Prostate International 12 (2024) 213–218

Contents lists available at ScienceDirect

Prostate International

journal homepage: https://www.journals.elsevier.com/prostate-international

Research Article

Whole gland versus partial gland ablation in patients with localized prostate cancer treated by high-intensity focused ultrasound ablation

Hae Sung Lee [a], Sang Hun Song [a], Hakmin Lee [a, *], Sung Kyu Hong [a, b, **]

[a] Department of Urology, Seoul National University Bundang Hospital, Seongnam, Korea
[b] Department of Urology, Seoul National University College of Medicine, Seoul, Korea

ARTICLE INFO

Article history:
Received 30 May 2024
Received in revised form
14 July 2024
Accepted 2 September 2024
Available online 5 September 2024

Keywords:
High-intensity focused ultrasound ablation
Partial gland ablation
Whole gland ablation

ABSTRACT

Background: Focal therapy is considered one of the treatment options for localized prostate cancer (PCa), particularly for low or very-low-risk patients. In this study, we compared the mid-term oncological outcomes in localized PCa patients treated with high-intensity focused ultrasound (HIFU).
Methods: We retrospectively analyzed 237 patients who underwent HIFU for localized PCa. Patients were divided into two groups based on ablation type: whole gland ablation (WGA) and partial gland ablation (PGA). Follow-up biopsies were performed after one year postoperatively, and the oncological outcomes were compared between the groups.
Results: Among the total of 237 patients, 54 subjects were treated by WGA and 183 subjects by PGA. After one year postoperatively, follow-up biopsies were conducted on 199 patients, revealing residual cancer in 21.4% of WGA group and 15.3% of PGA group. Additionally, clinically significant (CS) cancer was observed in 14.3% of WGA group and 8.3% of PGA group. Survival analyses revealed significantly longer failure-free ($P < 0.001$) and salvage-free survival ($P < 0.001$) in WGA group than in PGA group. Similarly, in the intermediate—high risk group, WGA group exhibited longer failure-free ($P = 0.005$) and salvage-free survival ($P < 0.001$).
Conclusion: HIFU was performed with acceptable oncological outcomes in localized PCa. Despite higher proportion of high-risk patients in WGA group, WGA was associated with significantly better failure-free survival and salvage-free survival. Further prospective and multi-center studies are warranted.

1. Introduction

Prostate cancer (PCa) is the most common malignancy among men in the United States. It has been projected that, in 2023, around 288,300 individuals received a PCa diagnosis in the United States, with approximately 34,700 deaths attributed to the disease.[1] In 2018, there were an estimated 1,276,106 new cases of PCa reported around the world, resulting in approximately 358,989 deaths.[2] Moreover, the rate of new cases of PCa in the United States increased by 3% annually between 2014 and 2019.[3]

Active surveillance (AS) is one treatment option for patients with low- and very-low-risk PCa.[4,5] However, leaving cancer untreated can cause anxiety for many patients, which may therefore necessitate further treatment.[6,7]

Advancements in more precise diagnostic techniques, like multi-parametric magnetic resonance imaging (mpMRI), have led to improved risk assessment by enabling precise locating of the primary lesion of the highest grade, known as the index lesion.[8,9] Delivering targeted treatment specifically to the index lesion has emerged as a promising approach that can minimize unnecessary harm while maintaining effective cancer control.[10,11]

Several methods have been developed and employed for the treatment of localized PCa, including cryoablation, laser ablation, brachytherapy, and high-intensity focused ultrasound (HIFU).[12] However, there are inherent challenges involved in introducing focal or partial gland treatments, which are largely attributable to the multifocal nature of PCa. Thus, patients are monitored regularly through the form of AS after HIFU.[13,14]

To this point, there have been few studies reporting on the oncological and functional outcomes of HIFU. Moreover, there have only been a few studies comparing whole gland ablation (WGA) and partial gland ablation (PGA). In the current study, we compared

* Corresponding author. Department of Urology, Seoul National University Bundang Hospital, 300, Gumi-dong, Bundang-gu, Seongnam-si, Kyunggi-do 463-707, Korea.
** Corresponding author. Department of Urology, Seoul National University Bundang Hospital, 300, Gumi-dong, Bundang-gu, Seongnam-si, Kyunggi-do 463-707, Korea.
E-mail addresses: 65828@snubh.org (H. Lee), skhong@snubh.org (S.K. Hong).

https://doi.org/10.1016/j.prnil.2024.09.001

the postoperative outcomes and perioperative adverse effects associated with HIFU treatment while stratifying our sample by ablation type and risk group.

