Early functional outcomes following partial gland cryo-ablation

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Introduction: *Given the increasing interest in partial gland cryo-ablation as a treatment modality and the lack of data surrounding urinary and sexual outcomes after the procedure, the goal of this analysis was to assess functional outcomes following partial gland cryo-ablation (PGCA) stratified according to baseline severity of lower urinary tract symptoms (LUTS) and erectile function (EF). A secondary goal was to also determine if there were any clinical factors associated with significant change in LUTS and EF.*

Materials and methods: *Since 3/2017, all men undergoing primary PGCA were offered enrollment into an IRB-approved prospective outcomes registry. Men were given International Prostate Symptom Score (IPSS) and Sexual Health Inventory for Men (SHIM) surveys prior to and 6 months post treatment. Differences in IPSS and SHIM scores are described, and factors associated with clinically significant change were assessed using univariate and multivariate analysis.*

Results: *A total of 100 men completed 6 month follow up. The mean IPSS for the overall cohort decreased 2.1 units ($p > 0.05$). The mean changes in IPSS for men with baseline mild, moderate, and severe LUTS were 0.9 ($p = 0.06$), -4.2 ($p = 0.001$), and -11.1($p = 0.001$) units, respectively. The mean changes in the SHIM score for all men were - 5.1 units ($p = 0.001$). The mean changes in SHIM score for baseline none, mild/mild-to-moderate, moderate-severe ED were -7.6 ($p = 0.001$), -6.5 ($p = 0.001$) and -1.1 units ($p = 0.27$), respectively. No variables of interest were significantly associated with changes in IPSS or SHIM scores.*

Conclusion: *Stratifying functional outcomes according to baseline IPSS and SHIM is imperative to assess the true impact of PGCA on functional outcomes.*

Key Words: functional outcomes, cryo-ablation, prostate cancer, partial gland ablation

Introduction

Radical prostatectomy (RP), radiation therapy (RT), whole gland ablation, and active surveillance (AS) are guideline recommended options for clinically localized prostate cancer.[1] Selecting treatment for clinically localized prostate cancer must balance both the risk of disease progression with the side effects of treatment. The enhanced ability of mpMRI targeted biopsy (MRTB) coupled with systematic biopsy (SB) to detect and localize significant prostate cancer(s)[2] has enabled partial gland ablation (PGA) to emerge as a potential treatment for clinically localized prostate cancer.

Several meta-analyses demonstrate that PGA is associated with favorable functional outcomes.[3-5] We have reported excellent short term oncological control following partial gland cryo-ablation (PGCA).[6] While long term oncological control following PGCA remains to be determined,[6] men with clinically localized prostate cancer may favor PGA recognizing long term oncological outcomes are uncertain in order to preserve functional status.

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The objective of this study is to critically examine quality of life following PGCA. The novel aspect of our study is assessing functional outcomes stratified according to baseline severity. Another unique objective is to elucidate demographic, disease, or treatment related factors associated with significant change in lower urinary tract symptoms (LUTS) and erectile function (EF) post-PGCA.

Materials and methods

Since March 2017, all men undergoing primary PGCA by two urologic oncologists at a single institution were offered enrollment into an IRB approved prospective outcomes registry (IRB #SI 7-00354). Candidates for prostate biopsy at our institution undergo pre-biopsy multi-parametric MRI (mpMRI). All regions of interest (ROI) with Prostate Image Reporting and Data System (PI-RADS) v2 scores > 1 are segmented using the Profuse software and MRTB of these ROIs is performed using the Artemis biopsy platform. Four biopsies are directed into all mpMRI ROI together with a computer generated 12-core SB. When referred to our institution following SB alone, mpMRI and repeat biopsies are not mandated if there is concordance between the mpMRI ROI and sites of disease. The prostate volume, greatest linear dimension of the ROI, and the site of the lesion (peripheral (PZ) versus transition zones (TZ)) was recorded. If the MRI lesion overlapped zones, it was assigned the dominant zone occupied.

