ORIGINAL RESEARCH

Robotic Radical Prostatectomy Experience of a Single Practitioner At and Beyond the Learning Curve

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Objective: To determine the proficiency of a single Urological Oncologist in performing Robotic Radical Prostatectomy (RRP) for localized prostate adenocarcinoma based on the following surgical and functional outcomes: 1) operative time, 2) estimated blood loss, 3) positive surgical margin rate, 4) postoperative complication rate, 5) open conversion rate, and 6) urinary continence rate.
Materials and Methods: The authors reviewed the records of a single Urological Oncologist from January 2010 to September 2017 for patients who underwent RRP for prostate adenocarcinoma. Patients were divided into 3 groups: Group 1 consisted of the first 30 cases done by the surgeon, Group 2 consisted of the next set of 30 cases, and Group 3 consisted of his cases done thereafter. The mean operative time, mean estimated blood loss, positive surgical margin rate, site of positive surgical margins (apex, midgland, or base), postoperative complication rate, open conversion rate, and urinary continence rate at 4, 8, and 12 weeks post-op were compared among the 3 groups.
Results: A total of 30 patients were included in Group 1, another 30 were included in Group 2, and 45 patients were included in Group 3 for a total of 105. There is significant difference in the mean operative times among the 3 groups with a Group 1 having a mean operative time of 302.1 minutes, 170.3 minutes for Group 2, and 146.7 minutes for Group 3 ($p<0.0001$.) There is a statistically significant difference in mean estimated blood loss among the 3 groups (706.9 mL, 528.2 mL and 386.3 mL, respectively; $p<0.0001$.) No open conversion was performed in all 105 patients and only 3 complications were noted in this study. There was no statistical significance with regards to positive surgical margin rates among the 3 groups (5.7%, 11.4% and 15.2%, respectively.) with the apex being the most common site of positive margin in this study. There is a statistically significant difference in 8-week urinary continence rate among the 3 groups (12.4%, 20% and 36.2%, respectively; $p=0.005$)
Conclusion: Robotic Radical Prostatectomy is quickly becoming a feasible and safe option in the management of localized and locally-advanced prostate cancer in the local setting. The learning curve of 30 cases, based on the experiences of the Urological Oncologist, is sufficient in establishing proficiency in performing the said procedure.

Key words: robotic radical prostatectomy, prostate adenocarcinoma

Introduction

Prostate cancer affects 117.2 to 131 in 100,000 Filipino men.[1] The incidence of men having localized prostate cancer has risen to 81% and the incidence of metastatic disease has decreased by 75% since the introduction of PSA testing.[2] Due to this, most newly-diagnosed prostate cancers can

be treated surgically. Advancements in technology aimed to improve surgical outcomes have led to the application of robotics in the surgical management of prostate cancer. In particular, the da Vinci Surgical System (Intuitive Surgical, Sunnydale, California) is widely being used in prostate cancer surgery due to its numerous advantages: intuitive finger-controlled movements, 10 times magnification, three-dimensional stereoscopic optics, computer elimination of tremor, end-of-wrist instrument with seven degrees of freedom of range of motion, and scaled-down movement.[3] In the United States, an overwhelming number of surgeons have already adopted Robot-assisted Laparoscopic Prostatectomy (RALP) as their surgical approach of choice in treating prostate cancer.[4]

This technology is relatively new in the Philippines, with only two tertiary hospitals having access to a da Vinci robot. In addition, only a few Filipino urologists are adept in performing Robotic Radical Prostatectomy. In lieu of this, the outcomes of Robotic Radical Prostatectomy and the proficiency of surgeons in performing the procedure have not been established in the local setting. A number of studies have previously defined the learning curve for RRP to be 20-30 cases based on the outcomes of their own patients.[5,6,7]

The objective of this study was to determine the proficiency of a single Urological Oncologist in performing Robotic Radical Prostatectomy (RRP) for localized prostate adenocarcinoma based on the following surgical and functional outcomes: 1) operative time, 2) estimated blood loss, 3) positive surgical margin rate, 4) postoperative complication rate, 5) open conversion rate, and 6) urinary continence rate.

