



Feasibility of in-office MRI-targeted partial gland cryoablation for prostate cancer: an IDEAL stage 2A study

Spyridon P Basourakos ¹, Bashir Al Hussein Al Awamlh,¹ Fernando J Bianco,² Neal A Patel,¹ Aaron Laviana,³ Daniel J Margolis,⁴ Juan M Mosquera,⁵ Timothy D McClure,¹ Miko Yu,¹ Jim C Hu ¹

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SPB and BAHAA contributed equally.

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¹Urology, NewYork-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York, USA

²Urology, Urological Research Network, Miami Lakes, Florida, USA

³Urology, Vanderbilt University Medical Center, Nashville, Tennessee, USA

⁴Radiology, NewYork-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York, USA

⁵Pathology, NewYork-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York, USA

Correspondence to

Dr Jim C Hu;
Jch9011@med.cornell.edu

ABSTRACT

Objectives Cryoablation for prostate cancer is typically performed under general anaesthesia. We explore the safety, feasibility and costs of in-office MRI-targeted prostate partial gland cryoablation (PGC) under local anaesthesia. We hypothesise that an office-based procedure under local anaesthesia may yield greater patient convenience and lower health costs with similar outcomes to a general anaesthesia approach.

Design/participants/setting/

interventions Retrospective study of men diagnosed with clinically significant prostate cancer (grade group (GG) ≥ 2) who elected to undergo in-office PGC under local anaesthesia.

Main outcome measures A total of 55 men with GG ≥ 2 prostate cancer underwent PGC under local anaesthesia, and 35 of 43 men (81.4%) who attained ≥ 6 months of follow-up post-treatment underwent MRI-targeted surveillance biopsy. We used MRI findings and targeted biopsy to characterise post-PGC oncological outcomes. Complications were categorised using Common Terminology Criteria for Adverse Events (CTCAE). Expanded Prostate Cancer Index-Clinical Practice was used to characterise urinary and sexual function scores at baseline, 4 and 9 months post-PGC. Time-driven activity-based costing was used to determine healthcare costs of in-office PGC.

Results Five (9.1%) men experienced CTCAE score 3 adverse events. Urinary and sexual function did not change significantly from baseline to 4 months ($p=0.20$ and $p=0.08$, respectively) and 9 months ($p=0.23$ and $p=0.67$, respectively). Twenty-two men (62.9%) had no cancer or GG1 and 13 (37.1%) men had GG ≥ 2 on post-PGC biopsy. Moreover, the median cost of in-office PGC was US\$4,463.05 (range US\$4,087.19–US\$7,238.16) with disposables comprising 69% of the cost.

Conclusions In-office PGC is feasible under local anaesthesia with favourable functional outcome preservation and adverse events profile at significantly lower costs compared with a general anaesthesia approach.

INTRODUCTION

The aim of partial gland ablation for prostate cancer is to eliminate cancer while sparing noncancerous prostate tissue to preserve

Key messages

What is already known about this subject?

► Partial gland cryoablation (PGC) is an ablation approach that has been described for prostate cancer focal therapy. It has emerged as an attractive treatment option as it offers minimally invasive cancer treatment with preservation of functional outcomes. Historically, PGC has been performed at ambulatory centres and under general anaesthesia.

What are the new findings?

► This is the first series of in-office PGC performed under local anaesthesia. We demonstrate that in-office PGC is feasible, well tolerated and has favourable functional outcomes with no significant change in pretreatment versus post-treatment urinary and sexual function. Furthermore, in-office PGC has oncological outcomes comparable to high-intensity focused ultrasound and PGC under general anaesthesia at a significantly lower cost.

How might these results affect future research or surgical practice?