Our inclusion criteria were as follows: a single reported mpMRI ROI concordant with biopsy Gleason grade group (GGG) < 4, no gross extra-prostatic extension on mpMRI, and no GGG > 1 or GGG 1 with core length > 5 mm contralateral to the target.

All PGCA was performed under general anesthesia in the dorsal lithotomy position. Between one to six cryo-probes were positioned under ultrasound (US) guidance to achieve a treatment plan with a 10 mm margin beyond the target when feasible. Six margin and safety temperature probes were positioned. A urethral warming catheter was passed over a guidewire under US guidance prior to initiating the first freeze cycle. A minimum of two freeze / thaw cycles were carried out using the Cryocare CS system.

Variables and measurements

Surveys assessing IPSS and SHIM scores were self-administered at baseline and 6 months post-PGCA. A single question on a 2 week, 3 and 6 month survey captured pad use for urinary incontinence. Use of medical therapy for EF was also captured at the baseline and 6 months office visit. Median age, pre-treatment PSA, and prostate volume were calculated for all included men. Other parameters of interest included race, PI-RADS score on MRI, location of lesion on MRI, maximal length of lesion on MRI, GGG on biopsy, and number of cryo-probes, with number of cryo-probes and zone of ablation (TZ vs. PZ) serving as indirect indicators for proximity to neurovascular bundles.

Mean SHIM and IPSS scores at baseline and 6 months were calculated for all men and for symptom subgroups. Men were stratified into three categories according to baseline LUTS severity: mild (0-7), moderate (8-18), or severe (> 18).[7] Similarly, men were stratified into another three categories of ED according to baseline SHIM scores: none (22-25), mild/mild-moderate (12-21), and moderate-severe/severe (< 12).[8] Our primary outcome of interest was whether the change in score between baseline and 6 months was clinically significant when stratified by baseline severity. We also assessed if there were variables of interest were associated with clinically meaningful change.

Statistical methods

A paired T-test was used to compare mean scores at baseline and 6 months. Linear regressions models were built based on a priori criteria to assess which demographic, disease and treatment related factors were associated with unit change in IPSS or SHIM score at 6 months.

Additional analyses were then performed in men who were in the moderate or severe baseline group for IPSS (IPSS > 7) and in the none, mild-moderate, and moderate categories for SHIM (SHIM > 11) at baseline. For IPSS, a 3-point change at 6 months from their baseline score was deemed meaningful.[9] For SHIM, a 4-point change at 6 months from their baseline score was deemed clinically meaningful improvement based on the Rosen et al study.[8] There is no validated threshold for a decrease in the SHIM corresponding to a clinically meaningful decrease in EF; therefore, a 4-point decrease in SHIM was utilized as a proxy for clinically meaningful deterioration. The number of men achieving meaningful changes in either direction at 6 months was first calculated. Next, a univariate logistic regression analysis was performed to determine whether any variables of interest were significantly associated ($p < 0.2$) with meaningful LUTS improvement (3-point decrease) or EF deterioration (4-point decrease) at 6 months. A stepwise forward addition multivariable logistic regression model was then constructed from the factors that met the threshold for significance on univariate analysis. Analyses were performed using the SPSS Statistical Software.[10]

TABLE 1. **Baseline demographic and clinical factors**

Baseline variables (n = 100)	
Age (median, IQR)	65 (60-72)
Pre-treatment PSA (median, IQR)	6.0 (4.6-7.9)
Prostate volume, in ccs* (median, IQR)	41 (32-53.5)
Race (%)	
Black	15%
White	66%
Other	19%
PI-RADS MRI (%)	
1	1%
2	15%
3	35%
4	38%
5	11%
Site of MRI lesion (%)	
Peripheral zone	76%
Transition zone	24%
Maximal length of ROI (%)	
< 6 cc	10%
6-12 cc	50%
> 12 cc	40%
Gleason grade group (%)	
1	15%
2	62%
3	23%
Number of probes used (%)	
1	1%
2	6%
3	26%
4	34%
5	16%
6	17%

