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Robot-assisted or conventional laparoscoic rectopexy for rectal prolapse? Systematic review and meta-analysis



F. Rondelli ^{a, b}, W. Bugiantella ^{a, c, *}, F. Villa ^d, A. Sanguinetti ^e, M. Boni ^a, E. Mariani ^a, N. Avenia ^b

- ^a "San Giovanni Battista" Hospital, General Surgery, USL Umbria 2, Via M. Arcamone, 06034, Foligno, Perugia, Italy
- ^b University of Perugia, Department of Surgical and Biomedical Sciences, Via G. Dottori, 06100, Perugia, Italy
- ^c University of Perugia, PhD School in Biotechnologies, Italy
- ^d "Bellinzona e Valli" Regional Hospital, 6500, Bellinzona, Switzerland
- ^e General and Specialized Surgery, "Santa Maria" Hospital, Via T. Di Joannuccio, 05100, Terni, Italy

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ABSTRACT

Aim: The use of robotic technology has proved to be safe and effective, arising as a helpful alternative to standard laparoscopy in a variety of surgical procedures. However the role of robotic assistance in laparoscopic rectopexy is still not demonstrated. Methods: A systematic review of the literature was carried out performing an unrestricted search in MEDLINE, EMBASE, the Cochrane Library, and Google Scholar up to 30th June 2014. Reference lists of retrieved articles and review articles were manually searched for other relevant studies. We meta-analyzed the data currently available regarding the incidence of recurrence rate of rectal prolapse, conversion rate, operative time, intra-operative blood loss, post-operative complications, re-operation rate and hospital stay in robot-assisted rectopexy (RC) compared to conventional laparoscopic rectopexy (LR), Results: Six studies were included resulting in 340 patients. The meta-analysis showed that the RR does not influence the recurrence rate of rectal prolapse, the conversion rate and the re-operation rate, whereas it decreases the intra-operative blood loss, the post-operative complications and the hospital stay. Yet, the RR resulted to be longer than the LR. Post-operative ano-rectal and the sexual functionality and procedural costs could not meta-analyzed because the data from included studies about these issues were heterogeneous and incomplete. Conclusion: The meta-analysis showed that the RR may ensure limited improvements in post-operative outcomes if compared to the LR. However, RCTs are needed to compare RR to LR in terms of short-term and long-term outcomes, specially investigating the functional outcomes that may confirm the costeffectiveness of the robotic assisted rectopexy.

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1. Introduction

Pelvic floor disorders (PFDs) include several clinical conditions as urinary incontinence, fecal incontinence, pelvic organ prolapse, sensory and emptying abnormalities of the lower urinary tract, defecatory dysfunction, sexual dysfunction and several chronic

pain syndromes. The three most common and definable conditions clinically encountered are urinary incontinence, anal incontinence and pelvic organ prolapse.

Rectal prolapse is a debilitating condition associated with significant comorbidity and a poor quality of life. Patients usually show tenesmus, pain, prolapse, bleeding, obstructed defecation or faecal incontinence and even acute rectal incarceration. Rectal prolapse frequently occurs in old women with a male to female rate of 1:6. In the US about 41% of women aged 50–79 years show some degree of pelvic floor disorder (PFD) in the form of symptomatic pelvic organ prolapse and it is likely that by the year 2050 nearly one-third of the adult female population in the US will be affected by a least one PFD [1,2]. Symptomatic PFDs require surgical correction and the need of surgery by age 80 has been estimated to be 7–12.2% [3].

Abbreviations: PFD, pelvic floor disorder; LR, laparoscopic rectopexy; RR, robotic rectopexy; RCT, randomized clinical trial.

^{*}Corresponding author. General Surgery, "San Giovanni Battista Hospital", AUSL Umbria 2, Via M. Arcamone, 06034, Foligno, Perugia, Italy.