► We demonstrate that in-office PGC is a promising and cost-effective approach with similar outcomes to ablation under general anaesthesia. Our approach may allow urologists to offer an office-based prostate cancer treatment procedure at a better cost and comparable outcomes to procedures under general anaesthesia. Nevertheless, more studies assessing long-term outcomes are needed before widespread dissemination.

urinary, sexual and ejaculatory function.¹ Interest in prostate gland ablation has grown in the USA due to the recent Food and Drug Administration approval of high-intensity focused ultrasound (HIFU) for prostate tissue ablation and increased use of MRI-ultrasound fusion targeted (MRI-targeted) prostate biopsy, which improves tumour localisation relative to conventional transrectal ultrasound-guided prostate biopsy.^{1,2} Various thermal energies such as cryoablation, HIFU, laser ablation and short electric pulses have

been used for partial gland ablation^{3,4}; however, there is a dearth of comparative outcomes and cost research.

The current post-treatment paradigm of partial gland ablation entails follow-up with active surveillance (prostate specific antigen (PSA), MRI, biopsy). Longitudinal costs of active surveillance have been shown to be more than radical prostatectomy, particularly for younger men with long life expectancy.⁵ Cryoablation has traditionally been a whole prostate gland treatment under general anaesthesia and is less costly compared with HIFU.² The ability to perform an office-based procedure would further attenuate expenses from ambulatory surgery centre and general anaesthesia costs while improving patient convenience. In this pilot study, we present our initial experience with in-office, MRI-targeted partial gland cryoablation (PGC) under local anaesthesia.

MATERIALS AND METHODS

Study population

This study included 55 men diagnosed with clinically significant prostate cancer (grade group (GG) ≥ 2) using targeted biopsy with systematic biopsy at Urological Research Network (n=5; Florida, USA) and NewYork-Presbyterian/Weill Cornell Medicine (n=50; New York, USA). Men were enrolled in clinical trials for PGC (NCT 02381990 and NCT 03492424, respectively). Men were

counselled that there was a dearth of long-term cancer control outcomes and comparative studies between PGC and whole gland treatment. Additionally, men were counselled regarding conventional treatment options (surveillance, surgery, radiation). All prostate MRIs were reviewed by an experienced urologist (DJM) to plan PGC, using the Prostate Imaging-Reporting and Data System (PI-RADS) V.2 recommendations. Lesions were graded accordingly⁶; none had gross evidence of extraprostatic extension or seminal vesicle invasion. The trial flow is demonstrated in figure 1.

Partial gland cryoablation

An oral antibiotic (fluroquinolone or trimethoprim/sulfamethoxazole) was given the morning of PGC and the procedures were conducted in the office setting. Only four men (7.3%) asked for a short-acting oral benzodiazepine and none required intravenous access. The perineum was shaved and prepped with betadine in the lithotomy position and a Foley catheter was inserted. The skin, subcutaneous tissue and periprostatic nerves were blocked with 20 mL of 1% lidocaine. A biplane ultrasound Noblus probe (Hitachi Aloka, Twinsburg, Ohio, USA) was inserted transrectally. All procedures were performed by two surgeons (JCH and FJB) using the Artemis platform (Eigen, Grass Valley, California, USA). The contoured prostate along with MRI planned ablation zone(s) were