*ccs = cubic centimeters

Results

A total of 100 men met the above selection criteria and completed baseline and 6 month follow up assessment of LUTS and ED. The age, race, pre-treatment PSA, prostate volume, PIRADS scores, maximum linear dimension on MRI, GGG, and number of cryo-probes are presented for the cohort in Table 1. None of the patients experienced urinary incontinence and therefore no further analysis of this functional outcome was performed. Similarly, 35% of men used PDE5i therapy at baseline versus 38% at 6 months (p = 0.15) suggesting no difference in medical therapy utilization during follow up.

The mean baseline, 6 month, and changes in IPSS and SHIM score are shown in Table 2. The mean IPSS score at baseline was 8.7 (95% CI: 7.3-10). The mean IPSS score for the overall cohort decreased 2.1 IPSS units [(95% CI: 3.3-1.0), p = 0.001]. The mean changes in IPSS were stratified according to baseline mild, moderate, and severe LUTS, Table 2.

Fifty-one percent of men presented with mild LUTS and they did not experience statistically significant change in their IPSS post-PGCA (p = 0.06). The mean changes in IPSS for men with baseline moderate and severe LUTS was -4 .2 units [(95% CI: -5.7 to -2.6), p = 0.001] and -11.1 units [(95% CI: -16.8 to -5.4), p = 0.003], respectively.

The mean SHIM score for the overall cohort decreased by 5.1 units [(95% CI: 6.5-3.7), p = 0.001)]. The mean changes in the SHIM scores were then stratified, and 33% of men presented with moderate-severe/severe ED. The mean change in SHIM for men with baseline moderate-severe/severe ED was -1.1 units [(95% CI: -3.0 to 0.9, p = 0.27]. The mean changes in SHIM scores for men presenting with mild/mild-moderate ED and no ED were -6.5 units [(95% CI: -9.0 to -4.1, p = 0.001] and -7.6 units [(95% CI: -10.1 to -5.1, p = 0.001], respectively.

A linear regression model was used to identify demographic, disease, and treatment related factors associated with changes in IPSS and SHIM scores following PGCA, Table 3. None of the factors examined were significantly associated with unit change in IPSS. However, there was a signal that larger prostates and TZ disease may predict improvement in LUTS. The lack of statistical significance may be attributed to sample size. There were no factors significantly associated with change in EF.

Table 4 shows the percentage of men presenting with IPSS > 7 who exhibited clinically meaningful changes in LUTS. Overall, 56.1% and 87.5% of men with baseline moderate and severe LUTS exhibited clinically meaningful improvement in LUTS. Based on the assumption that a 4 unit decrease in SHIM represents clinically meaningful change in EF, 64% and 63% of men with baseline SHIM > 11 exhibited a meaningful deterioration in EF.

Separate bivariate models were employed to identify factors associated with a meaningful improvement in LUTS for men with IPSS > 7 and significant deterioration in EF for men with SHIM scores > 12, Table 5. None of the factors included in the uni-variate or multi-variate models were associated with clinically or statistically meaningful changes in LUTS.