2. Materials and methods

Our study was approved by the Institutional Review Board at Seoul National University Bundang Hospital. We performed a retrospective analysis of data from 237 patients who had been diagnosed with localized PCa and subsequently treated with HIFU at Seoul National University Bundang Hospital between 2018 and 2022. Due to the retrospective nature of the study and the minimal risk posed to subjects, the requirement of informed consent was waived. Clinical and pathologic data were extracted from our prospective maintained database. All the patients had been diagnosed through a 12-core trans-rectal biopsy combined with targeted biopsy with mpMRI. The exclusion criteria for HIFU were evidence of metastatic or lymph node involvement on imaging, biopsy-proven extraprostatic extension of cancer, any contraindications for MRI or anesthesia, and prior rectal surgery that prevents the insertion of a transrectal probe. The inclusion criteria for PGA were the same as we have used in our previous studies: clinically unilateral disease in both biopsy and imaging, prostate-specific antigen (PSA) $\leq$ 10 ng/dl, $\leq$4 positive cores, maximal tumor involvement of each biopsy core $\leq$10 mm, Gleason grade $\leq$7 (4 + 3), and tumor located 5 mm or more away from apex.

2.1. HIFU procedure

The patient was placed in the lithotomy position under general anesthesia. Trans-urethral prostatectomy (TURP) was performed in a bipolar manner while a three-way Foley catheter was indwelled with continuous irrigation using cool normal saline fluid. The patient's position was then altered to the right decubitus position, at which point the HIFU probe was inserted into anus. The HIFU procedure was conducted using the Focal One device (Edaps TMS, France). Prostatic apex (5 mm from urethra) was typically preserved to ensure post-operative urinary function. Patients were discharged one day postoperative after the removal of the intravesical catheter.

After surgery, patients underwent regular follow-ups at intervals that ranged from three to six months during the initial two years and which—in the absence of recurrence—took place annually thereafter. At the six-month postoperative visit, diagnostic cystoscopy was performed to assess the postoperative status of the prostatic urethra. Postoperative mpMRI was performed at six months and yearly thereafter. A follow-up prostatic biopsy of a further 6 to 12 cores was performed to identify remnant disease at postoperative one year to identify residual disease one year after surgery.

2.2. Statistical analysis

Kaplan-Meier analysis was used to examine recurrence-free, failure-free, and salvage-free survival outcomes. Biochemical recurrence (BCR) after HIFU was defined as a PSA elevation of more than 2.0 ng/dL from nadir. Recurrence includes positive findings in follow-up biopsy results and BCR. We offered several treatment options, such as AS, 2nd HIFU, observation, androgen deprivation therapy (ADT), radical prostatectomy (RP), and radiation therapy (RT), for patients experiencing recurrence. Treatment decisions after recurrence were made following counseling in the outpatient clinic, and they were based on considerations of clinical features such as PSA levels, initial biopsy results, follow-up biopsy results, mpMRI findings, and other patient characteristics. Typically, for patients with a Gleason score of $\geq$7 (3 + 4) on biopsy, we recommend radical treatments such as RP or RT initially. Conversely, for patients with a Gleason score of 6 (3 + 3) on biopsy, we generally advise AS and 2nd HIFU as the initial approach. Salvage treatment involves administering additional treatment to patients who experience recurrence, such as 2nd HIFU, ADT, RP, or RT. Treatment failure is defined by the development of metastases detected in imaging studies, cancer-specific death, or patients who proceed to be administered radical treatments.