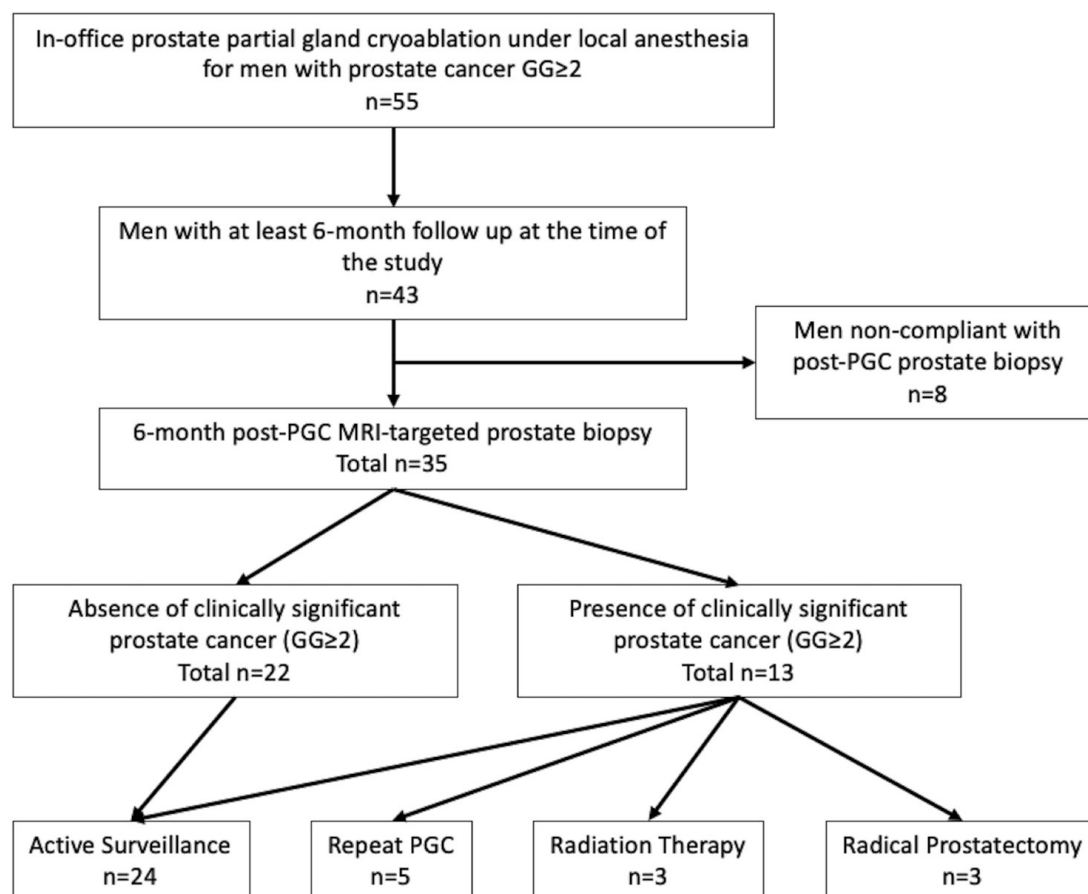


Figure 1 In-office prostate PGC under local anaesthesia trial flow. GG, grade group; PGC, partial gland cryoablation.

coregistered to ultrasound. A minimum of two cryotherapy probes were transperineally inserted using MRI targeting. The total number of probes used was dependent on the size of the lesion and was at the discretion of the treating surgeon. Men without MRI-visible disease underwent quadrant PGC. Two freeze thaw cycles to negative 40°C were performed to ensure tumour lysis⁷; safety of the procedures was enhanced by real-time image fusion monitoring where the ice-ball would cover the target area within the MRI prostate contour. The targeted ablation zone that extended 1.5cm beyond the border of the region of interest or reached the boundary of the prostate.⁸ Men were discharged home with an indwelling Foley catheter unless they had low volume tumours without definitive urethral ice-ball impingement.

Follow-up, quality of life and adverse events

Men followed up for catheter removal within 7 days and PSA 3 months after PGC. Complications were captured by research coordinators uninvolved with clinical care and classified outcomes using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) V.5.0.⁹ Urinary and sexual function were assessed using the Expanded Prostate Cancer Index for Clinical Practice (EPIC-CP), with lower scores indicating better outcomes, at baseline, at 4 months and 9 months post-PGC¹⁰ A total of 35 men (63.6%) attained 6-month follow-up. All men underwent post-PGC MRI-targeted and systematic surveillance biopsy at this time. Four men had insurance denial of the MRI and, thus, underwent MRI-targeted biopsy using the pretreatment MRI. Failure of in-office PGC was defined as the detection of clinically significant prostate cancer (GG≥2) on the 6-month post-PGC biopsy.

