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Does the type of cryoprobe affect oncological and functional outcomes in men with clinically localized prostate cancer treated with primary whole gland prostate cryoablation?

Tarek Taha[a], Wei Phin Tan[a], Ahmed Elshafei[b,c], Alireza Aminsharifi[a], Robert Given[d], Michael L. Cher[e], Thomas J. Polascik[a,*]

[a]Division of Urologic Surgery, Duke Cancer Institute, Durham, NC, USA; [b]Glickman Urological Institute, Cleveland Clinic Foundation, Cleveland, OH, USA; [c]Department of Urology, Medical School, Cairo University, Cairo, Egypt; [d]Department of Urology, Eastern Virginia Medical School, VA, USA; [e]Department of Urology, Wayne State University School of Medicine, Detroit, MI, USA

Abstract

Background: This study aimed to compare the oncological and functional outcomes of primary whole gland cryoablation of the prostate using the variable ice cryoprobe (V-Probe®) and the conventional fixed-size ice probe.

Materials and methods: We reviewed the Cryo On-Line Data Registry for men who were treated with primary whole gland prostate cryoablation from 2000 through 2017. A multivariate Cox proportional hazards model was used to compare timing to biochemical recurrence between the V-Probe® and fixed-size ice probe after adjusting for preoperative prostate-specific antigen (PSA), neoadjuvant androgen deprivation therapy, preoperative Gleason score, and preoperative T stage.

Results: A total of 1124 men were included. Median age, Gleason score, and pretreatment PSA were 70 years (interquartile range [IQR]: 65–74 years), 7 (IQR: 6–7) and 5.9 ng/mL (IQR: 4.6–8.1 ng/mL), respectively. The median follow-up time was 25.0 months (IQR: 11.2–48.6 months). V-Probes® were used in 269 (23.9%) cases and fixed-size ice probes in 858 (76.1%) cases. After adjusting for clinical T stage, PSA, neoadjuvant androgen deprivation therapy and preoperative Gleason score, on the multivariate Cox regression model, we found that there was no significant difference between the type of probe and timing to biochemical recurrence ($p = 0.35$). On multivariate logistic regression, using the V-Probe® was associated with a 91% increase in postoperative urinary retention compared to the fixed-size ice probe ($p = 0.003$).

Conclusions: The use of the V-Probe® versus conventional fixed-size ice probe was not associated with a difference in biochemical recurrence in patients undergoing primary cryoablation of the prostate.

Keywords: Conventional fixed-size ice probe; Cryotherapy; Prostate cancer; V-Probe®

1. Introduction

Radical prostatectomy and radiotherapy have been considered as standards of care for the management of patients with organ-confined, clinically significant prostate cancer and having adequate life expectancy. Despite long-term oncological control with these modalities, morbidities associated with treatment have been of great concern, especially to patients.[1,2]

Cryotherapy is an alternative minimally invasive treatment that aims to reduce the morbidity associated with radical therapy and avoid some of the potential peri- and postoperative complications while maintaining cancer control.[3] Cryotherapy has been applied to treat mostly low and intermediate-risk prostate cancer but has also been extended to men with high risk disease.[4] Biophysical features of the cryotherapy system such as the type of cryogen, contact area, cooling rate, minimum temperature achieved, duration of freeze, and the location and number of cryoprobes can affect the energy transfer to the tissue and therefore can have an impact on the overall outcome of this procedure.[5,6]

In recent years, the Variable Ice probe (V-Probe®, EndoCare, Austin, TX) was introduced to perform cryoablation of the prostate. The V-Probe® is 2.4 mm in diameter, with a 15 cm length that can generate a tear-shaped ice ball of maximal length 4.96 and 1.99 cm in diameter. The V-Probe® differs from other types of probes by its flexibility to adjust and customize the ice ball length on each probe as determined by the sagittal view of the prostate length.[7] In contrast, the conventional fixed-size ice probes have no control over length and, therefore, treating physicians may encounter more difficulty customizing treatment in men with smaller glands. To the best of our knowledge, no study has compared the characteristics and outcomes of the fixed-size ice probe and the V-Probe®. In this study, we aimed to evaluate the

* *Corresponding Author: Thomas J. Polascik, Division of Urology, Duke Cancer Institute, Room 1080, Yellow Zone, Duke South, Durham NC–27710, USA. E-mail address: thomas.polascik@duke.edu (T.J. Polascik).*

TT and WPT contributed equally to this work.

