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REVIEW

Completeness of total mesorectum excision of laparoscopic versus robotic surgery: a review with a meta-analysis

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Abstract

Background TME has revolutionized the surgical management of rectal cancer, and since the introduction of robotic TME (RTME), many reports have shown the feasibility and the safety of this approach. However, concerns persist regarding the advantages of robotic in surgery for the completeness of TME. The aim of this review is to compare robotic versus laparoscopic total mesorectal excision (TME) in rectal cancer, focusing on the completeness of TME.

Methods A systematic search was performed in the electronic databases for all available studies comparing RTME versus conventional laparoscopic LTME with declared grade of mesorectum excision. Data regarding sample size, clinical and demographic characteristics, number of complete, nearly complete, and incomplete TME were extracted. Primary outcome was the number of complete TME in robotic and laparoscopic procedures. Secondary outcomes were the numbers of nearly complete and incomplete TME in robotic and laparoscopic rectal resections.

Results Twelve articles were included in the final analysis. Complete TME was reported by all authors, involving 1510 procedures, showing a significant difference in favor of robotic surgery (OR = 1.83, 95% CI 1.08–3.10, $p = 0.03$). Nearly complete and incomplete TME showed no significant difference between the procedures. Meta-regression analysis showed that none of patients' and tumors' characteristics significantly impacted on complete TME.

Conclusions Our results underline that the robotic approach to rectal resection is the better way to obtain a complete TME. However, it is mandatory that randomized clinical trials should be performed to assess definitively if robotic minimally invasive surgery is better than a laparoscopic resection.

Keywords Robotic surgery · Laparoscopic surgery · Total mesorectum excision

Introduction

Laparoscopic colorectal surgery (LS) is currently offered as the standard of surgical care [1]. LS has been credited with facilitating early postoperative recovery without compromising oncological outcomes [2]. Furthermore, minimally invasive approaches are associated with less delay to the initiation of adjuvant systemic therapy and improved survival in patients with stage III colon adenocarcinoma [3].

However, laparoscopic rectal cancer (RC) surgery is a more technically demanding and has a steep learning curve than laparoscopic colon cancer surgery because it is performed in the narrow pelvic cavity.

It is important to highlight that total mesorectal excision (TME) introduced by Heald et al. [4] has revolutionized the surgical management of RC and recent experiences questioned the efficacy of laparoscopic surgery obtaining complete TME [5, 6].

Since the introduction of robotic total mesorectal excision (RTME), many reports have shown the feasibility and the safety of this minimally invasive approach. However, experience is still limited in RTME and although an increasing

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number of rectal carcinoma resections are performed robotically, concerns persist regarding the advantages of robotic in comparison with the laparoscopic surgery, specifically regarding the completeness of TME.

We therefore present a review with a meta-analysis of all the available evidence comparing the surgical and oncological outcomes of RTME versus LTME in rectal cancer, focusing on the completeness of TME.

Material and methods

A protocol for this review was prospectively developed, with specific objectives, detailed criteria for study selection and evaluation of study quality, and identification of the outcomes and of the statistical methods.

Literature search strategy

To identify all available studies, a systematic search was performed according to PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) flowchart [7] (Fig. 1) in the following electronic databases:

- PubMed
- Web of Science
- Scopus
- EMBASE

We used medical subject headings (MeSH) and free-text words using the following search terms in all possible combinations: laparoscopic, robotic, rectal, cancer, TME.

According to PICO framework (Problem/Population, Intervention, Comparison and Outcome), study selection criteria were exactly defined. Participants included adult population with primary histologically proven rectal cancer; interventions included were laparoscopic and robotic rectal resection with total mesorectal excision (TME). Primary outcome measure was the number of complete TME in robotic and laparoscopic procedures. Secondary outcome measures were the numbers of nearly complete and incomplete TME in robotic and laparoscopic rectal resections. Combined analyses