Time-driven activity-based costing

Time-driven activity-based costing (TDABC) is a described strategy to calculate the true cost of healthcare services.¹¹ Therefore, it was used to determine the costs of performing in-office, MRI-targeted PGC under local anaesthesia. A process flow map and detailed calculations of every step was performed by one of the authors (AL). Procedure times (the time from Foley catheter insertion to PGC completion) were recorded in the medical record. Personnel, equipment and material costs were all factored in to derive capacity cost rates, which also incorporated indirect costs such as depreciation and employee benefits. These capacity cost rates were then multiplied by the relevant process times, and TDABC was defined as the sum of its resources. We then determined the median cost of in-office PGC for all procedures and compared these costs to PGC under general anaesthesia and HIFU partial gland ablation as previously reported, excluding the follow-up costs.² We compared the cost of in-office PGC under local anaesthesia to PGC under general anaesthesia performed at an ambulatory surgery centre based on resource utilisation, process maps and times for five cases before this series. Furthermore, we compared

Table 1 Baseline characteristics

Age (years), median (IQR)	70 (63.43–74.96)
PSA (ng/mL), median (IQR)	6.6 (4.73–9.18)
MRI findings	
Volume (mL), median (IQR)	39 (31.50–54.45)
Max PI-RADS V.2, n (%)	
3	9 (17.65)
4	28 (54.90)
5	14 (27.45)
Biopsy of target (max GG), n (%)	
2	32 (58.18)
3	13 (23.64)
4	7 (12.73)
5	3 (5.45)

Prostate volume was obtained from prostate MRI. GG, grade group; PI-RADS V.2, Prostate Imaging-Reporting and Data System V.2; PSA, prostate specific antigen.

the in-office PGC to HIFU, because the latter is currently an alternative modality for partial gland ablation in the USA.^{2 11}

RESULTS

Patient characteristics

Median age was 70 years (IQR 63.4–75), median pretreatment PSA was 6.6 ng/mL (IQR 7.7–9.2) and median prostate volume was 39 cc (IQR 31.5–54.5) (table 1, figure 2). Forty-two men (83%) had PI-RADS category ≥4 lesions. Thirty-two (58.2%) men had GG 2, 13 (23.6%) had GG 3, 7 (12.7%) had GG 4 and three (5.5%) had GG 5 on pretreatment biopsy (table 1, figure 2). Two cryoablation probes were used in 38 (69%) men, three probes in 7 (12%) men and 4–6 probes were used for the other subjects. Four men were discharged from clinic without an indwelling catheter because the treatment area was deemed small and away from the urethra.

Post-treatment outcomes

We observed a 65% median PSA decline, although a quarter of patients had greater than a 94% decrease. The median duration of urethral catheterisation was 6 days (IQR 3–7). The prostate volume decreased by 18.3% on post-treatment MRI. On post-PGC MRI, almost half of men (n=15, 48.4%) did not have an identifiable lesion and nine men (29.1%) had PI-RADS 4 or 5 lesion. Twenty-two men had a benign (42.9%) or GG1 (20.0%) on post-PGC biopsy, whereas, 11 (31.4%) had GG2, 1 (2.9%) had GG3 and another (2.9%) had GG4 (table 2, figure 2). Out of the 13 (37%) men that had recurrence (GG≥2), 7 (54%) were found to have in-field while 6 (46%) had out-of-field recurrences (figure 3A).

Twenty-four (68.6%) men were opted for active surveillance after PGC (two with GG2 and seven with GG1).