TABLE 2. **Change in functional scores**

Baseline and changes in IPSS and SHIM at 6 months

	Mean score at baseline (95% CI)	**Mean score at 6 months (95% CI)**	**p value***
All (n = 100)	8.7 (7.3-10.0)	6.5 (5.5-7.6)	0.001
Baseline IPSS category			
Mild (0-7), n = 51	3.3 (2.6-3.9)	4.2 (3.3-5.1)	0.06
Moderate (8-18), n = 41	12.7 (11.6-13.8)	8.5 (6.8-10.2)	0.001
Severe (> 18), n = 8	22.6 (19.8-25.0)	11.5 (5.0-18.0)	0.003
All (n = 100)	15.9 (14.3-17.6)	10.8 (9.2-12.4)	0.001
Baseline SHIM category			
None (22-25), n = 36	23.9 (23.5-24.3)	16.3 (13.8-18.8)	0.001
Mild/mild to moderate (12-21), n = 31	17.8 (17.0-18.7)	11.3 (8.5-14.1)	0.001
Moderate to severe/ severe (< 12), n = 33	5.5 (4.0-6.9)	4.4 (2.8-5.9)	0.27
	Mean change from baseline (95% CI)	**Clinically meaningful improvement from baseline % (n)****	**Clinically meaningful deterioration from baseline % (n)*****
All (n = 100)	-2.1 (-3.3 to -1.0)	n/a	n/a
Baseline IPSS category			
Mild (0-7), n = 51	0.9 (-0.05 to 1.8)	n/a	n/a
Moderate (8-18), n = 41	-4.2 (-5.7 to-2.6)	56.1%	4.9% (2)
Severe (> 18), n = 8	-11.1 (-16.8 to -5.4)	87.5%	0% (0)
All (n = 100)	-5.1 (-6.5 to -3.7)	n/a	n/a
Baseline SHIM category			
None (22-25), n =36	-7.6 (-10.1 to -5.1)	0% (0)	64% (23)
Mild/mild to moderate (12-21), n =31	-6.5 (-9.0 to -4.1)	3.2% (1)	61.3% (19)
Moderate to severe/ Severe (<12), n = 33	-1.1 (-3.0 to 0.9)	n/a	n/a

*paired t-test comparing mean scores at baseline and 6 months among patients in each of the three baseline groups
**clinically meaningful improvement defined as a 3 point decrease from baseline and a 4 point increase from baseline for IPSS and SHIM, respectively
***clinically meaningful deterioration defined as a 3-point increase from baseline and a 4 point decrease from baseline for IPSS and SHIM, respectively

Discussion

RP and RT are known to adversely impact quality of life.[11] In a study of men undergoing RP, urinary incontinence was observed in over 20% of cases 1 year following treatment.[12] A tertiary center reported that only 30% of men with no evidence of pre-RP ED regained baseline EF 2 years post treatment with phosphodiesterase inhibitors.[13] Similarly, RT adversely impacts quality of life along with increased risk of bladder and rectal malignancies.[14,15]

The appeal of PGA is to provide oncological control of clinically localized prostate cancer while reducing the quality of life complications associated with whole gland treatments.[16] Favorable oncological outcomes following PGA relies on accurate identification and ablation of the index tumor.[17,18] Several consensus statements define candidates for PGA as follows:

TABLE 3. **Linear regression assessing functional outcomes**

Changes in IPSS (n = 100)		
Factor	**Coefficient (95% CI)**	**p value**
Age (per year)	-0.01 (-0.08 to 0.05)	0.69
Prostate volume (per 10 cc)	-0.46 (-1.05 to 0.14)	0.13
PIRADS 4-5 (vs. PIRADS 1-3)	-0.42 (-2.94 to 2.11)	0.74
TZ (vs. PZ)	-2.12 (-4.97 to 0.73)	0.14
Lesion 6-12 mm (vs. < 6mm)	-1.43 (-5.67 to 2.8)	0.50
Lesion >12 mm (vs. < 6mm)	-0.87 (-5.24 to 3.49)	0.69
GGG 2 (vs. GGG1)	1.41 (-2.18 to 5)	0.44
GGG 3 (vs. GGG1)	0.38 (-3.78 to 4.55)	0.86
4 probes (vs. 1-3)	1.38 (-1.56 to 4.32)	0.35
5-6 probes (vs. 1-3)	-1.46 (-4.53 to 1.61)	0.35
Changes in SHIM scores (n=100)		
Factor	**Coefficient (95% CI)**	**p value**
Age (per year)	0.04 (-0.05 to 0.12)	0.43
Prostate volume (per 10 cc)	-0.22 (-0.99 to 0.55)	0.57
PIRADS 4-5 (vs. PIRADS 1-3)	-1.36 (-4.62 to 1.89)	0.41
TZ (vs. PZ)	-1.46 (-5.13 to 2.22)	0.43
Lesion 6-12 mm (vs. < 6 mm)	-1.22 (-6.67 to 4.24)	0.66
Lesion >12 mm (vs. < 6 mm)	-0.02 (-5.64 to 5.6)	0.99
GGG 2 (vs. GGG1)	-1.77 (-6.39 to 2.86)	0.45
GGG 3 (vs. GGG1)	-3.18 (-8.54 to 2.18)	0.24
4 probes (vs. 1-3)	-0.98 (-4.76 to 2.81)	0.61
5-6 probes (vs. 1-3)	2.02 (-1.93 to 5.97)	0.31