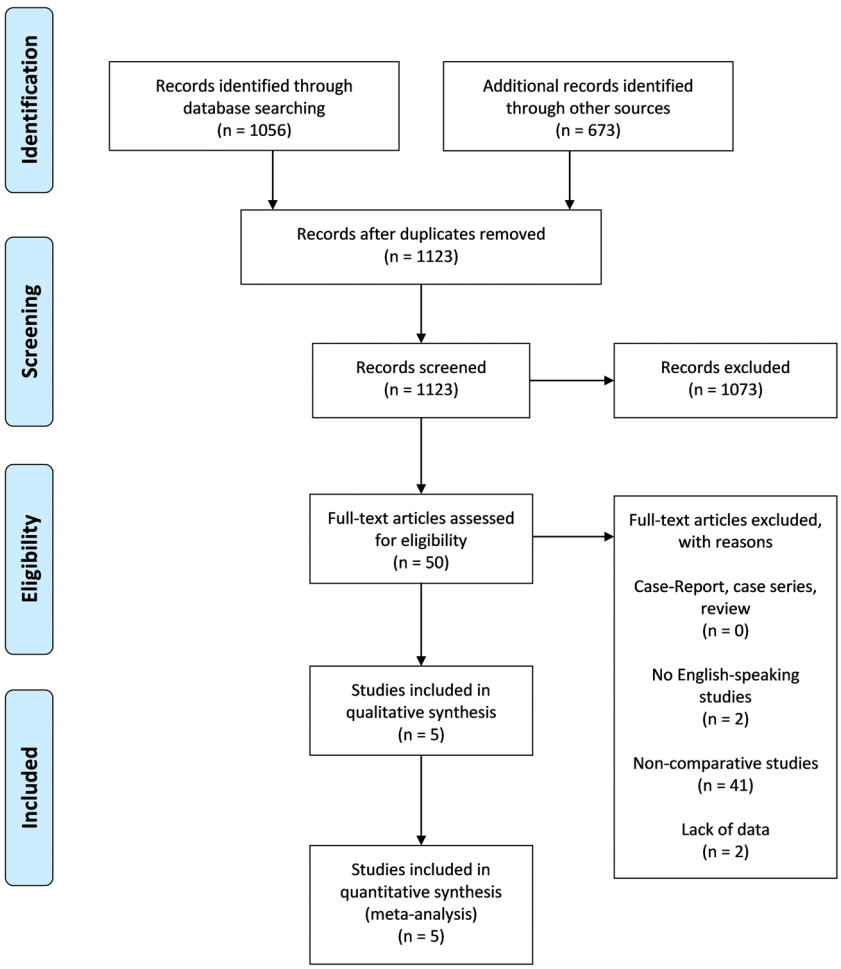

Fig. 1 PRISMA flowchart

included the number of complete and nearly complete TME, defining this outcome as "acceptable" TME, and the number of nearly complete and incomplete TME, defining it as "non-complete" TME. The last search was performed on July 2018. The search strategy was limited to articles written in the English language. In addition, the reference lists of all retrieved articles were manually reviewed. In case of overlap between centers or authors, the most recent or with higher quality study was selected.

Study selection

Two independent authors (MiM, NV) analyzed each article and performed the data extraction independently.

Duplicate studies were removed, and studies considered irrelevant were discarded. Two other authors (FM, GDDP) further reviewed independently the eligibility of studies in abstract form and in full text by assessing if the inclusion criteria and outcome measures were met. In case of disagreement, a fourth investigator was consulted (MM). Discrepancies were resolved by consensus.

Eligibility criteria were predetermined as follow:

- Adult participants (> 18 years of age) diagnosed with rectal adenocarcinoma with an indication to elective rectal resection.
- Comparison between elective robotic and laparoscopic surgery for resection of rectal cancer: anterior resection (AR), laparoscopic anterior resection (LAR), Hartmann resection, or abdomino-perineal resection (APR), with total mesorectal excision (TME) or partial mesorectal excision (PME) in case of upper rectum cancer.
- Studies including colorectal cancer or 3-arm studies (open, laparoscopic and robotic or transanal TME, laparoscopic and robotic) were eligible only if outcomes for rectal carcinoma could be extracted.
- Grade of completeness of TME clearly defined

Data extraction

Data regarding sample size, major clinical and demographic variables (patients gender, BMI, ASA Score, neoadjuvant chemoradiotherapy, AJCC stage, primary tumor location), number of complete, nearly complete and incomplete TME were extracted. Furthermore, acceptable and non-complete TME were analyzed.

Statistical analysis

Dichotomous variables were pooled using the odds ratio (OR) with a 95% CI. In case of zero total events trials, we used the risk difference (RD) as effect measure to maintain analytic consistency and to incorporate all available data. If studies reported only the median, range, and size of the trial, the means and standard deviations were calculated according to Hozo et al. [8]. Statistical analysis was realized with by using Review Manager (Revman version 5.3; Copenhagen, Nordic Cochrane Center, Cochrane Collaboration, 2014).