Materials and Methods

The authors reviewed the records of a single Urologic Oncologist from January 2010 to September 2017 for patients who underwent Robotic Radical Prostatectomy for prostate adenocarcinoma. There was a lull in performing the procedures from January 2012 to December 2014 due to logistic reasons. The procedures were performed by the aforementioned Urological Oncologist, who has extensive experience in performing Open Retropubic Radical Prostatectomy, via a standard transperitoneal 4-arm approach using the da Vinci Surgical System in two different institutions offering robotic surgery, the first 25 cases being done at the UST Hospital and the rest in other institutions. The surgical team consisted of the console surgeon, another Urological Oncologist adept in Robotic Radical Prostatectomy serving as first assist, a Urology resident, one scrub nurse, and one circulating nurse. Pelvic lymph node dissection and neurovascular bundle preservation were done upon discretion of the operating surgeon based on the risk of lymph node involvement according to the MSKCC nomogram and intraoperative tumor extent, respectively. A Jackson-Pratt drain was inserted through one of the port sites and removed prior to discharge when the output was less than 50 cc in 24 hours. The patients were placed on progressive diet postoperatively and advised ambulation on the 2nd post-op day.

Patients were divided into 3 groups: Group 1 consisted of the first 30 cases done by the surgeon, Group 2 consisted of the next set of 30 cases, and Group 3 consisted of his cases done thereafter. The age, clinical T-stage, Gleason score on biopsy, pre-operative PSA, volume of the prostate specimen, Gleason score on histopathology and pathologic T-stage of patients from the 3 groups were determined. The mean operative time, mean estimated blood loss, positive surgical margin rate, site of positive surgical margins (apex, midgland, or base), postoperative complication rate, open conversion rate, and urinary continence rate at 4, 8, and 12 weeks post-op were compared among the 3 groups. Urinary continence is defined as the use of no more than 1 sanitary pad per day.

Test of proportions was used to analyze pre-operative data and urinary continence rates while ANOVA was used to compare mean operative time and mean estimated blood loss among the 3 groups. Chi-square test of contingency was used to analyze positive surgical margin rates.

Results

A total of 30 patients were included in Group 1, another 30 were included in Group 2, and 45

patients were included in Group 3 for a total of 105.

There was no significant difference in mean age and mean pre-operative PSA result among the 3 groups (Table-1.) More than half of the patients in this study were categorized under clinical T2 stage, with 58 out of 105 patients falling under this category. For the biopsy Gleason score, majority of the patients are Gleason 6(3+3) and 7(3+4) with 32% and 26% of the population falling on those categories, respectively. Furthermore, there is a significant difference in the biopsy Gleason scores among the 3 groups. (Table 1)

Table 1. Pre-operative data.

	Group 1	Group 2	Group 3	p
Number of Patients	30	30	45	
Mean age, years	63.7	66.1	64.2	0.758
Mean PSA, ng/mL	12.4	10.6	12.3	0.479
Biopsy Gleason Score				
6	14	8	8	0.003
7 (3+4)	5	14	7	0.003
7 (4+3)	9	2	1	0.003
8	1	6	9	0.003
9-10	1	0	8	0.003
Clinical T-stage				
T1	7	11	6	0.11
T2	19	13	26	0.11
T3	4	6	13	0.11

Table 2. Post-operative results.

	Group 1	Group 2	Group 3	p
Mean Operative Time, mins.	302.1	170.3	146.7	<0.0001
Mean Estimated Blood Loss, mL	706.9	528.2	386.3	<0.0001
Open Conversion	0	0	0	-
Complications	2	1	0	0.473
Mean Prostate Volume, grams	39.3	41.5	43.5	0.295
Pathologic T-stage				
T2a	1	2	2	0.009
T2b	4	0	1	0.009
T2c	22	16	20	0.009
T3a	2	8	9	0.009
T3b	1	4	13	0.009
Post-operative Gleason Score				
6	10	7	7	0.016
7 (3+4)	16	20	16	0.016
7 (4+3)	1	2	11	0.016
8	1	0	2	0.016
9-10	2	1	12	0.016
Positive Surgical Margin Rate	6 (5.7%)	12 (11.4%)	16 (15.2%)	0.212
Positive Surgical Margin Location				
Apex	2	8	13	0.660
Midgland	3	5	7	0.660
Base	2	2	4	0.660

