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The effect of the *da Vinci*® *Vessel Sealer* on robot assisted laparoscopic prostatectomy complications

Francesco Pellegrino[1,2], **Amy L. Tin**[1], **Daniel D. Sjoberg**[1], **Nicole E. Benfante**[3], **Ryan C. Weber**[1], **Shaun P. Porwal**[1], **Alberto Briganti**[2], **Francesco Montorsi**[2], **James A. Eastham**[3], **Vincent P. Laudone**[3], **Andrew J. Vickers**[1]

[1]Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, USA.

[2]Division of Oncology/Unit of Urology, IRCCS San Raffaele Hospital, Urological Research Institute, Milan, Italy.

[3]Department of Surgery (Urology Service), Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A.

Abstract

Introduction: The da Vinci® Vessel Sealer is a major contributor to the total cost of robot assisted laparoscopic prostatectomy (RALP). We aimed to assess whether the use of the Vessel Sealer is associated with better surgical outcomes in a population of patients that underwent RALP with lymphadenectomy.

Materials and method: We tested whether the use of the Vessel Sealer is associated with the development of lymphocele and/or other surgical outcomes. Most surgeons used the Vessel Sealer in almost all or almost no patients. Thus, to avoid the potential confounding variable of surgeon skill, we performed the initial analyses using data from a single surgeon who changed practice over time, and then using the entire population.

Results: Overall, the Vessel Sealer was used in 500 (36%) RALPs. Surgeon 1 performed 492 surgeries, and used the Vessel Sealer in 191 (39%). The Vessel Sealer was not associated with better surgical outcomes in patients operated on by Surgeon 1. The odds ratio for development of lymphocele was 1.95 (95% confidence interval [CI]: 0.57–6.75). In the entire population, use of the sealer was significantly associated with a very small reduction of blood loss (22 cc, CI: 13–30) but a 32-minute increase in the operating room time (CI: 26–37).

Conclusion: Use of the Vessel Sealer will have, at best, a very small effect on RALP outcomes that is of highly questionable relevance given its cost. In light of these results, the Vessel Sealer will only be used at our institution in the context of clinical trials.

Correspondence: Francesco Pellegrino, Division of Oncology/Unit of Urology, IRCCS San Raffaele Hospital, Urological Research Institute, Milan, Italy; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, USA; Phone: +39 02 2643 7286; Fax: +39 02 2643 7298; pellegrino.francesco@hsr.it.

Conflict of interest

Andrew Vickers is named on a patent for a statistical method to detect prostate cancer that has been commercialized by OPKO Health as the 4Kscore. Andrew Vickers receives royalties from sales of the test and has stock options in OPKO Health.

Keywords

Prostate cancer; RALP; Lymphadenectomy; Outcomes; Complications

INTRODUCTION

The number of robot assisted laparoscopic prostatectomies (RALP) using the da Vinci robotic system (Intuitive Surgical, Sunnyvale, CA), has dramatically increased. Currently, RALP accounts for almost 80% of all radical prostatectomies performed in the United States[1–3]. Vascular control during minimally invasive surgery is crucial. Indeed, relatively small amounts of blood can obscure the view of the operative field and increase the risk of damage to important structures. One of the most common complications after RALP with lymphadenectomy is the formation of lymphoceles [4–6]. These, although asymptomatic in most cases, may be disabling and may necessitate readmissions and invasive procedures [4].

It has been suggested that several laparoscopic instruments – such as LigaSure™ and EnSeal®– might reduce the incidence of these complications, but their application during RALP has been limited since they are rigid and non-articulating, and require manual control by the bedside assistant. A step forward was the introduction in 2012 of the da Vinci® Vessel Sealer (Intuitive Surgical, Sunnyvale, CA) which is a bipolar-energy, articulating, robotic instrument that is maneuvered by the principal operator at the console. The Vessel Sealer cuts and seals blood and lymphatic vessels, and so should theoretically reduce bleeding and lymphocele formation. However, this single-use instrument has considerable cost and significantly impacts the total cost of surgery, a major drawback of RALP[7,8].

