)	1/207 (0.5)	—
Second focal ablation (not primary failure)	20/207 (9.7)	Not applicable	—
Deaths without prior failure	1/207 (0.5)	5/207 (2.4)	—
3-year FFS, % (95% CI)	89.4 (84.5–94.4)	92.1 (87.8–96.5)	–2.7 pp
5-year FFS, % (95% CI)	78.5 (70.9–86.0)	87.6 (81.5–93.6)	–9.1 pp (– 18.6 to 0.2)
5-year RMST, months	54.4	56.0	–1.6 (– 4.4 to 1.2)
Marginal robust Cox model	Focal therapy	Reference	HR 1.99 (1.13–3.51); p = 0.017
Pair-stratified Cox sensitivity	Focal therapy	Reference	HR 1.43 (0.72–2.83); p = 0.306
Biopsy-complete-pair sensitivity	Focal therapy	Reference	HR 1.87 (0.91–3.83); p = 0.088

Values are median (IQR), n (%), or Kaplan-Meier estimate (95% CI). First-event categories sum to all primary failures. Active post-index treatment comprised nonfocal treatment after focal therapy and any adjuvant or salvage radiotherapy and/or systemic therapy after prostatectomy; clinical intent did not alter classification. A second focal ablation was not a primary failure; all deaths without prior failure were attributed to other causes. Differences are focal therapy minus radical prostatectomy. Parenthetical intervals for absolute 5-year FFS and RMST differences are 95% percentile CIs from 10,000 bootstrap samples of matched pairs, conditional on the fixed matched sample. The marginal model used a robust sandwich variance clustered by matched pair. The pair-stratified sensitivity analysis included 34 informative events; the biopsy-complete analysis retained 138 pairs and 38 events. CI, confidence interval; FFS, failure-free survival; HR, hazard ratio; IQR, interquartile range; KM, Kaplan-Meier; pp, percentage points; RMST, restricted mean survival time.

Failure-free survival. Three-year FFS was 89% (95% CI 85–94) after focal therapy and 92% (88–97) after prostatectomy; 5-year FFS was 79% (71–86) and 88% (82–94), respectively (Fig. 3; Table 2). In the primary marginal model, focal therapy was associated with a higher failure rate (HR 1.99, 95% CI 1.13–

3.51; $p = 0.02$). In the pair-stratified sensitivity model, the estimate was attenuated and imprecise (HR 1.43, 95% CI 0.72–2.8; $p = 0.31$). The 5-year absolute FFS difference was – 9.1 percentage points (95% bootstrap CI – 19 to 0.2). Five-year RMST was 54 months after focal therapy and 56 months after prostatectomy, a difference of – 1.6 months (95% bootstrap CI – 4.4 to 1.2).

Exploratory analyses. Selected category-specific HRs ranged from 0.96 (95% CI 0.31–2.96) for PSA ≥ 10 ng/mL to 2.16 (0.8–5.85) for biopsy tissue involvement $\geq 5\%$; no treatment-by-subgroup interaction was significant (all p for interaction ≥ 0.16 ; Table S4). The two focal cT3a patients failed versus neither of the two prostatectomy cT3a patients; this subgroup was too small for a stable interaction estimate. Restricting analysis to the 138 pairs with biopsy tissue involvement available for both members produced a concordant but less precise estimate (HR 1.87, 95% CI 0.91–3.83; $p = 0.09$).

DISCUSSION

In 207 well-balanced pairs, focal therapy was associated with a higher risk of treatment failure than radical prostatectomy. However, FFS differed by only 2.7 percentage points at 3 years, and 79% of patients treated with focal therapy remained free from nonfocal treatment or metastasis at 5 years. The absolute 5-year difference was 9.1 percentage points, although with considerable uncertainty.

Direct comparative evidence remains limited. Shah et al. reported no significant 8-year FFS difference in 246 matched pairs, and van Son et al. found no significant 6-year difference after propensity weighting; more recent HIFU and cryoablation comparisons and a large functional comparison have added data but remain heterogeneous (6–10). Shah et al. matched on T stage and treatment year, while van Son et al. reported MRI in all patients and used T stage and treatment year, although T stage had to be simplified to T1 versus T2 because T2 subclassification was frequently missing. In our study, ISUP, MRI stage, and treatment period were matched exactly, while PI-RADS, continuous treatment year, positive-core percentage, PSA, age, prior active surveillance, and ASA class informed the propensity score. The cohort was mostly contemporary, with 99% of patients treated from 2017 onward and median treatment years of 2022 and 2021.

