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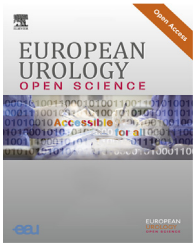

Prostate Cancer

Patient-reported Satisfaction and Regret Following Focal Therapy for Prostate Cancer: A Prospective Multicenter Evaluation

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Abstract

Background: Several reports are available regarding the treatment decision regret of patients receiving conventional treatments for localized prostate cancer (PCa); yet data on patients undergoing focal therapy (FT) are sparse.
Objective: To evaluate the treatment decision satisfaction and regret among patients who underwent FT for PCa with high-intensity focused ultrasound (HIFU) or cryoablation (CRYO).
Design, setting, and participants: We identified consecutive patients who underwent HIFU or CRYO FT as the primary treatment for localized PCa at three US institutions. A survey with validated questionnaires, including the five-question Decision Regret Scale (DRS), International Prostate Symptom Score (IPSS), and International Index of Erectile Function (IIEF-5), was mailed to the patients. The regret score was calculated based on the five items of the DRS, and regret was defined as a DRS score of >25.
Outcome measurements and statistical analysis: Multivariable logistic regression models were applied to assess the predictors of treatment decision regret.
Results and limitations: Of 236 patients, 143 (61%) responded to the survey. Baseline characteristics were similar between responders and nonresponders. During a median (interquartile range) follow-up of 43 (26–68) mo, the treatment decision regret rate was 19.6%. On a multivariable analysis, higher prostate-specific antigen (PSA) at nadir after FT (odds ratio [OR] 1.48, 95% confidence interval [CI] 1.1–2, p = 0.009), presence of PCa on follow-up biopsy (OR 3.98, 95% CI 1.5–10.6, p = 0.006), higher post-FT IPSS (OR 1.18, 95% CI 1.01–1.37, p = 0.03), and newly diagnosed impotence (OR 6.67, 95% CI 1.57–27, p = 0.03) were independent predictors of treatment regret. The type of energy treatment (HIFU/CRYO) was not a predictor of regret/satisfaction. Limitations include retrospective abstraction.

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Conclusions: FT for localized PCa is well accepted by the patients, with a low regret rate. Higher PSA at nadir, presence of cancer on follow-up biopsy, bothersome post-operative urinary symptoms, and impotence after FT were independent predictors of treatment decision regret.

Patient summary: In this report, we looked at the factors affecting satisfaction and regret in patients with prostate cancer undergoing focal therapy. We found that focal therapy is well accepted by the patients, while presence of cancer on follow-up biopsy as well as bothersome urinary symptoms and sexual dysfunction can predict treatment decision regret.

1. Introduction

Several management options are available for patients with localized prostate cancer (PCa), providing acceptable oncological outcomes, yet with significant treatment-related side effects [1–4]. Focal therapy (FT) has emerged as an alternative option with the goal of improving quality of life without compromising cancer control [5,6].

Counseling of patients to select a management strategy for localized PCa should incorporate shared decision-making. Several variables should be considered during this process, including cancer severity, patient preference, and life expectancy, as well as pretreatment status performance and genitourinary symptoms [1]. Expected post-treatment functional status and patient-reported outcomes following each management modality can also be helpful in selecting the most appropriate management strategy [7].

Several reports are available regarding the treatment decision regret of patients receiving conventional treatments (radical treatments and active surveillance [AS]) for localized PCa [8–10]. A systematic review showed that up to 25% of patients may experience regret following their treatment; the most common factors associated with regret were treatment toxicity, particularly sexual and urinary dysfunction [10]. However, data on patients who underwent FT are sparse and limited to single institution, single treatment modality, and small sample size studies [11,12].

Among patients undergoing FT, high-intensity focused ultrasound (HIFU) and cryoablation (CRYO) are associated with similar oncological and functional outcomes [13]. We have previously reported our experience with CRYO and HIFU FT for PCa [14,15]. Herein, we evaluate treatment satisfaction and regret, as well as factors contributing to patient-reported outcomes on those who underwent FT for localized PCa.