E-mail addresses: rondellif@hotmail.com (F. Rondelli), walterbugiantella@alice.it (W. Bugiantella), fabio.villa@eoc.ch (F. Villa), sanguinettiale@gmail.com (A. Sanguinetti), bonimarce@tiscali.it (M. Boni), enrico.mariani@uslumbria2.it (E. Mariani), nicolaavenia@libero.it (N. Avenia).

Surgical treatments can be either perineal or abdominal approach. Perineal approach includes Delorme's (mucosal sleeve resection) or Altemeier's (perineal rectosigmoidectomy) procedure. Both of them have a significant chance of recurrence (up to 40% and 16% respectively) and therefore they are often limited to elderly or peri-operative high risk patients [4]. The abdominal approach includes the rectopexy alone with the use of synthetic or biological mesh, (according to Ripstein's, Wells' or D'Hoore's technique) or the sigmoid resection and rectopexy (Goldberg—Frykman's procedure).

The abdominal approach ensures better outcomes with low recurrence and it can be often combined with cystopexy or colpopexy if need be [5]. Although incontinence is improved, the associated constipation may tend to get worse after surgery and occasionally a new-onset constipation may be a possible consequence of rectal denervation secondary to its postero-lateral mobilization as it occurs in posterior rectopexy [6]. Ventral rectopexy, proposed by D'Hoore, involves mobilization of the anterior wall of the rectum down to the levator ani muscle and anterior placement of a mesh which is sutured distally on the anterior wall of the rectum and secured proximally to the sacral promontory. This technique with laparoscopic approach showed successful long-term results (minor morbidity 7%, recurrence rate 3.7%), faster recovery, less blood loss, lower medical cost and less post-operative pain and this replaced the traditional open abdominal approach and it has led many authors to advocate this approach as the preferential technique [7–9].

Laparoscopic procedure is however technically demanding with a difficult learning curve because of the use of rigid instruments, limited freedom of wrist movement and technical difficulties operating in a deep pelvis. Development of robotics in surgery has overcome some of these limitations, thus introducing advantages as three-dimensional visualization, tremor filtering and motion scaling, enhanced dexterity and superior precision. However, some disadvantages of robot-assisted laparoscopic procedures must be considered, such as the loss of haptic feedback, the limited range of movement of the robotic harms, the increased operative time and the higher costs. Thus, the theoretical advantages and disadvantages of robotic surgical procedures might be carefully considered in order to justify the higher costs of robotic assistance.

There are few publications comparing robotic rectopexy (RR) and laparoscopic rectopexy (LR) to date in literature and there is no univocal conclusion about either technique is superior in terms of recurrence rate and post-operative outcome [10–15]. For this reason we have carried out a systematic review and meta-analysis of studies comparing robot-assisted with conventional laparoscopic rectopexy for rectal prolapse.

2. Materials and methods

A systematic review and a meta-analysis about the outcomes of RR compared to LR in patients undergoing elective rectopexy for rectal prolapse were performed.

A protocol was prospectively developed, detailing the specific objectives, criteria for study selection, approach to assess study quality, outcomes and statistical methods.

2.1. Study outcomes

The primary outcome of the study was to assess the incidence of recurrence of rectal prolapse in patients who underwent laparoscopic rectopexy with or without the use of robotic assistance.

The secondary outcomes were total operative time, intraoperative blood loss, conversion rate, post-operative complications, re-operation rate, hospital stay and post-operative mortality.

2.2. Search strategy and eligibility criteria

An unrestricted search was performed in MEDLINE, EMBASE, the Cochrane Library, and Google Scholar up to 30th June 2014. Research criteria included the terms "robotic", "robot-assisted", "laparoscopy", "laparoscopic", "rectopexy", and "rectal prolapse". Furthermore, reference lists of retrieved articles and review articles were searched manually for other relevant studies.

Two authors (RF and VF) independently performed the searches and reviewed all identified publications and abstracts for inclusion by using predetermined criteria. In order to be included in this review, studies needed to be reported on patients including what follows: number of patients who underwent RR and LR and incidence of recurrence in the two subgroups of patients. Disagreements were resolved by consensus with a third investigator (BM) and by means of discussion.