Survival rates were stratified based on ablation type and the D'Amico risk classification system. All statistical analyses were performed using SPSS software (SPSS 22.0, Chicago, IL, USA), with all *P*-values presented as two-sided, and significance set at $P < 0.05$.

3. Results

The clinical characteristics of the study sample are presented in Table 1. The median age was 71.0 (IQR 63.8–75.3) years old among WGA patients whereas it was 67.0 (interquartile range [IQR] 62.0–72.0) among PGA patients ($P = 0.024$). The median follow-up period was 49.0 months. Serum PSA levels were found to be higher in the WGA group ($P = 0.404$). The number of positive cores ($P < 0.001$), the percent of maximal core involvement ($P < 0.001$), and clinical stage ($P = 0.002$) were all significantly higher in the WGA group.

Recurrence was observed in seven (3.0%) patients in the WGA group and 36 (15.2%) patients in the PGA group ($P = 0.261$) after a median follow-up of 13.0 months (IQR 11.0–19.0). After a median follow-up of 18.5 months (IQR 16.0–40.5), treatment failure was not observed in any patients in the WGA group, while it was observed in 22 (9.3%) patients in the PGA group ($P = 0.007$).

After HIFU, while no patients in the WGA group required such intervention, salvage treatment was required for 35 (14.8%) patients in the PGA group ($P < 0.001$), after a median follow-up of 18.0 months (IQR 14.0–36.5). Out of a total of 35 patients, 11 (31.4%) underwent a second HIFU, nine (25.7%) underwent robot-assisted radical prostatectomy (RRP), three (8.6%) underwent RT combined with ADT, and 12 (34.3%) received ADT alone.

Kaplan-Meier analyses demonstrated significantly longer failure-free ($P < 0.001$) and salvage-free survival ($P < 0.001$) in the WGA group compared to the PGA group, but no significant difference in recurrence-free survival ($P = 0.163$) (Fig. 1). When considering different preoperative risk groups, we observed longer recurrence-, failure-, and salvage-free survival in the low-risk group, although these trends were not statistically significant (Fig. 2).

In subgroup analysis, patients were categorized into low-risk and intermediate—high-risk groups based on D'Amico risk stratification. Within the low-risk group, the WGA and PGA groups exhibited no significant difference in recurrence-free ($P = 0.477$), failure-free ($P = 0.593$), or salvage-free survival ($P = 0.477$) (Fig. 3). However, within the intermediate—high-risk groups, the WGA group demonstrated significantly longer failure-free ($P = 0.005$) and salvage-free survival ($P < 0.001$) (Fig. 4); there was no significant difference in recurrence-free survival ($P = 0.169$) (Fig. 4).

A 12-month follow-up biopsy was performed on 199 patients, representing 84.0% of all included patients. In total, 33 (16.6%) patients were revealed to have remaining disease regardless of Gleason grade at follow-up biopsy (Table 2). When comparing the WGA and PGA subgroups, there was no significant difference in the positive rate for any cancer (21.4% versus 15.3%, $P = 0.696$). CS cancer (defined as Gleason grade $\geq$7 (3 + 4)) was identified in 19 (9.5%) patients at one-year follow-up biopsy. However, no significant difference was observed between the WGA and PGA groups in terms of CS cancer rate at follow-up biopsy (14.3% versus 8.3%,

Table 1
Summarization of clinical characteristics of entire subjects.