Randomized comparative evidence is also sparse. The PART trial established the feasibility of randomizing men between partial ablation and radical prostatectomy but was not powered to assess comparative effectiveness. Beyond that feasibility study, FARP is the only randomized comparative oncologic trial to have reported results, currently in abstract form (17, 18). The HIFI study provides large prospective comparative evidence, but it was nonrandomized and evaluated whole-gland or subtotal HIFU rather than a strictly focal strategy (19). The recent HEAT and ICE registry update adds 10-year single-arm data for focal HIFU and cryotherapy, with low risks of metastatic and prostate-cancer mortality but a meaningful burden of repeat or radical treatment over time (20). These studies reinforce the need to report treatment pathways, not only recurrence surrogates.

Our primary endpoint compared treatment strategies rather than biological recurrence or local tumor control alone. A second focal session remained within the organ-preserving strategy, whereas radical

treatment, radiotherapy or brachytherapy, systemic therapy, or metastasis represented failure. Conversely, every active postoperative treatment after prostatectomy was counted as escalation beyond surgery alone. This differs from Shah et al., whose primary analysis excluded early adjuvant radiotherapy, but whose secondary definition counted it, and from van Son et al., who treated selected postoperative radiotherapy as part of primary treatment (6, 7). Endpoint handling may therefore explain part of the difference between studies. This also means that surveillance intensity and thresholds for additional treatment may influence when failure is recorded, particularly through differences in MRI and biopsy use and clinician recommendations. In the present cohort, 20 patients underwent a second focal ablation and 21/207 (10%) underwent salvage radical prostatectomy as their first failure event. Salvage prostatectomy is feasible, but systematic-review data suggest less favorable functional outcomes than primary prostatectomy (21). Functional preservation remains central to focal-therapy counseling, and comparative data suggest advantages in erectile function and early recovery, although this study did not collect patient-reported function, toxicity, or quality of life (5, 8).

This study has several limitations. Treatment allocation was not randomized, so matching cannot remove confounding by unmeasured anatomy, tumor focality, lesion location, clinician experience, or patient preference. The estimand applies only to the 76% of eligible focal patients who were matchable; unmatched focal patients differed in age, prior surveillance, tumor burden, and MRI features. Kaplan-Meier and Cox methods accommodate unequal observed follow-up under noninformative censoring, but they cannot eliminate bias from differential surveillance, treatment thresholds, or informative censoring. Late risk sets were sparse, and the composite endpoint joins events of unequal clinical severity. Strengths include exact control of grade, MRI stage, and treatment era, balance in every prespecified matching covariate, distributional diagnostics, and adequate sensitivity analyses.

CONCLUSIONS

Focal cryotherapy or IRE was associated with a higher rate of failure than radical prostatectomy in the primary analysis. Nevertheless, approximately four in five focal-therapy patients remained free of radical treatment or metastasis at 5 years. Focal therapy may therefore remain an option for selected patients seeking organ preservation, while accepting a greater chance of additional treatment over time. Longer prospective studies with standardized outcomes and functional assessment are needed.

DECLARATIONS

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Competing Interests: Juan Luis Casanova Ramón-Borja has served as a proctor for Fujifilm and Boston Scientific. José Luis Domínguez Escrig has received honoraria from AngioDynamics. The remaining authors have no relevant financial or non-financial interests to disclose.

Author contributions: Pedro de Pablos-Rodríguez had full access to the study data and takes responsibility for data integrity. Víctor Rodríguez Part performed the statistical analysis and takes responsibility for its accuracy. Study conception and design: Raimundo Domínguez Argomedo, Pedro de Pablos-Rodríguez, José Luis Domínguez Escrig, Argimiro Collado Serra, Juan Luis Casanova Ramón-Borja, and Álvaro Gómez-Ferrer Lozano. Drafting: Raimundo Domínguez Argomedo and Pedro de Pablos-Rodríguez. Statistical analysis, review, and validation: Víctor Rodríguez Part. Data curation and investigation: Raimundo Domínguez Argomedo, Manel Beamud Cortés, Ángel García Cortés, José Agustín López González, Augusto Wong Gutiérrez, Cristina Gutiérrez Castañé, Juan Colombas Vives, and Javier Hernández Falcón. Critical revision: all authors. Supervision: Pedro de Pablos-Rodríguez, José Luis Domínguez Escrig, Argimiro Collado Serra, Juan Luis Casanova Ramón-Borja, and Álvaro Gómez-Ferrer Lozano.

Ethics Approval: The institutional database was approved by the Ethics Committee of Fundación Instituto Valenciano de Oncología under code CAPROSIVO. The study complied with the Declaration of Helsinki.

Data availability: Deidentified data may be available from the corresponding author upon reasonable request, subject to institutional and ethics approvals.

