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ORIGINAL ARTICLE

Robotic laparoendoscopic single-site radical prostatectomy (R-LESS-RP) with daVinci Single-Site® platform. Concept and evolution of the technique following an IDEAL phase 1

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Abstract
To describe the evolution of robotic laparoendoscopic single-site radical prostatectomy (R-LESS-RP) performed with the daVinci Single-Site Platform® and a home-made multiport aimed to overcome classical drawbacks of LESS, still present with this platform. Between 09/2015 and 06/2017 12 patients underwent R-LESS RP for clinical localized prostate cancer. Following a "phase 1 (development-stage)" innovation, development, exploration, assessment, long-term study (IDEAL) framework, different solutions were drawn to overcome drawbacks of daVinci Single-Site Platform®, included 3 (A, B, and C) multi-ports developed and evaluated in term of advantages/drawbacks concerning ergonomy. The end points of this study were: feasibility, safety, efficacy, by reporting rational description of multiports configuration, demographics, perioperative variables, functional and oncological results. Semi-flexible robotic 5-mm needle-holder instead of Maryland forceps, 30° lenses up and barbed-suture allowed overcoming limits of robotic-platform. Multiport-C (GelPOINT Advanced-Access® and an extra 8-mm robotic trocar outside the multiport) showed the best compromise to ensure both surgeon and bed-side assistant to reproduce a standard robotic procedure. No conversion to either standard robotic or open technique or intraoperative complications occur in any case. Two patients experienced "high-grade" Clavien-Dindo complications. After 12.4 months follow-up, all patients were continent without any sign of biochemical relapse and among 5 preoperative potent patients submitted to nerve-sparing dissection, 4 reported good erectile-function. R-LESS-RP is feasible and safe in the hands of experienced minimally-invasive surgeons. Do date, we recommend a hybrid solution with a home-made multiport and use of an additional standard robotic trocar which allows the use endowrist® technology instruments.

Keywords Laparoendoscopic single site surgery · LESS · Prostate cancer · Robot-assisted radical prostatectomy · Robotic surgery

Introduction

In the last decade, the idea to undertake new routes in minimally invasive surgery to further reduce tissue trauma, minimize postoperative pain and expedite patients' recovery was developed. The shift from classic "multi-wound" laparoscopic to "single-wound" laparo-endoscopic single-site surgery (LESS) has been driven by the tendency towards a minimally invasive approach [1].

After the completion of more than 900 laparoscopic radical prostatectomy (RP) (2001–2009), in March 2009 we reported our initial experience with laparoendoscopic single-site radical prostatectomy (LESS-RP) [2]. At that time, we concluded that LESS-RP was feasible in highly selected cases, such as patients with normal BMI (< 25 kg/

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m^2), small prostates (< 30 cm^3) and no previous history of abdominal surgery. The main drawbacks were represented by the lack of triangulation, the limited retraction ability, the reduced operative space and the internal-external instrument clashing. Even if supported by specially designed equipment (i.e. flexible endoscope, pre-bented and articulated instrument), a "hybrid" technique (use of a further 5 mm trocar) was mandatory in order to restore proper angulation and to perform safe and effective procedures, with special regard of the vescico-urethral anastomosis. Similar conclusions were drawn in a large international cohort of over 1000 cases with almost 23% performed with additional port [3].

In contrast with latest decline in the use of LESS [4], the robotic-assistance seemed to improve the ergonomy and therefore boosting a new era for LESS, but the standard daVinci® platform had not been specifically designed for this purpose. Finally, the daVinci Single-Site® platform (Intuitive Surgical Inc, Sunnyvale, CA, USA) represented a step forward to provide an effective solution [5] and in 2015 we performed the first single-port robotic-assisted RP [6]. Despite several considerable progresses, the technical approach was limited by new drawbacks. The first was related to technological issues mainly due to the limitations to the new robotic platform itself. Indeed, Endowrist® technology was not available for bipolar graspers and monopolar scissors. Second, the extremely important role of bed-side assistant during RP was undermined by limited range of motion and impossible simultaneous use of multiple instruments.

To overcome this inconvenience, we have designed several solutions, especially for finding a multi-trocar port able to guarantee (1) easy ability to the surgeon and (2) the same capabilities to the bedside assistant.

In a phase 1 study, following the "innovation, development, exploration, assessment, long-term study (IDEAL)" guidelines [7], we performed a prospective investigational clinical study to report our transition from LESS-RP to robotic-LESS-RP (R-LESS-RP) performed with daVinci Single-Site® platform. We evaluated the clinical (1) feasibility, (2) safety and (3) efficacy of the new multi-port configuration, aimed at reducing external and internal conflicts at any steps of RP and allowing a proper use of both robotic semi-flexible instruments and bed-side assistant trocars.

Materials and methods

Study

Between 09/2015 and 06/2017, 12 highly selected patients affected by organ-confined prostate cancer (PCa) were enrolled in our prospective institutional review board–approved study at our institution.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 [8]. Informed consent was obtained from all patients for being included in the study.

The design of the study followed the "phase 1 (development stage)" as suggested by the Innovation, Development, Exploration, Assessment, Long-term Study (IDEAL) framework [7], mainly focused on the technical development of the procedure. A phase 0, planning of port placement and robotic arms configuration, was previously simulated in a dry lab, with the use of phantom and pelvic trainers. Different multiport configurations were developed following surgeon and assistant's impression and scores.

Patient selection

The study included patients with clinically localized PCa candidate to RP. Exclusion criteria were body mass index (BMI) > 30 kg/m^2, prostate volume > 90 ml, umbilical hernia, any form of pre-operative urinary incontinence as well as contraindications to laparoscopic surgery and steep Trendelenburg position, ASA score > 3, severe cardiac and/or lung insufficiency.

