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Same Operation, Same Robot, Different Countries: Does it make a Difference?

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Abstract

Objective: To investigate the impact that surgeon and operative room team experience rule in operative time and surgical outcomes.

Material and Methods: We retrospectively collected data of 150 robotic radical prostatectomy (RALPs) performed by the same surgeon in two different hospitals in different periods of his robotic experience. The first and the last 50 RALPs performed in a dedicated center of robotic surgery at University of Southern California were included respectively in group 1 and group 2. The first 50 RALPs performed at University Campus Bio-Medico of Rome were included in group 3. In this case, both first assistant and nursing team were at the beginning of their robotic experience. Monovariate analysis was performed comparing each group in terms of oncological and surgical outcomes. Multivariate logistic regression models were used to assess the risk of positive margin.

Results: The mean docking time in group 2 and 3 decreases significantly compared to group 1. In group 3 the operative time is significant longer. The mean estimated blood loss is higher in group 1 and the number of transfusions decreases in group 2 and 3. The probability to have surgical positive margins increases from pT2a-b-c to pT3b tumor stage. The study is limited because of its retrospective form.

Conclusion: Surgeon, assistant, and nurses have a cardinal role in operative and surgical outcomes. Tumor stage is the principle parameter that influences the oncological outcome. About 50 procedures are required to reach satisfactory operative outcomes although the learning curve continues for hundreds procedures.

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Introduction

Robotic-assisted surgery is one of the latest innovations in minimally invasive surgery. It is suited for pelvic surgery where the space constrains of the pelvic cavity is best dealt with using the robotic instruments with their degrees of freedom. Since the first robotic-assisted laparoscopic radical prostatectomy was performed by Binder and Kramer [1] in Frankfurt in May 2000, robotic technology has been increasing worldwide. The 4-arm da Vinci® Surgical System is rapidly gaining popularity among urologists especially for prostate cancer treatment. Systematic training in using a surgical robotic system is very important during and after residency [2,3]. The use of animal models has been shown to result in significant improvements in surgical skills [4]. The novice surgeon must confront a steep learning curve of approximately 20-25 cases required to achieve proficiency [5] however, there is no standardization of what constitutes a learning curve in the surgical literature [6]. The principal parameters that are most often evaluated [7,8] could be divided in operative outcomes (operative time, blood loss, hospital stay, complications), oncological outcomes (positive margin rate, recurrence) and functional outcomes (continence rates, erectile dysfunction rates). Robotic assisted laparoscopic prostatectomy (RALP) series tend to have longer operative time (OT) compared with Open Retropubic Prostatectomy although this gap decreases with experience [9]. Robot docking and exchange of robotic instruments are some of the maneuvers that are proved to become quicker with experience [10]. How experienced the robotic surgeon needs to be to achieve low positive surgical margin (PSM) rates, it is still unclear. The incidence

Table 1: Monovariate analysis of main variables.

Variables	Group 1 (50 patients)	Group 2 (50 patients)	Group 3 (50 patients)	p-value
Mean age (SD)	63.2 (6.2)	62.3 (7.6)	63.6 (6.5)	0.658
Positive surgical margin – n (%)	23 (46.9)	12 (24.0)	16 (32.0)	0.063
Positive lymph node– n (%)	2 (4.0)	1 (2.0)	0 (0.0)	0.360
Mean operative time	208.8 (47.3)	105.3 (24.2)	294.1 (90.8)	<0.001
EBL	498.2 (256.2)	194.8 (142.8)	313.2 (123.1)	<0.001
Transfusions n (%) - 0 - 1 - 2 - 3 - 4	 22 (44.0) 11 (22.0) 11 (22.0) 3 (6.0) 3 (6.0)	 49 (98.0) 1 (2.0) 0 (0) 0 (0) 0 (0)	 50 (100) 0 (0) 0 (0) 0 (0) 0 (0)	<0.001
Mean docking time (SD)	47.0 (14.8)	18.3 (6.4)	17.8 (8.7)	<0.001
Mean preoperative PSA value (SD)	5.4 (2.5)	5.9 (2.1)	6.3 (6.2)	0.056
Mean postoperative PSA value (SD)	0.2 (0.5)	0.78 (0.1)	0.09 (0.1)	0.14

EBL: Estimated Blood Loss; SD: Standard Deviation; PSA: Prostate Specific Antigen

of PSM is traditionally considered one of the strongest measures of operative outcome [11]. Surgical outcomes are however influenced by multiple variables as operative experience, fellowship training, high volume center of practice and all these parameters have been shown to play a significant role [12,13]. The aim of the present study is to investigate the impact that surgeon's experience and dedicated operative room team rule in operative time and surgical outcomes. To investigate the role of surgical experience in starting a new robotic program in different country, we have retrospectively collected data of 150 RALPs performed by the same surgeon (MB) in two different hospitals in different periods of his robotic experience. We have analyzed the most important variables like DT, OT, estimated blood loss (EBL) and PSM and individuated the ones that were affected the most. Furthermore, we have demonstrated that environmental changing as hospital, assistant, nursing team determine differences in operative RALP outcomes.

