A costing and health-related quality of life study of high intensity focused ultrasound in primary treatment of localized low or intermediate risk prostate cancer in Ontario

Bassem Toeama, MD,[1] Nathan Perlis, MD,[2] Paul Grootendorst, PhD,[1] William Orovan, MD,[3] Emmanuel Papadimitropoulos, PhD[1,4]

[1]Faculty of Pharmacy, University of Toronto, Toronto, Ontario, Canada
[2]Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
[3]Division of Urology, McMaster University, Hamilton, Ontario, Canada
[4]Eli Lilly and Company, Toronto, Ontario, Canada

TOEAMA B, PERLIS N, GROOTENDORST P, OROVAN W, PAPADIMITROPOULOS E. A costing and health-related quality of life study of high intensity focused ultrasound in primary treatment of localized low or intermediate risk prostate cancer in Ontario. *Can J Urol* 2024;31(4):11963-11970.

Introduction: *Prostate cancer is the third leading cause of death from cancer among Canadian men. High intensity focused ultrasound (HIFU) is a novel approach for primary treatment of localized prostate cancer. Little is known, however, about its costs. We aimed to collect the direct costs and health-related quality of life (HRQoL) data of HIFU in primary treatment of localized low and intermediate risk prostate cancer in Ontario.*

Materials and methods: *We collected direct costs and HRQoL data of 20 patients with localized low or intermediate risk prostate cancer who received whole-gland HIFU at a privately owned clinic in Ontario. We compared the direct costs of HIFU, open radical prostatectomy (ORP), robot assisted radical prostatectomy (RARP), and external beam radiation therapy (RT) in primary treatment of localized low and intermediate risk prostate cancer.*

Results: *The average direct costs of HIFU, ORP, RARP, and RT per case in 2023 are $14,886.78, $14,192.26, $21,794.55, and $17,377.51, respectively. The median and interquartile range (IQR) of the study participants' age and HRQoL data prior to the HIFU procedure were 64.5 (11.25) years, 94.5 (8.65), 38.5 (4), 6.0 (4.46), and 22.5 (8.32), respectively.*

Conclusion: *Our healthcare payer's perspective costing study revealed median direct costs per case of HIFU and favorable HRQoL outcomes compared to other treatment options for primary treatment of localized low and intermediate risk prostate cancer in Ontario. A health economic model is warranted to analyze the cost-effectiveness of HIFU compared to other treatment options in primary treatment of localized low and intermediate risk prostate cancer.*

Key Words: prostate cancer, high intensity focused ultrasound, health-related quality of life, healthcare payer's perspective, direct costs

Accepted for publication July 2024

Acknowledgements
We thank Janice Orovan (Maple Leaf HIFU Center) for collection of the demographics and baseline characteristics, clinical parameters, direct costs, and HRQoL data.

Address correspondence to Dr. Emmanuel Papadimitropoulos, Department of Pharmaceutical Sciences, Faculty of Pharmacy, University of Toronto, Toronto, Ontario Canada

Introduction

Prostate cancer is the most frequently diagnosed male cancer and the third leading cause of death from cancer among Canadian men.[1] In Canada, 1 in 7 men will have prostate cancer, and 1 in 27 will die of it.[2] There are different stages of prostate cancer that range from localized through locally advanced to advanced. Localized prostate cancer is confined

to the prostate gland and does not grow into nearby tissues; such cases are defined as having clinical Tumor Node Metastasis (TNM) stages cT1-T2 N0 M0 at presentation.[3] Localized prostate cancer is further classified into low, intermediate, and high risk groups of recurrence following radical treatment according to pre-treatment variables of prostate specific antigen (PSA), Gleason score, and clinical T stage. The low risk group has pretreatment variables of PSA < 10 ng/mL, Gleason score ≤ 6, and clinical T stages cT1c-T2a, while the intermediate risk group has pretreatment variables of either PSA 10-20 ng/mL, Gleason score 7, or clinical T stage cT2b.[4]

