SCANDINAVIAN JOURNAL OF UROLOGY
2022, VOL. 56, NO. 1, 53–58
https://doi.org/10.1080/21681805.2021.2002398

ARTICLE

Transition from open to robotically assisted approach on radical prostatectomies in Iceland. A nationwide, population-based study

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ABSTRACT

Objectives: In January 2015, radical prostatectomies (RPs) in Iceland changed almost entirely from being performed as open (ORP) to robotically assisted (RARP). This study assesses early surgical and short-term oncological outcome after ORP and RARP and evaluates the safety of transition between the two surgical techniques.

Methods: The study population involved 160/163 (98%) of all radical prostatectomies performed in Iceland between January 2013 and April 2016. Data on patients was collected retrospectively from medical records. Early surgical and short-term oncological outcomes were compared between the two surgical techniques.

Results: The ORP and RARP cohorts were comparable with respect to all clinical and pathological variables, except for median prostate volume, which was 45 mL in the ORP cohort and 37 mL in the RARP cohort ($p = 0.03$). Intraoperative blood loss was higher, hospital stay longer, catheterization time longer, and risk of complications within 30 days of surgery higher after ORP than RARP ($p < 0.01$). The operative time, positive surgical margin rate and recurrence free survival, within two years, was comparable between the two surgical techniques.

Conclusions: The transition from ORP to RARP in Iceland was safe and resulted in improved early surgical outcome. However, no conclusion can be drawn from this study regarding oncological outcome, due to short follow up and a small sample size.

ARTICLE HISTORY
Received 21 January 2021
Revised 25 October 2021
Accepted 29 October 2021

KEYWORDS
Prostate cancer; radical prostatectomy; robot-assisted, surgical technique; early outcomes

Introduction

Radical prostatectomy (RP) is the standard surgical treatment for localized prostate cancer. Originally, radical prostatectomies were performed with an open approach, but the surgical technique has evolved towards minimally invasive approach, including laparoscopic RP (LRP) and robotically assisted RP (RARP) [1]. LRP has not gained as much popularity as RARP, mostly due to a longer learning curve, lack of 3 D-visualization and freedom of motion, provided by RARP [2–5]. RARP is now the leading surgical approach for radical prostatectomies, with over 80% of all RPs in the US performed robotically assisted [6,7]. However, the main disadvantage of RARP is its considerable cost [8]. Despite the rapid distribution of RARP, there is no consensus on RARPs superiority over ORP, especially regarding oncological and functional outcomes [9]. Studies have shown that RARP is associated with less intraoperative blood loss, fewer blood transfusions [8], shorter hospital stays and catheterization time [3], and lower risk for major complications [10], as compared to ORP.

The robotically assisted approach was first introduced in Iceland in January 2015, and immediately took over the open approach. This milestone made it possible to compare ORP and RARP, regarding early surgical outcome and short-term oncological outcome, in a nationwide, population-based study. To the authors knowledge, the current study is the only nationwide, population based study assessing the safety of the transition from ORP to RARP.

Materials and methods

Study cohort and data collection

Patients eligible for the study were identified by the surgical codes for ORP and RARP, that were retrieved electronically from medical records. Data from the first 80 RARPs performed in Iceland were retrieved and compared to data from 80 ORPs performed two years prior to the introduction of RARP (January 2013 – December 2014). Virtually all (160/163 = 98%) of men diagnosed with prostate cancer, and who underwent RP in Iceland during the study period, had their surgery done at Landspitali University Hospital (LUH). In total, three men in the ORP group underwent surgery at another hospital and were excluded from the study. Five surgeons performed the ORPs, but 71 of 80 procedures (89%) were performed by three surgeons; A (31/80 = 39%), B (21/80 = 26%), and C (19/80 = 24%), with prior experience of

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>1000, >100 and >350 ORPs, respectively. One surgeon (B) performed 95% (76/80) of the robotically assisted RPs, with prior experience of >500 RARPs.