Materials and Methods

We retrospectively compared the first 50 cases of RALPs and the last 50 cases performed by a single surgeon (MB) at the University of Southern California (USC) from 2003 to 2007 and the first 50 RALPs performed by the same surgeon at Campus Bio-Medico University of Rome (UCBM) from 2011 to 2012. We have subdivided the first and the last 50 RALPs performed at USC in a dedicated center of robotic surgery with dedicated nursing team and senior first assistant, respectively in group 1 and group 2. This served as a measure of the single surgeon's learning curve going from novice to competent (first 50) to expert (last 50). The total number of cases performed in the USC series was 577 and only the first and last 50 were analyzed. The first 50 RALPs performed at UCBM were included in group 3. In this case, the center was not dedicated and both first assistant and nursing team were at the beginning of their robotic experience. All patients received general endotracheal anesthesia and were placed in steep Trendelenburg position with central docking. The 4-arm da Vinci® Surgical System and a 6 porttransperitoneal approach were used. All patients underwent RALP according to Montsouris's technique [14]. For each patient we analyzed: preoperative and postoperative Gleason score, preoperative and postoperative prostatic specific antigen (PSA) and the stage of cancer. The surgical specimens were staged according to the 2002 TNM staging system. We calculated for each procedure the DT, the OT; the EBL and the PSM rate.

Statistical analysis

Mean values for every numerical variable and relative frequency for every variable were calculated. Monovariate analysis was performed comparing each group of patient in terms of positive surgical margin rate, operative time and docking time, estimated blood loss and number of transfusions required. χ^2 test and one-way analysis of variance were used.Patients were divided into three different classes following the pathological postoperative stage: patients affected by pT2a-2b-2c tumor; patients affected by pT3a tumor and patient affected by pT3b tumor. Multivariate logistic regression models were used to compare the effect of covariates on the risk of having positive margin in each group. Group 3 was set as baseline. Linear regression was used to estimate the OT reduction in subsequent patients, divided into the three Groups. P-value in all tests was set at 0.05. Statistical analysis was performed with Stata 10 TM.

Results

Patients' mean age, preoperative and postoperative PSA value are similar for each group (63.2 for group 1; 62.3 for group 2 and 63.6 for group 3) and the differences between each group are not statistically significant (p= 0.658). The differences in the principal variables between the three groups have been compared in a monovariate analysis (Table 1). The surgeon has higher robotic experience in group 2 and 3 compared to being at the beginning of his learning curve in group 1; instead, in group 3 nursing team and first assistant are at the beginning of their robotic experience, while the surgeon resumes his robotic procedures in group 3 after 577 RALPs performed at USC and a 4-year hiatus.

Docking time

The mean docking time is similar in group 2 and in group 3 (respectively 18.3 and 17.8 minutes): it decreases significantly (p<0.001) compared to group 1 (47 minutes).

Operative time

The mean OT are lower in group 1 and group 2 (208 minutes for patients of group 1 and 105 minutes for patients of group 2) compared to group 3 (294 minutes). There are 5 cases in group 3 that are considerably longer but they are not correlated with operative contingencies. OT in group 1 are longer than group 2 (p< 0.001) and operative times in group 3 are longer than those in group 1 and group 2 (p< 0.001) (Table 1). Operative times tend to reduce with time.

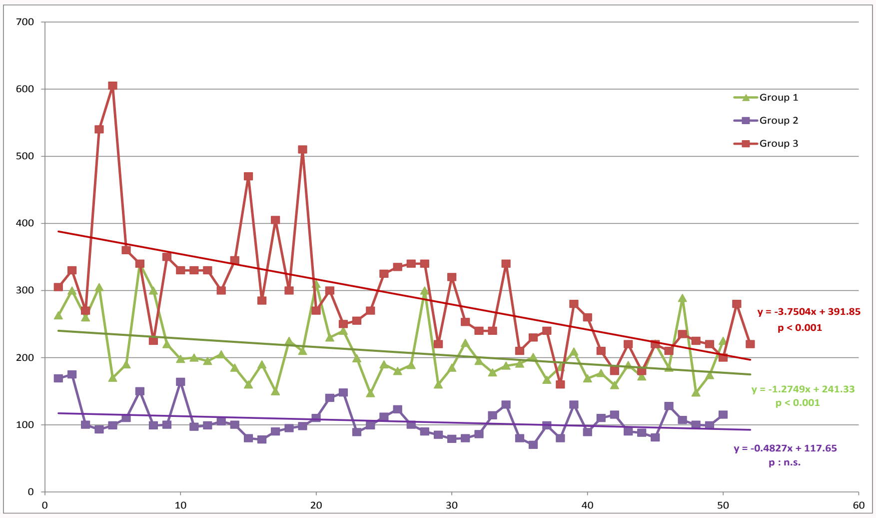

Figure 1: Time series of the three groups of patients, indicating the equation of the regression line and statistical significance.