clinically significant unilateral disease without evidence of extra-capsular extension or contralateral GGG > 1 disease.[19,20] We have shown that amongst men fulfilling the above criteria for PGA who undergo RP, the index tumor is reliably identified in over 90% of cases and only 20% harbor any contralateral Gleason pattern 4 disease outside the ablation field.[17] Only 2% of men meeting consensus guidelines for selection of candidates undergoing PGCA in our prospective outcomes study had > GGG1 disease in the ablation field at 6 months suggesting the index lesion can be reliably ablated.[6]

Our study was designed to critically examine changes in LUTS and EF following PGCA. We did not assess GI outcomes since PGA has not been shown to cause GI dysfunction.[21] We chose a 6 month time point, realizing that EF may improve over time. We have previously reported EF improves up to 7 years post-RP showing delayed recovery of EF following presumed treatment related injury to the cavernous nerves.[22]

The median age of our PGCA cohort was 65 years with 25% over 72 years. Most definitions of clinically localized prostate cancer include GGG > 1 with some definitions also include any cancer with a core length > 6 mm.[18] Eighty-five percent of men in our cohort had GGG > 1, and 90% of the MRI targets in our study had a greatest linear dimension over 6 mm. Only 4 GGG 1 cancers were associated with an MRI target < 6 mm. Therefore, our cohort based on age and disease risk justifies treatment.

While prior PGA functional outcomes studies have reported mean changes in LUTS and EF using the IPSS and SHIM, no prior studies have stratified changes in IPSS or SHIM according to baseline LUTS and EF. Barry et al observed a 3 unit decrease in IPSS

TABLE 4. **Unadjusted bivariate analysis for outcomes. LUTS improvement in men with baseline IPSS score =>8 (n = 49)**

	%	Unadjusted OR (95% CI)	p value
Age (per each year)	n/a	1.00 (0.96-1.01)	0.54
Prostate volume (per cc)	n/a	1.01 (0.98-1.05)	0.29
Race			
White (n = 29)	66%	Ref	
Black (n = 9)	67%	1.05 (0.21-5.12)	0.95
Other (n = 11)	46%	0.44 (0.11-1.80)	0.25
Site of MRI lesion			
PZ (n = 39)	56%	Ref	
TZ (n = 10)	80%	3.09 (0.58-16.48)	0.19
Size of MRI Lesion			
< 6 cc ROI 1 (n = 5)	40%	Ref	0.47
6-12 cc ROI 1 (n = 25)	68%	3.18 (0.44-23.0)	
> 12 cc ROI 1 (n = 19)	58%	2.10 (0.28-15.35)	
PIRADS MRI			
PIRADS 1, 2, 3 (n = 26)	50%	Ref	
PIRADS 4, 5 (n = 23)	74%	2.83 (0.85-9.47)	0.09
Gleason grade group			
GGG 1 (n = 8)	38%	Ref	
GGG 2 (n = 31)	71%	4.07 (0.80-20.75)	0.09
GGG 3 (n = 10)	50%	1.66 (0.25-11.07)	0.6
Number of probes used			
1-3 probes (n = 14)	71%	Ref	
4 probes (n = 15)	53%	0.45 (0.09-2.13)	0.32
5-6 probes (n = 20)	60%	0.60 (0.78-7.97)	0.49