Median (IQR) or number (percent)	Entire patients ($n = 237$)	Partial gland ablation ($n = 183$)	Whole gland ablation ($n = 54$)	*P* value
Age (years)	68.0 (62.5–73.5)	67.0 (62.0–72.0)	71.0 (63.8–75.3)	0.024
BMI (kg/m^2)	25.2 (23.2–26.9)	25.2 (23.2–26.9)	25.1 (23.6–27.1)	0.903
Diabetes mellitus	54 (22.8%)	44 (24.0%)	10 (18.5%)	0.463
PSA (ng/dl)	6.6 (4.6–8.9)	6.0 (4.4–8.5)	7.0 (4.8–10.0)	0.404
Prostate volume (g)	32.5 (25.0–43.7)	33 (25.0–46.0)	30 (23.1–40.0)	0.156
PSA density	0.189 (0.124–0.288)	0.19 (0.12–0.28)	0.2 (0.16–0.31)	0.073
Biopsy grade group				0.057
Group 1	49 (20.7%)	42 (23.0%)	7 (13.0%)	
Group 2	121 (51.1%)	95 (51.9%)	26 (48.1%)	
Group 3	47 (19.8%)	35 (19.1%)	12 (22.2%)	
Group 4	19 (8.0%)	10 (5.5%)	9 (16.7%)	
Group 5	1 (0.4%)	1 (0.5%)	0 (0%)	
Clinical stages				0.002
cT1	97 (40.9%)	66 (36.1%)	31 (57.4%)	
cT2	101 (42.6%)	89 (48.6%)	12 (22.2%)	
cT3	39 (16.5%)	28 (15.3%)	11 (20.4%)	
Risk groups (D'Amico)				0.257
Low	30 (12.7%)	25 (13.7%)	5 (9.3%)	
Intermediate	155 (65.4%)	122 (66.7%)	33 (61.1%)	
High	52 (21.9%)	36 (19.7%)	16 (29.6%)	
Number of positive cores (n)	2.0 (1.0–4.0)	2.0 (1.0–4.0)	4.0 (2.0–6.0)	<0.001
Maximal tumor involvement of positive core (%)	29.4 (18.8–47.2)	16.7 (8.3–29.3)	33.5 (21.4–44.7)	<0.001

BMI, body mass index; IQR, interquartile range; PSA, prostate-specific antigen.

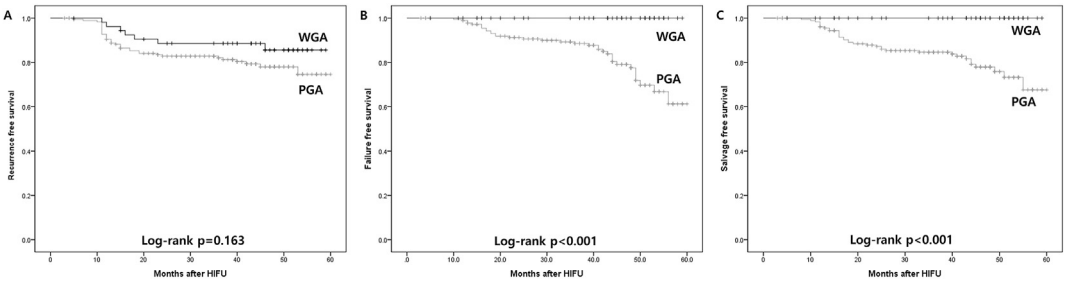

Fig. 1. Kaplan–Meier curves of recurrence-free (A), failure-free (B), and salvage-free (C) survival according to ablation type (dark gray: WGA, light gray: PGA).

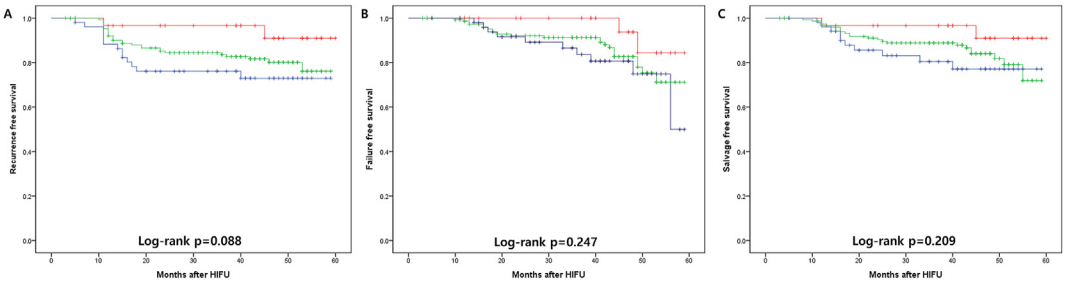

Fig. 2. Kaplan–Meier curves of recurrence-free (A), failure-free (B), and salvage-free (C) survival according to D'Amico risk stratification (red: low risk, green: intermediate risk, blue: high risk).

