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Pilot Study to Assess Safety and Clinical Outcomes of Irreversible Electroporation for Partial Gland Ablation in Men with Prostate Cancer

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Abstract

Purpose—Partial prostate gland ablation is a strategy to manage localized prostate cancer. Irreversible electroporation can ablate localized soft tissues. We sought to describe 30- and 90-day complications and intermediate-term functional outcomes in men undergoing prostate gland ablation using irreversible electroporation.

Materials and Methods—We reviewed the charts of 25 patients with prostate cancer who underwent prostate gland ablation using irreversible electroporation as a primary procedure and who were followed for at least 6 months.

Results—Median follow-up was 10.9 months. Grade 3 complications occurred in 2 patients including epididymitis (1) and urinary tract infection (1). Fourteen patients experienced grade 2 complications, mainly transient urinary symptoms, hematuria, and urinary tract infections. Of 25 patients, 4 (16%) had cancer in the zone of ablation on routine follow-up biopsy at 6 months. Of those with normal urinary function at baseline, 88% and 94% reported normal urinary function at 6 and 12 months after prostate gland ablation, respectively. By 12 months, only 1 patient with normal erectile function at baseline reported new difficulty with potency and only 2 patients (8%) required a pad for urinary incontinence.

Conclusions—Prostate gland ablation with irreversible electroporation is feasible and safe in selected men with localized prostate cancer. Intermediate-term urinary and erectile function outcomes appear reasonable. Irreversible electroporation is effective in ablation of tumor-bearing prostate tissue, as a majority of men had no evidence of residual cancer on biopsy 6 months after prostate gland ablation.

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Keywords

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INTRODUCTION

Organ sparing treatment options have been developed for several cancers in selected cases. Similarly, partial PGA has become a strategy for managing localized prostate cancer intended to provide local tumor control with minimal side effects for men with small tumors detected early. This approach is targeted to destroy the portion of the prostate gland that contains clinically significant cancerous tissue with less impact on QOL than whole gland treatments.

Partial gland focal therapies have been predominantly derived from modalities utilized for whole- or hemi-gland prostate ablation or for treatment in other organs and soft tissues. These include thermal modalities such as high-intensity focused ultrasound, cryotherapy, and interstitial laser ablation as well as non-thermal treatments such as vascular-targeted photodynamic therapy of the prostate.[1–3] In addition to studying the oncologic impact and safety of these treatments, side effects and functional results are also key investigational outcomes. Specific to prostate cancer care, patient-reported data regarding urinary and erectile function are important assessments of treatment.[4] Treatment techniques that can attain tumor control without harming important nearby tissues are needed in order to meet the expectations.[5]

IRE causes tissue ablation using short electric pulses delivered through thin electrodes to produce electric fields that create micropores in cellular membranes leading to cell death and tissue necrosis. One advantage of IRE, according to histology, is that cellular apoptosis occurs without apparent injury to extracellular matrices.[6] When the collective energy is sufficient, cells fail to recover normal integrity and die without apparent thermal damage to surrounding stroma.[7] Studies of IRE applied to soft tissues such as kidney parenchyma found no damage to surrounding tissues in the short- and mid-term.[8] Devices for IRE soft tissue ablation have received 510(k) clearance from the U.S. Food and Drug Administration and the favorable clinical profile has raised interest in application to soft tissues of the pelvis, including prostate.[9] IRE ablation of soft tissues, including prostate, liver, kidney, and pancreas, has been evaluated in preclinical settings and in routine clinical use in both normal and cancer-containing tissues.[5, 10–17]

Herein, we report our clinical experience in ablation using IRE applied to cancer-bearing prostate tissue to describe efficacy based on biopsy outcomes, the 30- and 90-day complications, and intermediate-term patient reported functional outcomes.

MATERIALS AND METHODS

All clinical documentation from men treated with PGA using IRE was maintained in a prospective database and constituted the data for review. We obtained institutional review

board approval to evaluate complications and patient-reported outcomes in men with localized prostate cancer who underwent PGA using IRE.

