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Original Article

Robot-assisted radical cystectomy with neobladder diversion in females: Safety profile and functional outcomes



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KEYWORDS

Sexual-sparing; Robot-assisted radical cystectomy; Female; Functional outcome; Continence; Sexual function Abstract Objective: Radical cystectomy (RC) is a standard treatment for localized muscle invasive bladder cancer and high-risk or very high-risk non-muscle invasive bladder cancer not responding to adequate endovesical therapy. In women, traditionally RC is performed with hystero-adnexectomy and resection of the anterior vaginal wall, often resulting in sexual disorders. Vaginal-sparing techniques have been developed to improve functional outcomes. The present study explores the safety and the functional outcome of vaginal-sparing techniques. Methods: We retrospectively analyzed all consecutive female patients undergoing robot-assisted RC (RARC) with neobladder diversion between October 2017 and February 2022. The indications for vaginal-sparing RC were absence of tumor on bladder neck or urethra and no sign of infiltration of posterior bladder wall at the preoperative MRI. Functional results were evaluated with the aid of five questions out of the Bladder Cancer Index questionnaire. Complications were reported according to the Clavien—Dindo classification and cancer control was evaluated by recurrence-free and cancer-specific survival.

Results: A total of 22 female patients underwent RARC with neobladder diversion. Neoadjuvant chemotherapy was given in 17 (77%) cases. Clavien—Dindo grades III—IV complications occurred in four (18%) cases. After a mean follow-up of 29 (interquartile range 16—44) months, six (27.3%) patients developed distant metastases, and one (4.5%) woman loco-regional relapse. Sexual-sparing surgery was performed in 19 (86%) patients, and in the others the

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anterior vaginal wall was resected, but neobladder was still performed. During daytime, no patients reported total incontinence and 73% (11/15) reported total continence or only occasional leaks. Sexual results showed that seven of 15 (47%) women regained sexual activity after surgery, with a quality reported as "good" or "very good" in 40% of all 19 cases. *Conclusion*: RARC in female with anterior vaginal wall preservation is feasible. The approach showed a good safety profile, with satisfying results on continence and sexual activity. Sexual-sparing approaches should be carried out after correct patient selection.

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1. Introduction

Radical cystectomy (RC) is a standard treatment for localized muscle invasive bladder cancer and high-risk or very high-risk non-muscle invasive bladder cancer not responding to adequate endovesical therapy [1]. Open RC and robot-assisted RC (RARC) have comparable oncologic outcomes and complication rates when done at experienced centers [2].

Current guidelines underline the importance of cisplatin-based neoadjuvant chemotherapy (NAC) before RC, as it demonstrated benefits on cancer-specific and all-cause mortality rates [1]. RC is composed of an excision phase (cystectomy and pelvic lymph node dissection), which is followed by urinary diversion. An orthotopic neobladder diversion can be offered to patients if the technology and oncology are feasible [1,3].

Bladder cancer is a tumor with an increasing incidence in female and young patients [4]. In women, traditionally RC is performed as an anterior pelvic exenteration, which includes also hystero-adnexectomy and resection of the anterior vaginal wall. Due to the extension of this anterior pelvic exenteration, RC in women often results in substantial changes in body image, urinary function, and sexual disorders [5]. To improve these side effects, surgical modifications were developed, such as sexual-sparing approaches and neobladder diversion. The usual aim of these techniques was the preservation of neurovascular bundles, vagina, uterus, and annexes [5]. Unfortunately, literature regarding sexual sparing RC is still scarce.

The advent of laparoscopic and especially RARC brought new interest in these approaches, but large multicenter studies are still lacking. In this work, we explore the safety profile, oncological results, and the functional outcome of sexual-sparing RARC in women.

2. Patients and methods

We retrospectively analyzed all consecutive female patients undergoing RARC with neobladder diversion between October 2017 and February 2022 at our tertiary referral center. This study was approved by the local review board (No: SARCO-NAC-IPC 2018-004) and consents were provided by all patients. Indications for cystectomy were muscle invasive urothelial bladder cancer or high- to very high-risk non-muscle invasive bladder cancer. Unless contraindicated,

patients with muscle invasive bladder cancer received NAC following the "methotrexate, vinblastine, adriamycin, and cisplatin" or "gemcitabine and cisplatin" protocols. All patients underwent systemic staging by chest and abdominopelvic CT scan and bone scintigraphy, and a local staging was done by contrast-enhanced pelvic MRI and cystoscopy. Preoperative indications for vaginal-sparing RC were absence of tumor on bladder neck or urethra on preoperative imaging, and no sign of infiltration of the posterior bladder wall at preoperative staging on MRI and cystoscopy.