According to the Canadian Cancer Society (CCS) guidelines, ORP, RARP, RT and active surveillance are the main lines of primary treatment for localized low and intermediate risk prostate cancer.[5] The Urological Cancer Care Pathway Development Group of Aberdeen recommended ablative focal therapies as alternative strategies for treating localized low and intermediate risk prostate cancer.[6] Ablative focal therapies include brachytherapy, cryotherapy, HIFU, laser therapy, radiofrequency ablation, and photodynamic therapy.[6] The Food and Drug Administration approved HIFU for treatment of localized low and intermediate risk prostate cancer.[7] Despite the increased interest in HIFU, there is limited data on the cost of this treatment. We aimed to collect the direct costs of whole-gland HIFU as performed at a privately owned clinic in Ontario to evaluate the healthcare payer's perspective and compare the collected direct costs of HIFU with the published direct costs of ORP, RARP, and RT in primary treatment of localized low and intermediate risk prostate cancer.

Materials and methods

Study design

Our costing study was a retrospective single cohort study conducted at the privately owned Maple Leaf HIFU clinic in Ontario. The study design and protocol were reviewed and approved by the University of Toronto Research Ethics Board. The study was registered and issued a human research protocol number (45076); personal health information (PHI) was anonymized and coded, and the privacy rights of the study participants were observed diligently. We conducted a micro-costing approach based on the available data collected from the study participants' healthcare records and collected the published direct costs of ORP, RARP, and RT in primary treatment of localized low and intermediate risk prostate cancer patients.

Study participants

Study participants were human males, adults ≥ 18 years old, with 1) histologically confirmed localized adenocarcinoma of the prostate TNM stage cT1-T2 N0 M0, 2) low or intermediate risk of recurrence with pre-treatment variables of PSA ≤ 20 ng/mL and Gleason Score ≤ 7, 3) had not received any previous treatment for prostate cancer (including hormonal therapy, radiation therapy, surgery, or chemotherapy), and finally 4) were candidates for primary treatment with HIFU.

Study procedures

Twenty study participants were randomly selected from a bigger target population of 83 eligible localized low or intermediate risk prostate cancer patients who received primary treatment with whole-gland HIFU at Maple Leaf HIFU clinic in Ontario during the fiscal years 2015-2019 (from January 1st, 2015, to December 31st, 2019). The anonymized coded PHI and demographic, clinical, costing, and health-related quality of life (HRQoL) data of the 20 randomly selected eligible study participants were collected from their corresponding healthcare records. Maple Leaf HIFU clinic removed all patient identifiers and assigned a study ID to each study participant. Once the records of the study participants in Maple Leaf HIFU clinic dataset had been assigned their study IDs, the patient identifiers were removed from the files. Patient identifiers include, but are not limited to, patient name, insurance information, date of birth, phone number, social insurance number, address, and photo.

As per the signed confidentiality agreement made by and between Maple Leaf HIFU clinic and the principal investigator, Maple Leaf HIFU clinic granted the principal investigator permission to access the confidential anonymized coded PHI in addition to the demographic, clinical, HRQoL, and costing data included in the records of the study participants. The direct healthcare costing data collected included costs of the procedure per case as staff cost per case (urologist cost per case, anesthesiologist cost per case, and nursing cost per case), clinic cost per case (rental cost of both the operating room and the recovery room per case), intraprocedural medications cost per case [intraprocedural Medications include 2 ampoules of anesthetic (Propofol), antibiotic (Ciprofloxacin), antispasmodic (Ditropan), analgesic (Tylenol 3), smooth muscle relaxant (Flomax), vasodilator (Cialis), and antiandrogen (Avodart)], consumables cost per case [consumables include syringes, needles, oxygen masks and lines, tape, bandages, protective pads, spinal tray, urology supplies, stockings, etc], and

amortization cost of Maple Leaf HIFU clinic medical equipment per case; maintenance cost per case (service agreement cost per case); costs of treatment of erectile dysfunction (ED), urinary incontinence (UI), diarrhea or any other adverse event following the HIFU procedure.