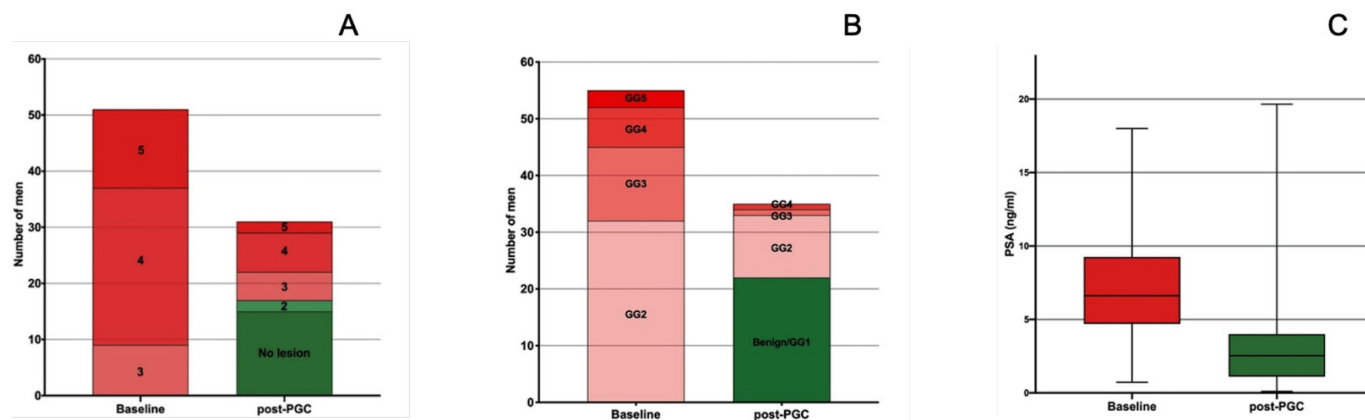


Figure 2 Changes in radiographical and pathological features between baseline and post-PGC. Bar graphs showing changes in PI-RADS category (A) and grade group (B) and box and whisker plots showing changes in PSA (C) between baseline and post-PGC. GG, grade group; PGC, partial gland cryoablation; PI-RADS, Prostate Imaging-Reporting and Data System.

The rest of the men with GG2 or above on surveillance biopsy underwent repeat PGC (n=5), radical prostatectomy (n=3) or radiation therapy (n=3) (figure 3B). The men who underwent salvage radical prostatectomy had

no postoperative complications. Two men had GG2 on both biopsy and prostatectomy specimens while the other man was downgraded from GG4 on biopsy to GG3 at prostatectomy.

There were no significant changes in mean EPIC-CP urinary and sexual function scores from baseline to 4 months (0.71 vs 1.17, p=0.20 and 3.41 vs 4.84, p=0.08, respectively) and from baseline to 9 months (0.71 vs 1.21, p=0.23 and 3.41 vs 3.83 p=0.67, respectively) post-PGC (table 3). No man experienced urinary incontinence.

All men completed the procedure successfully. Thirteen men (24%) experienced an adverse event (table 4). In total, there were 22 (40%) CTCAE V.5 score 2 and 5 (9.1%) score 3 events within the first 30 days, although no reported sequelae occurred beyond this interim. There were no severe adverse events (CTCAE grade >3).

Total costs

TDABC assessment demonstrated the median cost of in-office PGC under local anaesthesia was US\$4,463.05 (range US\$4,087.19–US\$7,238.16) with the majority of costs consisting of cryotherapy disposables (US\$3,086.45). Overhead, depreciation and the remaining fixed indirect costs of the procedure, Artemis device and MRI itself remained a substantial cost driver, totalling US\$1,376.61. In-office PGC has an approximately sixfold lower fixed cost compared with PGC under general anaesthesia, which contributes to an overall lower cost. Moreover, HIFU under general anaesthesia was almost twice as costly at US\$8,449.11 compared with in-office PGC. The higher costs of ASC PGC and HIFU are fueled by the need to be done under general anaesthesia and longer operative times (median length of procedure for in-office PGC 28 (range 16–58 min) minutes vs 120 min (range 90–150 min) for ASC PGC and HIFU) (table 5).

DISCUSSION

Advances in prostate MRI and targeted biopsy has piqued interest in prostate gland partial ablation.¹² Additionally, partial gland ablation offers the potential to avoid adverse

Table 2 Postpartial gland cryoablation outcomes

Catheter duration (days), median (IQR)	6 (3–7)
PSA decrease from baseline (ng/ml), median (IQR)	4.3 (2–6.2)
MRI findings	
% decrease in prostate volume from baseline, median (IQR)	18.3 (0–28.0)
Max PI-RADS V.2, n (%)	
No lesions/not identified	15 (48.40)
2	2 (6.45)
3	5 (16.13)
4	7 (22.57)
5	2 (6.45)
Post-treatment targeted biopsy (max GG), n (%)	
Benign	15 (42.86)
1	7 (20.0)
2	11 (31.43)
3	1 (2.86)
4	1 (2.86)
Recurrence, n (%)	
In-field	7 (20.00)
Out-of-field	6 (17.14)
Ablated site	10 (28.57)
Non-ablated site	3 (8.57)
Post-treatment plan, n (%)	
Active surveillance	24 (68.57)
Repeat PGC	5 (14.29)
Radical prostatectomy	3 (8.57)
Radiation treatment	3 (8.57)

GG, grade group; PGC, prostate gland cryoablation; PI-RADS V.2, Prostate Imaging-Reporting and Data System V.2; PSA, prostate specific antigen.