2. Patients and methods

2.1. Study population

Consecutive patients who underwent HIFU or CRYO FT (hemigland ablation) as the primary treatment for localized PCa between January 2010 and February 2020 at three US facilities were identified. After obtaining institutional review board approval (IRB# HS-17-00749), the patients' deidentified data were merged retrospectively. Patients undergoing three-quarters, subtotal, or whole-gland ablation as the primary treatment for PCa or any salvage HIFU or CRYO were excluded.

2.2. Survey questionnaires

A survey with validated questionnaires was mailed to all patients who met the inclusion and exclusion criteria between February and December 2020, including the (1) Decision Regret Scale (DRS), (2) International Index of Erectile Function (IIEF-5), and (3) International Prostate Symptom Score (IPSS). According to the protocol, the survey was resent to nonresponders 6 wk after the first attempt. If the patients did not respond to either survey, it was assumed that they did not want to participate. There was no incentive to respond to the survey.

All study procedures were carried out in accordance with the ethical standards of the institutional and/or national research committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all participants.

2.3. Patient selection, FT, and follow-up

Patients were selected for FT after being diagnosed with localized PCa by systematic and targeted biopsy of suspicious areas on multiparametric magnetic resonance imaging (mpMRI), as described elsewhere [14,15]. Patients with unfavorable intermediate- or high-risk PCa underwent metastatic workup as recommended by the current guidelines.

HIFU or CRYO FT was performed at the discretion of the patients and physicians, according to expertise and availability. FT was performed as hemigland ablation of the prostatic lobe harboring the unilateral index lesion, as described previously [14,15]. HIFU was performed transrectally, according to the standards recommended by the manufacturer, as described previously [14]. Hemigland CRYO was performed as two freeze-thaw cycles using a freehand technique under transrectal ultrasound (TRUS) guidance, as described elsewhere [15].

Patients were followed up every 3 mo in the 1st year and every 6 mo thereafter, assessing symptoms, validated questionnaires, and serum prostate-specific antigen (PSA) levels. Digital rectal examination (DRE) was performed at 3 mo, at the time of follow-up biopsy (6–12 mo), and annually thereafter. TRUS and mpMRI were recommended at 6–12 mo and annually thereafter. Follow-up biopsy was strongly recommended for all patients at 6–12 mo per protocol, or at any time if clinically indicated, such as biochemical failure, rising PSA, or suspicious PCa recurrence on DRE, mpMRI, or TRUS. Follow-up biopsies were performed using a technique similar to that used for diagnostic biopsies (systematic and image-targeted biopsies of suspicious areas) [14,15].

2.4. Decision Regret Scale

The DRS, an open-access validated questionnaire, was used to evaluate regret/satisfaction following FT. The regret score was calculated based on five items of the DRS (Supplementary material). Agreement with each item was measured on a five-point scale (1 = strongly agree to

5 = strongly disagree). The score of each item was converted to a 0–100 scale (items 2 and 4 were reversely coded). The final score was the average of items 1–5 [16,17].

2.5. Endpoint and outcome measurements

The primary endpoint of this study was treatment regret/satisfaction following FT. Regret was defined as a DRS score of >25, as described previously [9,18]. Baseline characteristics and functional and oncological outcomes were assessed to identify the predictors of regret/satisfaction. Patients who were impotent or incontinent prior to FT, as well as those who underwent radical treatment prior to the survey, were censored and not considered for impotency or incontinence during follow-up. Similarly, biochemical failure was considered up to repeated FT or radical treatment.

Potency and continence were defined as an IIEF-5 score of $\geq$18 and no pad usage, respectively. Oncological outcomes were defined as follows: (1) biochemical failure: PSA nadir + 2 ng/ml (Phoenix criteria); (2) clinically significant PCa (CSPCa): grade group $\geq$2 on follow-up biopsies; (3) repeat FT: HIFU or CRYO partial gland ablation retreatment on follow-up; (4) radical treatment and any radical/whole gland treatment, including ablation, radiation, or surgery; and (5) treatment failure: CSPCa on follow-up biopsies, any whole-gland treatment (radiotherapy [RT] criteria), initiation of systemic therapy, metastases, or PCa-specific mortality [14,15]. PCa was graded according to the International Society of Urological Pathology standards.