2.3. Data extraction and quality assessment

Data from included studies were independently extracted by 2 authors (VF and BW) and were confirmed by both. The following individual data were extracted for each study by using standardized extraction forms: general data (study design, year), characteristics of patients (number, gender, age, indication to surgery), main features of the interventions (surgical approach, total operative time, intra-operative blood loss, conversion rate), clinical outcome (post-operative complications, re-operation, hospital stay, post-operative mortality, recurrence of rectal prolapse).

The Meta-analysis Of Observational Studies in Epidemiology group checklist was used (MOOSE) [16]. The quality of studies was evaluated using the Newcastle—Ottawa quality assessment scale [17].

2.4. Selection of studies for meta-analysis

Data about patients with/without study outcomes and operated on with conventional/robot-assisted laparoscopy were required to be included in the meta analysis, thus allowing the creation of a 2×2 table.

2.5. Statistical analysis

We reported results according to fixed-effects model in absence of significant heterogeneity among the included studies. The appropriateness of pooling data across studies was assessed using the Cochran's χ -squared test and the I-squared test for heterogeneity which measures the inconsistency across the study results and describes the proportion of total variation in study estimates that is due to heterogeneity rather than sampling error. Statistically significant heterogeneity was considered to be present in case p < 0.10 and I squared greater than 50% [18]. Pooled odds ratios were reported with 95% confidence intervals (CIs). Funnel plots were used to assess for publication bias [19]. We planned to perform separate analyses of studies according to the different outcomes.

Analyses were performed using Review Manager 5.2 (The Cochrane Collaboration, Oxford, England).

The authors had full access to and take full responsibility for the integrity of all the data. All authors have read and agreed to the manuscript as written.

3. Results

Overall 6 studies were found: 3 retrospective studies [10–12], 2 pair-matched studies [13,15] and 1 prospective study [14]. The flow diagram for inclusion is shown in Fig. 1. A minimum of 33

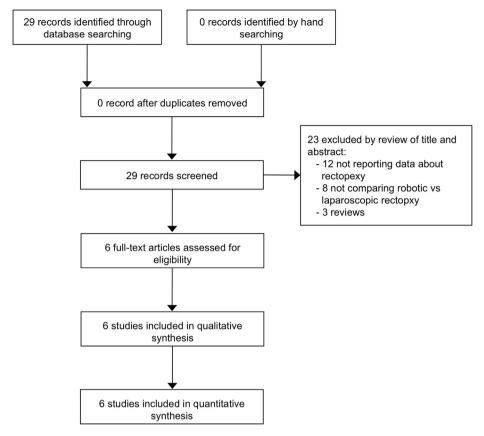


Fig. 1. Flowchart of the retrieved studies.

and a maximum of 118 patients were included in the studies. General characteristics of the study populations are shown in Table 1.

3.1. Meta-analysis

Six studies [10–15] were included in the meta-analysis with a total amount of 340 patients. The recurrence rate of rectal prolapse (5 studies with a total amount of 307 patients) showed no statistically significant differences (OR 0.91; 95% CI 0.32, 2.63; p=0.87) comparing the group of RR with the group of LR (Fig. 2) [11–15].

The operative time (4 studies with 255 patients) was significantly longer in patients who underwent RR compared to those who underwent LR (SMD 0.72; 95% CI 0.45, 0.98; p=0.04) (Fig. 3) [11–13,15].

The intra-operative blood loss (3 studies with 221 patients) was significantly lower in RR (SMD -0.44; 95% CI -0.71, -0.16; p=0.002) (Fig. 3) [12,13,15].

The number of total post-operative complications (4 studies with 272 patients) was significantly lesser in RR (OR 0.42; 95% CI 0.18, 0.97; p = 0.04) (Fig. 2) [12–15].

The length of hospital stay (3 studies with 221 patients) was significantly shorter in RR (SMD -0.33; 95% CI -0.60, -0.05; p = 0.02) (Fig. 3).