Preoperative evaluation included physical examination, digital rectal examination, chest X-ray, CT/MRI abdomen/pelvis and 5 items - International Index of Erectile Function (IIEF-5) and International Prostatic Symptoms Score (IPSS) questionnaires.

Data collection

Primary endpoints of the study were:

(1) *feasibility*, expressed as conversion rate. The first question was defined as the likelihood of R-LESS-RP to reproduce a standard robot assisted RP (RARP) as measured by surgeon and assistant's ergonomy,

(2) *safety*, estimated by complications rates. Each adverse event was recorded including the outpatient setting and classified as early (< 30days), intermediate (31–90), or late (> 90), depending on the date of onset and recorded according to the modified Dindo-Clavien classification [9],

(3) *efficacy*, consisting of the short-term functional (urinary continence and erectile function recovery) and oncological (positive surgical margins, lymph node yield and biochemical relapse) analysis.

Finally, perioperative-data [operative time, estimated-blood-loss (EBL), transfusion rate, length-of- hospital stay (LOS)] were also recorded and analyzed.

In order to define the best technical approach to R-LESS-RP, three port configurations were devised and tested.

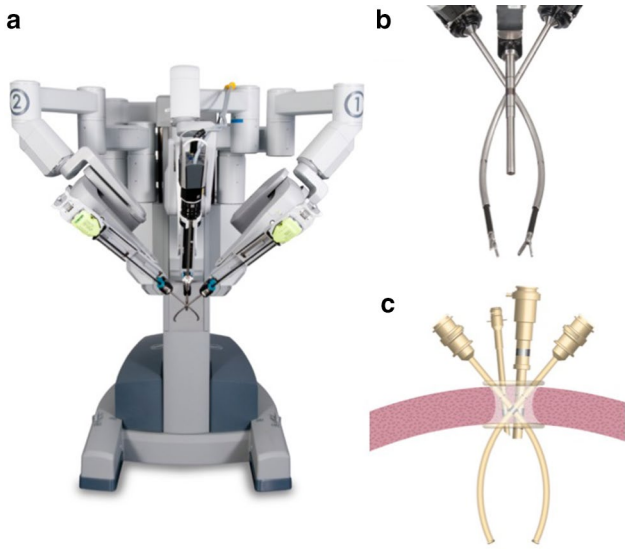

Fig. 1 daVinci Single Site® platform. **a** The platform is compatible with the da Vinci Si Surgical System®. **b** Semi-flexible robotic arm, curved cannula and camera cross. **c** Schematic view of cannula and camera within the Single-Site port® at level of fascia muscolaris

As previously reported [10], to maximize standardization of the procedure, R-LESS-RP was divided in 10 individual steps. We asked the surgeon/assistant to score each step (from 1 to 3) for each port configuration and pointing out specific advantages/drawbacks concerning ergonomy, namely range of instrument motion, simultaneous use of both robotic instruments, surgeon/assistant coordination, simultaneous use of both assistant trocars.

Surgical technique

Surgery was performed with the da Vinci Single-Site® platform [11, 12] (Fig. 1).

Three version of access multi-port were designed, tested and developed consecutively:

Multiport (A) (Fig. 2), Multiport (B) (Fig. 3), Multiport (C) (Fig. 4).

Port A was designed on paper and tested originally on dry lab. Port B and C have been modified based on drawbacks highlighted at each time of surgery, then tested on dry lab.

The surgical procedures replaced exactly the trans-peritoneal technique performed at our institution, and were