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oncological and functional outcomes of these 2 common types of commercially available cryoprobes in the setting of primary cryoablation for prostate cancer.

2. Materials and methods

We queried the Cryo On-Line Data (COLD) registry for patients with prostate cancer treated with primary whole gland cryotherapy from 2000 through 2017. The Endocare system was used for all patients who underwent cryotherapy with both the fixed iced probe and V-Probe®.

The COLD registry is a multi-institutional, prospectively collected, web-based database of patients with localized and locally recurrent prostate cancer treated with primary and salvage cryotherapy. The registry was sponsored by Endocare (Austin, TX), and the database was maintained by an independent research company (Watermark Research Partners, Indianapolis, IN). The COLD registry was designed to collect and report the outcomes of cryoablation from 37 different community and academic centers in a systematic manner. The COLD registry is supervised by a scientific board of urologists, and an independent audit of scientific data is conducted yearly at randomly chosen centers to ensure the quality and accuracy of data. All participating sites have approval from their institutional review board before submission of any data to the registry database. Moreover, the registry has a global institutional review board protocol since 2006.

2.1. Clinical and demographic data

Variables of interest were age (in years, continuous), race (Caucasian, African American, others), pretreatment data including serum prostate-specific antigen (PSA) level (ng/mL, continuous), highest biopsy Gleason score prior to primary cryotherapy (6–10), neoadjuvant androgen deprivation therapy (ADT) (yes/no), total prostate volume measured at the time of the treatment (mL, continuous), and posttreatment data including nadir PSA (ng/mL), and length of follow-up (months). We excluded patients with PSA $>$ 20 ng/mL, age $>$ 80 years, patients who received adjuvant ADT, patients with clinical stage T4 disease, patients with a positive bone scan, patients who underwent salvage or focal cryoablation of the prostate and patients who underwent hemiablation and focal ablation of the prostate.

Our primary outcome was biochemical recurrence as defined by the Phoenix criteria as PSA nadir + 2 ng/mL. The Phoenix criteria has been adopted and utilized as a surrogate endpoint after whole-gland cryotherapy.[8] The nadir PSA was defined as the lowest PSA level after treatment. Secondary analysis was functional outcomes that included urinary incontinence, erectile dysfunction, urinary retention, and recto-urethral fistula. Incontinence was defined as any urine leakage reported by the patient to the physician at the 12-month visit after cryoablation. The COLD registry utilizes a strict definition of not requiring any protective pads to be classified as continent. Erectile dysfunction was defined as the inability to have sexual intercourse with or without erectile aids, as assessed by the physician at the 12-month visit after the treatment. Complications analyzed in this report reflected the occurrence of postoperative urinary retention and recto-urethral fistula formation.

2.2. Cryotherapy procedure

Cryoablation of the prostate was performed per standard practice under the guidelines set by the manufacturer regarding use of their devices and cryoprobes. The patient is placed in dorsal lithotomy position and after sterile preparation and draping, a urethral Foley catheter is placed. The number and location of cryoprobes are based on the prostate volume and dimensions as setting forth per manufacturers' direction. Probes are placed under real-time ultrasound guidance using both transaxial and sagittal views. Following probe placement, the Foley is replaced with a urethral warming catheter that is employed to maintain the urethral temperature near 37°C in order to avoid thermal injury. In general, the community standard for performing cryotherapy utilizes a double freeze/thaw cycle with an optimal nadir temperature goal of −20 to −40°C achieved within the target prostatic parenchyma.[9,10] Thermocouples are inserted to measure the temperature of the urinary sphincter and the anterior rectal wall during the freezing cycle, with the intention to keep both structures free of collateral damage. Use of additional thermal temperature sensors was at the discretion of the treating physician. In addition to monitoring temperature, the freezing process and ice front were visualized in real-time by transrectal ultrasonography to avoid freezing of adjacent tissues.[11]

2.3. Statistical analysis

R 3.5.1 for RStudio version 1.1.456 (Boston, MA) was used for statistical analyses. Medians and their interquartile range (IQR) were used to summarize continuous variables while categorical variables were summarized with counts and percentages. Associations among type of probes were assessed using a chi-square test or Mann-Whitney U test where appropriate. Multivariate Cox proportional hazards model was used to analyze time to biochemical recurrence after adjusting for neoadjuvant ADT, preoperative PSA, preoperative Gleason score and preoperative T staging. Race and age were not included in the model in order to avoid oversaturation of the model. The multivariate logistic regression model was used to analyze postoperative urinary retention and erectile dysfunction at 12 months. For all statistical analyses, $p < 0.05$ was considered statistically significant.