No statistically significant differences were found in conversion rate (5 studies with 305 patients [10,12–15]; OR 0.30, 95% CI 0.09, 1.04; p=0.06) and in re-operation rate (4 studies with 272 patients [12–15]; OR 0.32; 95% CI 0.01, 8.26; p=0.49) comparing the group of RR with the group of LR (Fig. 2). No publication bias was shown.

3.2. Subgroups analysis

Among the patients of the included studies two subgroups were identified: those who underwent D'Hoore's procedure and those who were affected by rectal prolapse respectively.

The meta-analysis of the data from the patients undergoing surgery for rectal prolapse showed no statistically significant differences in recurrence rate (OR 0.69; 95% CI 0.14, 3.35; p=0.64), conversion rate (OR 0.16; 95% CI 0.02, 1.27; p=0.08) and post-operative complications (OR 0.13; 95% CI 0.01, 2.36; p=0.17) between RR group and LR group [10,11,14]. There were not enough data to meta-analyze the operative time, the intra-operative blood loss and the hospital stay.

The meta-analysis of the subgroup of patients undergoing D'Hoore's rectopexy showed a statistically significant lower incidence of post-operative complications in RR group whereas no statistically significant differences were reported in recurrence rate (OR 0.91; 95% CI 0.32, 2.63; p=0.57), conversion rate (OR 0.50; 95% CI 0.12, 2.10; p=0.34) and re-operation rate (OR 0.32; 95% CI 0.01, 8.26; p=0.49) between RR group and LR group [12–15]. The data about operative time, intra-operative blood loss and hospital stay were the same of the main meta-analysis.

4. Discussion

The meta-analysis, including 6 studies for a total amount of 340 patients, shows that the robotic assistance for rectopexy does not influence the recurrence rate of rectal prolapse, the conversion rate and the re-operation rate, whereas it decreases the intra-operative blood loss, the post-operative complications and the hospital stay. Yet, the RR seems to be a longer procedure than LR.

Table 1 Characteristics of the included studies.