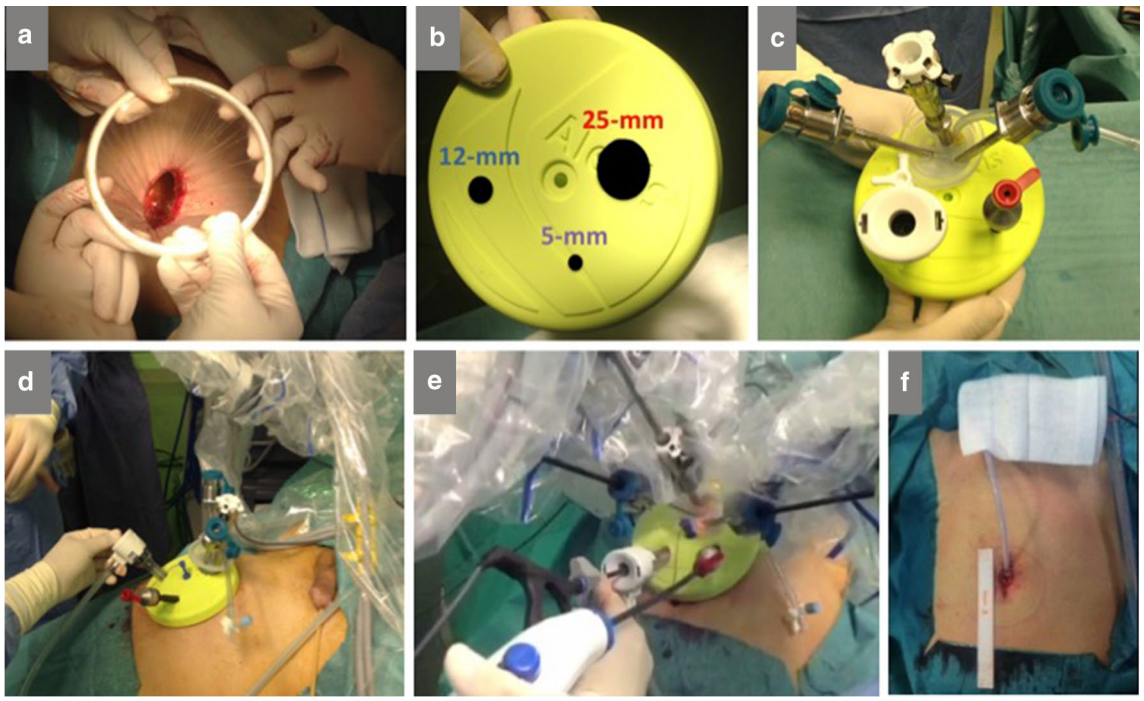

Fig. 2 *MultiPort A*. **a** Alexis O Wound Retractor® (Applied Medical, Rancho Santa Margarita, California, USA) was inserted through a 5-cm latero-umbilical incision. **b** The Laparoscopic Cap® was modified to allocate the Single-Site Port®, a 12- and 5-mm laparoscopic trocars. **c** Bench-table view of Multiport A. **d** Mutiport A allocated on Alexis O Wound Retractor®. **e** Introperative view of Multiport A showing a enough external range of motion for bed-side assistant. In consideration of drawbacks of daVinci Single Site ® platform we adopted: (1) Robotic 5-mm needle holder instead of Maryland forceps. Even if the force exerted was not always optimal, the endowrist® technology was mandatory. (2) Robotic 5-mm hook and lap scissors instead of Robotic 5-mm scissors. Even in this case, scissors without technology did not guarantee an adequate dissection of the tissues. (3) 30° lenses up. This choice widened the angle between the patient and primary axis of the optic, increasing assistant's range of motion. (4) Barbed suture. It speeded up and made suture easier without having to knit. **f** Closure of the surgical incision with drainage

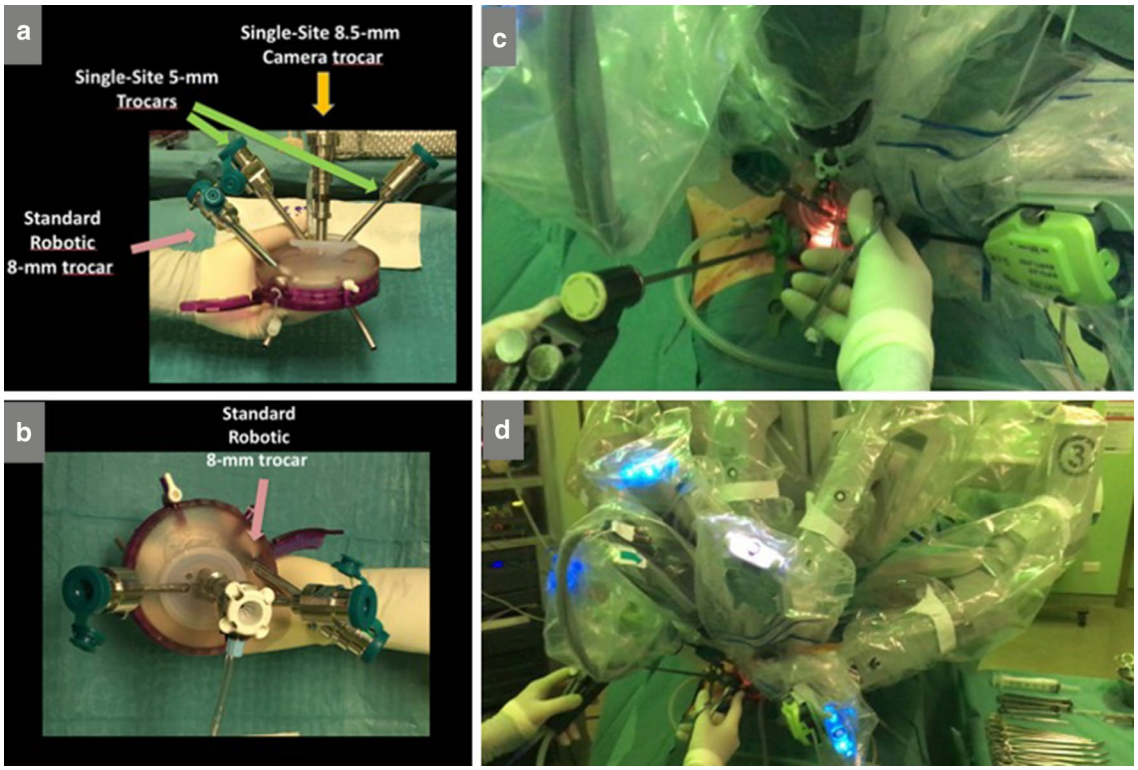

Fig. 3 MultiPort B. **a, b** Instead of the Laparoscopic cap®, a GelPOINT Advanced Access Platform ® was adopted to allocate Single-Site Port® and lap trocars. An extra standard daVinci 8-mm trocar was inserted within the homemade port by activating simultaneously the 4th arm on the console. **c, d** Intraoperative view and setting