2.6. Statistical analysis

Demographic and clinical features were analyzed using the chi-square and Wilcoxon tests for categorical and continuous variables, respectively. Univariate and multivariable logistic regression analyses were performed to assess the baseline and post-FT predictors of treatment decision regret. The statistical software package SAS (version 9.4; SAS Institute Inc., Cary, NC, USA) was used for all analyses. All p values reported were two sided, and $p < 0.05$ was considered statistically significant.

3. Results

A total of 236 patients met the inclusion criteria and were included in this study, of whom 143 (61%) responded to the survey. Baseline characteristics were similar between responders and nonresponders, except for the clinical stage, which was higher in responders (Table 1). Demographic data of patients who responded to the survey included a median age of 66 yr (interquartile range [IQR] 62–72), median PSA of 6 ng/ml (IQR 4.6–7.9), and median PSA density of 0.16 ng/ml^2 (IQR 0.11–0.24).

The median (IQR) follow-up time was 43 (26–68) mo. The median (IQR) IPSS values before and after FT were 7 (3–13) and 7 (3–11), respectively. All patients were continent before FT; only one patient (0.7%) developed urinary incontinence postoperatively. Overall, 33% of the patients reported impotence, including 11% with mild (IIEF-5 12–16), 3% with moderate (IIEF-5 8–11), and 19% with severe (IIEF $\leq$7) erectile dysfunction.

The median time to PSA nadir was 6.4 mo, and the median PSA level at nadir was 1.02 ng/ml, corresponding to a 79.5% PSA reduction from before to after FT. Overall, PCa and CSPCa were found in 24% and 18% of patients, respectively, on follow-up biopsy. At 3 yr, 84% of patients were biochemical failure free, 87% CSPCa free, 98% repeat FT free, 93% radical treatment free, and 83% treatment failure free (Table 2).

The overall treatment regret rate was 19.6%. Figure 1 shows the patients' responses to each DRS question. More than 80% of the patients self-reported that FT was the right decision, and that in hindsight, they would opt for the same choice. On the multivariable analysis, higher PSA at nadir after FT (odds ratio [OR] 1.48, 95% confidence interval [CI] 1.1–2, p = 0.009), presence of any PCa on follow-up biopsy (OR 3.98, 95% CI 1.5–10.6, p = 0.006), higher IPSS after FT (OR 1.18, 95% CI 1.01–1.37, p = 0.03), and newly diagnosed impotence (OR 6.67, 95% CI 1.57–27, p = 0.03) were independent predictors of treatment decision regret (Table 3). Baseline patient characteristics, operating center, duration of follow-up after FT, and the type of energy treatment modality were not predictors of regret/satisfaction.

4. Discussion

To our knowledge, this is the first multicenter study with a larger number of patients and longer follow-up to evaluate treatment decision satisfaction and regret after FT for localized PCa. We reported that FT was associated with a low treatment decision regret. Both functional treatment toxicities, such as postoperative impotence and higher IPSS, and oncological outcomes, such as higher PSA at nadir and presence of cancer on the follow-up biopsy, were independent predictors of treatment decision regret.