We conducted a cost audit at our institution and found that, in a multivariable linear model adjusting for surgery and patient characteristics, the use of Vessel Sealer was a major cause of variation in surgical costs. The use of this tool could naturally be justified if it significantly improves surgical outcomes, but only a few studies have evaluated Vessel Sealer effects on robotic surgery outcomes, with data on RALP outcomes being particularly sparse [9–12]. Moreover, the majority of these studies were limited by the use of small populations, and they were focused on specific complications. We aimed to assess whether the use of the Vessel Sealer is associated with better surgical outcomes in a population of patients that underwent RALP with lymphadenectomy to understand whether its cost is justified.

MATERIALS AND METHODS

Patient selection

After obtaining Institutional Review Board approval (IRB: 17–629), we identified 1,402 patients who underwent RALP with lymphadenectomy at our tertiary referral center between June 2016 – when RALP moved to a new surgical unity - and June 2020, when our study database was closed for the cost audit. All patients underwent anatomically defined extended pelvic lymph node dissection with removal of the external iliac, obturator, and hypogastric lymph nodes The Vessel Sealer was used only for the lymph node dissection in 500 cases.

When the da Vinci® Vessel Sealer was not used, the lymph node dissection was performed with bipolar cautery and Hem-o-lock clips. Clips were applied by the surgeon using the robotic clip applier or by the bedside assistant. The extent of vessel sealer, cautery, and clip use during the lymph node dissection was at the discretion of the surgeon per their normal practice. Complications were scored using the Clavien-Dindo score system [13], and those with Clavien-Dindo score ≥ 3 were considered as severe.

Objective

The objective of the study was to assess whether the use of the Vessel Sealer is associated with better surgical outcomes as tracked by these variable parameters: development of lymphocele, blood loss during surgery, operatory room time, severe complication (grade ≥3), hemorrhagic complication, blood transfusion, length of stay, readmission within 30 and 90 days after surgery.

Statistical analyses

RALPs were performed by 8 surgeons. To evaluate whether the use of the Vessel Sealer and various clinical information were uniform among surgeons, we calculated populational characteristics for patients grouped according to the individual surgeon by whom RALP was performed (Supplementary table 1). We found that most surgeons either did or did not use the Vessel Sealer, with all but 3 surgeons having fewer than 20 discordant cases. Surgeon 1 performed approximately 35% of the RALPs in our population (492 cases) and used the Vessel Sealer in 39% of his surgeries. This was due to a change in practice over time, with the Vessel Sealer being used more frequently for recent cases. In that surgeon's experience, the most common surgical complication requiring intervention within 90 days was a lymphocele. The use of Vessel Sealer by this surgeon was a specific attempt to reduce the frequency of that particular complication. However, surgeon 1 is very experienced, with several thousand prior cases, and a change in surgical skills during the study period due to the learning curve is unlikely.

We first tested whether clinical characteristics were associated with the use of the Vessel Sealer using multivariable logistic regression. We then tested whether the use of the Vessel Sealer was associated with surgical outcomes: univariable logistic regression analyses to assess the association with each individual dichotomous outcome (severe complication, hemorrhagic complication, transfusion after surgery, readmission within 30 and 90 days after surgery, and the composite outcomes of at least one of the previous complications) due to the low number of events, and multivariable linear analyses to assess the association with each individual continuous variable (estimated blood loss, operating room time, and length of stay). Multivariable models were built with use of Vessel Sealer as a dichotomous variable, and adjusted for other variables that we thought might be associated with complications, such as naive abdomen (no previous abdominal surgery and/or radiotherapy), seminal vesicle invasion, extra-prostatic extension, high pathological ISUP grade group, lymph node invasion, and neurovascular bundle status after surgery. Finally, we repeated the same analyses for the entire population. In this case, we added "high volume surgeon" to the variables used to build the previous multivariable models to represent surgeon experience. We considered as "high volume surgeon" those surgeons who have performed ≥ 250

procedures in our population [14]. Statistical analyses were performed using R version 4.0.2 statistical software.

RESULTS

Patient characteristics are reported in Table 1. These were similar between the Surgeon 1 and other surgeons cases, except that the percentage of positive digital rectal examination was slightly higher in the first (51% vs 31%). Vessel sealer was used in approximately the same percentage of cases among the other surgeons and Surgeon 1 populations (34% and 39%, respectively), and hemostatic agents were used in almost all procedures. Table 2 shows surgical outcomes. These were similar between Surgeon 1 cases and the entire population. Overall, 22 patients developed lymphocele. All of these required deviation from the normal post-operative course (grade ≥1) and 20 were grade ≥3. The most frequent complication was readmission within 90 days from surgery that occurred in 62 (4.4%) and 19 (3.9%) cases among the entire population and the patients operated on by Surgeon 1, respectively. The readmission reasons are reported in Supplementary table 2.