Data was collected retrospectively from medical records. The following variables were recorded; Age, BMI, prostate volume in mL, preoperative PSA level in ng/mL, American Society of Anaesthesiologists score (ASA score), clinical and pathological tumour stage, Gleason-scores (GS) from biopsies and surgical specimens, surgeon, preservation of erectile nerves during surgery, lymph node removal and pathological lymph node status. Primary endpoints were operative time, estimated blood loss, perioperative blood transfusions, length of hospital stay (LOS), catheterization time, readmissions and complications within 30 days of surgery, positive surgical margins (PSM), and recurrence free survival (RFS) within two years of surgery. The study was approved by The National Bioethics Committee (Number 15-229).

Definition of outcome variables

Patients were risk stratified into three groups according to EAU guidelines [11]. Lymph node removal was coded for as 1/0 (removed or not). Nerve sparing procedures were coded for as 1/0 (performed or not), on either side, on one side or on both sides. No further subcategorization was made on lymph node removal and nerve sparing procedures due to small numbers of surgeries.

Estimated blood loss during surgery was determined by the anaesthesiologist. Length of hospital stay (LOS) was calculated by subtracting the admission date from the date of discharge. Prolonged length of stay (pLOS) was defined as a hospitalization beyond the median LOS in the cohort. We examined possible complications that occurred during or after RP, within 30 days of surgery. Complications were stratified according to the revised Clavien-Dindo classification system [12]. Minor complications were defined as Clavien-Dindo grade I–II and major complications as Clavien-Dindo grade III–V. Surgical margins were defined as positive (PSM) if tumour cells reached the surgical border of the specimen. Recurrence was defined as one of the following events; PSA level of $\geq$0.2 ng/ml after surgery, metastasis, or death of prostate cancer. The definition includes an initial unmeasurable PSA value. The earliest date for any of these events was defined as the date of recurrence.

Statistical analysis

Statistical analysis was done using the R software for statistical analysis (version 3.5.1). For descriptive statistics, continuous variables were reported as medians and interquartile ranges (IQRs), and categorical variables as counts and percentages. The chi-square test and Mann–Whitney *U* test were used to identify statistically significant differences in proportions and medians between ORP and RARP groups. Univariate and multivariate logistic regression analysis was used to assess the impact of surgical approach on complication rates and early oncological outcome adjusting for age, BMI, prostate volume, pathological staging, pathological Gleason-score, and lymph node removal. Results were reported as odds ratio (OR) and 95% confidence interval. Recurrence was defined as any report of biochemical recurrence, metastasis, or death of prostate cancer, where the earliest date available was used as the recurrence date. Kaplan–Meier plot was used to illustrate recurrence-free survival (RFS), the log-rank test was used to compare RFS between groups. All statistical tests were two-sided with a level of significance set at p less than 0.05.

Results

Patient and tumour characteristics

In total, 160 patients were included in the study, of which 80 patients underwent ORP and 80 patients underwent RARP. The median age at surgery was 63 and 64 years for ORP and RARP, respectively ($p = 0.4$). The two groups were comparable regarding all clinical and pathological factors, except median prostate volume; ORP patients had a larger prostate volume than RARP patients; 45 mL and 37 mL, respectively ($p = 0.03$). Most patients in both groups had an organ confined disease (pT2, 59% ORP and 65% RARP; $p = 0.6$) and pathological Gleason-scores of $\leq 4+3$ (80% ORP and 71% RARP; $p = 0.5$). For one patient in the ORP group, malignant cells were not seen in the specimen, although found in the biopsy. He was excluded from the multivariate analysis, as it required information on tumour stage and Gleason-score. He was not excluded from analysis on rate of complications. Lymph node dissection was more often conducted in ORP ($p < 0.001$) and nerve sparing procedure was more often performed in RARP ($p = 0.04$). Overall PSM rates did not differ significantly between the two cohorts; 34% for ORP and 24% for RARP ($p = 0.2$). Of patients with organ confined disease (pT2), 13/47 = 28% ORP patients and 5/52 = 10% RARP patients had positive surgical margins (Table 1).