We also collected data on the costs of mandatory laboratory and imaging tests per case. A mandatory laboratory test is any medical procedure that involves testing a sample of blood, urine, or any other substance from the body prior to the day of HIFU procedure to determine a diagnosis, plan treatment, monitor the disease, or determine the course of treatment. These mandatory laboratory tests include PSA, complete blood count, electrolytes, and creatinine. A mandatory imaging test is any medical procedure that involves taking detailed pictures of areas inside the body prior to the day of HIFU procedure to reach a diagnosis, plan treatment, monitor the disease, or determine the course of treatment. These mandatory imaging tests include transrectal ultrasound, biopsy, and electrocardiogram In addition, the research involved extraction of demographic data and baseline characteristics as age, province, city, and marital status; clinical parameters as PSA level prior to the HIFU procedure and at 3-, 6-, 9-, 12-, 15-, 18-, 21-, 24-, 30-, 36-, 42-, and 48-months post HIFU procedure, Gleason score, prostate volume, number of core needle biopsies taken from the prostate and number of positive core needle biopsies, tumor stage, family history, and American Society of Anesthesiology (ASA) classification; and HRQoL data as the scores of Quality of Life Scale (QoLS) with a score range from 16 to 112, Incontinence – Quality of Life Questionnaire (I-QoL) with a score range from 22 to 110, International Prostate Symptom Score (IPSS) with a score range from 0 to 35, and Sexual Health Inventory for Men (SHIM) with a score range from 5 to 25, prior to the day of the HIFU procedure and at 6-, 12-, 18-, and 24-months post HIFU procedure.

We collected the published costing data of ORP and RARP from a Health Technology Assessment report developed at Health Quality Ontario, the published costing data of RT from a costing model developed by Yong et al, and compared the costing data of this retrospective study with the published costing data of ORP, RARP, and RT.[8,9]

End points

The costing study collected the direct costs of HIFU to evaluate the healthcare payer's perspective of HIFU in Ontario. Secondary endpoints included PSA levels and HRQoL data prior to and post HIFU procedure and comparison of the collected direct costs of HIFU with the published direct costs of ORP, RARP, and RT in primary treatment of localized low and intermediate risk prostate cancer patients.

Statistical analysis

Our study is a retrospective single cohort study. As there aren't any previously published or ongoing Canadian studies that assessed the costing of HIFU in primary treatment of localized low and intermediate risk prostate cancer in Ontario, the minimum number of the study participants to be recruited (sample size) was based on feasibility. The assessment outcomes were analyzed with Microsoft Excel's Data Analysis Toolpak version 16.77 and XLSTAT version 2023.2.1414. Shapiro wilks test was used to assess normality of data. Quantitative data was expressed as mean, median, standard deviation (SD), and interquartile range (IQR), while qualitative data was expressed as numbers, frequencies, and percentages. Comparisons between parametrically distributed quantitative variables were done with independent paired Student's t-test or analysis of variance (ANOVA) test followed by post hoc analysis with Turkey or Hochberg test, between non-parametrically distributed quantitative variables with Mann-Whitney test or Kruskal Wallis test followed by post hoc analysis with Dunn test, and between qualitative variables with Chi-square test or Fisher Exact test, respectively.[10,11] The confidence interval was set to 95% and the margin of error accepted was set to 5%. Any comparison considered statistically significant was at $p < 0.05$ or less and highly significant at $p < 0.01$. Missing data was estimated with multiple imputations using the non-linear iterative partial least squares (NIPALS) method.[12]

TABLE 1. **Average PSA levels of the study participants**

	Post treatment			
	3 months Post	**12 months**	**24 months**	**48 months**
Mean ± SD of PSA level in ngm/mL	0.19 ± 0.244	0.33 ± 0.384	0.40 ± 0.478	2.30 ± 0.055
Median (IQR) of PSA level in ngm/mL	0.1 (0.22)	0.2 (0.47)	0.2 (0.39)	2.3 (0.07)