Using only patients operated on by Surgeon 1, no pre-operative characteristic was associated with the use of Vessel Sealer in multivariable logistic regression analysis (Table 3). We then evaluated whether the use of this tool was associated with surgical complications. None of the complications were significantly associated with the use of Vessel Sealer in univariable logistic regression analyses (Table 4). The odds ratio for development of lymphocele was 1.95 (95% confidence interval: 0.57, 6.75). The largest central estimate for effect size was 0.26 (95% confidence interval: 0.01, 1.53). However, the incidence of blood transfusion is very low and so this effect is of questionable clinical relevance: if confirmed as a true effect, close to 70 patients would need to be treated with the Vessel Sealer to prevent one transfusion. The Vessel Sealer was also not associated with a significant reduction of estimated blood loss, operating room time, and length of stay in multivariable logistic regression analyses (Table 5).

We then repeated our analyses using the entire population. High volume surgeon, hemostatic comorbidity, and positive digital rectal examination were associated with use of Vessel Sealer in multivariable logistic regression analysis, the odds ratios were 2.49 (95% confidence interval: 1.80, 3.49), 1.99 (95% confidence interval: 1.06, 3.77), and 1.32 (95% confidence interval: 1.05, 1.67), respectively (Supplementary table 3). Also using the entire population, the use of this tool was not associated with any complication in univariable logistic regression analyses (Supplementary table 4). The lowest Number Needed to Treat was 78 for readmission within 90 days (odds ratio: 0.73, 95% confidence interval: 0.41, 1.25). On the other hand, the use of Vessel Sealer was associated with a minimal reduction in estimated blood loss (β: 22; 95% confidence interval: 30, 13) but a 32-minute increase of the operating room time (95% confidence interval: 26, 37) (Supplementary table 5).

DISCUSSION

Using a large cohort of patients who underwent RALP with lymphadenectomy at a tertiary referral center, we did not find evidence that use of the Vessel Sealer improves outcomes.

We also found that any plausible effects of the Vessel Sealer were small, and hence of questionable relevance given the cost of the instrument.

A few studies have compared characteristics of vessel sealing devices in animal models between bipolar and other devices, such as monopolar and ultrasonic. Those have shown the superiority of the most recent bipolar devices over the others in terms of speed of coagulation, thermal spread, and voltage needed, suggesting less operative time and less risk of damage to surrounding tissues [15–18]. Although the theoretical advantage of the most recent bipolar instruments seems to be clear, the clinical outcomes of the application of Vessel Sealer in robotic surgery are yet to be fully determined. We were able to find only one study that evaluated the use of this tool during RALP with lymphadenectomy [12]. In this prospective randomized trial, 114 patients underwent RALP with bilateral lymphadenectomy, and each man was randomized to which side of his lymphadenectomy would be performed either with the conventional technique (via robotic electrocautery scissors and fenestrated Maryland bipolar instruments with preferential use of bipolar over monopolar energy, and clip/ robotic Hem-o-lok placement) or using the Vessel Sealer. The aim of the study was to evaluate if the use of this tool prevents the development of lymphoceles as evaluated with a CT performed 3 months after surgery. Consistent with our results, the authors found no differences in lymphocele rate or size between the sides performed on by the conventional technique and those performed on using the Vessel Sealer (lymphocele rate: 9 vs 10% [p= 0.4]; mean largest lymphoceles diameter: 3.6 vs 4.3 cm [range: 1.4, 8.0 vs 5.8, 1.8; p= 0.3]). Their results also did not show significant differences in operating time between the two approaches (mean lymphadenectomy operating time: 11.1 vs 11.3 min [p=0.6]). This finding is apparently in contrast with the results of our secondary analyses where the use of this tool was associated with an increased operatory room time. This contrast could be partially explain by the different outcome used. Indeed, we evaluated the total operative room time (from the patient's entrance into the operative room until his exit), thus including also instruments preparation and changes, whereas they analyzed only the time required to perform the lymphadenectomy. A few studies instead evaluated the effects of the Vessel Sealer for robotic procedures other than radical prostatectomy and they reported contradictory results. Ortenzi et al [9] suggested that the use of this tool results in shorter surgical time and lower estimated blood loss, but the methodology was questionable, as the authors compared their results from 34 patients who underwent robot-assisted colectomy using the Vessel Sealer with those published by other authors whose patients underwent the same procedures but with other sealing instruments. Kong et al [10] showed no statistically significant difference when comparing surgical time and estimated blood loss between a group of 17 patients who underwent robot-assisted gastrectomy using the Vessel Sealer and another group of 52 patients who underwent the same procedure without the Vessel Sealer, but very low patient numbers raise questions of statistical power. Similarly, a recent study on robotic thyroidectomy [11] did not find statistically significant differences in complications comparing the same two tools. The authors reported only a significantly highest number of camera cleanings during first lobectomy in the procedures performed using ultrasonic shear force. This study has a similarly very small sample size (n=35).