The surgical technique was described elsewhere [6]. Briefly, sexual-sparing RARC in female consists in extended pelvic lymph node dissection, which is associated to one of the following options: (i) cystectomy, hysterectomy, and adnexectomy with complete preservation of the vagina; (ii) cystectomy and hysterectomy with complete preservation of the vagina and annexes; (iii) cystectomy without touching the genital organs leading to complete preservation of the vagina, uterus, and annexes. In the first six (27%) cases of the series, an intracorporal Studer neobladder was performed, and in the following 16 (73%) cases, an intracorporal Bordeaux neobladder was performed [3,7]. The switch in the type of reconstruction during the study period was with the aim to homogenize the technique inside of our team. All procedures were done by three surgeons (Pignot G, Maubon T, and Walz J), with each of them having done at least 30 cases of cystectomy with neobladder diversion during their careers.

Preoperative characteristics, perioperative results, and postoperative outcomes were prospectively collected. Complications were recorded using the Clavien—Dindo classification [8]. For the analysis of complications, only Clavien—Dindo grades III—V complications were taken into account. Preoperative data were age, body mass index, American Society of Anesthesiologists score, Charlson Comorbidity Index, pathology before RC, and NAC administration. Intra- and peri-operative outcomes of interest were the type of surgery (i.e., full sexual organ sparing, vaginal sparing, or full anterior pelvectomy), surgical time, blood loss, time to bowl movement, length of stay, ureteral stent and Foley catheter removal, readmission rate, and postoperative complications after discharge.

Pathology findings (pathological tumor stage [pT], pathological node stage [pN], number of nodes at pathology, and surgical margin status) were also taken into consideration, and cancer control was evaluated by means of recurrence-free and cancer-specific survival. For functional results, only

patients who underwent a procedure with total or partial genital preservation were included. Functional outcomes were evaluated with the aid of the Bladder Cancer Index (BCI) questionnaire [9]. This questionnaire broadly evaluates many aspects of continence and sexual life of patients undergoing RC. We focused our attention on five particular questions that were addressed to patients during the post-operative follow-up visit at least 6 months after surgery [9]. Self-catheterization was also evaluated to investigate the rate of chronic urinary retention.

Descriptive analyses were used. Frequencies and proportions were reported for categorical variables. Means and interquartile ranges (IQRs) were reported for continuously coded variables. Metastasis-free survival and cancer-specific survival were plotted by the Kaplan—Meier method. The statistical analysis was done using SPSS software (version 28.0, IBM Inc., Armonk, NY, USA).

3. Results

3.1. Perioperative analysis

A total of 22 female patients underwent RARC with neo-bladder during the study period. Preoperative data are summarized in Table 1. The mean age was 62 (IQR 57–66) years, and Charlson Comorbidity Index was three or less in 11 (50%) patients. Preoperative pathology findings showed pT2 disease in 20 (91%) patients, and carcinoma *in situ* was present in three (14%) cases. All patients had urothelial cancer and no patient showed any histological variant in the preoperative or postoperative specimen. Clinical regional nodes (cN⁺) were detected at preoperative staging in two (9%) cases. NAC was given in 17 (77%) patients. The preoperative renal clearance was 73 (IQR 59–86) mL/min.

Variable	Value
Age, mean (IQR), year	62 (57–66)
BMI, mean (IQR), kg/m ²	23.73 (21.05-25.67
ASA score, n (%)	
1–2	17 (77)
3	5 (23)
CCI, n (%)	
≤3	11 (50)
>3	11 (50)
pT before RC, n (%)	
≤T1	2 (9)
T2	20 (91)
Presence of Cis	3 (14)
cN ⁺ , n (%)	2 (9)
Neoadjuvant chemotherapy, n (%)	17 (77)
Cycle received, median (range), n	3 (1-4)
Preoperative eGFR, mean (IQR), mL/min	73 (59–86)

IQR, interquartile range; BMI, body mass index; ASA, American Society of Anesthesiologists; CCI, Charlson Comorbidity Index; RC, radical cystectomy; Cis, carcinoma *in situ*; cN⁺, clinical regional nodes; eGFR, epidermal glomerular filtration rate; pT, pathological tumor stage.