LUTS improvement defined as 3 point or more decrease in IPSS Score at 6 months

represented a clinically meaningful change.[9] Since the mean change in IPSS for the entire cohort was -2.1 IPSS units, one may conclude PGCA does not have a clinically meaningful effect on LUTS.[9] Fifty-one percent, 41%, and 8% of our study cohort presented with baseline mild, moderate and severe LUTS, respectively. The observed +0.9 unit change in IPSS for the mild baseline LUTS sub-group indicates that PGCA does not significantly impact LUTS for these men. Conversely, men with baseline IPSS > 7 exhibited improvements that were both statistically and clinically meaningful. In the 49% of men with baseline IPSS > 7, 61%, 35%, and 4% exhibited significant decrease, no change, or significant worsening of LUTS following PGCA, respectively. Therefore, the majority of men presenting with IPSS > 7 can expect clinically meaningful change in their baseline LUTS.

Given the 5.1 unit decrease in SHIM for the overall cohort, short term EF is significantly impacted by PGCA. Overall, 36%, 33%, and 31% of our study cohort presented with none, mild/mild-to-moderate, and moderate-to-severe/severe ED, respectively. A univariate analysis failed to identify significant associations between demographic, treatment or disease factors and changes in SHIM scores. A potential limitation of the SHIM score is that it does not discriminate between lack of sexual activity versus decline in EF.[23]

As mentioned, we chose a 4 unit decrease in the SHIM to represent a clinically meaningful decrease in EF based on Rosen et al.[8] A clinically meaningful deterioration in EF was observed in 63% of men with baseline SHIM > 11. The adverse impact of PGCA on EF in our study appears greater than other studies reported in the literature.[21,24,25] Our oncological outcomes at 6 months far exceed other studies suggesting superior oncological outcomes may have been achieved at the expense of EF preservation.[6,24,26]

TABLE 5. **Unadjusted bivariate analysis for outcomes. ED worsening in men with baseline SHIM score => 12 (n = 67)**

	% with change	Unadjusted OR (95% CI)	p value
Age (per each year)	n/a	1.0 (0.97-1.02)	0.98
Prostate volume (per cc)	n/a	0.99 (0.97-1.01)	0.51
Race			
White (n = 48)	65%	Ref	
Black (n = 8)	63%	0.91 (0.19-4.3)	0.91
Other (n = 11)	55%	0.66 (0.17-2.47)	0.54
Site of MRI lesion			
PZ (n = 49)	63%	Ref	
TZ (n = 18)	61%	0.91 (0.3-2.77)	0.87
Size of MRI lesion			
< 6 cc ROI 1 (n = 5)	80%	Ref	
6-12 cc ROI 1 (n = 34)	59%	0.36 (0.04-3.55)	0.38
> 12 cc ROI 1 (n = 28)	64%	0.45 (0.04-4.59)	0.5
PIRADS MRI			
PIRADS 1, 2, 3 (n = 36)	61%	Ref	
PIRADS 4, 5 (n = 31)	65%	1.16 (0.43-3.12)	0.77
Gleason grade group			
GGG 1 (n = 10)	60%	Ref	
GGG 2 (n = 45)	58%	0.91 (0.23-3.7)	0.9
GGG 3 (n = 12)	83%	3.33 (0.46-24.05)	0.23
Number of probes used			
1-3 probes (n = 23)	61%	Ref	
4 probes (n = 24)	67%	1.3 (0.39-4.23)	0.68
5-6 probes (n = 20)	60%	0.96 (0.28-3.3)	0.95

ED worsening defined as 4 point or more decrease in SHIM at 6 months

Our outcomes support the impression that some men with no ED experience an adverse impact on EF but retain the ability to engage in sexual intercourse. The greatest impact is observed in men with baseline mild/mild-to-moderate ED. For the 21% of men with severe ED, the impact of PGCA on EF is not meaningful. We will reassess EF at 1 and 2 years to see if EF improves.[22] Based on the present study, we now offer daily phosphodiesterase inhibitors when return of EF is a high priority.