	J. Makela-Kaikkonen et al.	R.K. Mehmood et al.	S. Mantoo et al.	M.T.C. Wong et al.	D.E.N.M. de Hoog et al.	J. Heemskerk et
Year	2014	2014	2013	2011	2009	2007
Study design	Pair-matched	Prospective	Pair-matched	Retrospective	Retrospective	Retrospective
Study quality (Newcastle—Ottawa scale)	******	*******	*****	******	******	******
Patients						
Fotal (M/F)	40 (6/34)	51 (3/48)	118	63 (63)	35	33 (11/22)
		1 1 1	44	, ,		
Robotic (M/F)	20 (3/17)	17 (0/17)		23 (23)	20	19 (7/12)
aparoscopic (M/F)	20 (3/17)	34 (3/31)	74	40 (40)	15	14 (4/10)
Age (mean, ±SD/range)						
l'otal		59 (25-89)				52
Robotic	60.7 ± 17.4	na	62 ± 12	61 ± 11	na	55
aparoscopic	60.4 ± 17.0		61 ± 12	59 ± 13		47
Pre-operative BMI (mean, +SD/range)						
otal						
Robotic	25.0 ± 5.4	na	26 ± 4	27 ± 4	na	na
		IId			IId	IId
aparoscopic	24.6 ± 3.3		25 ± 4	24 ± 4		
Previous surgery						
Well (robotic/laparoscopic)	1/1		na	na	na	na
Other prolaspe surgery (robotic/	2/1	21				3/4
laparoscopic)						
Hysterectomy (robotic/laparoscopic)	8/5	29				3/5
ndication to surgery	- 1 -					- 1 -
Rectal prolapse (robotic/laparoscopic)	13/14	17/34	12/23	0	20/15	19/14
	,	'				,
ntussusception (robotic/laparoscopic)	7/6	0	0	0	0	0
Rectocele	0	0	32/51	63	0	0
urgical procedure						
Vell (robotic/laparoscopic)					na	7/4
O'Hoore single mesh (robotic/laparoscopic)	20/20	17/34	32/52	6/26		12/10
D'Hoore double mesh (robotic/laparoscopic)			12/12	17/14		•
Total operative time (mean \pm SD/range)			,			
Robotic	221 . 20	1275 (110 2424)	101 - 26	221 + 20	154 . 47	152
	231 ± 39	137.5 (110–242.4)		221 ± 39	154 ± 47	
aparoscopic	234 ± 41	115 (55–198)	163 ± 39	162 ± 60	119 ± 31	113
ntra-operative blood loss (mean \pm SD/ran						
Robotic	25 ± 49	17.5 (10-27.5)	8 ± 34	6 ± 23	na	na
aparoscopic	37 ± 50	25 (5-100)	42 ± 88	45 ± 91		
Convension rate						
Robotic	0	0	1	1	na	0
aparoscopic	0	1	3	4	iiu	4
	o .	1	,	7		-
Post-operative complications			_			
Robotic	2	0	5	0	na	na
aparoscopic	1	6	15	5		
Re-operation						
Robotic	0	0	0	0	na	na
aparoscopic	1	0	0	0		
Post-operative mortality						
Robotic	0	0	0	0	0	0
aparoscopic	0	0	0	0	0	0
lospital stay (days ± SD/range)		a / a . 1)			0.0(4.0)	
Robotic	3.1 ± 2.0	2 (1-4)	4 ± 1	5 ± 1.6	2.6 (1-6)	3.5
aparoscopic	3.3 ± 1.3	2 (1-6)	5 ± 2	5 ± 2.0	3.5 (1-14)	4.3
Recurrence						
Robotic	0	0	3	0	4	na
aparoscopic	1	0	3	0	4	_
Vexner score		5	•	•		
		no 45			110.02.07.04	
Robotic (pre – post)	na	na – 4.5	na	na	$11.9 \pm 8.3 - 8.7 \pm 6.4$	ııa
Laparoscopic (pre — post)		na – 7			$13.1 \pm 8.9 -$	
					10.0 ± 9.2	
DL score						
Robotic	na	na	na	na	$8.3 \pm 1.3 - 4.7 \pm 2.5$	na
aparoscopic					$8.4 \pm 1.4 - 3.9 \pm 3.3$	
Sollow-up (months)					o.¬ ± 1.¬ ¬ J.J ± J.J	
F ollow-up (months) Fotal (mean)	3	12	6	C	21.2	
	4	1.7	h	6	31.2	na

Laparoscopic correction of the rectal prolapse became the referential surgical approach in the last decade, combining the advantages of the abdominal approach (low recurrence rate than the perineal approach) with those of laparoscopy (less blood loss, less post-operative pain, faster recovery, lower medical costs). Posterior rectopexy progressively left space to anterior rectopexy. In fact, although posterior rectopexy improves incontinence, it tends to worsen the constipation as a possible consequence of

rectal denervation secondary to postero-lateral mobilization and division of the lateral ligaments of the rectum [6]. Concomitant colonic resection to overcome this problem is effective, but it is often followed by anastomotic leakage risk or anastomotic stricture. Ventral rectopexy involves the mobilization of the anterior wall of the rectum down to the levator ani muscle and the anterior placement of a mesh which is sutured distally on the anterior wall of the rectum and proximally to the sacral promontory [7]. The

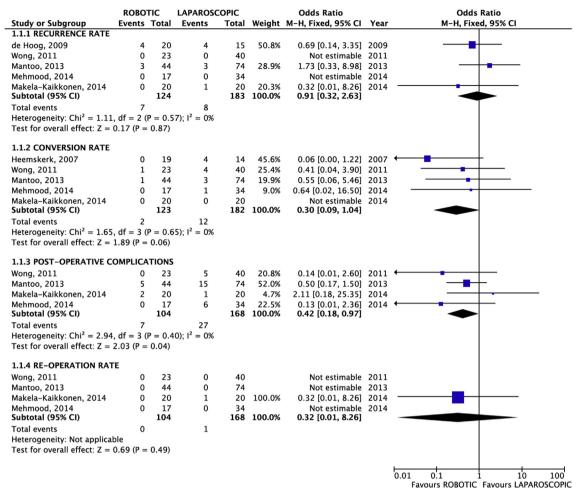


Fig. 2. Forest plots of the meta-analysis of recurrence rate, conversion rate, post-operative complications and re-operation rate.