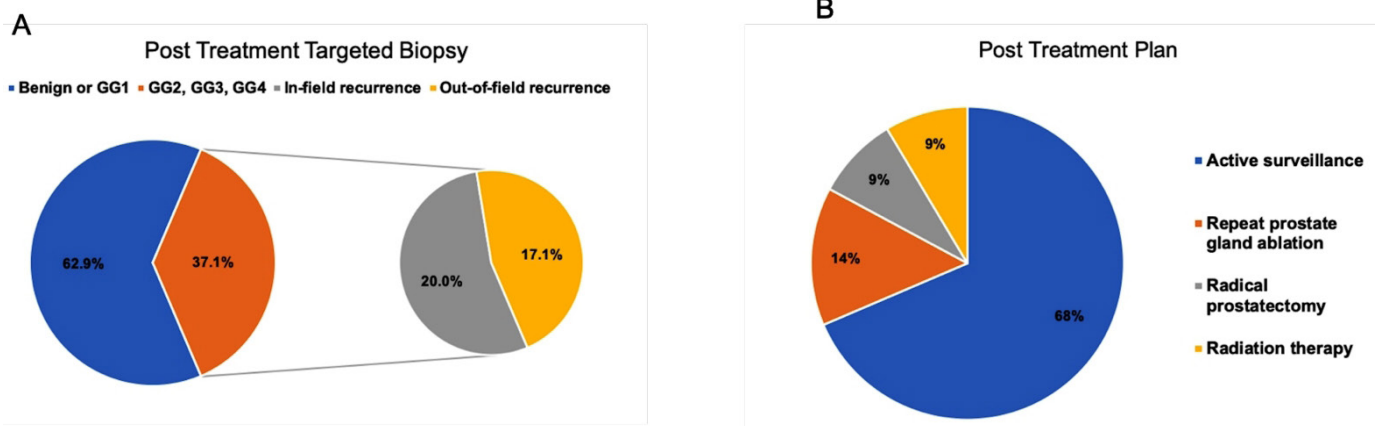


Figure 3 Oncological outcomes and treatment plans following prostate PGC for 35 men. (A) Post-treatment targeted biopsy results. (B) Treatment plan after prostate PGC. GG, grade group; PGC, partial gland cryoablation.

effects associated with traditional whole-organ therapy, such as urinary incontinence and sexual dysfunction.¹² As men are willing to make trade-offs between side effects of treatment and cancer control, prostate gland ablation may preserve health related quality of life and delay definitive therapy.¹³ However, the Idea, Development, Exploration, Assessment and Long-term study (IDEAL) categorises partial gland ablation at development stage 2A for surgical innovation because comparative outcome evidence is lacking.¹⁴

Our pilot IDEAL stage 2A study has several important findings. It is the first to demonstrate that in-office PGC under local anaesthesia is feasible, reproducible and well tolerated. Natarajan *et al* described the performance of focal laser ablation in a clinic setting under local anaesthesia; however, all subjects had intravenous access for pain medications and sedation administration.⁴ In the current series, none of the subjects required intravenous sedation and only four (7.3%) needed an oral benzodiazepine for the procedure. Furthermore, there may inherent advantages in performing cryoablation versus, other energy modalities under general anaesthesia. For instance, once the cryoablation probe is activated and ‘stuck’, it remains fixed in place refractory to moderate