3. Results

A total of 1124 men met our inclusion criteria from the COLD registry. Median age was 70 years (1st/3rd quartile: 65/74), median Gleason score was 7 (1st/3rd quartile: 6/7) and median pretreatment PSA was 5.9 ng/mL (1st/3rd quartile: 4.6/8.1). The median follow-up time was 25.0 months (1st/3rd quartile: 11.2/48.6). V-Probes® were used in 269 (23.9%) cases and fixed-size ice probes in 858 (76.1%) cases (Table 1).

On univariate analysis, the V-Probe® arm had statistically significant lower clinical stage disease, and preoperative Gleason score ($p < 0.05$) (Table 1). Biochemical-free recurrence at 2 and 5 years between the V-Probe® versus the fixed-size ice probe was 92 versus 90% and 85 versus 77%, respectively. However, there was no statistically significant difference in timing to biochemical recurrence between patients who underwent cryoablation with the V-Probe® versus the fixed-size ice probe on log-rank test ($p = 0.2$) (Fig. 1).

After adjusting for clinical T stage, PSA, neoadjuvant ADT, and preoperative Gleason score, there was still no statistical significance with timing to biochemical recurrence on multivariate Cox proportional regression analysis ($p = 0.35$). However, this model shows that preoperative PSA, neoadjuvant ADT and preoperative clinical stage were significantly associated with type of probe in this cohort of patients (Table 2).

In terms of functional outcome, on univariate analysis, patients who underwent cryoablation with the V-Probe® were more likely

Table 1

Patient demographics and probe type.

Characteristic	V-Probe® (n = 269)	Fixed-size ice probe (n = 858)	*p*
Median age (IQR), years	70 (66–75)	70 (65–74)	0.95
Race, n (%)			0.23
Caucasian	199 (74.0)	345 (40.2)	
African American	34 (12.6)	39 (4.5)	
Other	6 (2.2)	12 (1.4)	
Missing	30 (11.2)	462 (53.8)	
Median pretreatment PSA (IQR), ng/mL	5.7 (4.6–7.6)	6 (4.6–8.2)	0.21
Median preoperative prostate volume* (IQR), mL	35.4 (28.4–46.6)	33.1 (26.0–41.8)	0.06
Neoadjuvant ADT, n (%)	45 (17)	193 (22.5)	0.06
Clinical stage, n (%)			<0.001
T1	194 (72.1)	301 (35.1)	
T2	66 (24.5)	290 (33.8)	
T3	1 (0.4)	23 (2.7)	
Missing	8 (3.0)	244 (28.4)	
Gleason score, n (%)			<0.001
6	99 (36.8)	448 (52.2%)	
7	134 (49.8)	313 (36.5%)	
8	25 (9.3)	63 (7.3%)	
9	5 (1.9)	26 (3.0%)	
10	0 (0)	2 (0.2%)	
Missing	6 (2.2)	5 (0.6%)	

ADT = androgen deprivation therapy; IQR = interquartile range; PSA = prostate-specific antigen.
* Volume as measured at the time of cryoablation, e.g., following ADT, if applicable.

to experience early urinary retention (19% vs. 11.8%, $p = 0.003$) but less likely to have erectile dysfunction at 12 months (40.7% vs. 56.1%, $p = 0.005$) (Table 3). However, on multivariate logistic regression after adjusting for preoperative PSA, neoadjuvant ADT status, preoperative Gleason score and clinical T staging, there was no statistical difference between probe type and erectile dysfunction ($p = 0.055$). On multivariate logistic regression, using the V-Probe® was associated with a 91% increase in early postoperative urinary retention compared to the fixed-size ice probe (Table 4).

Table 2

Multivariate Cox regression model on timing to biochemical recurrence and its association with type of probe.