Perioperative and early oncological outcome

Perioperative outcomes are presented in Table 2. Operation time was similar in both groups; 129 and 123 min for ORP and RARP, respectively ($p = 0.2$). Median estimated blood loss during surgery was significantly lower in RARP than in ORP (100 mL versus 600 mL; $p < 0.001$). Six (8%) ORP and one (1%) RARP patients required perioperative blood transfusion ($p = 0.1$). The median length of hospital stay after surgery was two days after ORP and one day after RARP ($p < 0.001$). No patient had an in-day surgery. Number of patients readmitted within 30 days of surgery were comparable between the two groups; Six (8%) after ORP and four (5%) after RARP ($p = 0.7$). Catheters were withdrawn earlier after RARP, with median catheterization time being seven days, compared to 13 days after ORP ($p < 0.001$).

During the two-year follow-up there were 11 recurrence events after ORP and seven after RARP. Median time to recurrence was 1.30 years after ORP and 0.75 years after RARP. At two-year follow-up, 65/80 (81%) and 67/80 (84%)

Table 1. Patient and disease characteristics of patients who underwent open radical prostatectomy (ORP), between January 2013 and December 2014, and robotically assisted radical prostatectomy (RARP), between January 2015 and April 2016, at Landspitali University Hospital, Iceland.

Variable	ORP	RARP	*p* Value
Number of patients	80	80	
Age, years			
≤55	12 (15)	6 (8)	0.6
56–60	19 (24)	17 (21)	
61–65	19 (24)	23 (29)	
66–70	20 (25)	22 (28)	
>70	10 (123)	12 (15)	
BMI	27 [25, 30]	27 [25, 30]	0.4
Prostate volume, mL	45 [35, 58]	37 [30, 53]	0.03
Preoperative PSA level, ng/mL			
<10	28 (35)	36 (45)	0.1
10–20	31 (39)	33 (41)	
>20	21 (26)	11 (14)	
Biopsy Gleason-score			
3 + 3	35 (44)	26 (33)	0.4
3 + 4	25 (31)	27 (34)	
4 + 3	10 (13)	10 (13)	
8–10	10 (13)	17 (21)	
Clinical tumour stage			
T1	43 (54)	39 (49)	0.7
T2	30 (38)	33 (41)	
T3	7 (9)	7 (9)	
T4	0 (0)	1 (1)	
ASA score			
1	17 (21)	18 (23)	0.9
2	54 (68)	51 (65)	
3	9 (11)	10 (13)	
Risk category			
Low	18 (23)	11 (14)	0.2
Intermediate	34 (43)	44 (55)	
High	28 (35)	25 (31)	
Pathological Gleason-score*			
0 + 0	1 (1)	0 (0)	0.5
3 + 3	18 (23)	12 (15)	
3 + 4	29 (36)	30 (38)	
4 + 3	16 (20)	15 (19)	
8–10	16 (20)	23 (29)	
Pathological tumour stage*			
pT0	1 (1)	0 (0)	0.6
pT2	47 (59)	52 (65)	
pT3a	21 (26)	16 (20)	
pT3b	11 (14)	12 (15)	
Nerve-sparing procedure			
None	41 (51)	25 (32)	0.04
Unilateral	11 (14)	15 (19)	
Bilateral	28 (35)	39 (49)	
Lymph nodes removed			
No	33 (41)	67 (84)	<0.001
Yes	47 (59)	13 (16)	
Pathological lymph node status			
N0	73 (91)	77 (96)	0.3
N1	7 (9)	3 (4)	
Surgical margin status			
Negative	53 (66)	61 (76)	0.2
Positive	27 (34)	19 (24)	
pT2[†]	13 (28)	5 (10)	
pT3[#]	14 (44)	14 (50)	

All variables are given as median [IQR] or number (%). *Cancer was not found in one surgical specimen, although found in the biopsy. [†]Percentage in parentheses shows the proportion of all pT2 tumours in each group. [#]Percentage in parentheses shows the proportion of all pT3 tumours in each group.
ASA: American Society of Anaesthesiologists; BMI: body mass index; IQR: Interquartile range; risk category: low risk (PSA <10 ng/mL and GS <7 and cT1), intermediate risk (PSA 10–20 ng/mL or GS 7 or cT2), high risk (PSA >20 ng/mL or GS >7 or cT3/cT4).

were recurrence free after ORP and RARP respectively. Kaplan-Meier analysis demonstrated no difference in RFS between the surgical techniques ($p = 0.07$).