Heterogeneity was investigated by the use of I^2 statistic. For I^2 of between 0 and 30%, heterogeneity was considered as probably not important, between 30 and 60% moderate, between 50 and 90% substantial, and between 75 and 100% considerable. In order to be as conservative as possible, the random effect method was used for all analyses to take into account the variability among included studies.

In order to be as conservative as possible, the random-effect method was used for all analyses to take into account the variability among included studies.

Furthermore, we performed a meta-regression analysis to assess the possible effect of clinical, surgical, and demographic variables (gender, BMI, ASA Score, neoadjuvant chemotherapy and radiation, AJCC stage, tumor location) on the incidence of the primary outcome. To assess the possible effect of such variables in explaining different results observed across studies, we planned to perform meta-regression analyses after implementing a regression model with incidence of the main outcome as dependent variable (y) and the abovementioned covariates as independent variables (x). Meta-regression analyses were realized using Comprehensive Meta-analysis (Version 2, Biostat, Englewood NJ (2005)).

Risk of bias assessment

Publication bias was assessed by the Egger's test and represented graphically by funnel plots for each outcome. Visual inspection of funnel plot asymmetry was performed to address for possible small-study effect, and Egger's test was used to assess publication bias, over and above any subjective evaluation. A $p < 0.05$ was considered statistically significant [9]. In case of a significant publication bias, the Duval and Tweedie's trim and fill method was used to allow for the estimation of an adjusted effect size [10].

Quality assessment

The quality of each included study was assessed. For randomized clinical trial (RCT), it was evaluated according to the Cochrane Collaboration tool for assessing risk of bias [11]: seven distinct domains were identified and evaluated as "Low risk of bias" or "High risk of bias" or "Unclear": sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential threats to validity. For assessing the quality of nonrandomized studies, the Newcastle-Ottawa Scale

(NOS) was used [12]: the NOS contains eight items, categorized into three domains: (1) selection of study (four points); (2) comparability of groups (two points); (3) ascertainment of exposure and outcomes (three points) for case–control and cohort studies, respectively. A star system is used to allow a semi-quantitative assessment, and researchers assign up to a maximum of nine points.

Results of risk of bias assessment are reported in Fig. 5a, b in the Appendix.

Results

Literature search

After excluding duplicate results, the search retrieved 364 references. Of these studies, 277 were excluded because they were off the topic after scanning the title and/or the abstract, 13 for language, 19 because of the type of manuscript, and 28 for lack of data. Of 15 studies, the online full-length version was not available and it was not possible to extract data from the online abstract. Thus, 12 articles were included in the final analysis [13–24] (Fig. 1).

Characteristics of the included studies

Characteristics of the studies' population are summarized in Table 1. Of the 12 included studies, 11 were case–control studies [13–17, 19–24], while only one was high-quality multicentric RCT [18]. The included studies involved 1510 patients (range from 40 to 466 per study), of whom 687 robotic and 823 laparoscopic rectal resections.

The number of patients varied from 40 to 466, mean age from 55.41 to 66 years, and the prevalence of male gender from 56.66 to 71.7%. Mean body mass index (BMI) varied from 22 to 35.04 kg/m^2. The prevalence of ASA Score I varied from 0 to 60.14%, of ASA Score II from 22.5 to 68.46%, of ASA Score III from 1.44 to 77.5, and of ASA Score IV from 0 to 7.14%.

Prevalence of patients undergone to neoadjuvant radiotherapy was reported by 2 studies [13–24] and varied from 5.38 to 45%; prevalence of patients undergone neoadjuvant chemotherapy reported by Valverde et al. [24] was 1.54%; and prevalence of patients undergone neoadjuvant chemoradiotherapy was reported by 9 authors [13–17, 19, 20, 23, 24] and varied from 39.62 to 100%. Prevalence of tumors' localization was reported from 3 authors [16, 18, 24] and varied from 16.15 to 25.34% for lower rectum (< 5 cm from the anal verge), from 39.17 to 44.16% for middle rectum (5–10 cm), and from 13.3 to 44.6% for upper rectum (> 10 cm). Clinical AJCC staging of the tumor was reported by 3 authors [13, 18, 23]. Prevalence of tumors with clinical AJCC stage I varied from 0 to 29.67%, with stage II from 16.8 to 39.8%, with stage III from 38 to 59.16%, and with stage IV from 0 to 29.93%.