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Figures

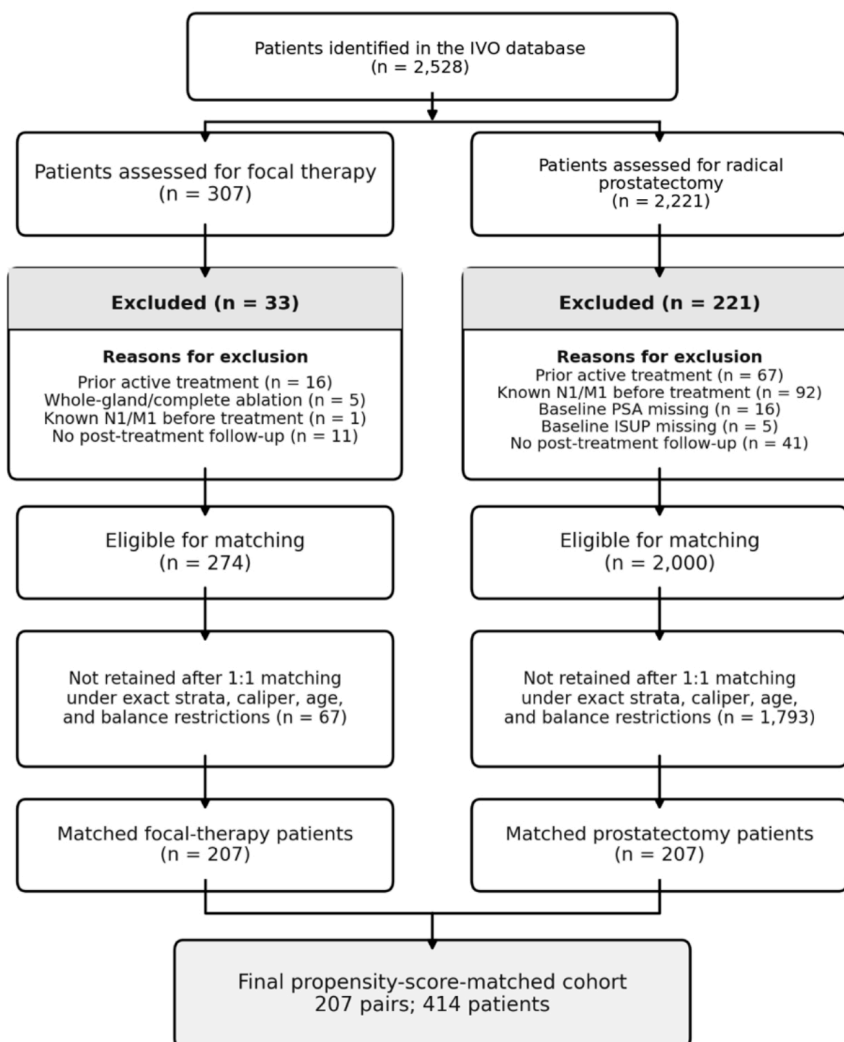


Figure 1

Patient flow diagram. Hierarchical, mutually exclusive exclusions are shown for the focal-ablation and radical-prostatectomy pathways. ISUP, International Society of Urological Pathology; PSA, prostate-specific antigen.