We did not observe any predictors of change in IPSS or SHIM for the total cohort. We also examined predictors of clinically meaningful improvements in LUTS or deterioration of EF in the 49% of men with baseline IPSS > 7 and 79% with baseline SHIM > 11. We hypothesized that men with larger prostates, TZ tumors, and greater ablation volumes were more likely to exhibit clinically meaningful improvement in LUTS. We also hypothesized that PZ lesions due to proximity to the neurovascular bundle, smaller prostates, and greater volume ablations would experience greater adverse impact on EF. None of these factors were associated with clinically meaningful changes in LUTS or EF.

There are many strengths to the present study. All data was entered into the database in real time, and our selection criteria identified cases with clinically localized prostate cancer since 85% had GGG > 1 disease and only 4% had GGG1 associated with an MRI lesion < 6 mm. This is the first study to our knowledge stratifying functional outcomes according to baseline severity of LUTS and EF.

The two treating authors have performed approximately 500 PGA using various energy sources and so our results cannot be generalized to less experienced surgeons. One limitation is that we did not control for the use of medical therapies for LUTS

or phosphodiesterase inhibitors pre or postoperatively. Medical therapies for LUTS were not withdrawn or added during the 6 months post-ablation interval. While the addition of phosphodiesterase inhibitors was allowed, we did not capture compliance on these medications. An additional limitation is that there is no validated definition of a clinically meaningful decrease in SHIM score. Since a 4 unit decrease in SHIM has been shown to represent a clinically significant improvement in subjects undergoing treatment for ED, we used a 4 unit decrease in SHIM as the threshold for clinically meaningful decrease in EF. Lastly, despite this being one of the larger single center experiences published to date, the size of our cohort may have underpowered our ability to detect individual factors that were significantly associated with our functional outcomes.

Conclusion

Stratifying changes in LUTS and EF according to baseline severity provides highly relevant information for making informed decisions regarding functional outcomes following PGCA. Men with baseline moderate/severe LUTS may expect clinically meaningful improvement in LUTS. Men with baseline none/mild/moderate ED experience some loss of EF in the short term [6 month] but further longitudinal follow up is needed to ascertain if there are men whose EF improves with time. □