TABLE 2. **Clinical parameters of the study participants**

	Prostate volume in mL		**No. of core needle biopsies taken from the prostate**			**No. of positive core needle biopsies**	
Mean ± SD	32.83 ± 9.922		12.3 ± 1.380			5.70 ± 2.618	
Median (IQR)	32 (13.5)		12 (0)			5.5 (3.25)	
	Gleason score			**Tumor stage**			**Family history**
	Count	**%**		**Count**	**%**		**Count**	**%**
≤ 6	3	15%	T1c	11	55%	No	20	100%
7 (3+4)	14	70%	T2a	9	45%	Yes	0	0%
7 (4+3)	3	15%	Total	20	100%	Total	20	100%
Total	20	100%						

Results

Demographics and baseline characteristics

The demographics and baseline characteristics of the study participants showed a median (IQR) age of 64.5 (11.25) years, 40% resided in the province of Ontario, 15% resided in the city of Calgary in Alberta, and 90% were married.

Clinical parameters

The PSA levels and clinical parameters of the study participants are presented in Tables 1 and 2, respectively. The median (IQR) PSA level prior to the HIFU procedure was 7.3 (2.925) ngm/mL that declined markedly to 0.1 (0.22) ngm/mL at 3-months post HIFU procedure and increased gradually to reach 2.3 (0.07) ngm/mL at 48-months post HIFU procedure, the median (IQR) prostate volume was 32 (13.5) mL, 70% of the study participants had Gleason score of 7 (3+4), 55% of the study participants had tumor stage T1C and 45% of the study participants had tumor stage T2A, 100% of the study participants had a negative family history, and 70% of the study participants had ASA Classification class 2, respectively. The mean ± SD number of core needle biopsies taken from the prostate was 12 ± 1.38 and the mean ± SD number of positive core needle biopsies was 5.7 ± 2.62.

Direct costs

The direct costs of HIFU in Canadian currency (2019) are presented in Table 3. The cost of operation per case was $12,200.99; the maintenance cost per case was $650.23; the cost of treatment of adverse events per case was $0.00; and the cost of mandatory imaging and laboratory tests per case was $75.00. The direct costs of HIFU per case are $12,926.22 in 2019.[13]

HRQoL data

The HRQoL data of the study participants is presented in Table 4. The median (IQR) scores of the QoLS were 94.5 (8.65) prior to the day of HIFU procedure that dropped to 88.85 (15.44) at 6-months post HIFU procedure indicating below average quality of life (QoL) and increased gradually to reach 91.8 (12.4) at 24-months post HIFU procedure reflecting partial recovery of the QoL; the median (IQR) scores of the I-QoL were 38.5 (4) prior to the day of HIFU procedure that peaked at 48.9 (20.6) at 12-months post HIFU procedure indicating partial improvement in the UI and higher QoL then decreased gradually to reach 37.7 (4) at 24-months post HIFU procedure reflecting worse UI and lower QoL; the median (IQR) scores of the IPSS were 6.0 (4.46) prior to the day of HIFU procedure that increased gradually to reach 15.65 (11.16) at 6-months post HIFU procedure indicating moderate lower urinary tract symptoms and peaked at 19.35 (3.9) at 24-months post HIFU procedure reflecting worsening lower urinary tract symptoms; and the median (IQR) scores of the SHIM were 22.5 (8.32) prior to the day of HIFU procedure that dropped to 6.2 (6.04) at 6-months post HIFU procedure indicating severe post procedural ED and increased gradually to reach 13.5 (8.8) at 24-months post HIFU procedure reflecting partial recovery of the erectile function, respectively.