Table-2 shows that there is significant difference in the mean operative times among the 3 groups with Group 1 having a mean operative time of 302.1 minutes, 170.3 minutes for Group 2, and 146.7 minutes for Group 3. Both Groups 2 and 3 have statistically significant lower operative times compared to Group 1. There is also a statistically significant difference in mean estimated blood loss among the 3 groups (706.9mL, 528.2mL and 386.3mL, respectively). In addition, Group 3 has a statistically significant lower mean estimated blood loss compared to both Groups 1 and 2 while Group 2 has a statistically significant lower mean estimated blood loss compared to Group 1. No open conversion was performed in all 105 patients. Only 3 complications were noted in the entire study, 2 cases of retained blood clots in Group 1 and 1 case of prolonged JP removal in Group 2. Otherwise, no major postoperative complications were noted. There is a significant difference in the distribution of postoperative Gleason score and pathologic T-stage among the 3 groups, with Group 3 comprising of higher Gleason scores and pathologic T-stage compared to Groups 1 and 2 (Table-2.) There was no statistical significance with regards to positive surgical margin rates among the 3 groups (5.7%, 11.4% and 15.2%, respectively). with the apex being the most common site of positive margin in this study (Table 2.)

Only the 8-week urinary continence rate showed statistical significance among the 3 groups (Table 3) with values of 12.4%, 20% and 36.2%, respectively. Despite an increasing trend in urinary continence rates at 4 and 12 weeks among the 3 groups, they were not statistically significant.

Discussion

Several studies have reported their Robotic Radical Prostatectomy outcomes earlier on from the conception of the said procedure. Menon, et al. from the Vattikuti Urology Institute made an interim analysis of 200 patients who underwent RRP at 6-month follow-up and reported a complication rate of 5% and a positive surgical margin rate of 9%.[8] They also reported a continence rate of 96%. The erectile function and successful intercourse were reported as 82% and 64%, respectively, for men younger than 60 years; for men older than 60 years, results were 75% and 38%, respectively.[8] Ahlering, et al. at the University of California in Irvine compared the outcomes of the 60 open radical prostatectomies and their latest 60 RRP cases, excluding their first 45 RRP cases in order to eliminate bias produced by the operator's skill level. Operating time was 231 minutes for robotic prostatectomy and 214 minutes for open RP. Robotic prostatectomy compared favorably with open RP for estimated blood loss (103 vs. 418 cc), transfusion rate (0% vs. 2%), length of hospital stay (25.9 vs. 52.8 hours), complication rate (6.7% vs. 10%), and Foley catheter duration (7 vs. 9 days). The positive surgical margin rate was 16.7% and 20% for the robotic and open RP, respectively. At 3-months postoperatively, urinary continence was 76% in the robotic group and 75% in the open group.[9] Bentas, et al. reported on the early Frankfurt experience, using a cadaveric interface between open RP and RRP, providing outcomes on 40 consecutive patients at a follow-up duration of 12 months.[10] Operating time was 9.9 hours, estimated blood loss was 570 cc (range, 100-2500), and transfusion rate was 32.5%. The complication rate was 32.5%. Complications include obturator nerve injury (1), trocar injury to the epigastric

Table 3. Urinary continence Rates at 4, 8 and 12 weeks post-op.

	Group 1	Group 2	Group 3	p
4-weeks UC rate	5 (4.8%)	6 (5.7%)	18 (17.1%)	0.470
8-week UC rate	14 (12.4%)	21 (20%)	37 (36.2%)	0.005
12-week UC rate	27 (24.8%)	29 (27.6%)	44 (42.9%)	0.274

artery (1), DVT (1), PE (2), and prolonged anastomotic leak (4). Overall, 2.5% of patients were required to return to the operating room. The positive surgical margin rate was 30%. At one-year, urinary continence (0 pads) was 68%, and 20% of patients had regained sexual activity.[10] Cathelineau, et al. reported the Montsouris experience with robotic prostatectomy in 105 patients during a 3-year period.[11] The initial 70 cases were performed with the transperitoneal approach and the subsequent 35 cases using an extraperitoneal approach. Median operating time was 180 minutes (range, 120-290), median blood loss was 500 cc (range, 150-2000) and transfusion rate was 6%. There were 8 complications consisting of rectal injury (1), sigmoid injury (1), extraperitoneal abscess (1), hematoma (2), and prolonged urinary leaks (3). The overall positive surgical margin rate was 22%. The positive surgical margin rate was 11.7% for pT2 tumors and 43% for pT3 tumors.[11]