Patient Selection

Patients with a diagnosis of prostate cancer who were counseled and offered conventional management options (surveillance, surgery, radiation) but did not accept and requested PGA were considered for this approach. Patients in the primary PGA cohort included men with Gleason grade 4+3 prostate cancers. A subset of patients treated with salvage PGA had been previously treated with radiation and/or cryotherapy and were excluded from analysis. Patients were evaluated with pretreatment multiparametric prostate MRI, with confirmation on targeted and standard 12-core TRUS-guided prostate biopsy.

IRE Procedure

All interventions were performed using general anesthesia with pharmacologic paralytics. PGA was performed by a single surgeon (JAC) using a commercially available pulse generator (NanoKnife; AngioDynamics, Queensbury, New York, USA). All patients received perioperative antibiotics. Under TRUS guidance, 18-gauge electrodes were placed using transperineal stereotactic ultrasound with biplanar imaging (Hitachi Aloka Medical, Wallingford, Connecticut, USA) using a 5×5 mm template. The placement was based on MRI, biopsy location and ultrasound. The number of paired electrodes was dependent on the target zone of ablation. Needles were spaced in parallel 10 to 20 mm apart and 5 mm from capsule, bladder, or urethra. Measurements of distances between probes and exposure lengths were obtained as depicted in figure 1. Figure 2 shows a representative ultrasound image of probe configuration to ablate the zone of the prostate corresponding to positive biopsies and MRI imaging. Energy for soft-tissue ablation was delivered in 2 components, with the first 20 pulses delivered to characterize the electrical current dynamics between each probe pair. Adjustments were made accordingly and the final component consisting of a train of 70 pulses per probe pair was used to produce the tissue ablation. Voltages were chosen to attain effective electric field strength of >1600 V/cm between any probe pair. Following the procedure, cystoscopic evaluation of the urethra and bladder was performed to confirm normal findings and a urinary catheter was placed per urethra for subsequent removal within 48 hours of treatment.

Follow-up

After ablation, patients were followed and evaluated for 30- and 90-day complications, using office visits and nursing assessments. Any findings were graded using a standardized reporting system compatible with Clavien-Dindo classification.[18] Any need for continued urinary bladder drainage (i.e., re-catheterization) beyond 3 days from procedure was recorded as a grade 2 adverse event.

Patients underwent contrast-enhanced MRI 4 to 6 weeks after IRE to evaluate local ablation effects, prostate volume, and radiographic changes to surrounding tissues. Six months after IRE, patients underwent routine TRUS-guided template prostate biopsy (12 cores). Prostate-specific antigen was obtained every 3 to 6 months to monitor serologic response.

QOL Assessments

Patient-reported QOL was assessed at 6 and 12 months after PGA. The Prostate Quality of Life Survey is a standardized and previously validated questionnaire used for the evaluation of urinary and sexual function in men with prostate cancer managed at our institution.[19–21] Normal urinary function was defined as a total score of 17 on the urinary function part of the survey and potency was defined as a total score of 22 on the sexual function part of the survey. Continence was defined as documentation of no use of pads by patient or provider.

Oncologic Outcomes

Ablation efficacy was assessed by tissue evaluation after standardized systematic prostate biopsy and MRI-targeted biopsy in patients with suspicious lesions at 6 months following PGA. Any cancer on any core obtained within the zone of PGA at 6 months was defined as primary failure. Any patient subsequently treated for prostate cancer progression within the zone of ablation or on the contralateral prostate lobe was reported as treatment failure. All tissue specimens were evaluated by dedicated genitourinary pathologists at our institution.

RESULTS

Patient Characteristics

From May 2011 to October 2014, 35 patients underwent PGA of prostate tumors using IRE. Eight salvage PGA cases treated with prior radiation therapy were excluded from the analysis of primary PGA. One grade 3 adverse event (worsening of preexisting intraprostatic urethral stricture requiring transurethral resection) was seen in the group of salvage PGA patients. Of the remaining 27 patients, 2 had less than 6 months of follow-up. Median follow-up of the 25 men in the main cohort was 10.9 months (IQR, 6.7–19.3). Patient characteristics of these 25 are provided in table 1.