Variable	Hazard ratio	95% confidence interval	*p*
V-Probe® vs. fixed-size ice probe	0.78	0.45–1.32	0.344
Preoperative PSA	1.09	1.03–1.15	0.003
Neoadjuvant ADT	1.65	1.07–2.54	0.022
Preoperative Gleason score	1.03	0.81–1.32	0.811
Preoperative ≥cT2 compared to cT1	1.56	1.03–2.37	0.035

ADT = androgen deprivation therapy; cT1 = clinical stage T1 [non-palpable disease]; cT2 = clinical stage T2 [organ-confined palpable disease]; PSA = prostate-specific antigen.

We performed 2 sensitivity analyses by creating a second model for oncological outcome using probe type, clinical T stage, PSA, neoadjuvant ADT and the year cryoablation was performed, and we found that probe type had no association with biochemical recurrence on multivariate Cox proportional regression analysis ($p = 0.2$). For our third model, we removed high-risk prostate cancer as defined by the NCCN guidelines,[12] and found that time to probe type had no association with biochemical recurrence after adjusting for neoadjuvant ADT, preoperative PSA, preoperative Gleason score and preoperative T staging on Cox proportional hazards analysis ($p = 0.34$).

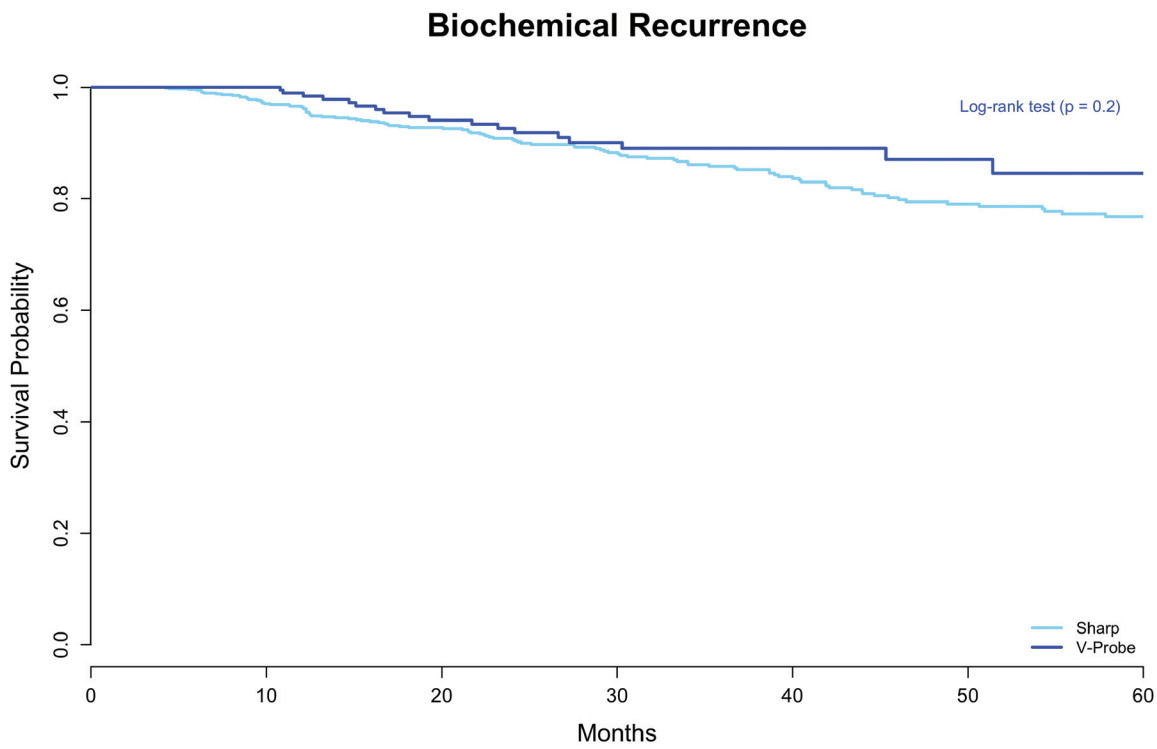

Figure 1. Biochemical recurrence following prostate cryoablation using the Sharp vs the V-probe.

Table 3

Univariate analysis comparing functional outcomes associated with the V-Probe® and fixed-size ice probe.