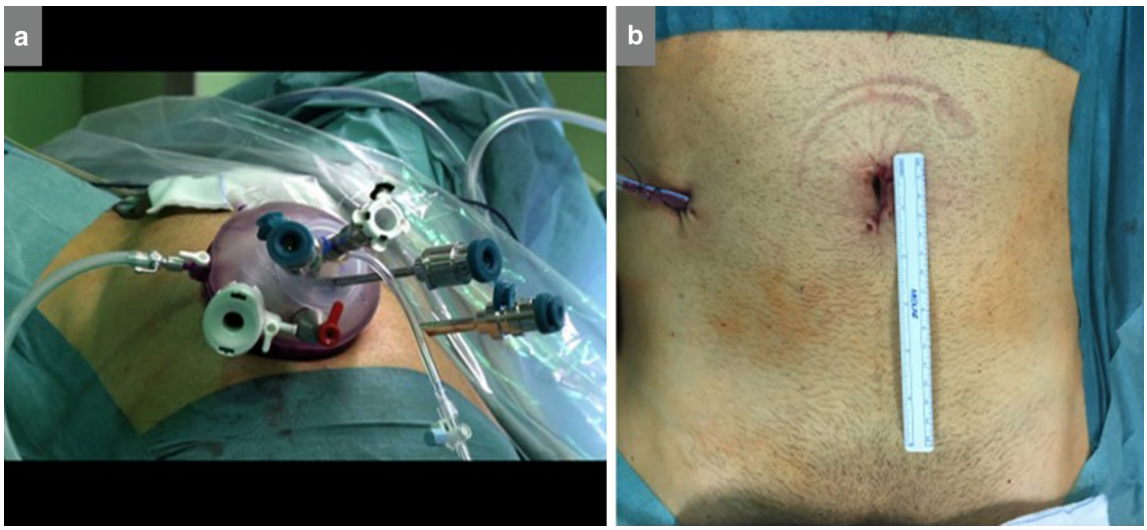

Fig. 4 MultiPort C. **a** The Multiport B was modified and the extra standard daVinci 8-mm trocar placed outside the GelPoint. **b** Closure of the surgical incision and drainage

performed by an experienced minimally-invasive surgeon (FG) with more than 3000 minimally invasive RP (2000 laparoscopic and 1000 robotic) experience. Patients were positioned in a 30° Trendelenburg position. The sub-steps were: (1) Bench-table multiport configuration and periumbilical placement by Hasson technique; (2) bladder take-down; (3) endopelvic fascia incision (with puboprostatic ligament-sparing or total endopelvic fascia-sparing in case of nerve-sparing procedure) and bladder neck dissection; (4) vasa deferentia and seminal vesicles dissection, (5) incision of

posterior Denonvilliers fascia and dissection of recto-prostatic space, (6) prostatic pedicles dissection, (7) nerve sparing (irrespectively to preoperative erectile function state, mono- or bilateral grade 1–2 [13] dissection was always offered following oncologic risk, in regarding the possible advantage conferred to continence recovery) [14], (8) apical dissection, (9) late suture of Santorini Plexus and (10) posterior reconstruction and urethro-vesical anastomosis with barbed suture (Filblock 90 3/0 45 cm, Assut Europe, Rome, ITA). Figure 5 shows the most salient intraoperative steps.

Postoperative evaluation

Follow-up was conducted at 45 postoperative day (POD) and by 3-month intervals during the first year and by 6-month intervals during the second year. Continence status was