References

1. Sanda MG, Cadeddu JA, Kirkby E et al. Clinically localized prostate cancer: AUA/ASTRO/SUO guideline. Part I: risk stratification, shared decision making, and care options. *J Urol* 2018;199(3):683-690.
2. Ahdoot M, Wilbur AR, Reese SE et al., MRI-targeted, systematic, and combined biopsy for prostate cancer diagnosis. *N Engl J Med* 2020;382(10):917-928.
3. Golan R, Bernstein AN, McClure TD et al. Partial gland treatment of prostate cancer using high-intensity focused ultrasound in the primary and salvage settings: a systematic review. *J Urol* 2017;198(5):1000-1009.
4. Bass R, Fleshner N, Finelli A, Barkin J, Zhang L, Klotz L. Oncologic and functional outcomes of partial gland ablation with high intensity focused ultrasound for localized prostate cancer. *J Urol* 2019;201(1):113-119.
5. He Y, Tan P, He M et al. The primary treatment of prostate cancer with high-intensity focused ultrasound: a systematic review and meta-analysis. *Medicine (Baltimore)* 2020;99(41):e22610.
6. Wysock JS, Becher E, Gogaj R, Velazquez N, Lepor H. Early oncological control following partial gland cryo-ablation: a prospective experience specifying reflex MRI guided biopsy of the ablation zone. *Prostate Cancer Prostatic Dis* 2021;24(1):114-119.
7. Booth L, Skelton DA, Hagen S, Booth J. Age and gender stratified normative values for the International Prostate Symptom Score for adults aged 60 years and over. *Neurourol Urodyn* 2018;37(8):2732-2739.
8. Rosen RC, Allen KR, Ni X, Araujo AB. Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale. *Eur Urol* 2011;60(5):1010-1016.
9. Barry MJ, Cantor A, Roehrborn CG, Group CS. Relationships among participant international prostate symptom score, benign prostatic hyperplasia impact index changes and global ratings of change in a trial of phytotherapy in men with lower urinary tract symptoms. *J Urol* 2013;189(3):987-992.
10. IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY:IBM Corp.
11. Penson DF, Litwin MS. Quality of life after treatment for prostate cancer. *Curr Urol Rep* 2003;4(3):185-195.
12. Holmberg L, Bill-Axelson A, Steineck G et al. Results from the Scandinavian Prostate Cancer Group Trial Number 4: a randomized controlled trial of radical prostatectomy versus watchful waiting. *J Natl Cancer Inst Monogr* 2012;2012(45):230-233.
13. Bianco FJ Jr, Scardino PT, Eastham JA. Radical prostatectomy: long-term cancer control and recovery of sexual and urinary function ("trifecta"). *Urology* 2005;66(5 Suppl):83-94.
14. Potosky AL, Davis WW, Hoffman RM et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the prostate cancer outcomes study. *J Natl Cancer Inst* 2004;96(18):1358-1367.
15. Resnick MJ, Koyama T, Fan KH et al. Long-term functional outcomes after treatment for localized prostate cancer. *N Engl J Med* 2013;368(5):436-445.
16. Valerio M, Cerantola Y, Eggener SE et al. New and established technology in focal ablation of the prostate: a systematic review. *Eur Urol* 2017;71(1):17-34.
17. Kenigsberg AP, Llukani E, Deng FM, Melamed J, Zhou M, Lepor H. The use of magnetic resonance imaging to predict oncological control among candidates for focal ablation of prostate cancer. *Urology* 2018;112:121-125.
18. Ahmed HU, El-Shater Bosaily A, Brown LC et al., Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. *Lancet* 2017;389(10071):815-822.
19. Bekelman JE, Rumble RB, Chen RC et al. Clinically localized prostate cancer: ASCO Clinical Practice Guideline Endorsement of an American Urological Association/American Society for Radiation Oncology/Society of Urologic Oncology Guideline. *J Clin Oncol* 2018;36(32):3251-3258.
20. van der Poel HG, van den Bergh RCN, Briers E et al. Focal therapy in primary localised prostate cancer: The European Association of Urology Position in 2018. *Eur Urol* 2018;74(1):84-91.
21. Onik G, Vaughan D, Lotenfoe R, Dineen M, Brady J. The "male lumpectomy": focal therapy for prostate cancer using cryoablation results in 48 patients with at least 2-year follow-up. *Urol Oncol* 2008.26(5):500-5055.
22. Sivarajan G, Prabhu V, Taksler GB, Laze J, Lepor H. Ten-year outcomes of sexual function after radical prostatectomy: results of a prospective longitudinal study. *Eur Urol* 2014;65(1):58-65.
23. Rosen RC, Cappelleri C. The sexual health inventory for men (IIEF-5): reply to Vroege. *Int J Impot Res* 2000;12(6):342-343.
24. Shah TT, Peters M, Eldred-Evans D et al. Early-medium-term outcomes of primary focal cryotherapy to treat nonmetastatic clinically significant prostate cancer from a prospective multicentre registry. *Eur Urol* 2019;76(1):98-105.
25. Tay KJ, Polascik TJ, Elshafei A et al. Primary cryotherapy for high-grade clinically localized prostate cancer: oncologic and functional outcomes from the COLD registry. *J Endourol* 2016;30(1):43-48.
26. Mufarrij P, Sankin A, Godoy G, Lepor H. Pathologic outcomes of candidates for active surveillance undergoing radical prostatectomy. *Urology* 2010;76(3):689-692.