Patient-reported outcome is one of the most important factors contributing to the optimal treatment selection for localized PCa. Given that treatment modalities differ in terms of oncological and functional outcomes, regret/satisfaction rates may vary among these options. In a study of long-term survivors 15 yr after local therapy, Hoffman et al [8] reported an overall regret rate of 14.6%, with 16.6% expressing regret after external-beam RT or brachytherapy, 15% after radical prostatectomy (RP), and 8.2% after AS. Similar trends were demonstrated in a recent study reporting an overall regret rate of 23% after 12 mo of follow-up after treatment for localized PCa. The highest treatment regret rate was reported in patients undergoing external-beam RT (37%), followed by RP (23%), AS (20%), and brachytherapy (18%). Nevertheless, there was no statistically significant difference between these treatment modalities [9]. In a systematic review of 28 articles assessing treatment outcomes of patients with localized PCa, regret rates varied between 0.5% and 31% for RP, 9.2% and 24% for external-beam RT, and 0% and 24% for brachytherapy [10]. However, it is hard to compare these studies appropriately and make a robust conclusion given the heterogeneity of the scales used for the evaluation of regret as well duration of follow-up. Several studies used DRS as their scale and, similarly to our study, some used a DRS score of >25 as a definition of regret [9,12,18–21]. Others employed Clark et al's [22] two-item questionnaire or original scales [10]. Among those that used the DRS, the regret rates ranged between 9.2 and 12.7 for external-beam RT and 12 and 24 for RP [10].

Table 1 – Baseline features of patients undergoing focal therapy for prostate cancer, stratified by survey response status

Variables	All patients	Responders	Nonresponders	*p* value
No. of patients	236	143	93	–
Age (yr), median (IQR)	66 (61–72)	66 (62–72)	66 (59–72)	0.49
PSA (ng/ml), median (IQR)	6.1 (4.6–8)	6 (4.6–7.9)	6.5 (4.6–8)	0.3
PSA density (ng/ml^2), median (IQR)	0.16 (0.11–0.24)	0.16 (0.11–0.24)	0.16 (0.1–0.24)	0.49
Clinical stage, *n* (%)				
T1c	168 (71.2)	92 (64.3)	76 (81.7)	0.005
T2a-c	62 (26.3)	45 (31.5)	17 (18.3)	
T3a-b	6 (2.5)	6 (4.2)	0 (0)	
ISUP grade group, *n* (%)				
1	50 (21.2)	30 (20.1)	20 (21.5)	0.36
2	123 (52.1)	79 (55.2)	44 (47.3)	
3	49 (20.8)	28 (19.6)	21 (22.6)	
4	13 (5.5)	5 (3.5)	8 (8.6)	
NCCN risk group, *n* (%)				
Very low and low	44 (18.6)	25 (17.5)	19 (20.4)	0.38
Intermediate	175 (74.2)	110 (76.9)	65 (69.9)	
High	17 (7.2)	8 (5.6)	9 (9.7)	
IIEF-5 score, median (IQR)	21 (15–24)	22 (15–25)	20 (15–24)	0.45
IPSS, median (IQR)	7 (3–13)	7 (3–13)	6.5 (3–14.5)	0.9

IIEF-5 = International Index of Erectile Function; IPSS = International Prostate Symptom Score; IQR = interquartile range; ISUP = International Society of Urological Pathology; NCCN = National Comprehensive Cancer Network; PSA = prostate-specific antigen.

Table 2 – Oncological outcomes after focal therapy for prostate cancer

Variables	Value
No. patients	143
Follow-up (mo), median (IQR)	43 (26–67.5)
PSA nadir (ng/ml), median (IQR)	1.03 (0.43–2.17)
Time to PSA nadir (mo), median (IQR)	6.4 (3.3–12.3)
Percent of PSA decreased, median (IQR) [a]	79.5 (54.2–89.4)
3-yr free survival (%)	
Biochemical failure [b]	84
Clinically significant prostate cancer [c]	87
Repeat focal therapy	98
Radical treatment [d]	93
Failure [e]	83

IQR = interquartile range; PCa = prostate cancer; PSA = prostate-specific antigen.

[a] Percent of PSA decreased at nadir = (PSA at entry – PSA nadir)/(PSA at entry × 100%).

[b] Phoenix criteria (PSA nadir + 2 ng/ml).

[c] Prostate cancer grade group ≥2 on follow-up biopsy.

[d] Radical treatment was defined as any whole-gland treatment.

[e] Failure was defined as grade group ≥2 PCa on follow-up biopsy, any whole-gland treatment, initiation of systemic therapy, metastases, or prostate cancer–specific mortality.