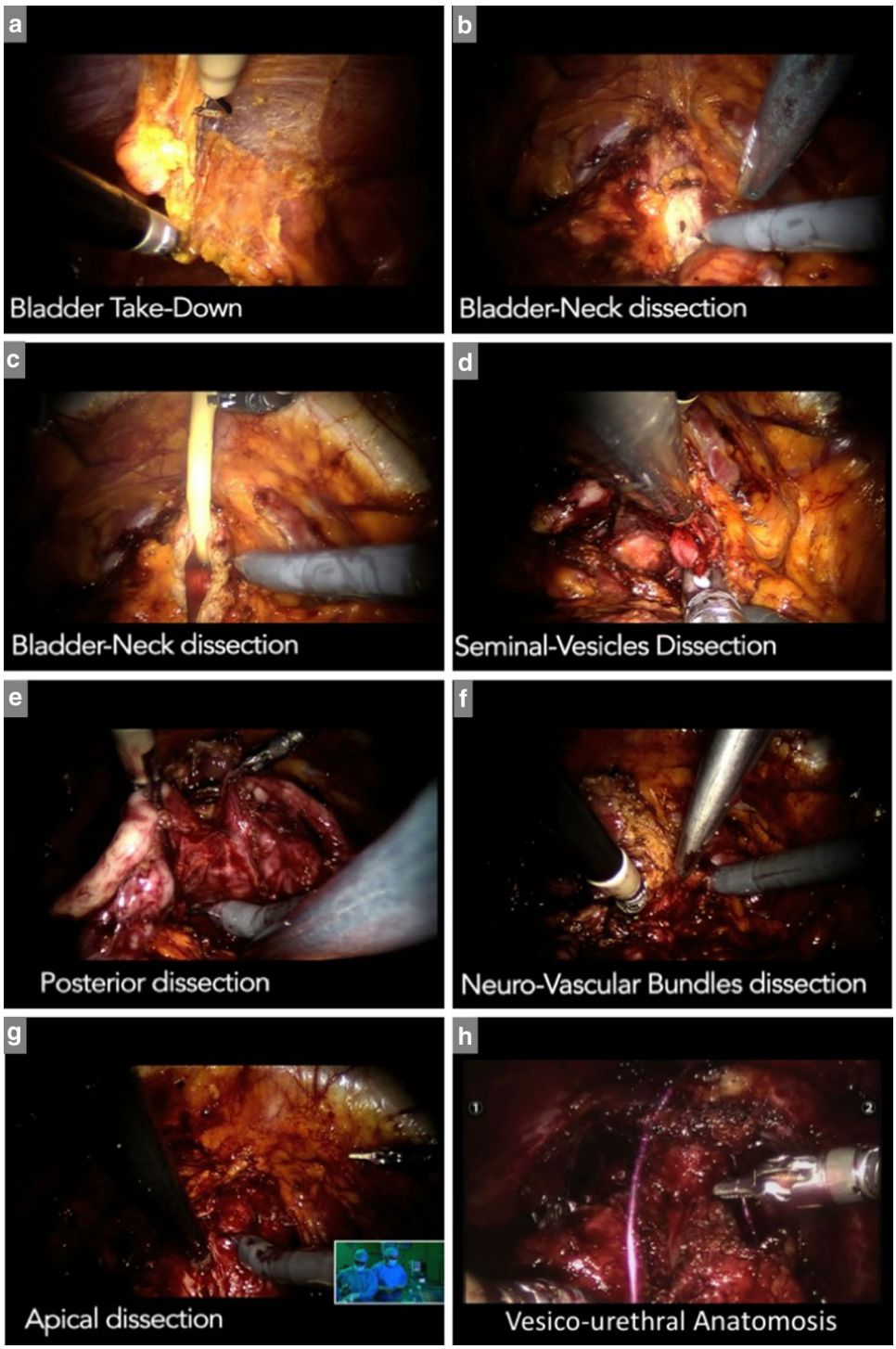

Fig. 5 Endoscopic view of the most salient steps. **a** Bladder take down. **b, c** Bladder neck dissection. **d** Seminal-vesicles dissection. **e** Posterior Denonvilliers Fascia incision and recto-prostatic space dissection. **f** Neuro-vascular bundles dissection. **g** Apical dissection. **h** Vesico-urethral anastomosis

Table 1 Detailed description, evolution, grade of ergonomy, advantage and disadvantage of each multiport configuration

	Port A (Fig. 2)	Port B (Fig. 3)	Port C (Fig. 4)
Access and Multiport configuration	1. 5-cm Latero-umbilical incision 2. Alexis O Wound Retractor® (Applied Medical, Rancho Santa Margarita, California, USA) 3. Laparoscopic cap® (Applied Medical), with a. Single-Site Port® (Intuitive Surgical Inc, Sunnyvale, CA, USA) b. 12- and 5-mm Assistant trocar	1. 3-cm Latero-umbilical incision 2. Alexis O Wound Retractor® 3. Gel point® (Applied Medical) with a. Single-Site Port® b. 8-mm Robotic port (scissors) c. 12- and 5-mm Assistant trocar	1. 3-cm Sub-umbilical incision 2. Alexis O Wound Retractor® 3. Gel point® with a. Single-Site Port® b. 12- and 5-mm Assistant trocar 4. 8-mm Robotic port (scissors)
Robotic instruments	1 × Flexible 5-mm Hook 2 × Flexible 5-mm needle-holder	2 × Flexible 5-mm needle-holder 1 × Standard 8 mm large scissor	2 × Flexible 5-mm needle-holder 1 × Standard 8 mm large scissor
Laparoscopic instruments	1 × 10-mm Hem-o-lok® applier (Weck Surgical Instruments, Teleflex Medical, Durham, NC, USA) 1 × 5-mm Titanium clip applier 1 × Johann grasping forceps 1 × Laparoscopic scissors	1 × 10-mm Hem-o-lok® applier 1 × 5-mm Titanium clip applier 1 × Johann grasping forceps	1 × 10-mm Hem-o-lok® applier 1 × 5-mm Titanium clip applier 1 × Johann grasping forceps

Steps	Surgeon	Assistant	Surgeon	Assistant	Surgeon	Assistant
1. Port configuration and placement	n/a	[a]Not easy to cut laparoscopic cap	n/a	[b]Easy to perform and to place but really crowded	n/a	[c]Good compromise for assistant
2. Bladder Take Down	[b]Remember to move camera together with single-site instruments	n/a	[b]External conflict	n/a	[b]	n/a
3. Endopelvic fascia incision and Bladder Neck dissection	[a]Hook not optimal to perform dissection	[b]Gas leakage internal conflict with robotic camera	[b]Standard robotic scissors improve job, but external conflict make impossible simultaneous use of 3 robotic instruments	[b]Still some internal confict but easy to change trocar position without gas leakage	[c]Perfect ergonomy with hybrid solution	[c]Perfect ergonomy
4. Vasa deferentia and seminal vesicles dissection	[a]Lack of good retraction	[a]Internal conflict. Simultaous use of Hem-o-Lok and laparoscopic grasper	[b]Improved retraction but still external conflict	[b]Easy use of Hem-o-Lok and other lap instrument	[c]Perfect retraction with flexible robotic isntrumentt and free scissors use	[c]Perfect use of 10- and 5-mm trocars
5. Incision of posterior Denonvilliers fascia and dissection of rectoprostatic space	[a]Lack of good retraction	[a]Internal conflict. Simultaous use of Hem-o-Lok and laparoscopic grasper	[b]Improved retraction but still external conflict	[b]Easy use of Hem-o-Lok and other lap instrument	[c]Perfect retraction with flexible robotic isntrumentt and free scissors use	[c]Perfect use of 10- and 5-mm trocars
6. Prostatic pedicles dissection	[b]	[b]Internal conflict with camera	[c]Scissors made possible nerve sparing procedure	[c]Easy use of Hem-o-Lok and other lap instrument	[c]Perfect retraction with robotic instrument and scissors use	[c]Perfect use of 10-mm and 5-mm trocars
7. Nerve sparing	[a]Almost impossible to perform without use of robotic scissors	[a]Lack of good angle and range of motion	[b]Scissors made possible nerve sparing procedure	[b]Easy use of Hem-o-Lok and other lap instrument	[c]Perfect retraction with robotic instrument and scissors use	[c]Perfect use of 10-mm and 5-mm trocars

Table 1 (continued)