Table 2: pT and PSM distribution among groups.

pT distribution in groups of patients				
	pT2	**pT3a**	**pT3b**	**tot**
Group 1 (% distribution)	38 (76)	6 (12)	6 (12)	50 (100)
Group 2 (% distribution)	47 (94)	2 (4)	1 (2)	50 (100)
Group 3 (% distribution)	37 (74)	7 (14)	6 (12)	50 (100)
Positive surgical margin (PSM) distribution in groups of patients correcting for tumor stage				
	pT2	**pT3a**	**pT3b**	**tot**
n. PSM Group 1 (%)	11 (28.9)	6 (100)	6 (100)	23 (46.0)
n. PSM Group 2 (%)	9 (19.1)	2 (100)	1 (100)	12 (24.0)
n. PSM Group 3 (%)	7 (18.9)	4 (57.1)	5 (83.3)	17 (32.7)

Furthermore, our results demonstrate that during the last 10 cases of group 1 and 3, the difference between the OT is not statistically significant (p: n.s.). The reduction of OT in group 3 is higher than in group 1 (-3.7 min/int vs -1.2 min/int, $p<0.001$). Time line of data for each group, in term of operative times, is showed in Figure 1.

Estimated blood loss

The mean estimated blood loss was about 500 ml in patients of group 1 and respectively 194 ml and 313 ml in group 2 and 3 ($p<0.001$).In group 3, transfusion was never required while 54 blood transfusions have been needed at the beginning (group 1) and then this value remarkably decreases in the last 50 procedures (group 2) ($p< 0.001$).

Limph nodes

The differences in number of positive lymph nodes found in each group at histopatological examination do not resulted statistically significant (p= 0.360).

Positive surgical margin

In group 1 there is a probability of 46% to have surgical positive margins instead of 24% of group 2. The probability to have surgical positive margins in group 3 is 32.7% (Table 2). As the distribution of tumor stage was not equal in groups, we have repeated the analysis correcting for tumor stage. Results indicate that the variable that influences the PSM outcome is the tumor stage and not the group of intervention. Patients affected by pT3a and pT3b prostate cancer have respectively 13 and 47 times more likely to have surgical positive margins than pT2 tumor stage patients, corrected by intervention group (Table 3).

Discussion

Robotic radical prostatectomy has changed the clinical management of prostate cancer profoundly. It is a minimally invasive surgery for localized prostate cancer and its use is increased recently [1,15]. There is a large body of literature suggesting that robotic-assisted laparoscopic prostatectomy is associated with improved perioperative and postoperative outcomes and similar cancer control rates compared to open radical prostatectomy [16]. In order to do that, surgeons must confront a steep learning curve. In a surgical context, the term learning curve means the time course/case number required to perform an operation satisfactorily [6]. The early learning curve for RALP appears safe and results in equivalent functional and oncologic outcomes, when compared with the results of open surgery. What is still unclear from the literature is how experienced the robotic surgeons need to be to achieve these results. Patel et al. [5] reported that the novice surgeon must confront by a steep learning curve of approximately 20-25 cases required to achieve proficiency. In a multi-institutional study of 3794 patients, Sooriakumaran et al. [6] have suggested that the learning curve for PSM rates needs over 1250 cases for a significant decrease and that the OT < 4 h is reached

Table 3: Estimation of relative risk to have positive surgical margins corrected by group of intervention and pT.

Variable	Odds Ratio	P value	95% Confidence Interval
pT2	1	-	-
pT3a	13.49	<0.001	3.7548.58
pT3b	47.25	<0.001	5.56401.19
Group 1	0.67	0.46	0.231.95
Group 2	1.83	0.21	0.704.73
Group 3	1	-	-