IRE Procedure Details

Ablations were unilateral except for anterior tumors, which included probe placement to allow treatment across the midline. Designation of anterior and posterior tumor locations were limited in number and therefore not substratified. The median ablation time was 14 minutes (IQR, 6.9–27 minutes). Three (12%), 6 (24%), 9 (36%), and 7 (28%) patients required 3, 4, 5, or 6 probes for tissue ablation, respectively. The median total voltage delivered was 2340 V/cm (IQR, 1650–2700 V/cm).

Safety and Complications

All patients were discharged within 24 hours and no patients were readmitted. Two patients required prolonged catheterization after a failed initial trial of void. Standardized reporting of adverse events at 30 and 90 days is provided for the 27 primary patients who had at least 90 days of follow-up (table 2). No cases of rectourethral fistula or evidence of rectal injury on MRI has been encountered with any patient managed with IRE PGA at our institution.

QOL Outcomes

Twenty-two patients had baseline QOL scores available. Prior to IRE of the prostate, 2 of these men reported the use of PDE5I and continued these medications following PGA. At 6 months after IRE, no other patients required the use of PDE5I for erections. Table 3 shows the number of patients reporting good erectile function (score ≥ 22) and normal urinary function (score ≥ 17) at baseline, 6 months, and 12 months after PGA. Seventeen patients reported normal urinary function at baseline and of those, only 2 and 1 patient reported a decrease in score (< 17) at 6 and 12 months, respectively. Of the 13 patients with normal erectile function at baseline, 85% (11) and 92% (12) reported normal function at 6 and 12 months, respectively. Figure 3 demonstrates the change in mean scores of both urinary and erectile function from baseline across these follow-up intervals. Use of pads was documented in 1 and 2 men at 6 and 12 months, respectively.

Oncologic Outcomes

At 6 months follow-up (n=25), 7 (28%) patients were found to have prostate cancer on template biopsy. Primary failure was observed in 4 (16%) of these patients. Two of the primary failures had unilateral ablation to the base of the prostate and the other had unilateral apical ablation. One with apical ablation had upgrading from Gleason score 3+3 to 3+4 disease. Clinical characteristics of the 4 failures are shown in table 4. Three men received subsequent definitive surgical treatment, 1 for Gleason 3+4 of ipsilateral lobe and 2 for Gleason 3+4 in the contralateral lobe.

DISCUSSION

This study after PGA provides data regarding the safety of IRE for ablation of cancer bearing prostate tissue. In this series we found approximately 50% of men experienced grade 1 or 2 adverse events consisting mainly of transient lower urinary tract symptoms. Higher grade events were rare though notable and associated with complicated infections requiring additional management. In men with good preoperative urinary and sexual function greater than 90% maintained this function.

Our results are compatible with previously published studies of prostate IRE ablation. A recent study involving 2 patients who underwent IRE PGA and subsequent radical prostatectomy with matched histology findings suggested that electric field should exceed 1072 ± 119 V/cm to ablate tumor-bearing prostate tissue.[5] In our study, the mean electrical field generated between probes was >2100 V/cm. Valerio et al studied 34 patients with prostate cancer who underwent IRE PGA and reported only low-grade urinary (grade 1–2) complications.[13] Further evaluation of our 2 cases with grade 3 events revealed no identifiable findings in the details of these procedures. Both had received standard antibiotic regimens and procedure notes were unremarkable. One patient with a 61 mL prostate and pre-existing obstructive symptoms transiently required intermittent self-catheterization and developed epididymo-orchitis unresponsive to antibiotic therapies. Some notable differences among the reported experiences include the treatment of only anterior tumors and the use of suprapubic tubes for bladder decompression in the previous series. It is possible that urethral manipulation could predispose patients to infectious complications.