initial description of ventral rectopexy was by Orr—Loygue who proposed the full rectal anterior mobilization and the suture of two meshes on the antero-lateral rectal wall [20]. Later, a purely anterior rectal mobilization with limited posterior dissection has been proposed by D'Hoore: since the dissection is performed anteriorly between the rectum and vagina and only a very superficial peritoneal window is opened starting from the sacral promontory on the right side of the rectum, the nerves are respected and no rectal denervation inertia or new onset constipation is expected to occur [7]. It would improve ano-rectal function and even have advantages for the middle pelvic floor compartment. Laparoscopic ventral rectopexy by D'Hoore reported successful long-term results with minor morbidity of 7% and recurrence rate of 3.7% [7], thus leading many authors to advocate this approach as the preferential technique [8,9].

Development of robotic assistance in surgery has overcome some limitations of conventional laparoscopy (such as difficulties due to the use of rigid instruments, limited freedom of wrist movement and technical difficulties operating in a deep pelvis), introducing advantages as endowristed movements in every plane, three-dimensional view, tremor elimination, motion scaling, ambidexstrous capability, better ergonomics and less fatigue. However, the disadvantages of robotic assistance, such as loss of tactile feedback, bulky robotic cart, consumption of operating room resource, increased operative time and high costs, need a careful and pondered assessment of robotic system applications. The use of robotic technology procedures has proved to be safe and effective,

arising as a helpful alternative to standard laparoscopic surgery in a variety of colorectal procedures, specially when dealing with complex pathology [21–23]. Several studies have shown the feasibility and safety of robot-assisted rectopexy, but to date none has systematically compared the conventional laparoscopic approach to the robot-assisted one [10–15,24,25].

The meta-analysis showed that the recurrence rate of rectal prolapse did not differ between RR and LR. This result may be due to the fact that, although the robotic assistance may ease some laparoscopic procedures, it does not improve skills when the operations are performed by expert laparoscopic surgeons. The lack of statistically significant differences in conversion rate and reoperation rate between RR and LR may be interpreted in this sense. The meta-analysis showed that the operative time is significantly longer in RR than LR. This is due to the time needed to set the arms of the robot before the surgical acts and to remove them at the end of the procedure. Moreover, the experience of the équipe in the operative room, the learning curve and the surgeon's skill are all important aspects that influence the operative time. The meta-analysis showed that RR is associated with a significant lower incidence of intra-operative blood loss than LR. This is most likely due to the easier endowristed movements of the devices and to the better tridimensional vision of the robot. These advantages might enable a more selective approach to the pelvis with less blood loss and preservation of nervous structures. Although the difference was statically significant between RR and LR, the amount of intraoperative blood loss was small in both the two groups (range

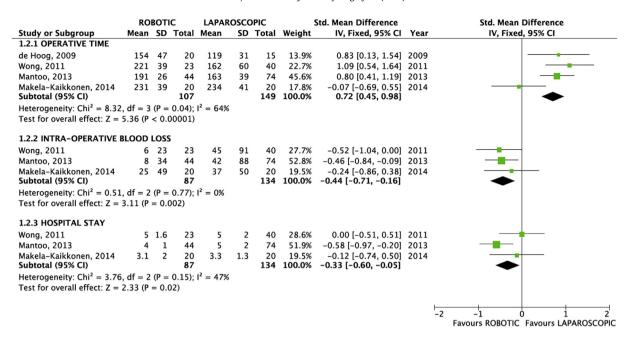


Fig. 3. Forest plots of the meta-analysis of operative time, intra-operative blood loss and hospital stay.