after approximately 750 cases. Operative duration reflects the time surgeon needs to perform the entire procedure and this parameter can be used as one measure of the learning curve. As can be seen from our results, overall operative durations are significantly longer in Italian group (group 3) compared with group 1 and group 2. Although the surgeon is at the end of his surgical learning curve in group 3, the mean operative time is longer than other groups most likely because there is not a dedicated team (nurses and assistants) in the O.R.. These results emphasize the critical role of dedicated nursing team and of an experienced first assistant. If the surgeon doesn't work in a dedicated high volume robotic center, the operative time is inevitably longer even if he or she is accomplished in robotic surgery. Operative times in group 1 are significantly longer than in group 2 because surgeon is at the beginning of his robotic experience. This improves in the last 50 cases after a total amount of 577 cases (group 2). Furthermore, during the last 10 cases of the group 1 and group 3, the difference between the operative times is not statistically significant (p: n.s.). As reported in the literature [5], a robotic naive operative team obtains proficiency after about 35-40 cases. Our data suggest that the operative time becomes lower incrementing the surgical experience: the learning curve continues for hundreds cases. The reduction of OT in the last 50 cases of surgeon (group 2) is no longer significant because after more than 500 procedures, surgeon has become expert and he/she is probably at the end of his/her learning curve. Furthermore, in the last cases of group 3 the operative times are similar to those in group 1 where surgeon, assistant, and nurses were expert. This aspect is confirmed by the linear regression model (Figure 1) that shows an improvement of 3.7 minutes after each procedure for surgeries of the group 3 instead of an improvement of 1.2 minutes for each intervention in group 1. We can assume that the group 3 learning curve in terms of operative times is faster than that in group 1 because surgeon is expert and influences the operative room team for faster improvement. Based on our results, the longer operative duration in group 3 is not correlated with a higher PSM rate. The prevalence of PSM rates reported in literature is 10-45% [17-19]. Novara et al. [20] Summarized the prevalence of PSMs in the surgical series published between 2008 and 2011: the prevalence of PSMs ranged from 6.5% to 32%, with a mean value of 15%. Although its prognostic significance is controversial, is abundantly delineated that the positive surgical margin is traditionally considered a measure of operative outcome [21,22]. In fact, a recent multivariate analysis [20] showed that PSM is associated with an increased risk of biochemical recurrence, local recurrence, and salvage treatment. The mean PSM rate of Novara and colleagues was 9% (range: 4–23%) in pT2 cancers, 37% (range: 29–50%) in pT3 cancers, and 50% (range: 40–75%) in pT4 cancers [20]. Also Ficarra et al. [23] demonstrated that pT stage was the unique pathologic predictor ($p < 0.001$). Zorn et al. [24]; Samadi et al. [25], Kwon et al. [26] and Leroy et al. [27], evaluated the association of surgeon experience with PSM rates. Atug et al. [19] reported that the PSM tended to diminish from 45.4%, 21.2% to 11.7% as the surgeon's experience increased over approximately 30 cases. Conversely, we have demonstrated that the probability to have positive surgical margin is strictly related to the pathological tumor stage and not to the surgeon's experience. Patients affected by pT3a and pT3b tumor have higher probability to have PSM than patients affected by pT2 (a-b-c) tumor (Table 3). Furthermore, as shown in regression models, both patient age and preoperative PSA value do not influence the postoperative margin status. Controlling for those parameters, patients in group 1 still have the highest probability to have PSMs. The docking time seems becoming quicker with the experience of the surgeon and the operative room staff: it is similar between group 2 and group 3 while is longer in group 1. The estimated blood lossdepends on surgeon's ability and it is strictly correlated with patient's postoperative hospitalization and with the number of transfusions required during the postoperative care. The mean EBL significantly decreases in group 2 and in group 3; patients in group 3 have never required transfusions. Our series suggest that surgeon's extensive experience reduces the necessity of blood transfusions. Our results support the issue that both surgeon's and operative room team's experience influence oncological and functional outcomes of RALP and introduce the need of specialized training for surgeons and the other components of the operative team. Currently, there is no a standardized program of what constitutes a learning curve. It has been shown that personal training is the most effective parameter to perfect robotic technique and close mentoring during RALP determines a significant potentiation in surgical maneuvers, although the optimal duration of this mentoring is not clear [7]. Another important consideration has to be directed to the demographic differences existing in robot-assisted laparoscopic radical prostatectomy patient population between high and low volume hospitals. Higher volume hospitals have showed fewer complications and lower costs than low volume hospitals on a national basis. These findings support referral to high volume centers for robot-assisted laparoscopic radical prostatectomy to decrease complications and costs [26].

Conclusions

Robotic-assisted surgery is becoming more popular in the recent few years. Experience of surgeons and dedicated operative room staff plays a cardinal role for the outcomes in terms of docking time and operative time, estimated blood loss and number or transfusions required. Tumor stage remains the main parameter that influences oncological outcome. We believe that 50 procedures are required to reach satisfactory operative outcomes although the learning curve continues for hundreds procedures. Experienced surgeons moving to a new environment (and country) need to take into account various factors independent from their expertise when counseling patients regarding surgical outcomes such as EBL and Operative time.

New robotic urology programs, in order to optimize results, will need to implement pathways for training each component of the operative team.

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