Comparison of the direct costs of HIFU, ORP, RARP, and RT

Comparison of the direct costs of HIFU, ORP, RARP, and RT is presented in Table 5. The average annual Canadian inflation rate from 2019 to 2023 was 3.59% adjusting the direct costs of HIFU per case from $12,926.22 in 2019 to $14,886.78 in 2023. The average annual Canadian inflation rate from 2016 to 2023 is 2.88% adjusting the direct costs of ORP per case from

TABLE 3. **Direct costs of high intensity focused ultrasound (HIFU) per case as of 2019 (1 USD = 1.3005 CAD as of 31-Dec-2019)**

	Currency: CAD/USD
Costs of operation	
1. Staff cost	
a) Urologist cost	$ 2,000.00 (CAD)
b) Anesthesiology cost	$ 1,200.00 (CAD)
c) Nursing cost	$ 450.00 (CAD)
2. Clinic cost [Rental of OR and recovery room]	$ 5,000.00 (CAD)
3. Intraprocedural medications cost [Intraprocedural medications include 2 ampoules of Anesthetic (Propofol), Antibiotic (Ciprofloxacin), Antispasmodic (Ditropan), Analgesic (Tylenol 3), Smooth Muscle Relaxant (Flomax), Vasodilator (Cialas), and Antiandrogen (Avodart)]	$ 515 (CAD)
4. Consumables cost [Consumables include syringes, needles, oxygen masks and lines, tape, bandages, protective pads, spinal tray, urology supplies, Stocking, etc.…]	$ 175.00 (CAD)
5. Amortization cost equivalent to $2,860.99 (CAD)	$ 2,200.00 (USD)
Cost of maintenance [service agreement] equivalent to $650.23 (CAD)	$500.00 (USD)
Costs of treatment of adverse events after the day of the procedure	$0.00 (CAD)
Costs of laboratory tests prior to and after the day of the procedure	$75.00 (CAD)
Maple Leaf HIFU clinic direct costs per case as of 2019	$12,926.22 (CAD)

TABLE 4. **Health related quality of life data of the study participants**

	Health related quality of life measurement tool			
	QoLS	**I-QoL**	**IPSS**	**SHIM**
Mean ± SD at 6 months	86.20 ± 12.109	45.22 ± 16.706	16.07 ± 7.439	8.37 ± 5.697
Median (IQR) at 6 months	88.9 (15.44)	39.9 (12.59)	15.6 (11.16)	6.2 (6.04)
Mean ± SD at 12 months	87.79 ± 11.592	50.79 ± 19.276	14.97 ± 6.762	8.36 ± 3.949
Median (IQR) at 12 months	89.8 (10.35)	48.9 (20.59)	15.9 (9.86)	8.4 (5.10)
Mean ± SD at 18 months	93.47 ± 9.664	45.52 ± 11.527	12.14 ± 4.468	9.94 ± 6.407
Median (IQR) at 18 months	93.5 (9.16)	41.3 (11.82)	12.0 (2.45)	8.0 (8.24)
Mean ± SD at 24 months	91.02 ± 7.318	37.96 ± 4.820	19.42 ± 3.128	13.07 ± 5.234
Median (IQR) at 24 months	91.8 (12.4)	37.7 (4.02)	19.3 (3.91)	13.5 (8.82)

TABLE 5. **Comparison of the direct costs of high intensity focused ultrasound (HIFU) per case, open radical prostatectomy (ORP) per case, robot assisted radical prostatectomy (RARP) per case, and external beam radiation therapy (RT) per case as of 2023**

	HIFU – 2019 CAD	ORP – 2016 CAD	RARP – 2016 CAD	RT – 2016 CAD
Costs of operation (including staff cost, clinic or hospital cost, medications cost, consumables cost, and amortization cost)	$12,200.99	$11,259	$15,411	$12.253.10
Costs of maintenance (service agreement)	$650.23	N/A	$2,233.00	$580.90
Costs of treatment of adverse events after the day of the procedure or surgery	$0.00	$377.00	$225.00	N/A
Costs of imaging and laboratory tests prior to and after the day of the procedure or surgery	$75.00	N/A	N/A	N/A
Direct costs per case	$12,926.22	$11,636.00	$17,869.00	$12,834
Average annual Canadian inflation rate	3.59%	2.88%	2.88%	2.19%
Direct costs per case in 2023	$14,886.78	$14,192.26	$21,794.55	$17,377.51