Table 2. Perioperative outcomes on patients who underwent open radical prostatectomy (ORP), between January 2013 and December 2014, and robotically assisted radical prostatectomy (RARP), between January 2015 and April 2016, at Landspitali University Hospital, Iceland.

Variable	ORP	RARP	*p* Value
Number of patients	80	80	
Operative time, min	129 [112, 150]	123 [110, 142]	0.2
Intraoperative blood loss, mL	600 [450, 900]	100 [75, 200]	<0.001
Perioperative blood transfusion	6 (8)	1 (1)	0.1
Length of stay, days	2 [2, 3]	1 [1, 1]	<0.001
Prolonged length of stay (>2 days)*	39 (49)	1 (1)	<0.001
Catheterization time, days	13 [12, 13]	7 [7, 7]	<0.001
Readmission within 30 days of surgery	6 (8)	4 (5)	0.7
Clavien-Dindo complication[†]			0.003
None	54 (68)	70 (88)	
Minor (I–II)	15 (19)	9 (11)	
Major (III)	11 (14)	1 (1)	

All variables are given as median [IQR] or number (%).
*Exceeding median for cohort. [†]Patients can be listed in >1 category.
IQR: interquartile range.

Table 3. Complications after radical prostatectomy in patients undergoing open radical prostatectomy (ORP), between January 2013 and December 2014, and robotically assisted radical prostatectomy (RARP), between January 2015 and April 2016, summarized according to type and stratified by Clavien-Dindo (CD) grade.

	ORP			RARP		
Type of complication*	Any	Minor	Major	Any	Minor	Major
Gastrointestinal	2	1	1	1	1	0
Infectious	31	21	10	10	10	0
Urinary tract complication	2	1	1	1	1	0
Other	3	1	2	4	2	2
Total	38	24	14	16	14	2

All variables are given as numbers.
*There are 80 patients in each group. Patients experiencing multiple complications are counted more than once.
Any complication: CD-grade I–V; minor complication: CD-grade I–II; major complication: CD-grade III.

Complications

There was a significant difference in 30-day complication rates between the two groups. Complications were reported for 36 (33%) ORP and 10 (12%) RARP patients ($p = 0.003$) of which 15 (19%) patients in the ORP cohort, and nine (11%) in the RARP cohort had a Clavien-Dindo grade I and II as the highest grade of complication. In total, 12 patients had a Clavien-Dindo grade III as the highest grade of complication, 11 (14%) in the ORP and one (1%) in the RARP cohort. No patient had a complication of Clavien-Dindo grade IV or V (Table 2).

The most common complications in both groups were infections (Table 3). Of all complications, $31/38 = 82\%$ and $10/16 = 63\%$ were post-operative infections after ORP and RARP, respectively. One of the ORP patients, who suffered from major surgical wound infection, underwent intervention under anaesthesia eight times in 30 days, due to wound care. No patient in the RARP group had a major surgical infection. One patient in the RARP group had a pulmonary embolism postoperatively, which was treated with anticoagulation therapy. Subsequently he developed hematoma in the operative area, which required reoperation.

In a multivariate regression analysis, adjusted for age, BMI, prostate volume, pathological staging, pathological Gleason-score, and lymph node removal, RARP was associated with

Table 4. Impact of surgical approach on complication rates and early oncological outcomes, for patients undergoing open radical prostatectomy (ORP), between January 2013 and December 2014, and robotically assisted radical prostatectomy (RARP), between January 2015 and April 2016.