Reporting of post-PGA QOL outcomes has not been standardized. As we have done, existing questionnaire formats have been used while others have relied on physician reported outcomes. Our results are similar to those of Valerio and colleagues in regard to 6-month outcomes.[13] However, our methods were dissimilar in that the QOL data in our study relied on patient reporting.[13] Additionally, we report on 12-month data in our cohort, allowing us to demonstrate durability. In our study, similar to other reports of PGA with IRE in both humans and canines, there were no rectal or urethral injuries and no fistulous formation.[5, 10, 13]

Focal therapy, including PGA, of the prostate gland has the theoretical ability to destroy tumors while reducing morbidity to noncancerous tissue such as the neurovascular bundles and urinary sphincter.[22] PGA is still preliminary in prostate cancer and needs further studies to determine the best candidates, risk factors for progression, and patient acceptance of the therapy. Prostate cancer is known to be multifocal: 80% of patients harbor bilateral tumors on pathology after radical prostatectomy and up to 86% have >2 cancer foci.[23] Prostate glands typically range from 20 to 60 cm³ in volume; therefore, with a mean cancer volume of 1 to 2 cm³ at diagnosis, there may be a role for preservation of greater than half the prostate in a majority of patients.[24, 25] As a focal therapy, PGA with IRE often requires physicians to treat only the index lesions, defined as the 1 or 2 lesions having the largest volume and highest grade.[26] It can be difficult to identify these lesions, even with the combination of prostate biopsy, MRI, and intraoperative TRUS guidance. In our cohort, 3 men proceeded to definitive therapy and 2 of these were for progression of contralateral prostate gland lesions, which may be related to misclassification associated with biopsy. This may also be a consequence of the difficulty in identifying the lesion with highest risk for progression, which may not be the one identified as the index lesion.[22] Treatment of specific locations within the prostate can present challenges as well. A consensus conference on focal therapy concluded that technical limitations often preclude treatment of anterior or apical lesions.[27] In our study, however, there were lesions treated throughout the base, mid-gland, and apex of the prostate. Of note, 2 of the 4 patients who had a primary failure at 6 months in this PGA cohort had apical ablations; the other 2 patients had lesions at the prostatic base. We recognize the limitations of prostate cancer diagnosis using ultrasound-guided biopsy, including misclassification of multifocal lesions. In addition, misclassification during ultrasound-guided prostate biopsy can impact treatment success. However, we incorporated MRI-targeted biopsies for patient selection prior to treatment and during follow-up to evaluate efficacy. A consensus on focal therapy trial design in prostate cancer states that TRUS biopsy taken between 6 and 12 months after treatment is optimal. [28]

Several limitations of our study should be noted. The generalizability of our findings is limited by the small population in this study. In addition, patients were not randomized to treatment, but instead were counseled on conventional options and requested PGA. Although we were able report patient pathologic characteristics prior to treatment, we did not have standard criteria to measure volume of disease or designate a treatment plan prior to treatment. We also did not have functional data for all patients before treatment and during follow-up. Finally, in the absence of surgery we had no surgical specimen pathology to confirm the biopsy data.

Our results add to an expanding body of literature that suggests PGA is feasible and safe for localized prostate cancer. This pilot study prompts recommendations for conducting future trials in PGA. First, intermediate- and long-term outcomes to demonstrate clinical benefit for patients need to be defined. Second, the role of PGA in the management of localized prostate cancer will require a comparative trial.

CONCLUSIONS

In men with localized prostate cancer treated with PGA, IRE is feasible and safe in treatment-naïve patients. IRE is effective in ablating prostate tumors, with an expectation of biopsy negative response seen in most patients at a 6-month follow-up prostate biopsy. Further, the majority of men report favorable intermediate-term urinary and erectile function after treatment. PGA using IRE should continue to be investigated in prospective multi-center clinical trials.

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Abbreviations and Acronyms

IRE	irreversible electroporation
MRI	magnetic resonance imaging
PDE5I	phosphodiesterase-5 inhibitors
PGA	prostate gland ablation
PSA	prostate-specific antigen
QOL	quality of life
TRUS	transrectal ultrasound

Figure 1.