$11,636 in 2016 to $14,192.26 in 2023 and the direct costs of RARP per case from $17,869 in 2016 to $21,794.55 in 2023, respectively. The average annual Canadian inflation rate from 2009 to 2023 is 2.19% adjusting the direct costs of RT per case from $12,834 in 2009 to $17,377.51 in 2023.[8,9,14]

Discussion

Prostate cancer is the third leading cause of cancer death among Canadian men. ORP, RARP, and RT are three main lines of primary treatment for localized low and intermediate risk prostate cancer. HIFU is an alternative treatment to ORP, RARP, and RT that hasn't been publicly funded in Ontario. Real world evidence studies that explore cost effectiveness of HIFU compared to ORP, RARP, and RT and show positive impact of HIFU on prostate cancer specific HRQoL are required for public funding of HIFU. There are very few private clinics offering HIFU in Ontario. The direct and indirect costs of HIFU aren't available in the Canadian Management Information System Database (CMDB) and the Canadian Patient Cost Database (CPCD) of the Canadian Institute for Health Information (CIHI). There is an out-dated newsletter "Health Technology Update" published by the Canadian Agency for Drugs and Technologies in Health (CADTH) in September 2006, which mentioned $21,580 as the direct costs of HIFU.[15] Also, another report was published by CADTH on November 19, 2009, that confirmed $22,000 as the approximate direct costs of HIFU. These direct costs of HIFU procedure are based on information gathered as of November 5, 2009, and may not reflect current information.[16] We estimated the direct costs of HIFU to be $14,886.78 per case in Ontario as of 2023. Compared with ORP, HIFU costs $694.52 more per case, and compared with RT and RARP, HIFU costs $2,490.73-$6,907.77 less per case, respectively.

Clinical evidence review of the studies comparing the main and alternative lines of primary treatment for localized low and intermediate risk prostate cancer showed heterogeneity in the PSA levels after HIFU, ORP, RARP, and RT. A single arm cohort

study by Uchida et al reported a 1-year biochemical disease free survival (BDFS) rate of 76.6% for HIFU (95% CI: 0.66-0.87) and 3 single arm cohort studies by Blana et al, Mearini et al, and van Velthoven et al reported 5-year BDFS rates for HIFU ranging from 58% to 85.4% (95% CI: 0.44-0.9).[17-20] A recent systematic review by Toeama et al revealed 1 single arm cohort study which reported 5-year BDFS rate of 73.7% for RT (95% CI: 0.67-0.79), 1 triple arm cohort study which reported 1-year BDFS rate of 94.3% for ORP vs. 75.7% for RT (95% CI: 0.89-0.99 vs. 0.62-0.90) and 5-year BDFS rate of 76.1% for ORP vs. 70.3% for RT (95% CI: 0.67-0.85 vs. 0.56-0.85), and 1 double arm cohort study which reported 3-year BDFS rates of 81.9% for ORP vs. 93.3% for RT (95% CI: 0.79-0.85 vs. 0.89-0.98), respectively.[21] Breyer et al found significant difference in the 3-year BDFS rate of ORP (87%) vs. RARP (81%), favoring ORP (log-rank p = 0.02).[22] Our costing and HRQoL study reflected an initial downward trend followed by an upward trend in the time series of PSA level.