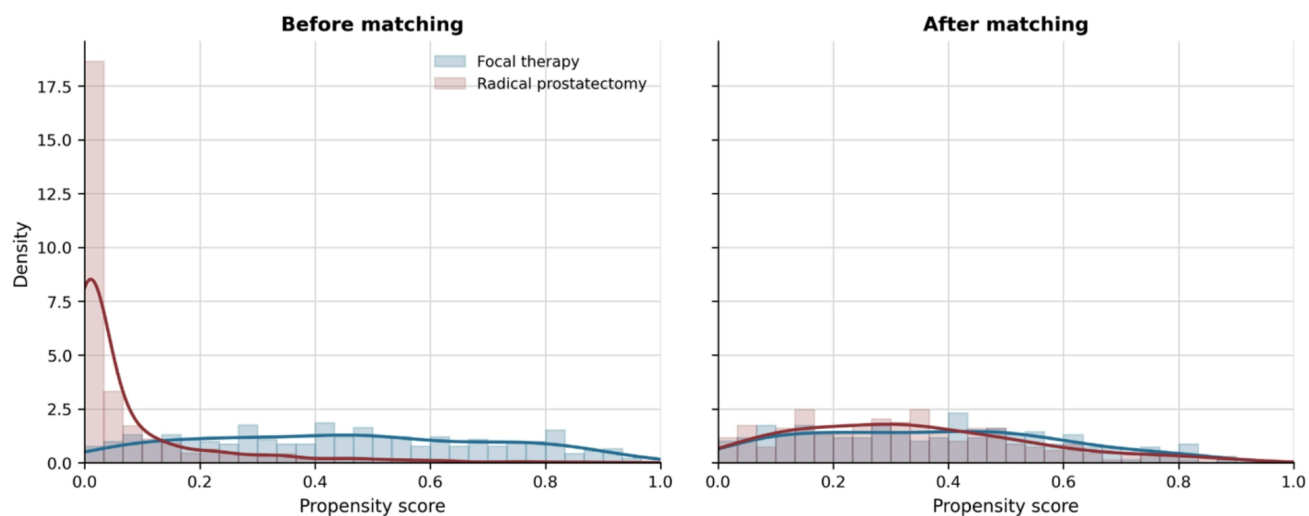


Figure 2

Propensity-score distributions before and after matching. Histograms and kernel-density curves show the propensity-score distributions for focal therapy and radical prostatectomy in the eligible and matched cohorts.

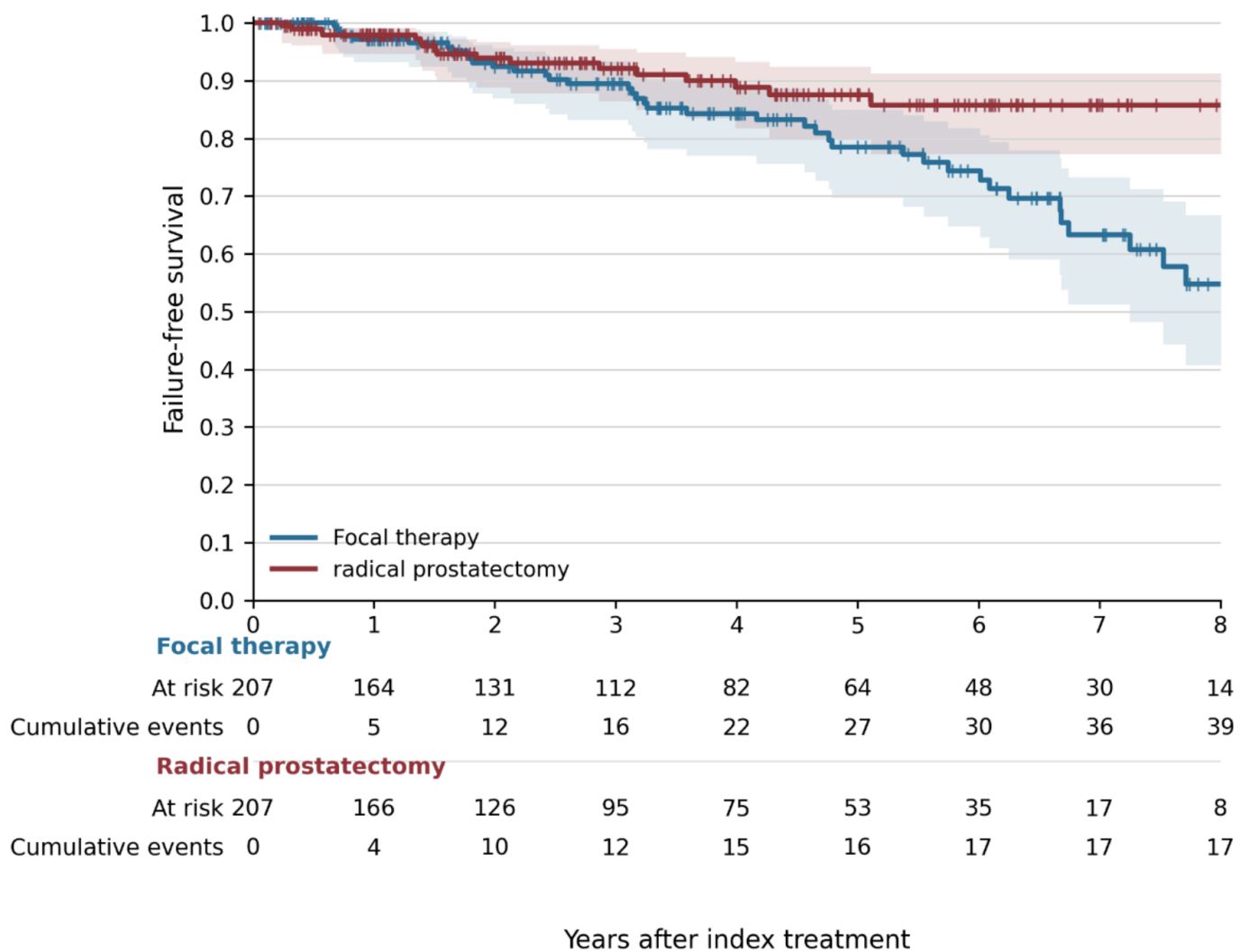


Figure 3

Kaplan-Meier failure-free survival after focal therapy and radical prostatectomy.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SupplementaryMaterialFocalvsRadicalProstatectomy.docx](#)