movement; whereas other energies require complete absence of movement.¹⁵

Second, we found favourable functional outcomes with no significant change in pretreatment versus post-treatment urinary and sexual function. This is consistent with a multicentre prospective study of 122 men from the UK, who underwent focal cryotherapy for intermediate-risk to high-risk prostate cancer. Similarly, none of the men had urinary incontinence at 3 years, although 16% experienced erectile dysfunction.¹⁶ Moreover, our in-office approach for PGC was safe and adverse event evaluation showed 22 CTCAE V.5 score 2 and only five CTCAE V.5 score 3 complications in 55 men. The most common CTCAE V.5 score 2 adverse events were urinary retention and urinary tract infections that were treated with urethral catheter drainage and oral antibiotics, respectively. These adverse events compare favourably to other series. For instance, 6 out of 10 men had a CTCAE V.5 score 2 adverse events after focal laser ablation therapy under local anaesthesia.⁴ Bass *et al* reported Clavien-Dindo grade I in 35 (23%) men, grade II in 12 (8%) men and grade III in four (2.6%) out of 153 men that underwent HIFU for localised prostate cancer. Similarly to our series, urinary retention was the most common adverse

Table 3 Baseline, 4 months and 9 months post prostate partial gland cryoablation quality-of-life outcomes

EPIC-CP, n (%)	Baseline	4 months post-PGC	9 months post-PGC	P value
Overall urinary function				
No problem	22 (52.38)	19 (57.58)	13 (59.09)	
Very small problem	4 (9.52)	8 (24.24)	2 (9.09)	
Small problem	8 (40)	4 (12.12)	6 (27.27)	
Moderate problem	6 (14.29)	1 (3.03)	1 (4.55)	
Big problem	2 (4.76)	1 (3.03)	0 (0.00)	
Incontinence symptom score, mean (SD)	0.71 (1.37)	1.17 (1.56)	1.21 (1.72)	0.20/0.23*
Sexual function score, mean (SD)	3.41 (3.32)	4.84 (3.55)	3.83 (3.76)	0.08/0.67*

*Baseline vs 4 months PGC and 9 months PGC, respectively.

EPIC-CP, Expanded Prostate Cancer Index-Clinical Practice; PGC, partial gland cryoablation.

**Table 4** Adverse events reported at 30 days after prostate partial gland cryoablation

Complication	CTCAE V.5 score	Number of men with adverse events
Bladder spasm, antispasmodics indicated	2	1
Erectile dysfunction, intervention indicated	2	4
Hematuria, irrigation indicated	2	1
Urinary frequency, medical management indicated	2	2
Urinary retention, recatheterisation indicated	2	9
UTI, oral intervention indicated	2	5
UTI, IV intervention indicated	3	2
UTI, IV and invasive intervention indicated	3	1
Erectile dysfunction, intervention not helpful	3	2

CTCAEV.5, National Cancer Institute Common Terminology Criteria for Adverse Events V.5; IV, intravenous; UTI, urinary tract infection.

event (20 men, 13.1%).¹⁷ In contrast to HIFU and focal laser ablation, PGC may be monitored with real-time ultrasonography, with 0°C temperatures at the leading edge of the ice-ball.⁷

The short-term oncological outcomes of in-office PGC were comparable to other partial gland ablation modalities under general anaesthesia. In our series, the recurrence rate was 37% at 6 months. Similarly, Mortezavi *et al* report a 41% detection rate of clinically significant prostate cancer on 6-month biopsy after HIFU.¹⁸ Likewise, Natarajan *et al* recently reported an in-office, transrectal focal laser ablation experience using Artemis guidance, and described an in-field recurrence rate of 40% with GG

2 or 3 on follow-up 6-month biopsy.⁴ The difference in in-field recurrence rates between Natarajan *et al* and our study may be due to the lower radius of laser ablation as compared with cryoablation. Furthermore, all 10 participants in the Natarajan *et al* study had higher GG disease (GG≥3) compared with our study, where only 23 out of 55 patients (41.8%) had GG≥3. This may also help explain our lower recurrence rates.