Steps	Surgeon	Assistant	Surgeon	Assistant	Surgeon	Assistant
8. Apical dissection	[a]Lack of robotic scissors make the procedure difficult	[a]Need to use laparoscopic scissors to cut urethra	[b]Scissors made possible almost a normal procedure	[b]	[c]Perfect	[c]
9. Late suture of Santorini Plexus	[a]Difficult to reach santorini	[a]Need to push down and caudally multiumbilical trocar to reach anastomosis site	[a]Difficult to reach urethra	[c]Easy needle insertion	[c]Subumbilical multitrocar make anastomosis easier	[c]Easy needle insertion
10. Posterior reconstruction and urethro-vesical anastomosis	[a]Difficult to reach urethra	[a]Need to push down and caudally multiumbilical trocar to reach anastomosis site	[a]Difficult to reach urethra	[c]Easy needle insertion	[c]Subumbilical multitrocar make anastomosis easier	[c]Easy needle insertion
Pros		It eliminated instrument crossing compared to LESS, superior ergonomic for surgeon, widened external range of motion for assistant, safe needle/suture insertion/extraction easy specimen extraction	It properly eliminated gas leakage Relocating assistant's trocars position whenever necessary without gas leakage The surgeon had the chance to use the standard robotic 8-mm scissors with a proper angulation		Ability to use 8-mm robotic standard scissors at any step Both flexible robotic instruments adopted to provide a proper dissection and traction	
Cons		Almost impossible to perform a proper nerve-sparing procedure without availability of robotic scissors with ndowrist® technology The Laparoscopic cap® was made of rigid polimer and not built to allocate extra-trocars, leading to continuous gas leakage The assistant experienced internal conflict because instruments were parallel to laparoscope. Impossible to relocate assistant trocars, otherwise impossible to maintain pneumoperiteum	Almost impossible to use the 8-mm standard scissors due too almost constant external conflicts			

Ergonomy compared to standard RALP: *: bad; **: good ***: perfect. n/a: not applicable

assessed by recording the number of pads used per day. Risk of urethral stricture was assessed through uroflowmetry. Biochemical recurrence was defined according to current guidelines as single prostate-specific antigen (PSA) > 0.2 ng/ml followed by a subsequent rise [15]. IIEF-5 questionnaire settled erectile dysfunction. Erectile recovery rate was defined only in preoperative potent patient (IIEF-5 ≥ 22).

Results

daVinci Single-Site® platform drawbacks (Fig. 1)

Scissors and Maryland forceps lacked of Endowrist ® technology unlike conventional robotic da Vinci instruments.

Needle holder was still too weak and occasionally this made difficult to apply force, especially during posterior reconstruction of the rhabdosphincter and anastomosis.

The specifically designed Single-Site Multichannel Port® allowed for the access of 2 robotic flexible 5 mm instruments, 8.5-mm scope and one additional conventional 5-mm laparoscopic entrances for the assistant. The latter was difficult to use because external and internal conflict. Moreover, as always adapted in our LESS-RP and RARP experience, at least a 10-12-mm trocar for assistant was required to apply 10-mm clip and to perform and easy and safe needle insertion/extraction.

Advantage and drawbacks of each multiports

Table 1 and Figs. 2, 3, 4 report each multiport configuration included materials adopted, surgeon and assistant's scoring regarding ergonomy and advantage and disadvantage for each sub-steps.

Patient population

Table 2 resumes demographics and preoperative data. Mean age was 62.3 years, mean PSA was 6.1 ng/ml. Six patients (54.5%) had previous abdominal surgery. The majority of patients (63.6%) had intermediate PCa while 36.4% of patients had low risk PCa. All patients were preoperative fully continent with severe symptoms [international prostatic symptoms score (IPSS) > 20] in 3 cases, and with normal erectile function [International Index of Erectile Function (IIEF-5) ≥ 21] in 5 cases. Mean prostate volume was 47.5 cm3.

Peri- and postoperative outcomes

Table 3 reports peri- and post-operative data. Port configuration "C" was adopted in the last 9 cases ensuring the ability to reduce operative time and to offer always a-thermal nerve-sparing procedure. Based on clinical stage and oncological safety mono or bilateral nerve-sparing procedure was performed in 9 (75%) patients. Bilateral pelvic lymph node dissection was performed in 8 patients (66.6%). None of the cases was converted to standard RARP and/or open approach. High grade complications were reported in 2 patients (16.6%). The first patient suffered from myocardial infarction immediately after surgery in recovery room requiring coronary angioplasty and stenting (grade IVa). Subsequent therapeutic administration of high-dose heparin induced hemorrhage requiring surgical revision. Neither the clear source of hemorrhage was found no further complications were recorded. The second patient experienced umbilical hernia (grade IIIb) and underwent thereafter repair with net 75 days after surgery.

Mean catheterization time was 8.7 days. Retrograde cystography performed on post-operative day 6 showed

Table 2 Demographic and preoperative data

Demographic and preoperative data	
Patients (*n*)	12
Age, year (mean, DS, range)	62.3 ± 7.7 (53.6–77)
BMI (kg/m^2) (mean ± SD, range)	26 ± 2 (23–29)
American Society of Anesthesiologists (ASA) Score (mean ± SD, range)	1.8 ± 0.7 (1–3)
Previous abdominal surgery, *n* (%)	6 (50)
Prostate volume, cm^3 (mean ± SD, range)	47.4 ± 15.7 (35–85)
Preoperative continence *n* (%)	12 (100)
IPSS	12.2 ± 9.2 (0–25)
Severe sympthoms, *n* (%)	3
Patient IIEF-5	
No erectile dysfunction (≥ 21)	5
Erectile disfunction (< 21)	7
Preoperative PSA (ng/ml, mean ± SD, range)	6.1 ± 1.6 (3.2–8.5)
Clinical stage, n (%)	
cT1	10 (83.3)
cT2a	1 (8.3)
cT2b	1 (8.3)
Gleason score and ISUP-WHO group (2016), *n* (%)	
3 + 3, Group 1	5 (41.7)
3 + 4, Group 2	5 (41.7)
4 + 3, Group 3	2 (16.6)
D'Amico risk stratification, *n* (%)	
Low	5 (41.7)
Intermediate	7 (58.3)
High	5 (41.7)