Outcome	ORP (*n* (%))	RARP (*n* (%))	OR [95% CI]
Op time > 125 min*	41 (51)	35 (44)	1.06 [0.47, 2.44]
Catheterization time > 12 days*	45 (56)	5 (6)	0.04 [0.01, 0.12]
Length of stay > 2 days*	38 (48)	1 (1)	0.03 [0.00, 0.14]
Readmissions within 30d	6 (8)	4 (5)	0.44 [0.06, 2.68]
Any Clavien-Dindo grade	26 (33)	10 (13)	0.23 [0.08, 0.65]
Clavien-Dindo grade III–V	11 (14)	1 (1)	0.08 [0.00, 0.59]
Positive surgical margins	27 (34)	19 (24)	0.56 [0.21, 1.41]

Adjusted for age, BMI, prostate volume, pathological staging, Gleason-score and whether lymph node removal was performed or not. Lower OR favour the RARP group.
*Exceeding median for cohort.
OR: odds ratio; IQR: interquartile range; CI: confidence interval.

decreased risk of prolonged length of stay (>two days), a catheterization time of >12 days, any Clavien-Dindo complication, as well as major Clavien-Dindo complications (Table 4).

Discussions

In this nationwide, population-based study, we compared early surgical and short-term oncological outcome after open and robotically assisted radical prostatectomies. It is extremely rare that patients from Iceland go abroad to have RP. Thus, the study includes almost all men receiving RP as a treatment for prostate cancer during the study period.

According to The Icelandic Cancer Society, the proportion of men with prostate cancer, that received RP as the first treatment, was slightly higher in the RARP cohort (23% in years 2015 – 2017), as compared to the ORP cohort (20% in years 2012 – 2014) [13]. RARP showed considerable advantages over ORP regarding intraoperative blood loss, length of hospital stays, catheterization time, and complications within 30 days of surgery. No significant difference was seen between groups regarding biochemical recurrence within two years. However, this result must be interpreted with caution, due to few BCR events in the cohort and a short follow-up.

A longer operative time, often due to a surgeon's learning curve, is commonly seen when a new surgical technique is introduced [2]. A systematic review of ten studies, suggested that RARP was more time consuming than ORP in the earlier phase of the learning curve. However, with the surgeons' increasing experience, the difference in operative time disappeared [14]. We did not see a significant difference in operative time between the surgical approaches, although the robotic technique was first introduced to Iceland during the study period. This is most likely explained by the main RARP surgeon's prior experience, as he had already passed his learning curve. The range in operative time was considerably wider in the ORP group. That could be explained by more surgeons performing the ORPs and thus more inconsistency in operative time.

Consistent with previous studies, there was considerably less blood loss in the RARP group and fewer blood transfusions, than in the ORP group [8,9,15]. A systematic review, conducted by V. Ficarra et al., showed that blood transfusion rates varied from 9 to 29% for patients undergoing ORP, and 0 to 3% for RARP [14]. That is comparable with the current study, where 8% of ORP patients and 1% of RARP patients required blood transfusion. With the transition from ORP to RARP, length of hospital stay decreased significantly. That is consistent with a systematic review, which showed that hospital stay was significantly shorter for patients undergoing RARP than ORP [16]. In our study, there was more variability in LOS in the ORP group, with hospital stay ranging from two to twelve days. However, in the RARP group LOS was relatively consistent, with hospital stay ranging from only one to three days. These results indicate that with the introduction of RARP at Landspitali University Hospital, hospital stays after RP have become more predictable than before. Furthermore, shorter LOS in the RARP group suggests that RARP patients recovered faster than ORP patients, whereas LOS is often considered to be a measure of patient well-being.

In a study from Taiwan, in a cohort of 2741 patients, 90-day readmission were more frequent after ORP than RARP: 11 versus 4% ($p < 0.001$) [17]. In our study, no significant difference was seen in readmission rates between the two groups; 8% (6 patients) for ORP and 5% (4 patients) for RARP ($p = 0.7$). Due to few cases in each group, it is hard to draw any conclusion regarding these results. In our study, RARP patients had the catheter removed almost a week before ORP patients ($p < 0.001$). These results must be interpreted with caution, where they can be explained by a difference in catheterization protocol between surgical approaches.