Real world evidence revealed variation in the QoL outcomes with invasive versus non-invasive lines of primary treatment for clinically localized low and intermediate risk prostate cancer. For example, studies have shown higher incidence rates of urinary and sexual problems with ORP versus higher incidence rates of bowel problems with RT.[23] Even a single ablation session of whole-gland HIFU has a HRQoL profile different from that attained by RT sessions delivered every weekday for 1-8 weeks. A non-randomized study by Haglind et al reported a non-significant difference between ORP and RARP with 1-year UI rate of 20.2% for ORP vs. 21.3% for RARP (OR: 1.08, 95% CI: 0.87-1.34).[24] A recent systematic review by Toeama et al revealed 5 single arm cohort studies which reported 1-year UI rates for HIFU ranging from 0% to 6% (95% CI: 0.0-0.13), 2 double arm cohort studies which reported 1-year UI rate favoring ORP compared to RARP (OR = 0.54, 95% CI = 0.10-2.89), 4 single arm cohort studies which reported 1-year ED rates for HIFU ranging from 11.4% to 38.7% (95% CI: 0.01-0.56), and 2 double arm cohort studies which reported 1-year ED rate favoring ORP compared to RARP (OR = 0.46, 95% CI = 0.12-1.73), respectively.[21] Our costing and HRQoL study reflected a paradoxical worsening QoL and erectile function versus improving urinary continence and lower urinary tract symptoms at 6-months post HIFU procedure followed by recovering QoL and erectile function versus deteriorating urinary continence and lower urinary tract symptoms at 24-months post HIFU procedure, respectively.

Strengths and limitations

Our study is the first study to estimate the direct costs of HIFU in Ontario from a healthcare payer perspective. Our direct cost estimates were derived from Canadian costing data collected from the study participants' healthcare records at Maple Leaf HIFU clinic in Ontario during the fiscal years 2015-2019 (from January 1st, 2015, to December 31st, 2019) and they were compared to the direct costs of ORP, RARP, and RT which were derived from a Health Technology Assessment report developed at Health Quality Ontario and a Canadian costing model developed by Yong et al, respectively.[8,9] The demographics and baseline characteristics, PSA levels, and clinical parameters reflected the natural history of localized low and intermediate risk prostate cancer in Canadian patients, and the collected HRQOL data showed the impact of HIFU on the HRQoL of Canadian patients with localized low and intermediate risk prostate cancer. Our study's sample size represented a significant proportion (more than 20%) of the study's target population. The 20 study participants were randomly selected from 83 eligible localized low or intermediate risk prostate cancer patients treated at Maple Leaf HIFU clinic in Ontario during the fiscal years 2015-2019 (from January 1, 2015, to December 31, 2019), which isn't far away from the published sample size of 192 study participants reported in Silva et al study.[25] Nevertheless, our study isn't an outcomes study but an observational study focusing on the direct costs of HIFU. The per case cost does not vary with patient volume nor does it, within fairly narrow parameters, from clinic to clinic. On the other hand, our study has limitations. Our costing study had a small sample size with only whole-gland HIFU performed by a single treating physician. There is lack of data on the post procedural pathologic outcomes. The study didn't take into consideration the societal perspective and had missing data which was estimated with multiple imputations using the non-linear iterative partial least squares (NIPALS) method allowing the inclusion of the 20 randomly selected study participants and the analysis of their demographics and baseline characteristics, PSA levels, clinical parameters, HRQoL data, and direct costs based on the treatment assigned. While our ORP and RARP cost estimates were derived from a Health Technology Assessment report developed at Health Quality Ontario, and our RT cost estimates were derived from a costing model developed by Yong et al,[8-9] our HIFU cost estimates were derived from a small sample size at a single center (Maple Leaf HIFU clinic) in Ontario. Further validation is required for generalizability to other HIFU centers in Ontario.

Conclusions

Our micro-costing study of HIFU revealed median direct costs per case and favorable HRQoL outcomes compared to other treatment options for primary treatment of localized low and intermediate risk prostate cancer. In addition, our study paves the way for other studies to assess the direct costs of HIFU for primary treatment of localized low and intermediate risk prostate cancer in Canada. The direct costs, efficacy parameters, and functional outcomes of HIFU and other treatment options for localized low and intermediate risk prostate cancer can populate an economic model to calculate the incremental cost effectiveness ratio and incremental cost utility ratio, evaluate the cost-effectiveness and cost-utility of HIFU, and comment on the trade-off of HIFU with other treatment options for primary treatment of localized low and intermediate risk prostate cancer. □

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