10—49 ml in RR and 5—136 ml in LR), thus not requiring intraoperative transfusion. Post-operative total complications resulted lesser in RR: although they were not specified in some studies, they were minor complications in most cases, insomuch as there were no statistically significant differences in re-operation rate. Hospitalstay resulted shorter in RR, probably conditioned by the incidence of post-operative complications.

Some limitations must be taken into account in the metaanalysis. Firstly, it included only 6 studies with no randomized clinical trial (RCT). Secondly, the number of the included patients was relatively small: a total amount of 340. The paucity of the available studies and the small number of patients are due to the recent beginning of the robot-assisted laparoscopic approach, therefore RCTs are needed to compare RR to LR.

Thirdly, in the included studies there were differences about the previous surgery, the indication to PFD surgery and the surgical procedures. Thus, the studies were divided into two subgroups: those with only rectal prolapse and those which were performed only according to D'Hoore's procedure: the meta-analyzed data confirmed the results of the main meta-analysis. It could be interesting to investigate the post-operative outcomes depending on the previous operations for PFD, the different indications to surgery and the different procedures performed, but data were not enough. These are the intrinsic limits of the meta-analysis approach, which combines heterogeneous datasets and does not often allow adjustment for confounders. This might be feasible in case of a patient level meta-analysis, but data about individual patients were not available.

Two very important outcomes of rectopexy are the post-operative ano-rectal and the sexual functionality. Data about these issues were heterogeneous in the included studies and could not be meta-analyzed. A very important aspect of robotic assistance is its costs that are higher compared to those of conventional lap-aroscopy: this is due not only to the expense of the dock console and the devices, but also to the prolonged occupation of the operative room. It could be interesting to analyze the costs of RR and LR but only Heemskerk reported the costs of the two procedures (with an increased cost of RR) [10]. An updated systematic analysis of the costs could very important in order to assess if the RR might

improve outcomes (ano-rectal and sexual functionality, recurrence rate, post-operative complications, hospital stay) so to justify an increased expense respect to LR.

In the end it must be pointed out that in literature there are no RCT comparing the outcomes between RR and LR to date, thus the role of the robotic assistance in laparoscopic rectopexy cannot be definitively assessed so far. We believe that, since the functional outcomes are the main target of the surgical correction of the PFD, if the RCTs will show that the robotic approach ensures a lower recurrence rate and better functional results compared to conventional laparoscopic approach, the cost-effectiveness of the robotic approach will be confirmed.

5. Conclusion

The meta-analysis confirmed that RR is a safe and feasible surgical approach if compared to LR. The robotic assistance improves minimal advantages in terms of intra-operative blood loss, post-operative complications and hospital stay compared to the conventional laparoscopic rectopexy, with not statistically significant differences about recurrence rate and with increased procedural costs. Thus, it may not justify the use of the robotic assistance in laparoscopic rectopexy to date.

However, RCTs are needed to compare RR to LR in terms of short-term and long-term outcomes, specially investigating the functional outcomes that may confirm the cost-effectiveness of the robotic assisted rectopexy.

Ethical approval

None required.

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All Authors have no source of funding.

Author contribution

Rondelli Fabio: Participated substantially in conception, design and execution of the study, and in the analysis and interpretation of the data; also participated substantially in the drafting and editing of the manuscript.

Bugiantella Walter: Participated substantially in conception, design and execution of the study, and in the analysis and interpretation of the data; also participated substantially in the drafting and editing of the manuscript.

Villa Fabio: Participated substantially in conception, design and execution of the study, and in the analysis and interpretation of the data.

Sanguinetti Alessandro: Participated substantially in the drafting and editing of the manuscript.

Boni Marcello: Participated substantially in the analysis and interpretation of data, drafting and editing of the manuscript.

Mariani Enrico: Participated substantially in the analysis and interpretation of the data; also participated substantially in the editing of the manuscript.

Avenia Nicola: Participated substantially in editing and reviewing of the manuscript.

Conflict of interests

All Authors have no conflict of interests.

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