BMI body mass index, *PSA* prostate-specific antigen, *IPSS* international prostatic symptoms score, *IIEF* International Index of Erectile Function

22–25: no erectile dysfunction, 17–21: mild erectile dysfunction; 12–16: mild to moderate erectile dysfunction; 8–11: moderate erectile dysfunction; 5–7: severe erectile dysfunction

anastomotic leakage (Clavien-Dindo grade I) in 2 patients, and a prolonged transurethral catheterization was adopted.

One focal positive margin (< 1 mm) occurred in a pT3a, Gleason score 3 + 4 disease with port configuration B, (first nerve-sparing attempt of the series). Lymph nodes were positive in one case (Gleason score 3 + 4, pT2c).

With a relative short-term follow-up (12 ± 8.4 [2–28]), all patients were fully continent with no sign of PSA relapse. Among 5 preoperative potent patients submitted to nerve-sparing procedure, 4 (80%) reported good recovery of erectile function with or without oral administration of iPDE5 (IIEF > 17).

Discussion

With this prospective investigational clinical study we report the first experience of R-LESS-RP with the daVinci Single-Site® platform, monitoring our center's learning curve started in 2015. Only a case report describing RP has been published with the same platform [16].

Up to date the use of the daVinci Single-Site® platform has been mainly applied in pyeloplasty [17], a procedure where the role of the bed-side assistant is minimal, and where internal and external conflicts are tolerable. However, these potential drawbacks are not negligible in RP. These conclusions had already emerged in our experience in LESS-RP from 2009 [2]. Especially for RP, the most important drawbacks of LESS (lack of triangulation, limited retraction ability, limited operative space and internal/external instrument clashing) were amplified, since suturing appeared very demanding, making learning curve very steep and operative time long due to the lack of bed-side assistant's range of motion in tissue exposition and suction.

Despite LESS was introduced in the urological world in 2008 [18] to date less than 130 LESS-RP cases have been published [19] and therefore the real benefits have not been definitively endorsed. Lately, the introduction of robotic-assistance seemed could overcome some of the over mentioned disadvantages. Standard daVinci S® or SI® platform has been applied trough a single incision in a "rhomboid" configuration (separate fascial mucolaris incision) [20] or through multiport via trans-vesicle [21], trans-peritoneal [22, 23] or trans-perineal [24] approach. Even though R-LESS-RP had overcome some of the technical barriers, the bulky daVinci Si® was not specifically built for R-LESS [25] and only less than 40 cases (Table 4) have been performed from different group.

Finally in 2010, the specifically made da Vinci single-Site® (Ves-Pa® technology) was build [5]. The use of semirigid tools inserted over rigid curved trocars allowed enough instrument distance and triangulation with adequate rigidity of instruments and has allowed to regain a certain triangulation, suitable to guarantee an expert surgeon a certain manageability. Nevertheless, the issue of lack of proper bed-side assistance remained and technical refinements were needed with particular attention to the configuration of a multiport.

A home-made multiport (A, Fig. 2) allowed us to ensure the assistant the simultaneously use of both instruments through a 5- and 12-mm access (hem-o-lock clips, suction device, etc), even if not satisfactory due to important internal clashing with robotic camera arm and assistant trocars remained. Moreover the rigid plastic material of the Laparoscopic Cap® (Applied Medical, Rancho Santa Margarita, California, USA) did not allow a possible repositioning of the assistant's trocars, otherwise generating a continuous gas leakage. Therefore, the introduction of GelPoint® (Applied Medical, Rancho Santa Margarita, California, USA) (Multiport B, Fig. 3) characterized by a thick layer of gel has made possible to overcome this problem, ensuring a quick choice and modification of any trocar site without loss of gas. Once this problem was overcome, the lack of Endowrist® technology remained. If this detail was surmountable by replacing robotic graspers with needle-holders, this was not the case with the scissors, essential during neurovascular-bundles dissection. We then activated the 4th robotic-arm equipped with standard scissors and inserted into the Gel Point (Multiport B, Fig. 3) and hence alternated with semi-flexible instruments. However, while respecting the principles of a pure-LESS technique, external conflicts remained bothersome.

Finally, we have identified the best approach using an additional 8-mm standard robotic trocar (Multiport C, Fig. 4), which allowed the use of standard instruments (scissors for the dissection and needle-driver for the anastomosis).

If at the beginning of the experience a 5-6cm incision was adopted, thereafter we noticed a 3-4cm incision was adequate to allocate all the multiport. We have also moved the abdominal incision from periumbilical to subumbilical, since we experienced troubles to reach more distant targets (prostatic apex dissection and suture anastomosis) because the Single-Site port® was allocated at the Gelpoint® level, about 2 cm above the level of the rectal fascia muscolaris.

Indeed, even in the hands of very experienced laparoscopic and robotic surgeons, the pure R-LESS approach presents limitations that are extremely difficult to be solved.

In 2014 the specifically designed daVinciSP® were presented: three articulating endoscopic endowrist® instruments and an articulating endoscopic camera are inserted through a single robotic port [26]. Despite US Food and Drug Administration (FDA) approval, the system is going to be commercially available not earlier than mid-2018. Until then, we will not be able to evaluate if the technology can further solve the problems of the LESS.