Treatment decision regret following FT for PCa has sparsely been reported. Westhoff et al [11] recently reported treatment decision regret among 52 patients who received focal HIFU for low- to intermediate-risk PCa. They used Clark et al's [22] validated scale and showed a treatment decision regret rate of 20.8% with a median follow-up of 38 mo. This was a single-institution study that evaluated a single FT modality. In another study, Flegar et al [12] evaluated 31 patients with localized PCa who underwent FT with vascular-targeted photodynamic therapy. In this single-center study, DRS was used to assess regret/satisfaction 12 mo after the treatment. Using a DRS score of >25 as a definition, 9.7% of the patients reported a clinically significant level of decision regret. Of note, patients undergoing photodynamic therapy had low, not intermediate, risk PCa and underwent short-term follow-up [12]. The treatment regret rate of 19.7%, with a median follow-up of 43 mo, is comparable with conventional treatments as well as the aforementioned studies on FT. Our study is the first study in the literature that assesses treatment regret in patients treated with CRYO, one of the most commonly used FT treatment modalities to date [23]. On the regression analysis, the type of energy used (HIFU/CRYO) for treatment was not an independent factor affecting regret following FT.

The evaluation of factors affecting treatment regret is of utmost importance, given that addressing these factors can increase patient satisfaction. Both the functional and the oncological outcomes have been shown to be contributing factors. A prospective multicenter study among patients undergoing conventional treatments for localized PCa revealed that more hormonal/masculinity-related symptoms, positive surgical margins after surgery, and lower educational level were the independent predictors of treatment regret at 12 mo of follow-up [9]. Other studies also showed additional factors, such as African American race, older age, postoperative bowel dysfunction, and longer time since treatment, as independent predictors of treatment regret [21,24,25]. In a systematic review of studies reporting treatment satisfaction/regret in patients with localized PCa, the most common factors associated with regret were sexual and urinary dysfunction [10]. In the study of patients undergoing focal HIFU, cancer recurrence (OR 12.31) and general health worry (OR 1.07) were independent predictors of treatment regret [11]. Similarly, we found postoperative impotence and a higher IPSS (ie, urinary dysfunction), as well as higher nadir PSA and PCa on the follow-up biopsy as independent predictors of treatment decision regret. In our study, sexual dysfunction was the strongest factor affecting treatment regret (OR 6.67) following FT. It is worth mentioning that a very strict definition of impotence was used in our study (ie, IIEF-5 <18), which may overestimate the rate of erectile dysfunction. In addition, other factors, including underlying comorbidities and the long-term interval between FT and erectile evaluation, may have affected our findings [26].