Intra- or peri-operative results and complications are shown in Table 2. Mean blood loss and mean operative time were 222 (IQR 113–300) mL and 381.0 (IQR 360.0–417.5) min, respectively. Ureteral catheters were removed after a mean of 6.8 (IQR 6.0–7.0) days; bladder catheter was removed after a mean of 13.4 (IQR 11.0–15.0) days; and patients were discharged after a mean of 12.31 (IQR 8.25–13.00) days. Clavien–Dindo grades III–IV complications occurred in four (18%) cases. In the first 3 months after surgery, readmission was needed in three (14%) cases.

3.2. Postoperative analysis

Pathology reports and oncological outcomes are shown in Table 3. After a mean follow-up of 29 (IQR 16—44) months and median follow-up of 24 months, six (27.3%) patients developed distant metastases and one (4.5%) woman locoregional relapse in the common iliac lymph nodes. Three (13.6%) patients died during the follow-up period, all of which were bladder cancer-related. The 3-year metastasis-free survival rate was 71% and the 3-year cancer-specific survival rate was 80%. The 1-year metastasis-free survival rate was 78% and the 1-year cancer-specific survival rate was 100%. The Kaplan—Meier curves of the 3-year metastasis-free survival and the cancer-specific survival are shown in Fig. 1.

3.3. Functional outcomes

Functional outcomes were analyzed at least 6 months after surgery, and are shown in Fig. 2. Sexual-sparing surgery was performed in 19 (86%) patients; in the others the anterior vaginal wall was resected, but neobladder was still performed. A total of 15 patients were included in the functional outcome analysis using the BCI questionnaire. During daytime, no patient reported severe incontinence, and 11

Table 2 Intra- or peri-operative results and complications (n=22).

13-300)
(360.0-417.5)
3.00-6.75)
.0-7.0)
11.0-15.0)
(8.25-13.00)
)

Variable	Value
pT, n (%)	
Т0	8 (36.4)
Tis	3 (13.6)
Ta	0 (0.0)
T1	2 (9.1)
T2	3 (13.6)
T3	6 (27.3)
pN, n (%)	
NO	14 (63.6)
N1	5 (22.7)
N2	3 (13.6)
Node retrieved, mean (IQR), n	18.04 (11.00-19.75
Surgical margin, n	
Negative	22
Positive	0
Follow-up, mean (IQR), month	29 (16-44)
Postoperative recurrence, <i>n</i> (%)	7 (31.8)
Distance	6 (27.3)
Local	1 (4.5)
Death related to bladder cancer, n (%)	3 (13.6)
Postoperative eGFR, mean (IQR), mL/min	64.41 (59.25–77.75
Sexual preservation, n (%)	
No	3 (13.6)
Anterior vaginal wall	17 (77.3)
Total preservation	2 (9.1)

IQR, interquartile range; eGFR, epidermal glomerular filtration rate; pT, pathological tumor stage; pN, pathological node stage.

(73%) reported total continence or the need of one pad per day. Nighttime continence outcomes showed severe incontinence in three (20%) patients, and seven (47%) women reported total continence or only occasional leaks. Of all patients, two (13%) needed self-catheterization for incomplete and three (20%) women for complete urinary retention. There was no difference observed between the continence results in patients undergoing a Studer neobladder diversion or the Bordeaux neobladder diversion $(p{>}0.05)$.

4. Discussion

RARC is a well-established procedure that shows reliable oncologic outcomes and a good safety profile [10]. Despite good cancer control, cystectomy has a substantial influence on urogenital function, body perception, and body image [5]. For this reason, the neobladder diversion was developed to avoid the urostomy of the Bricker diversion and to maintain a normal body image. Even in very recent cystectomy series, neobladder diversion is largely underutilized [2]. In the very recent iROC trial, exploring the benefit of RARC versus open RC with regards of 90-day morbidity and mortality in the UK, only 10%—12% of patients underwent a continent or neobladder diversion [2]. In female patients, the rate of neobladder diversion is even lower, as there is a strong doubt about the functional outcome of this

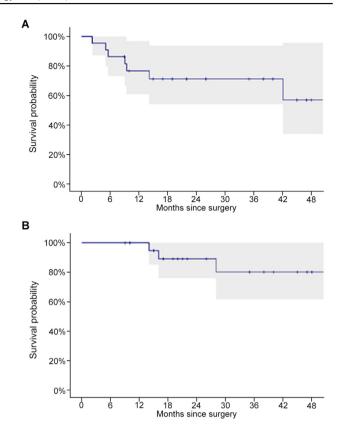


Figure 1 Kaplan—Meier estimates at 3 years. (A) Metastasisfree survival; (B) Cancer-specific survival.