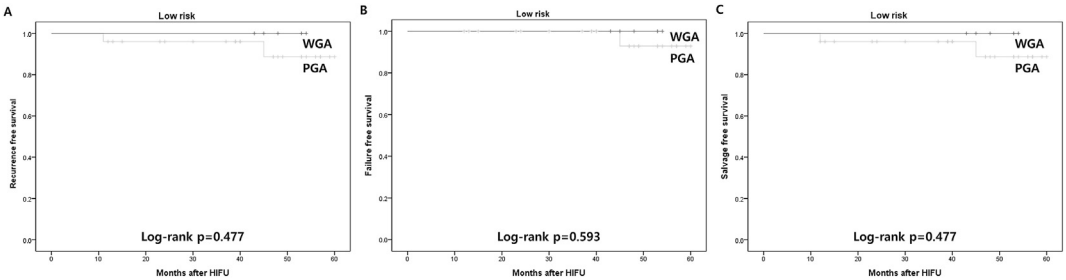

Fig. 3. Kaplan–Meier curves of recurrence-free (A), failure-free (B), and salvage-free (C) survival in the low-risk subgroup (dark gray: WGA, light gray: PGA).

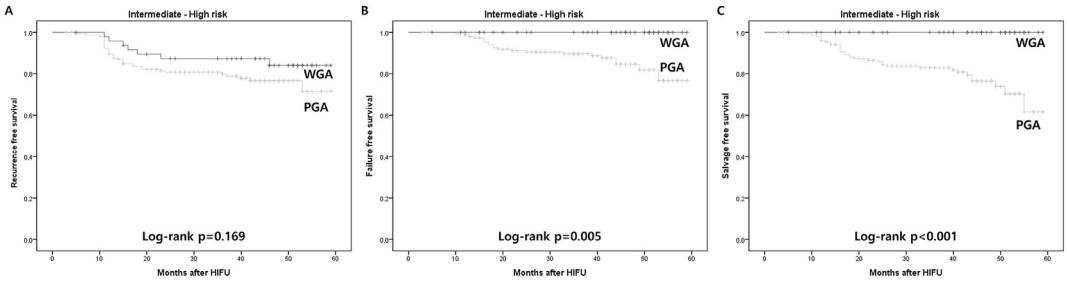

Fig. 4. Kaplan–Meier curves of recurrence-free (A), failure-free (B), and salvage-free (C) survival in the intermediate to high-risk subgroup (dark gray: WGA, light gray: PGA).

Table 2
Results of 1-year follow-up biopsy after high-intensity focused ultrasound ablation.

	All patients ($n = 199$)	Whole gland ablation ($n = 42$)	Partial gland ablation ($n = 157$)
Any positive biopsy after HIFU	33 (16.6%)	9 (21.4%)	24 (15.3%)
Infield positive	19 (9.5 %)	9 (21.4%)	10 (6.4%)
Outfield positive	9 (8.5%)		9 (5.7%)
Both positive	5 (2.5%)		5 (3.2%)
CS cancer-positive biopsy after HIFU	19 (9.5%)	6 (14.3%)	13 (8.3%)
Infield positive	13 (6.5%)	6 (14.3%)	7 (4.5%)
Outfield positive	3 (1.5%)		3 (1.9%)
Both positive	3 (1.5%)		3 (1.9%)

CS, clinically significant; HIFU, high-intensity focused ultrasound.

$P = 0.244$). Among the WGA group, nine patients (21.4%) had PCa in the treated lobe (defined as infield positive) (Table 2). Among the PGA group, 10 patients (6.4%) had PCa in the treated lobe, nine patients (5.7%) had PCa in the untreated lobe (defined as outfield positive), and five patients (3.2%) had PCa in both the treated and untreated lobes (defined as both positive). In the WGA group, CS cancer was found in the treated lobe in six patients (14.3%). Meanwhile, in the PGA group, CS cancer was found in the treated lobe in seven patients (4.5%), in the untreated lobe in three patients (1.9%), and in both the treated and untreated lobes in three patients (1.9%).