Functional outcome	V-Probe®	Fixed-size ice probe	*p*
Urinary retention, *n* (%)	51 (19.0)	101 (11.8)	0.003
Erectile dysfunction, *n* (%)	48 (17.8)	217 (25.3)	0.005
Urinary incontinence, *n* (%)	8 (3.0)	26 (3.0)	1
Recto-urethral fistula, *n* (%)	3 (1.1)	8 (0.9)	1
Total, *n*	269	858	

4. Discussion

The use of cryotherapy as an alternative treatment modality for the management of patients with low volume, low to intermediate risk prostate cancer has been growing.[4,13] The aim of cryosurgery is to provide a well-tolerated, outpatient, minimally invasive therapy that minimizes the morbidity of radical treatment while maintaining competitive oncological outcomes.[13] However, there is no study to date comparing the V-Probe® and fixed-size ice probe. In this study, we sought to evaluate the oncological and functional outcome in patients who had underwent cryotherapy to the prostate comparing V-Probe® and fixed-size ice probe. We found that there was no difference in oncological outcome between the 2 probes on multivariate analysis. However, the V-Probe® was associated with a higher rate of urinary retention upon removal of the catheter.

The engineering of the cryoprobe is an important factor that determines the rate, overall creation and extent of the ice ball. The type of probe and cryogen, probe distribution within the prostate, rate of cooling, and prostate size among other factors, collectively govern the success of the cryotherapy procedure. The 2 types of cryoprobes compared in this study are manufactured by Endocare (Austin, TX). The gas delivery in both probes similarly utilizes argon for freezing and helium for thawing and is based on the Joule-Thomson effect.

The advantages of using the V-Probe® include integration with the control unit's treatment planning software and flexibility of the probe that allows the physician to adjust the length and overall size of the isotherms to match the area of treatment. Moreover, the formation of the ice ball can be much larger compared to the fixed-size ice probe.[7] The V-Probe® can also save the operator time since it is a customizable ice field that creates a larger zone of destruction that does not require a pull-back, which was an older technique that was occasionally required when the ice created by a fixed-length probe did not match the intended area of treatment. Both the conventional fixed-size ice cryoprobe and the V-Probe® have an integrated thermocouple within each probe that allows the operator to monitor core probe temperature. This temperature feature, along with several other safety measures including instantaneous monitoring of temperatures at critical anatomical areas via separately placed temperature thermocouples, real-time observation of the ice ball formation under transrectal ultrasonography, coupled to features such as the use of the argon/helium cryogen system and probe design, can directly affect the safe performance of cryosurgery and potentially impact the oncological outcome of the procedure.[14,15]

Table 4

Multivariate logistic regression model on urinary retention postcryoablation.

Variable	Odds ratio	95% confidence interval	*p*
V-Probe® compared to fixed-size ice probe	1.91	1.24–2.95	0.003
Neoadjuvant ADT	1.16	0.69–1.88	0.57
Preoperative PSA	1.01	0.95–1.08	0.65
Preoperative Gleason score	0.84	0.66–1.08	0.17
Preoperative ≥cT2 compared to cT1	0.97	0.62–1.50	0.89

ADT = androgen deprivation therapy; cT1 = clinical stage T1 [non-palpable disease]; cT2 = clinical stage T2 [organ-confined palpable disease]; PSA = prostate-specific antigen.

Given the lack of consensus on the definition of biochemical recurrence after prostate cryotherapy, we used the Phoenix criteria as applied to postradiotherapy recurrence.[14,16,17] Several studies have shown that the rate of biochemical failure in patients who have been treated with primary whole gland cryotherapy using cryoprobes of 2.4 mm diameter ranged between 15 and 21% during early follow-up in the initial 24 months.[15,18,19] In our study, the rate of recurrence at 24 months is 8% in the V-Probe® group and 10% in the fixed-size ice probe. We believe this may be in part because 48.5% of our cohort consisted of Gleason 6 on pretreatment biopsy.