We observed that definitive treatment after PGC was feasible and safe. None of the three men who underwent salvage radical prostatectomy experienced complications. All three men required 0–1 pads (EPIC-CP score 0–1) and had erections sufficient for intercourse at 4-month follow-up (EPIC-CP score 0–1). Consistent with our results, a recent systematic review on treatment options after failure of focal therapy showed promising oncological outcomes, and urinary and sexual function outcomes that are not markedly different from those associated with primary treatment.¹⁹

Finally, with greater emphasis on value-based care nationally, with value defined as outcomes/costs, we examined resource utilisation and costs of this versus other partial gland ablation approaches. Therefore, we performed TDABC analysis to evaluate in-office PGC under local anaesthesia. We demonstrated that the cost of in-office PGC is almost 50% and 75% of the costs of HIFU and PGC at an ambulatory surgery centre, respectively. The major cost driver of PGC was disposables that comprised more than two-thirds of the total cost. Nevertheless, by eliminating the need for general anaesthesia and/or sedation, we demonstrated that in-office PGC is a cost-effective alternative to ASC PGC and HIFU. In the absence of demonstrating superior outcomes for competing partial gland ablation technologies, the lowest cost approach offers the best value.

Our study must be interpreted in the context of the study design. First, this is a non-comparative study and long-term outcomes are needed to assess cancer control. Because this is an IDEAL 2A study, our focus is on safety and feasibility. Additional follow-up is needed to attain long-term oncological outcomes for in-office PGC. However, our study is noteworthy, as it illustrates that

Table 5 Comparison of time-driven activity-based costing between in-office prostate PGC, ambulatory surgery centre PGC and HIFU prostate gland ablation

	In-office PGC	ASC PGC	HIFU
Disposable costs	US\$3,086.44 (2,753.71–5,753.71)	US\$3,086.44 (2,753.71–5,753.71)	US\$2,400.00*
Fixed costs	US\$305.73 (262.60–413.57)	US\$1,859.31 (1,404.78–2,995.63)	US\$6,049.11 (4,912.79–7,185.43)
MRI-targeting biopsy platform cost	US\$1,070.88	US\$1,070.88	N/A
Total costs	US\$4,463.05 (4,087.19–7,238.16)	US\$6,016.63 (5,229.37–9,820.22)	US\$8,449.11 (7,312.79–9,585.43)

Median (range) in dollars.

*Disposable cost is fixed

ASC, ambulatory surgery centre; ;HIFU, high-intensity focused ultrasound; N/A, not available; PGC, partial gland cryoablation.

an office-based treatment paradigm for prostate cancer is feasible, particularly in light of greater emphasis on value-based care.² Second, we used PI-RADS to assess our subjects post-PGC surveillance MRI, despite the fact that PI-RADS was not conceived for post-treatment MRI evaluation. There is currently no framework in place to enable standardised reporting and interpretation of post-PGC surveillance MRI.²⁰ Our recurrence rates are consistent with similar studies. Third, the ability to differentiate between in and out of field recurrences is limited by prostate volume reduction that cannot be clearly delineated with post-treatment MRI.²¹ Finally, although the TDABC analysis demonstrates the cost-effectiveness of in-office PGC, we did not model costs of complications related to PGC.

In summary, in-office PGC is a promising approach with similar outcomes to ablation under general anaesthesia. However, adherence to biopsy surveillance is critical, as the proper follow-up beyond a clinical trial mandated end of study biopsy is still uncertain.²¹

CONCLUSIONS

We demonstrate that in-office PGC under local anaesthesia is technically feasible and safe for men with localised prostate cancer. In-office PGC demonstrated comparable short-term oncological control and functional outcomes versus HIFU and PGC series performed under general anaesthesia. Despite favourable short-term outcomes, more studies assessing long-term biopsy results are needed before widespread dissemination.

Twitter Spyridon P Basourakos @sbasourakos and Jim C Hu @jimhumd

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Institutional Review Boards of Urological Research Network (FL, USA) and NewYork-Presbyterian/Weill Cornell Medicine (NY, USA) approved this study (13–1010 and 1702018011, respectively).

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ORCID iDs

Spyridon P Basourakos <http://orcid.org/0000-0002-7458-4593>
Jim C Hu <http://orcid.org/0000-0003-2562-8024>

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Supplementary Table 1. Recurrence data for men with GG1 disease on post-PGC follow up biopsy.

Recurrence, n (%)	
In-field	4 (11.43)
Out-of-field	3 (8.57)
Ablated site	5 (14.29)
Non-ablated site	2 (5.71)

GG: Grade Group; PGC: partial gland cryoablation