Stratification based on D'Amico risk classification revealed that four (2.0%) low-risk patients, 20 (10.1%) intermediate-risk patients, and nine (4.5%) high-risk patients exhibited positive biopsies after HIFU (Table 3). Subgroup analysis according to risk classification unveiled that, within the respective categories, one patient (0.5%) in the low-risk group, 12 patients (6.0%) in the intermediate-risk group, and six patients (3.0%) in the high-risk group exhibited CS cancer rates after HIFU. Within the WGA group, PCa was detected in one patient (2.4%) in the low-risk group, six patients (14.3%) in the intermediate-risk group, and two patients (4.8%) in the high-risk group. Meanwhile, in the PGA group, PCa was detected in three patients (1.9%) in the low-risk group, 14 patients (8.9%) in the intermediate-risk group, and seven patients (4.5%) in the high-risk group.

Regarding CS cancer, in the WGA group, CS cancer was found in one patient (2.4%) within the low-risk group, three patients (7.1%) within the intermediate-risk group, and two patients (4.8%) within the high-risk group. By contrast, in the PGA group, CS cancer was found in nine patients (5.7%) within the intermediate-risk group, four patients (2.5%) within the high-risk group, and zero patients within the low-risk group.

In total, 100 (42.4%) patients were revealed to have any kind of postoperative complications after HIFU (Table 4). When stratified by the Clavien-Dindo classification, 88 patients (37.1%) were classified as having Grade I complications, while 11 patients (4.6%) experienced Grade III complications. The WGA group exhibited a higher percentage of Grade III complications compared to the PGA group (9.3% vs. 3.3%, WGA vs. PGA, $P = 0.132$).

4. Discussion

Our study compared the results of WGA versus PGA using HIFU in localized PCa patients. One year after HIFU, a follow-up prostate biopsy revealed that 16.6% of the patients had residual PCa whereas 9.5% of the patients had CS PCa. Among the WGA group, 14.3% of the patients showed CS cancer-positive biopsy results. By contrast, only 8.3% of the PGA group showed CS cancer-positive biopsy results. These measurable CS cancer-positive biopsy results in both the WGA and PGA groups reflect the importance of conducting follow-

Table 3
Results of 1-year follow-up biopsy after high-intensity focused ultrasound ablation, categorized by D'Amico risk stratification.

	All patients ($n = 199$)	Whole gland ablation ($n = 42$)	Partial gland ablation ($n = 157$)
Any positive biopsy after HIFU	33 (16.6%)	9 (21.4%)	24 (15.3%)
Low risk group	4 (2.0%)	1 (2.4%)	3 (1.9%)
Intermediate risk group	20 (10.1%)	6 (14.3%)	14 (8.9%)
High risk group	9 (4.5%)	2 (4.8%)	7 (4.5%)
CS cancer-positive biopsy after HIFU	19 (9.5%)	6 (14.3%)	13 (8.3%)
Low risk group	1 (0.5%)	1 (2.4%)	0 (0%)
Intermediate risk group	12 (6.0%)	3 (7.1%)	9 (5.7%)
High risk group	6 (3.0%)	2 (4.8%)	4 (2.5%)

CS, clinically significant; HIFU, high-intensity focused ultrasound.

Table 4
Rate of complications after high-intensity focused ultrasound ablation according to Clavien-Dindo classification.