diversion in females [11]. It is obvious that RC in the female, often done as anterior pelvectomy, substantially influences urinary function and sexual function. A Bricker diversion can have a major negative impact on quality of life [12]. In a recent series with at least 6 months of follow-up, mean values for the emotional functioning in the European Organisation for Research and Treatment of Cancer quality of life questionnaire-C30 as well as the mental health in the Short Form Health 36 guestionnaire were significantly higher in the orthotopic neobladder group compared to the Bricker diversion group [12]. Moreover, the orthotopic neobladder group showed a higher mean score in the physical and role functioning than the Bricker diversion group. Functional outcomes after RARC in women have been poorly investigated in the literature [10]. A recent systematic review by Jue et al. [13] showed that functional outcomes after RARC have often been studied in a very heterogeneous way without the aid of validated questionnaires. The sexual function is substantially influenced, as the resection of the anterior vaginal wall reduces substantially the vaginal cavity, and this reduction of vaginal cavity reduces sexual function. In our series, evaluated with the help of the BCI questionnaire, it is possible to achieve satisfactory urinary function after neobladder diversion with 73% of patients reporting complete daytime continence (no pad or one safety pad per day) and no patient reporting complete incontinence. These data are comparable to other series. For example, the series of Lavallee et al. [11] showed in 23 female patients with

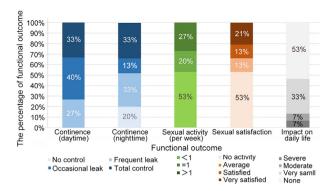


Figure 2 Functional outcomes (Bladder Cancer Index domains).

neobladder diversion that 70% achieved daytime continence. A more frequent problem of neobladder diversion is nighttime incontinence due to uncontrolled intestinal contractions leading to intravesical pressure peaks and absence of conscious continence reflexes during the sleep. In general, nighttime continence rates after neobladder diversion are worse than daytime continence rates. A recent multicenter series of 732 male neobladder patients reported a daytime continence rate of 86% (defined as no pad or one safety pad per day) and a nighttime continence rate of 66% (defined as no pad or one safety pad per day) [14]. In our series, 47% of female patients were considered continent during nighttime, suggesting poorer nighttime continence rates in female than in male patients. Another problem of neobladder diversion might be urinary retention. Nerve-sparing cystectomy is thought to prevent the problem in female patients by preserving the innervation of the pelvic floor and the innervation of the continence mechanism [15]. In male patients, the risk of retention is rare and was reported in the above multicenter series to be at 4%-5% [14]. In female patients, the rate of urinary retention or hyperactive continence is higher. In the series of Lavallee and Wiklund [7], 50% of patients needed to perform daily clean intermittent catheterization. In our series, the urinary retention rate was 34% with 20% needing systematic clean intermittent catherization and 14% needing a catherization once or twice daily. It is of note that we applied clean intermittent catherization only in cases with urinary retention identified in routine ultrasound evaluations of residual post-void urine during the follow-up. Clean intermittent catherization after neobladder diversion might be considered a failure in the outcome [16]. However, the clean intermittent catherization technique is easy to learn and easy to apply, and does not have a major impact on the quality of life of our patients. Many patients preferred clean intermittent catheterization over the urostomy and its changes in body image. Substantial self-reported changes in patients' function and overall health status are linked to bladder cancer, and the neobladder diversion might be a solution to lower the extent of those changes [17]. A more proactive use of clean intermittent catherization might be of help to improve continence rates and reduce urinary tract infections [18]. It needs to be stated that continence results in female patients are less favorable than in male patients, though the

rates remain high as only one quarter of patients might experience some degree of incontinence whereas three guarters recover normal continence after RC. The slightly higher rate of incontinence might trade off the disadvantages of the Bricker diversion and its consequences in female patients. Another reason to give preference to Bricker diversions instead of neobladder diversions is the fear of complications. In the iROC trial, 88%-90% of diversions were Bricker diversions [2]. In the robotic arm, the rate of complications was reduced by 6% relative to the open surgery arm. In this series, the rate of severe complications, defined as Clavien-Dindo grades III-V, was 17% in the robotic arm [2]. Taking into account the 88% of Bricker diversions in the iROC trial, our rate of Clavien-Dindo grades III—V (no Grade V in our series) compares favorably, despite the fact that all patients underwent neobladder diversion. In our series, it seems that neobladder diversion is not associated with an increased risk of severe complications. It might be noteworthy that there are no differences with regards of the neobladder reconstruction technique between female and male patients in our center. In our series, the same steps, standards, and sequence of neobladder reconstruction are applied in male as in female patients. The key to successful cystectomy with neobladder diversion in female patients lies in the preservation of the anterior vaginal wall via thoroughly done patient selection.