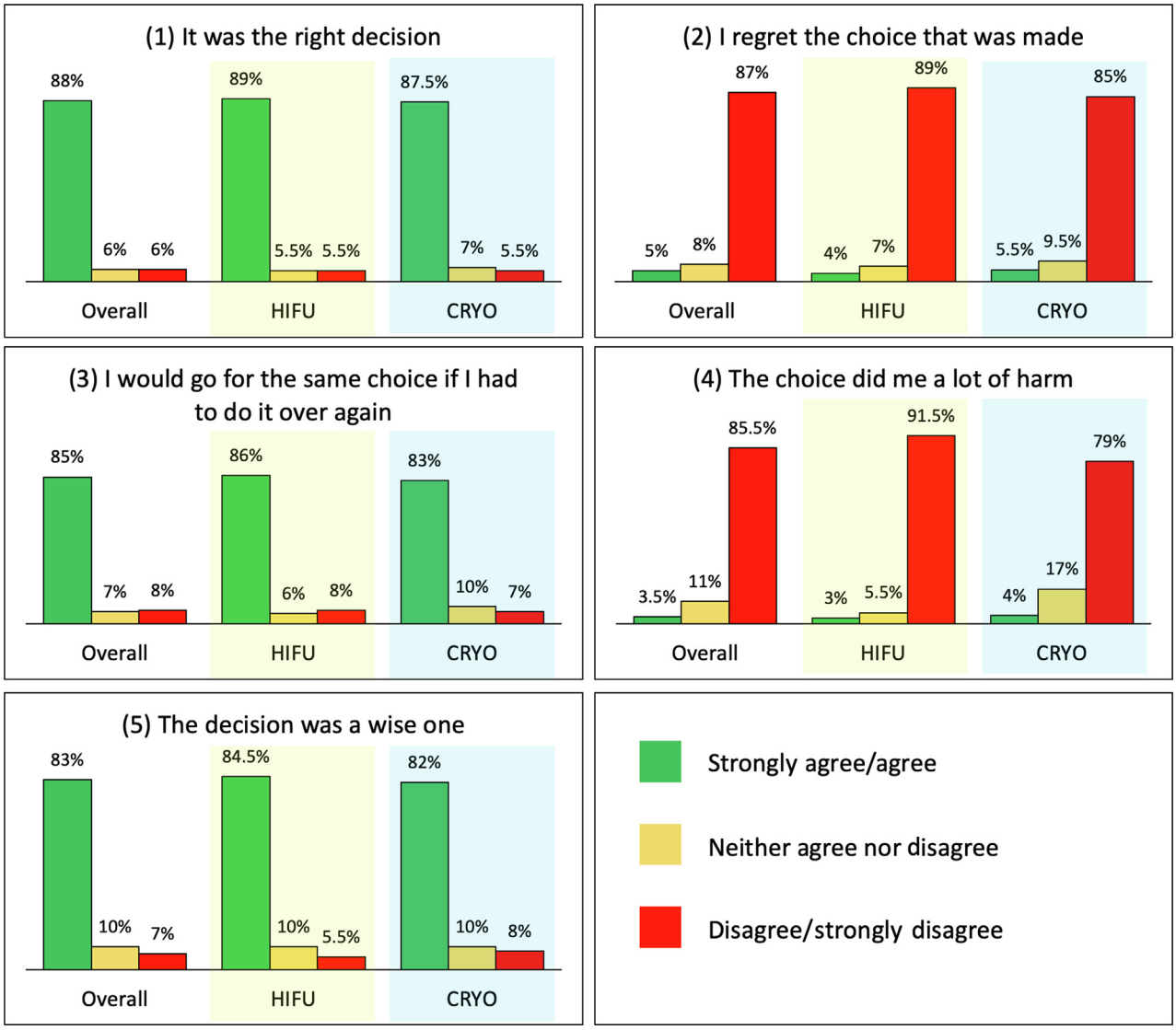

Fig. 1 – Patients' response to each question of the Decision Regret Scale. CRYO = cryoablation; HIFU = high-intensity focused ultrasound.

Consideration of all the aforementioned factors is important in the preoperative counseling of patients with localized PCa. Two randomized controlled trials showed that patients with localized PCa who were randomized to receive personalized decision support showed significantly decreased regret compared with those who received usual care prior to a final treatment decision [27,28]. Given the negative impact of impotence and urinary dysfunction on patient satisfaction following PCa treatment, patients should be informed about the rate of these toxicities following each treatment modality. Previous studies from our group showed that these toxicities were significantly lower with FT than with conventional modalities (ie, radiation and RP) [13–15]. Patients should also understand that there is no consensus on the oncological endpoints following FT, particularly the optimal postoperative PSA, as there is prostatic tissue preservation. As such, higher postoperative PSA alone, without other recurrence findings such as CSPCa on biopsy or the need for radical treatment, should not concern the patients or affect their quality of life.

Our study has several limitations. Although the questionnaires were prospectively sent and collected, the patient characteristics and outcomes were retrospectively recorded. The response rate in our study was 61%. However, this was a volunteer study with no incentive for participation, and this response rate is comparable with that in prior studies [8]. Additionally, baseline characteristics of responders and nonresponders were similar. However, the treatment regret may have been overestimated in our study given the fact that unhappy patients would be more inclined to reply. Other variables, such as comorbidities, socioeconomic status, and race/ethnicity, may affect decision satisfaction/regret and were not recorded in this study—an additional factor to consider when interpreting findings of this study.