Complication rates for ORP and RARP vary greatly between studies, mostly due to lack of standardized reporting methods [8]. Song et al., who classified complications according to the Clavien-Dindo classification system, found that 30-day complication rates were significantly higher for ORP than RARP; 31 and 7%, respectively ($p < 0.001$) [18]. Our study revealed similar results, where 30-day complication rates, according to the Clavien-Dindo classification system, were 33% for ORP and 12% for RARP ($p = 0.003$). Complications after ORP were mostly due to infections. The results from the current study suggest that RARP has some advantages regarding post-operative infections. Of all infections reported in the study 31/41 (76%) occured after ORP. This is in line with results from Carlsson et al. who found that RARP was associated with significantly decreased risk of infectious complications compared to ORP [19].

Positive surgical margins are considered predictors of early oncological outcome, as they are associated with future biochemical recurrence [20,21]. A recent systematic review showed significant differences in PSM for ORP and RARP, with higher rates for ORP [15]. However, a randomized controlled trial, conducted by Yaxley et al., showed no significant difference in PSM rates between ORP and RARP [9]. That is consistent with our study, where PSM rates did not differ significantly between the two groups.

PSM rates vary greatly between studies. A systematic review on five studies comparing ORP and RARP, showed that PSM rates ranged from 14 to 22% after RARP, and 8 to 32% after ORP [8]. This variability in PSM rates between studies could be explained by a difference in surgeons' experience [22], and by a difference in pathologists' methods on reporting PSM [23]. Furthermore, pathological stage is an important factor regarding PSM, as the risk for PSM increases with extracapsular extension of the tumour. Margin status in pT2 disease is an important measure of surgical quality, and in our study there were considerably more patients with pT2 disease in the ORP group, that had positive surgical margins; 13 patients versus 5 in the RARP group. However, due to few cases, the difference seen here is most likely due to random variation. More nerve sparing procedures were performed in the RARP group than in the ORP group ($p = 0.04$), but that did not result in increased number of PSM in either group.

Similar to another nationwide study [3], lymph node dissection was more often conducted in ORP patients than RARP patients; 59 and 16%, respectively ($p < 0.001$). That is mostly explained by a difference in surgical protocol between the surgical techniques. The rate of biochemical recurrence at two-year follow-up was similar between groups; 19% for ORP and 16% for RARP. That is consistent with another single-centre study, where recurrence rates were 17% for ORP and 16% for RARP, at three-year follow-up [24]. However, due to only 18 BCR events in the cohort of the current study, no conclusions can be drawn regarding difference in recurrence free survival between groups.

Strengths of the study include the nationwide, population-based cohort, including data on 98% of all RPs performed in Iceland during the study period. However, there are several limitations. The retrospective nature of data collection is not ideal and could have resulted in missing data. However, all data was collected systematically by the first author who had full access to all electronical medical records, which minimizes the risk of missing data. The relatively small sample size resulted in wide confidence interval of the results which limits the conclusions that can be drawn from the study, especially with regard to oncological outcomes. Approximately 95% of the RARP surgeries were performed by the same surgeon, who was highly skilled, with prior experience of >500 RARPs. Clearly this is a limitation to our study where this might contribute to better results in the RARP group in some areas, and might explain why there is no significant difference in OR time between groups. On the other hand, all ORP surgeries were performed by experienced surgeons, at the same hospital were the surgeons followed the same surgical and post-operative protocols. Nonetheless, this decreases the generalizability of the results and needs to be counted for. Two years is a short follow-up concerning oncological outcomes and is a limitation to our study.

Conclusions

The transition from ORP to RARP in Iceland was safe and resulted in improved early surgical outcome. However, no conclusion can be drawn from this study regarding oncological outcome, due to short follow up and a small sample size. We consider the conclusion valid for the purpose of quality assuring the implementation of a new technology.

Acknowledgments

We would like to thank all doctors, nurses and secretaries, at the Department of Urology, at LUH, for their general advices and assistance with data collection.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This work was supported by The Lions Club *Njördur*, Iceland.

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