When it comes to sexual function, our study showed that half of the female patients take up a sexual activity after cystectomy when sexual-sparing surgery was performed, and the vast majority of the patients were satisfied with the functional outcome. No patient was unsatisfied with the sexual function and 72% (5 out of 7 sexaully active women) were describing the activity as good or very good. Similar rates were observed in the series of Lavallee and Wiklund [7], where 13 out of 23 patients regained sexual activity after cystectomy and one (8%), seven (54%), and five (38%) had a low, moderate, and high level of sexual satisfaction, respectively. It seems that sexual function preservation during RC is possible and provides reasonable functional results for female patients.

In addition to the functional outcome of neobladder diversion, there is also doubt about the oncological safety of sexual organ sparing cystectomy in the female. Often neobladder diversion is done concomitant with sexual organ sparing surgery, at least at the level of the vagina with a preservation of the anterior vaginal wall. This is done to maintain pelvic floor stability, provide a possible support of the neobladder in the small pelvis, and preserve the innervation of the urinary sphincter and the pelvic floor in the female patient. Especially, the later seems to be relevant in order to maintain normal urinary function [15]. The preservation of the anterior wall of the vagina needs a dissection between the vagina and posterior bladder wall, increasing the risk of positive surgical margins if the cancer is located at this location. Similar issues could be observed when the uterus is preserved, which increases the surface of dissection between the bladder and female genital organs. For the risk of positive surgical margins, oncological efficacy might be hampered.

There are several tools to reduce the oncological risk in these patients and to increase the rate of patients where sexual organ sparing surgery can be safely offered. The first tool is careful patient selection. In our series, we used pelvic MRI and cystoscopy before surgery to rule out the presence of urothelial cancer at the level of the bladder neck or at the level of the posterior bladder wall. The first is of relevance when sectioning the bladder neck from the urethra during the procedure where cancer lesions at the bladder neck would lead to positive surgical margins and possible tumor spillage. The latter is of relevance to have a low-risk of entering in contact with the cancer lesions during the dissection between the vagina and the overlaying posterior bladder wall. Presence of urothelial cancer at that level would also increase the risk of positive surgical margins. Careful patient selection seems feasible but also mandatory to avoid oncologically compromised outcomes in these patients. It is of note that, based on the careful preoperative patient selection, no intraoperative evaluations were done. We believe that any intraoperative decision making in favor or against vaginal-sparing based on local tissue aspects during surgery would be connected to an inacceptable risk of positive margins and tumor spillage. Therefore, careful preoperative selection seems essential and the key for such procedures. The second tool to avoid positive surgical margins is the use of NAC. The systematic use of NAC leads to substantial down staging and local complete remissions. In the very recent VESPER trial [19]. the use of up to six cycles of dose dense MVAC chemotherapy resulted in a local complete response rate (ypT0) in 42% and a down staging to non-muscle invasive disease (ypTis, ypTa, ypT1) in 21%.

Such down staging with NAC substantially increases the possibility for sexual organ sparing surgery and neobladder diversion in the female without increasing the risk of suboptimal cancer control. As a proof of concept, no patient had positive surgical margins on final pathology and no local recurrence was observed in our series, confirming the safety of the selection criteria and the multimodal concept including NAC. The patient recurring loco-regionally was pN1 after surgery and recurred at the level of the common iliac vessels, therefore outside of the cystectomy field.