The strengths of our study include the larger and multicenter patient cohort as well as the prospective study design using validated questionnaires. Additionally, this is the first report on treatment/satisfaction regret in patients undergoing both HIFU and CRYO FT. Therefore, the outcomes herein reported could be generalizable. Additionally,

Table 3 – Univariate and multivariable analyses to predict regret after focal therapy for prostate cancer

Variables	Univariate		Multivariable	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Before focal therapy				
Age	0.98 (0.93–1.04)	0.55		
PSA	0.98 (0.85–1.11)	0.77		
Prostate volume	1.02 (0.998–1.038)	0.07		
PSA density	0.09 (0–2.62)	0.26		
ISUP GG ≥2 vs GG 1	0.62 (0.25–1.67)	0.33		
cT stage ≥cT2 vs cT1c	1.76 (0.75–4.07)	0.19		
NCCN risk				
Intermediate vs low/very low	0.94 (0.34–3.09)	0.71		
High vs low/very low	1.33 (0.16–8.18)	0.71		
IPSS	1.02 (0.94–1.09)	0.67		
IIEF-5	1.08 (1.01–1.18)	0.05		
Operating center				
Center 1 vs 3 (ref)	1.31 (0.43–4.27)	0.85		
Center 2 vs 3 (ref)	2.05 (0.73–6.38)	0.18		
After focal therapy				
PSA nadir	1.11 (1.48–1.97)	0.007	1.48 (1.10–1.99)	0.009
PSA decreased %	0.98 (0.97–0.99)	0.007		
Biochemical failure—Phoenix criteria	1.80 (0.59–5.03)	0.27		
PCa on follow-up biopsy	2.93 (1.21–7.07)	0.02	3.98 (1.50–10.56)	0.006
Clinically significant PCa [a]	2.11 (0.78–5.43)	0.13		
Repeat focal therapy	NA [b]	–		
Radical treatment [c]	4 (0.74–31.70)	0.13		
Treatment failure [d]	3.17 (1.30–7.67)	0.01		
IPSS	1.10 (1.03–1.17)	0.003	1.18 (1.01–1.37)	0.03
IIEF-5	0.96 (0.92–1.01)	0.18		
Impotent vs potent	7.14 (1.96–33.30)	0.004	6.54 (1.57–27)	0.01
Continent vs incontinent	NA [b]	–		
CRYO vs HIFU	1.69 (0.71–4.01)	0.22		
Follow-up duration	0.97 (0.82–1.03)	0.65		

CI = confidence interval; CRYO = cryoablation; GG = grade group; HIFU = high-intensity focused ultrasound; PCa = prostate cancer; NCCN = National Comprehensive Cancer Network; IIEF-5 = International Index of Erectile Function; IPSS = International Prostate Symptom Score; ISUP = International Society of Pathological Urology; NA = not available; OR = odds ratio; PSA = prostate-specific antigen.

[a] Prostate cancer Grade Group ≥2 on follow up biopsy.

[b] The number of outcomes is too low for an accurate analysis.

[c] Radical treatment was defined as any whole-gland treatment.

[d] Failure was defined as grade group ≥2 PCa on follow-up biopsy, any whole-gland treatment, initiation of systemic therapy, metastases, or PCa-specific mortality.

we provided an overall longer follow-up than reported in similar studies in the literature.

5. Conclusions

FT for localized PCa is well accepted by patients, with a low regret rate. Independent predictors of treatment decision regret following FT included higher PSA at nadir, presence of cancer on follow-up biopsy, bothersome postoperative urinary symptoms, and newly diagnosed impotence.

***Author contributions*:** Andre Luis Abreu had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Ghoreifi, Kaneko, Abreu.
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Drafting of the manuscript: Ghoreifi, Sugano.
Critical revision of the manuscript for important intellectual content: Peretsman, Cacciamani, Park, Lebastchi, Ukimura, Bahn, Gill.
Statistical analysis: Cai.
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Supervision: Abreu.
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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2023.02.003.

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