Primary outcome

Primary outcome is shown in Fig. 2. Complete TME was reported by all authors, involving 1510 procedures (687 robotic and 823 laparoscopic), showing a statistical significant difference in favor of robotic surgery (OR = 1.83, 95% CI 1.08–3.10, $p = 0.03$), with a significant heterogeneity among the studies ($I^2 = 47\%$, $p = 0.03$).

Table 1 Characteristics of studies' population

Study	Patients	Lap/rob	Mean age	Male sex (%)	Mean BMI	ASA Score (%)				Upper rectum (lap/rob %)	RCTx (lap/rob %)
						I	II	III	IV		
Allemann et al. 2016	60	40/20	64.67	56.66	24.77	13.33	60.00	26.07	0.00		60/65
Bernajian et al. 2014	40	20/20	62.50	60.00	22.00	0.00	22.50	77.50	0.00		55/50
Colombo et al. 2016	120	60/60	61.00	68.33	24.80	31.67	51.67	15.84	0.84	21.7/13.3	65/78.3
Gorgun et al. 2016	56	27/29	59.52	67.86	35.04	0.00	32.14	60.71	7.14		51.8/65.5
Jayne et al. 2017	466	230/236	64.94	67.90		38.14	58.22	20.78	0.00	30/30.1	
Kim et al. 2016	99	66/33	57.80	69.70	23.33	52.52	43.43	4.04	0.00		100/100
Lim et al. 2017	138	64/74	64.96	69.56	23.08	60.14	38.40	1.44	0.00		
Ramji et al. 2016	53	27/26	62.9	71.70	27.65	7.54	22.64	66.04	3.77		22.2/57.7
Serin et al. 2015	79	65/14	55.41		25.80						
Silva-Velazco et al. 2016	174	118/66	59.64	63.04	27.9	0.54	36.41	56.52	6.52		49.1/51.5
Valverde et al. 2017	130	65/65	66.00	66.92	25.00	19.22	68.46	18.46	0.00	44.6/18.4	36.9/47.6

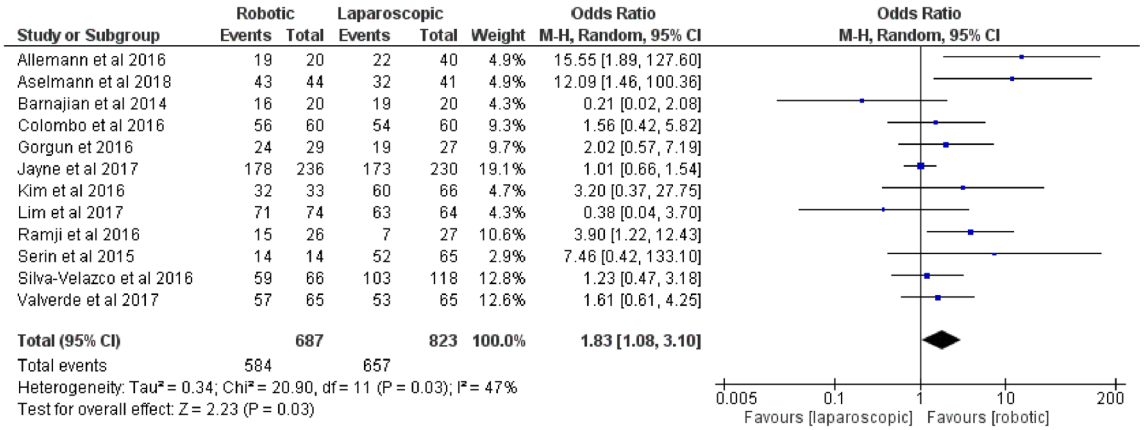

Fig. 2 Primary outcome: complete TME

Secondary outcomes

Secondary outcomes are shown in Fig. 3. Nearly complete TME was analyzed by 9 authors [13–20, 23, 24], including 1378 procedures, of whom 647 robotic and 731 laparoscopic; no significant difference was shown by the analysis (OR = 0.62, 95% CI 0.37–1.02, $p = 0.06$), with no significant heterogeneity among the studies ($I^2 = 16\%$, $p = 0.30$).