Our study is potentially affected by several potential biases associated with observational studies. In particular, although we did not find important differences between patients depending on the use of the Vessel Sealer in our main analyses, we cannot entirely discount the possibility of unmeasured confounding. In particular, for our secondary analyses, we cannot be sure whether differences in outcomes for patients undergoing procedures that used the Vessel Sealer correspond to the effects of the Vessel Sealer, or reflect differences between the surgeons who tend to use or avoid the Vessel Sealer. That said, our main analysis included only a single surgeon and the results of this analysis were sufficient to exclude an important effect of the tool on the analyzed outcomes. Finally, we could not account for other potential confounders, such as the bedside assistant experience, that may be associated with some of the outcomes analyzed.

One of the major criticisms of the RALP is its elevated cost when compared to open or laparoscopic approaches [7,8]. Minimizing the expense of this approach is crucial. The Vessel Sealer, single-use instrument, has a much higher cost compared to that of surgical clips used in the standard technique [19]. The use of such an expensive instrument might be justified if it improved surgical outcomes, but in our analyses, we did not find evidence that this was the case. Given these findings, this instrument should be used only in the context of a prospective randomized trials designed to either investigate the effects of different hemostatic approaches on surgical outcomes, or in different settings including low volume surgeons and surgeons in training. The latter because using of vessel sealer can improve surgical education by enabling surgeons in training more autonomy performing the surgery.

CONCLUSION

We did not find evidence that use of the Vessel Sealer improved outcomes in patients undergoing robotic radical prostatectomy. Use of this instrument should be restricted to clinical trials to more formally test is effectiveness and cost-effectiveness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Study conception and design: Andrew J. Vickers, Vincent P. Laudone

Data acquisition: Nicole E. Benfante, Ryan C. Weber

Analysis and interpretation of data: Francesco Pellegrino, Amy L. Tin, Daniel D. Sjoberg, Shaun P. Porwal, Alberto Briganti, Francesco Montorsi, James A. Eastham

Drafting of the manuscript: Francesco Pellegrino, Daniel D. Sjoberg, Amy L. Tin, Nicole E. Benfante, Ryan C. Weber, Shaun P. Porwal

Critical revision of the manuscript for important intellectual content: Alberto Briganti, Francesco Montorsi, James A. Eastham, Vincent P. Laudone, Andrew J. Vickers

Statistical analysis: Francesco Pellegrino, Daniel D. Sjoberg, Amy L. Tin, Nicole E. Benfante

Supervision: Alberto Briganti, Francesco Montorsi, James A. Eastham, Andrew J. Vickers, Vincent P. Laudone

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Table 1.

Descriptive characteristics of 1,402 patients treated by RALP with lymphadenectomy. Data are given as median (quartiles) or frequency (percentage).