	All patients ($n = 237$)	Partial gland ablation ($n = 183$)	Whole gland ablation ($n = 54$)	P value
Complications by grade				
Grade I	88 (37.1%)	62 (33.9%)	26 (48.1%)	0.057
Grade II	1 (0.4%)	0 (0%)	1 (1.9%)	0.228
Grade III	11 (4.6%)	6 (3.3%)	5 (9.3%)	0.132
Grade IV	0 (0%)	0 (0%)	0 (0%)	
Total	100 (42.2%)	68 (37.2%)	32 (59.3%)	0.004

up prostate biopsy after HIFU. Ganzer et al (2018) conducted a follow-up prostate biopsy six months after HIFU and found that 36.7% of PGA patients exhibited positive biopsy results from untreated lesions.[15] In our study, when compared to the aforementioned study that only included 15.7% of PGA patients with grade group 2 (GG2) or greater disease, we included a higher proportion of patients with GG2 or greater disease (77.0%) in the PGA group. Other published studies involving PGA have shown a larger proportion of patients with GG1 (ranging from 37.0% to 86.6%).[16–19] In our study, extending the inclusion criteria to GG2 disease did not result in a worse prognosis in biopsy results, suggesting that lenient criteria can be applied for HIFU if a strict follow-up is ensured.

The results of Kaplan-Meier analyses showed that the WGA group exhibited longer failure-free and salvage-free survival compared to the PGA group (both $P < 0.001$). Similar trends were observed in the intermediate to high-risk subgroup but not in the low-risk group. In the low-risk group, both WGA and PGA could be considered treatment options for well-selected localized PCa patients. However, in the intermediate to high-risk groups, WGA should be prioritized given its superior failure-free and salvage-free survival rates.

HIFU therapy targets comparable oncological outcomes with a higher rate of functional outcomes, such as erectile function and continence, than traditional therapy. A comparison of HIFU and RRP for localized PCa found that HIFU may provide equivalent cancer control and better quality of life, particularly in terms of urinary function improvement and sexual function preservation.[20] HIFU was also found to have similar local control and biochemical free survival rates as conformal external radiation beam therapy, with potency being the functional outcome that was impacted the most.[21,22]

There have only been a small number of studies directly comparing the oncological and functional outcomes of WGA and PGA. Lei et al (2019) conducted such a comparison in a retrospective study involving 61 patients in the WGA group and 25 patients in the PGA group.[23] These groups showed similar oncological outcomes, but complications such as acute urinary retention (44.3% vs 20.0%) and urethral strictures (26.2% vs 4.0%) were more frequent in the WGA group. Borges et al (2021) also performed a retrospective study that compared 105 patients in the WGA group and 195 patients in the PGA group.[24] Acute urinary retention was found to be the most common complication in the overall population, as it occurred in 42 (14.2%) patients. The rates of all complications were significantly higher among the WGA group. A grade IIIa complication was observed more frequently in the WGA group than it was in the PGA group (6.7% vs 1.5%). These results correspond with our present study, which also showed a significantly higher occurrence of adverse effects among the WGA group.

Despite including more high-grade and high-risk patients than the PGA group, the WGA group exhibited significantly longer failure-free and salvage-free survival intervals. These results underscore the potential oncological benefits of more extensive ablation techniques. While no statistically significant differences in recurrence-free survival were noted between the PGA and WGA cohorts, the trend toward longer recurrence-free survival in the WGA group warrants further investigation considering larger cohorts.

The current study has several limitations. First, it was retrospective in nature and subject to inherent structural bias. Prior to HIFU treatment, nearly all patients undergo mpMRI, with patient selection done based on MRI findings and targeted biopsy results. Due to the absence of absolute criteria for HIFU treatment, selection bias may be present. The study's relatively small sample size also limits its generalizability. Further prospective, multicenter studies are needed to validate these findings. Despite these limitations, our study contributes valuable data regarding the oncological outcomes of both WGA and PGA groups.

5. Conclusion

In our study, HIFU was performed with acceptable oncological outcomes in localized PCa. The number of complications was found to be lower overall in the PGA group, with a higher incidence of low-grade complications. Despite having a higher proportion of high-grade and high-risk patients when compared to the PGA group, the WGA group exhibited significantly longer periods of both failure-free and salvage-free survival.

Funding

This work was approved by institutional grant (02-2021-0043) from SNUBH Research Fund.

Conflicts of interest

None.

Acknowledgments

None.

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