As the number of cases of RRP and the number of surgeons gaining proficiency in performing the procedure increase, a number of studies have deduced the exact number of cases to be set at the learning curve. Patel, et al. reported on the outcomes of 200 RRP cases over an 18 month period.[5] Average operative time was 141 minutes with an estimated blood loss of 75 cc. The intraoperative complication rate was 1% with no mortality, re-exploration or transfusion. Of the patients 95% were discharged home on postoperative day 1 (1 to 3) with hematocrit average of 34.5 (range 25 to 45). The average difference in preoperative and postoperative hematocrit levels was 3 points (range -2 to 15). Average catheter time was 7.2 days (range 5 to 15). The positive margin rate was 10.5% for the entire series, 5.7% for T2 tumors, 28.5% for T3a, 20% for T3b and 33% for T4a. Of these patients, 95% had undetectable PSA (less than 0.1 ng/ml) at average follow-up of 9.7 months. Continence at 1, 3, 6, 9 and 12 months was 47%, 78%, 89%, 92% and 98%, respectively.[5] Based on their experience, they have set the learning curve at 20-25 cases. Follow-up analysis of 500 RRP cases over a 30-month period also done by the same principal investigator revealed that the mean OR time was 130 minutes; all procedures were successful, with no intraoperative transfusions or deaths. The mean estimated blood loss was 10-300 mL; 97% of patients were discharged home on the first day after RRP with a mean hematocrit of 36%. The mean duration of catheterization was 6.9 days. The positive margin rate was 9.4% for all patients: 2.5% for T2 tumors, 23% for T3a and 53% for T4. The overall biochemical recurrence free (PSA level < 0.1 ng/mL) survival was 95% at mean follow-up of 9.7 months. There was complete continence at 3 and 6 months in 89% and 95% of patients, respectively. At 1 year, 78% of patients were potent (with or without the use of oral medications), 15% were not yet able to sustain erections capable of intercourse, and another 7% still required injection therapy.[12] The said results of the latter study were comparable with the findings of the former. After establishing the learning curve at 30 cases, Ou, et al. compared the outcomes of the first 30 cases of RRP (Group 1) with the latest 30 cases of RRP (Group 2) done by a single surgeon.[6] The vesicourethral anastomosis time showed a statistically significant reduction from 46.38 minutes in Group 1 to 31 minutes in Group 2. The continence rate at 3 months in Group 2 was higher than that in Group 1 (97.6% vs. 76.7%) and the mean duration to continence was shorter in Group 2 than in Group 1 (70.26 ± 67.37 days vs. 39.63 ± 36.48 days). Group 2 had shorter postoperative stays (3.93 vs. 7.33) and longer durations of Foley catheter removal (9.0 vs. 7.7) than Group 1, representing a statistically significant difference.[6] Another study of 100 first consecutive cases of RRPs done by a single surgical team was made, dividing the population into 3 equal groups (Group 1: first 30 cases, Group 2: second 30 cases, Group 3: last 34 cases), comparing the positive margin rate among the 3 groups.[7] The positive margin rates were 45.4%, 21.2%, and 11.7% for groups 1, 2, and 3, respectively, which were statistically significant. Furthermore, positive margin rates declined specifically at the apex and bladder neck when comparing the first 33 patients to the last 34 patients. The said findings demonstrated a learning curve of approximately 30 cases.[7]

Comparing the results of the present study to those done by international investigators, the authors could say that the surgical proficiency of

the local Urological Oncologist is at par with those of his foreign counterparts. Even though the positive surgical margin rates are not statistically significant in the present study, this may be explained by the fact that the latter cases done by the Urological Oncologist were more locally advanced (higher T-stage and Gleason score) compared to the earlier ones as he may have already developed the confidence to perform more challenging cases as his proficiency in RRP increases. The proficiency of the operative surgeon is made apparent by the marked improvement in mean operative time and estimated blood loss. A more long-term follow-up of these patients is needed in order to determine more clinically impactful oncologic and functional outcomes, such as biochemical recurrence and erectile function, and can be addressed in future studies.

Conclusion

Robotic Radical Prostatectomy has evolved to become a feasible and safe option in the management of localized and locally-advanced prostate cancer in the local setting. The learning curve of 30 cases, based on the experience of the Urological Oncologist, is sufficient in establishing proficiency in performing the said procedure.

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