Table 3 Peri- and post-operative data

Peri- and post-operative data			
Surgical technique *n* (%)			
Pure	3 (25)		
Hybrid	9 (75)		
Port Configuration "A"	2 (16.7)		
"B"	1 (8.3)		
"C"	9 (75)		
Nerve sparing (grade 1–2) attempted	9 (75)		
Lymphadenectomy, *n* (%)	8 (66.6)		
Conversion to traditional RARP, *n* (%)	0 (0)		
Hemoglobin drop, g/dl (mean ± SD,range)	4.7 ± 1.6 (2.9–8.1)		
EBL, ml (mean ± SD,range)	165 ± 120 (50–450)		
Operative Time, min. (mean ± SD range)	256.2 ± 62 (153–355)		
Port configuration "C" (last 9 cases)	217 ± 41 (153–290)		
Catheter removal, days (median, mean ± SD,range)	8.7 ± 3.4 (6–14)		
Length of stay (Days)	6.54 ± 1.1 (4–8)		
Pathologic TNM Stage, *n* (%)			
pT2a	2 (16.7)		
pT2c	7 (58.3)		
pT3a	3 (25)		
Pathologic Gleason score			
3 + 3	3 (25)		
3 + 4	7 (58.3)		
4 + 3	1 (8.3)		
4 + 4	1 (8.3)		
Nodes yield, *n*	6 ± 3.3 (2–10)		
Positive nodes, *n* (%)	1 (8.3)		
Positive surgical margins, n (%)	1 (8.3), focal < 1 mm (closest tumor grade 3)		
Complications (Clavien Dindo)			Stage
1	2 anastomosis leakage	Prolonged catheterisation	Early
2	3 postoperative anemia	Blood transfusion	Early
3a	0	/	
3b	1 Umbilical hernia	Hernioplasty with net	Intermediate
4a	1 Postoperative myocardial infarction	Coronary angioplasty	Early
Follow-up, months (mean, SD, range)	12 ± 8.4 (2–28)		
Follow-up, n (%)			
Biochemical recurrence	0 (0)		
Continent (1 or no pads)	12 (100)		
Erectile function with or without iPDE5 (only preoperative IIEF ≥ 21)			
IIEF > 17	4/5 (80)		
IIEF < 17	1/5 (20)		

EBL estimated blood loss, *PDE5i* phosphodiesterase type 5 inhibitors, *IIEF* International Index of Erectile Function

Complication stage: early < 30sdays, intermediate 30–90 days, late > 90 days

Thanks to this IDEAL-phase 1 study, we have standardized the procedure. However, clinical benefits for the patient versus standard RARP remain unproven. An IDEAL-phase 2 study is ongoing and will feature more consistent case studies and follow-ups, covering possible cosmetic benefits and will try to understand if LESS really offers minimally invasive advantage in patients affected by PCa.

Table 4 R-LESS-RP series from 2008

	Author	Year	Cases	Approach	Access	Robot Model (Intuitive)	Extraport	Conversion	Lymph Node Dissection	Total time (min)	Catheter removal	Length of Stay (day)	BMI	EBL
1	Desai [21]	2008	2 cadavers	Transvesicle	Single abdominal incision & Qaudprort (Olympus Medical, Orangeburg,NY, USA)	daVinci S	no	n/a	no	220	n/a	n/a	n/a	n/a
2	Barret [23]	2009	2 pt	Transperitoneal	Single abdominal incision	daVinci SI	1/2 5-mm 1pt	n/a	no	210	n/a	n/a	n/a	300
3	Leewansangtong [20]	2010	1 pt	Transperitoneal	Single incision	daVinci S	no	no	no	335	14	4	22	250
4	White [22]	2010	20 pt	Transperitoneal	SILS-port (Covidien, Mansfield, MA, USA)	daVinci SI	2.5%	2.5%	60%	188	8.6	2.5	25.4	129
5	Kaouk [26]	2014	11pt	Transperitoneal	2.5 cm single abdominal incision	daVinci SP	no	no	18.2%	239	7	5	25.8	350
6	Akca [24]	2015	2 pt	Transperineal	Perineal semicircural incision & GelPOINT Mini advanced access platform (Applied Medical, Rancho SantaMargarita, CA, USA)	daVinci SI	no	no	no	300	7 and 21days	<24 h	n/a	50
7	Mattevi [16]	2017	1 pt	Transperitoneal	da Vinci Single-Site port (Intuitive)	Da Vinci SI and single-site platform	12-mm Air Seal (surgiquest)	no	no	300	6	n/a	26	400
8	Our series	2017	11 pt	Transperitoneal	Laparoscopic cap or Gel Point (Applied Medical, Rancho SantaMargarita, CA, USA) da Vinci Single-Site port (Intuitive) and a 5- and 10-12-mm standard troca	Da Vinci SI & single-site platform	8-mm robootic port in 72.7%	no	72.7%	256.2 217 port C configuration=	8.7 mean	6.56	26	165

Pt Patient, *n.a.* not available

Conclusions

R-LESS-RP is feasible and safe in the hands of experienced laparoscopic and robotic surgeons. However, until a new specifically designed daVinci SP® platform will be available, we recommend a hybrid solution with a home-made multiport and use of an additional standard robotic trocar which allows the use endowrist® technology instruments. Such approach allows the benefits of reducing the number of port as compared to RARP overcoming the technical issues related to the pure R-LESS approach.

Compliance with ethical standards

Conflict of interest All authors involved in the article had nothing to disclose about commercial associations that might create a conflict of interest in connection with submitted manuscripts. Franco Gaboardi, Giovannalberto Pini, Nazareno Suardi, Francesco Montorsi, Giovanni Passaretti, Salvatore Smelzo declare that they have no conflict of interest.

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