There are several limitations to our study. The first is the low number of patients included. This is a limitation often seen with female cystectomy and neobladder diversion series. The series of Lavellee et al. [11] included also only 23 patients. Moreover, if the same proportion of neobladder diversion (10%–12%) would have been applied to the female patient cohort (20%-22% female patients) in the iROC trial, only seven female patients out of 317 patients in total would have had a neobladder diversion [2]. To obtain the 22 patients of our series, three iROC trials would have been necessary. This makes it, once more, obvious that the neobladder diversion in female patients is underutilized. An editorial from Gallioli et al. [20] described the potential advantages of robotics with special focus on sexual-sparing RARC in female patients, but found the literature in this field is still sparse. With this study, we try to improve this situation. Moreover, it could be stated that this series represents the learning curve of cystectomy with neobladder diversion. In fact, the procedures were done by three experiences surgeons who have operated at least 30 cases of cystectomy with neobladder diversion done during their careers. We would consider these surgeons to be out of their learning curves for cystectomy and neobladder

diversion. The second limitation is the lack of functional outcomes in all patients. Unfortunately, not all patients were willing to answer the functional outcome questionnaire during the follow-up. Still data from 79% (15/19) of patients were available, which might be considered as representative. Moreover, continence data were evaluated only by validated questionnaires (BCI) and no quantitative evaluations such as the number of used pads per day or a pad-test were used. This might be considered a flaw of our study, but it seems that there is preference for validated questionnaire-based evaluations instead of a simple quantitative non-standardized evaluation when it comes to the functional outcome in urology. In addition, evaluation by questionnaires might not provide the full spectrum on the functional outcome of neobladder diversion. An urodynamic evaluation might be considered an additional important criterion [21,22]. We did not provide such urodynamic evaluation in our series, but the same surgical technique that was used in our series in the vast majority of cases (Bordeaux neobladder) was recently urodynamically evaluated [3]. In this report, the authors showed an average compliance at 33.1 (range 11-160) mL/cmH₂O; the mean maximal capacity was 431 (median 445, range 200-553) mL and the first sensation of bladder fullness was perceived at an average volume of 337 (range 150-500) mL [3]. These numbers are comparable to other neobladder techniques such as the Padua neobladder or the Florin neobladder [21]. In a recent series, the corresponding number for the Padua neobladder was a mean compliance at 30 (range 15.5-48.5) mL/cmH₂O; mean maximal capacity was 302 (range 225-360) mL, and the first sensation of bladder fullness was perceived at a mean volume of 235 (range 200-350) mL. The corresponding data for the Florin neobladder include a mean compliance at 25 (range 20-31) mL/cmH₂O and a mean maximal capacity of 230 (range 195-270) mL; and the first sensation of bladder fullness was perceived at a mean volume of 210 (range 190-237) mL [21]. It seems that these neobladder reconstruction techniques provide comparable results with regards of the urodynamic evaluation. Third, a long-term follow-up is lacking which might render the results on oncological outcomes premature. It is of note that the majority of recurrences in bladder cancer patients occurred during the first 3 years after surgery; the median follow-up in our series was 24 months; and many of the possible recurrence probably were captured. Finally, we lack a control group for comparisons with regards of the complication rates and oncological outcomes. However, these are secondary outcomes of our series and we feel that the comparison to other prospective series is sufficient to proof that these outcomes are comparable; and our series does not show increased complication rates or poorer oncological outcomes. However, formal conclusion cannot be drawn.

5. Conclusion

RARC in female with anterior vaginal wall preservation is feasible. The approach showed a good safety profile, with satisfying results on continence and sexual activity. This sexual-sparing approach should be carried out after correct patient selection and ideally after NAC.

Author contributions

Study concept and design: Andrea Pacchetti, Geraldine Pignot, Jochen Walz.

Data acquisition: Andrea Pacchetti, Alberto Caviglia, Vito Lorusso, Nicolas Branger, Thomas Maubon, Stanislas Rybikowski, Davide Perri, Giorgio Bozzini.

Data analysis: Andrea Pacchetti, Geraldine Pignot, Jochen Walz.

Drafting of manuscript: Andrea Pacchetti, Alberto Caviglia, Vito Lorusso, Nicolas Branger, Thomas Maubon, Stanislas Rybikowski, Davide Perri, Giorgio Bozzini, Geraldine Pignot, Jochen Walz.

Critical revision of the manuscript: Andrea Pacchetti, Alberto Caviglia, Vito Lorusso, Nicolas Branger, Thomas Maubon, Stanislas Rybikowski, Davide Perri, Giorgio Bozzini, Geraldine Pignot, Jochen Walz.

Conflicts of interest

Jochen Walz received honoraria from Intutive Surgical Stystems (Intuitive Surgical Systems, Sunnyvale, CA, USA). The other authors declare no conflict of interest.

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