Electrode metrics. [A]. Axial representation of probe placement geometry utilizing probe insertion initiated in the periurethral position (large black dot) with additional probes configured radially (black dashed lines) from this point. The closest distance from each probe to capsule or urethra (arrows) was no more than 5 mm. Distance between probe pairs (dashed lines) used for ablation was between 10 to 20 mm. [B]. Distance between probes (d) and length of needle exposure within tissues (L) are obtained to provide data for initial energy settings. Measurements were obtained to confirm parallel orientation (d) and 5 mm distance tip to capsule (arrows).

Figure 2. Images of prostate treated with IRE. [A]. Axial ultrasound image of the mid-gland depicting the outline of the prostate (dashed line) with needle probes arrayed within the gland for ablation of the left lobe (arrows). Probes are placed 5 mm from the capsule. [B]. Longitudinal image of the same patient noting the needle placement (arrows) with annotation from measurement of the proximal and distal portion of needle exposure. [C]. Pre-ablation axial T1 contrast enhanced image of the prostate. [D]. Post-ablation (4 weeks) axial T1 contrast enhanced image depicting the region of ablation effect extending to the prostate capsule laterally and posteriorly and outline of the periurethral tissue centrally.

Figure 3.

Change in functional outcomes from baseline in 17 men for urinary function and 15 men for erectile function undergoing PGA who all completed questionnaires at all 3 time points.

Table 1

Clinical characteristics of primary PGA patients (n=25)

Characteristic	
Age (year)	63.1 (59.3–67.6)
Pre-IRE PSA, ng/dL	4.3 (3.3–5.6)
6 month post-IRE PSA, ng/dL	2.2 (1.1–3.8)
Pre-IRE prostate volume, mL	40.5 (27.4–59)
6 week post-IRE prostate volume, mL	45 (23.5–60)
Gleason score	
3+3	18 (72%)
3+4	6 (24%)
4+3	1 (4%)
American Urology Association risk classification	
Low risk	18 (72%)
Intermediate risk	7 (28%)
High risk	0 (0%)

Data reported as median (IQR) or number (percent)

Prostate volume was obtained from prostate MRI or ultrasound

Table 2

Adverse events reported at 30 days and 90 days after primary partial PGA

Grade	30 days	90 days
n = 27 [*]	No. of patients (%)	No. of patients (%)
1	6 (22%)	0 (0%)
Hematuria	4	0
Dysuria	1	0
Hematospermia	1	0
2	7 (26%)	1 (4%)
Urinary retention	6	0
Urinary tract infection	1	0
Epididymitis	0	1
3	1 (4%)	1 (4%)
Epididymitis	0	1 [‡]
Urinary tract infection	1 [‡]	0
4	0 (0%)	0 (0%)
5	0 (0%)	0 (0%)

^{*} Included are all patients undergoing primary PGA (25 patients with > 6 months follow up and 2 patients with 90 days to <6 months follow-up).

[‡] Epididymitis in this patient led to abscess formation requiring simple orchiectomy

Table 3

Functional Outcomes after Partial Prostate Gland Ablation with Irreversible Electroporation: Scores on the Prostate Quality of Life Survey

	Baseline (n = 22)	6 months (n = 16)	12 months (n = 17)
	No. of patients (%)	No. of patients (%)	No. of patients (%)
Urinary function score 17	17 (77%)	13 (81%)	15 (88%)
Erectile function score 22	13 (59%)	7 (44%)	11 (65%)

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Table 4

Pre- and post-ablation characteristics in those with primary treatment failure

Patient	Pre-PGA with IRE				Post-PGA with IRE		
	PSA (ng/dL)	Biopsy grade	Positive cores [*]	Prostate volume [†]	PSA (ng/dL)	Biopsy grade	Positive cores [*]
1	8.8	3+3	4(14)	68	5.55	3+3	1(14)
2	5.59	3+3	2(15)	52	4.44	3+3	1(14)
3	3.96	3+3	3(14)	54	3	3+3	2(14)
4	9.58	3+3	1(12)	37	14.07	3+4	4(18)

^{*} number of positive cores and (total number of cores obtained)

[†] volume (in grams) from pre-operative and 4- to 6-week post-operative MRI