Even though we found that probe type had no statistical difference on biochemical recurrence on log-rank test, we chose to adjust for preoperative PSA, Gleason score, status of neoadjuvant ADT and clinical T stage in the multivariate model as that was decided a priori. Furthermore, the patients in the V-Probe® group appeared to have a lower cT stage, preoperative PSA and lower use of preoperative ADT compared to the fixed-size ice probe group. We believe this is largely due to the V-Probe® being introduced in recent years, where we are witnessing a shift in stage, PSA and grade. However, adjusting for cT stage, preoperative PSA and use of preoperative ADT should address this limitation. In addition, we chose to exclude patients who underwent adjuvant ADT in our analysis as this might similarly confound the timing to biochemical recurrence, given these patients likely did not have complete treatment of their prostate cancer if they were prescribed ADT following cryoablation of the prostate.

Regarding functional outcomes, there was no significant difference in the rate of urinary incontinence following primary cryoablation of the prostate when utilizing the V-Probe® versus fixed-size ice probe. Our urinary incontinence rate was 3%, which is lower than that reported in the literature. Rodriguez et al.[18] and Oishi et al.[19] reported that the rate of urinary incontinence was 5.6% and 4%, respectively, following whole gland prostate cryotherapy using the V-Probe®. The rate of erectile dysfunction in our study was 52.5%. This is within the range of erectile dysfunction of 52.3%–89% as described in the literature.[19,20]

In terms of early postoperative retention, we found that patients who underwent cryoablation with the V-Probe® had a higher rate of urinary retention compared to those treated with the fixed-size ice probe (19% vs. 11.8%). This result differs from that of the literature, in which the postoperative retention rate was 3%.[19] We believe that this may be in part due to surgeons using the V-Probe® may feel more confident in doing a maximal freeze of the prostate gland because the variable length probe provides a measure of safety for surrounding structures. A more intense freeze may lead to more retention. An alternative

explanation is that this occurrence may be attributable to a lack of a standardized protocol within the COLD registry for the duration of the catheter. Some of the catheters might have been removed immediately following cryoablation and this could account for the higher rate of transient urinary retention in our study, due to the persistent prostate edema when compared to a single surgeon/single center experience with a well-defined follow-up protocol. However, this does suggest caution regarding the timing of a voiding trial posttreatment, and a premature one might be associated with a higher risk of urinary retention.

This study has several limitations that warrant mention. First, there is a selection bias given the retrospective nature of the study. Second, the COLD registry is a database largely contributed by community and some academic urologists. The absence of a formal protocol for patient selection, performance of the cryoablation procedure and subsequent voiding trial, and for data collection may result in significant heterogeneity. The choice of utilizing the V-Probe® and fixed ice probe was at the discretion of the individual physician. Third, the Phoenix criteria was used to assess the biochemical recurrence rate and might lead to an over- or underestimate of the true recurrence rate. Posttreatment biopsy may provide more insight into the oncological outcome but is still limited due to the nature of random sampling associated with conventional prostate biopsy. Fourth, the V-Probe® is the latest iteration, and thus comparing it with a previous technology will result in some degree of time-analysis bias. Finally, the functional outcomes were self-reported by patients and recorded by the physician with a lack of validated instruments and uniform data collection. However, we used very strict criteria of no pad requirement to be considered continent. Nonetheless, we offered a large real-world series of patients undergoing cryoablation of the prostate, showing that there was no difference in terms of oncological outcome and intermediate-term functional outcome after adjusting for potential confounders. However, cryoablation of the prostate utilizing the V-Probe® in the primary setting was associated with a 91% increased risk of early postoperative urinary retention, and this finding needs to be investigated in future studies. To the best of our knowledge, this is also the first series in the literature comparing the type of probes used in prostate cryoablation.

5. Conclusion

The use of the V-Probe® and fixed-size ice probe was not associated with a difference in biochemical recurrence in patients undergoing cryoablation of the prostate. Postoperative urinary retention was lower in the fixed-size ice probe arm, but long-term functional outcomes were comparable between both probes. This study suggests that both type of probes have similar oncological and functional outcomes and that urologists should use the type of probe that they are most comfortable with when performing cryoablation of the prostate.

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Statement of ethics

All authors followed the highest ethical standards.

Conflicts of interest statement

No conflict of interest has been declared by the author.

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Author contributions

Research idea: Elshafei, Polascik, Cher, Given
Stats: Elshafei, Tan
Drafting of manuscript: Taha, Tan, Elshafei
Oversight: Polascik, Elshafei
Contributions to data: Cher, Given, Elshafei, Polascik, Aminsharifi
All authors participated in review of drafts and final product.

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