	Surgeon 1 cases	Other Surgeon cases
Characteristic	**N = 492**	**N = 910**
Age, years	62 (57, 68)	62 (57, 67)
Hemostatic comorbidity	15 (3.0%)	27 (3.0%)
Charlson Comorbidity Index	0 (0, 0)	0 (0, 0)
Naive Abdomen	324 (66%)	611 (67%)
Salvage RALP	1 (0.2%)	9 (1.0%)
Digital Rectal Examination	249 (51%)	284 (31%)
ISUP Grade group 4–5 at biopsy	111 (23%)	179 (20%)
PSA, ng/ml	6.1 (4.2, 8.9)	6.2 (4.5, 8.7)
Preserved Neurovascular Bundle		
No	6 (1.2%)	92 (10%)
Unilateral	127 (26%)	194 (21%)
Bilateral	359 (73%)	624 (69%)
High Volume Surgeon (≥250 cases)	492 (100%)	649 (71%)
ISUP Grade group 4–5 at RALP	67 (14%)	108 (12%)
Extra-prostatic Extension	252 (51%)	416 (46%)
Seminal Vesicle Invasion	54 (11%)	95 (10%)
N° of Lymph Nodes Removed	18 (13, 25)	16 (10, 24)
Lymph Nodes Invasion	63 (13%)	105 (12%)
Use of Hemostatic Agents	474 (96%)	796 (87%)
Floseal	28 (5.7%)	23 (2.5%)
Surgicel	473 (96%)	757 (83%)
Surgiflo	9 (1.8%)	34 (3.7%)
Arista	0 (0%)	122 (13%)
Use of Vessel Sealer	191 (39%)	309 (34%)

Table 2.

Surgical outcomes. Data are given as median (quartiles) or frequency (percentage).

	Surgeon 1 cases	Other Surgeon cases
Characteristic	**N = 492**	**N = 910**
Blood Loss during Surgery, cc	150 (100, 200)	150 (100, 200)
Operatory Room Time, min	283 (264, 306)	295 (266, 333)
Lymphocele	11 (2.2%)	11 (1.2%)
Severe Complications (grade ≥3)	12 (2.4%)	20 (2.2%)
Hemorrhagic Complications	6 (1.2%)	5 (0.5%)
Blood Transfusion after Surgery	7 (1.4%)	6 (0.7%)
Length of Stay, hours	26.60 (24.20, 27.93)	27.37 (24.62, 28.48)
Readmission within 30 days	14 (2.8%)	36 (4.0%)
Readmission within 90 days	19 (3.9%)	43 (4.7%)
At least one complication	24 (4.9%)	48 (5.3%)

Table 3.

Multivariable logistic regression analysis to assess the association between clinical characteristics and the use of Vessel Sealer only for surgeries performed by Surgeon 1 (492 patients, Vessel Sealer used in 191 cases). There are no clear differences between patients who did and did not receive the Vessel Sealer.

Characteristic	Odds Ratio	95% Confidence Interval	p-value
Age, years	1.00	0.97, 1.02	0.7
Charlson Comorbidity Index	0.87	0.68, 1.08	0.2
Hemostatic comorbidity	1.04	0.33, 3.04	>0.9
Naive Abdomen	0.79	0.53, 1.17	0.2
Digital Rectal Examination	0.84	0.58, 1.22	0.4
ISUP Grade group 4–5 at biopsy	1.01	0.63, 1.60	>0.9
PSA, ng/ml	1.03	1.00, 1.06	0.059

Table 4.

Univariable logistic regression analyses to assess association between the use of Vessel Sealer and complications only for surgeries performed by Surgeon 1 (492 patients, Vessel Sealer used in 191 cases).

Outcome	Event N	Odds Ratio	95% Confidence Interval	p-value
Lymphocele	11	1.92	0.57, 6.75	0.3
Severe Complications (grade ≥3)	12	1.13	0.33, 3.59	0.8
Hemorrhagic Complications	6	0.00		>0.9
Blood Transfusion after Surgery	7	0.26	0.01, 1.53	0.2
Readmission within 30 days	14	1.19	0.39, 3.47	0.8
Readmission within 90 days	19	1.44	0.56, 3.64	0.4
At least one complication	24	1.35	0.58, 3.09	0.5

Table 5.

Multivariable linear regression analyses to assess the association between the use of Vessel Sealer and surgery outcomes only for surgeries performed by Surgeon 1 (492 patients, Vessel Sealer used in 191 cases)

Outcome	β	95% Confidence Interval	p-value
Estimated blood loss, cc	−3.7	−17, 9.3	0.6
Surgery time, min	3.0	−3.2, 9.1	0.3
Length of stay, hours	−1.4	−3.5, 0.58	0.2