Incomplete TME was reported by all authors, showing no significant difference between the procedures (RD = 0.00, 95% CI − 0.02–0.03, $p = 0.85$) and significant heterogeneity among the studies ($I^2 = 45\%$, $p = 0.04$). Combined analysis is shown in Fig. 4. It showed no significant difference between the procedure about acceptable TME (RD = 0.01, 95% CI − 0.02–0.04, $p = 0.37$) and non-complete TME (OR = 0.74, 95% CI 0.42–1.31, $p = 0.30$), with

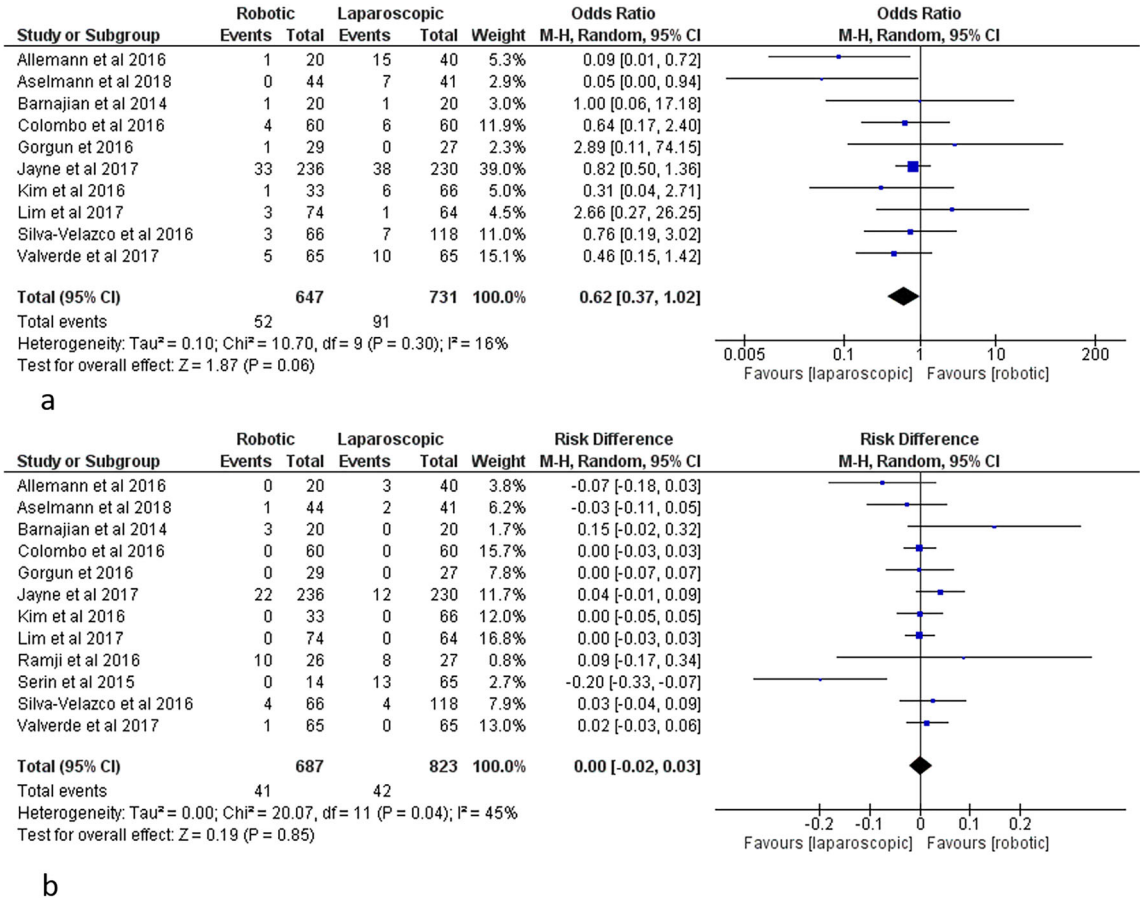

Fig. 3 Secondary outcomes: **a** nearly complete TME and **b** incomplete TME

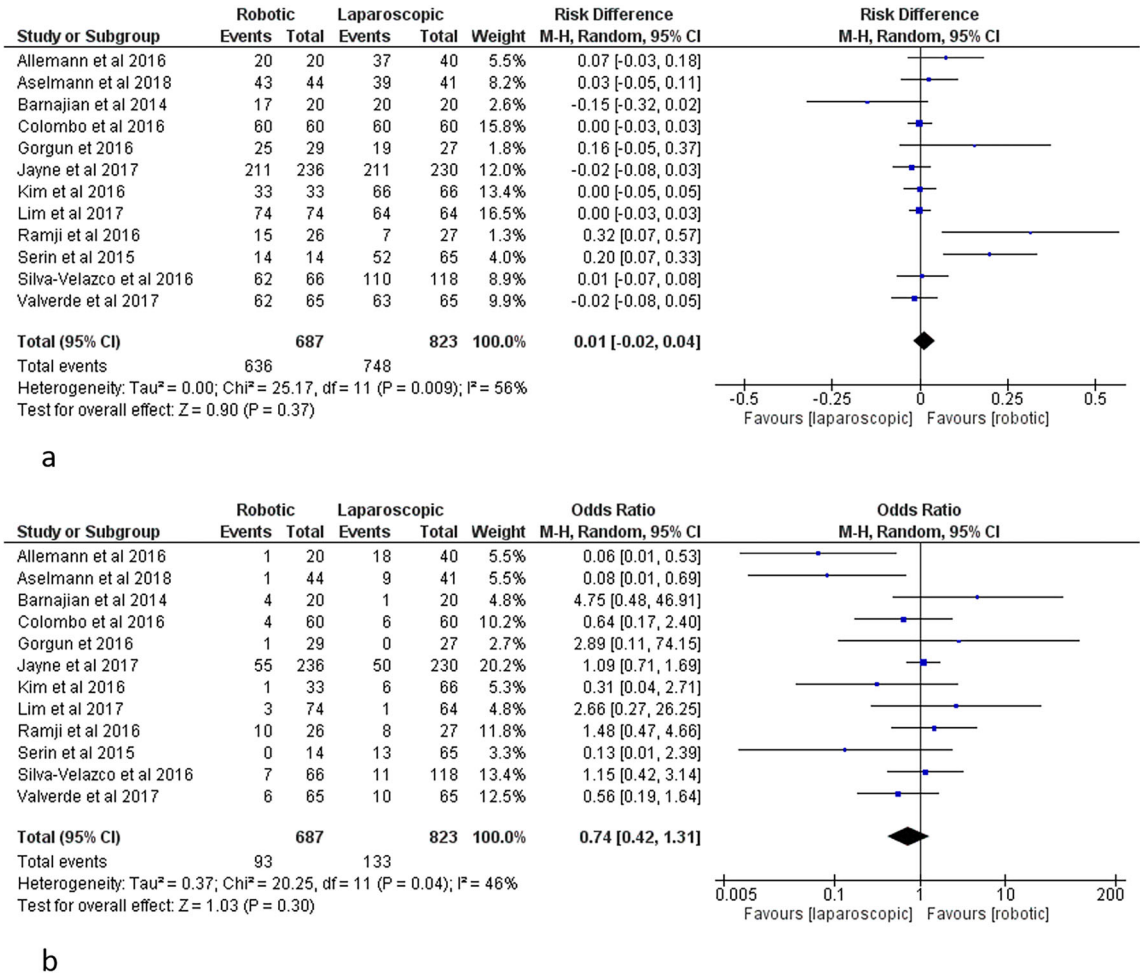

Fig. 4 Combined analysis: **a** acceptable TME and **b** non-complete TME

significant heterogeneity among the studies ($I^2 = 56\%$, $p = 0.009$ and $I^2 = 46\%$, $p = 0.04$, respectively).

Meta-regression analysis

Meta-regression analysis showed that none of patients' and tumors' characteristics (age, male gender, BMI, ASA Score, neoadjuvant chemoradiotherapy, tumor's localization, and AJCC stage) significantly impacted on complete TME.

Publication bias

Because it is recognized that publication bias can affect the results of meta-analyses, we attempted to assess this potential bias using funnel plot analysis. The distribution of studies evaluating primary and secondary outcomes was symmetrical, and no publication bias was found by the Egger's test ($p = 0.11$, $p = 0.37$, $p = 0.69$, $p = 0.08$, and $p = 0.25$, respectively (Appendix Figs. 6, 7, and 8).

Discussion

The main focus in cancer surgery is to optimize cure and to maximize quantity and quality of life with and minimization of treatment complications. Although high-quality evidence indicates that minimally invasive treatment of colon carcinoma is better than the open approach in terms of short-term and long-term safety and quality outcomes, nothing can be affirmed with certainty on the carcinoma of the rectum.

The only certain data in literature is the TME approach which has remained the gold standard surgical treatment for rectal cancer since its introduction in 1986; moreover, the quality of the TME has been shown to be a significant prognostic factor for cancer-specific survival. This technique has evolved from traditional "open" to minimal access approaches, such as laparoscopic, robotic, and more recently, transanal techniques. However, we are still far from identifying one as better or even equivalent to the others.

Minimally invasive surgery has been one of the most critical changes in surgical practice over the past several years. Advances in device and technique have enabled the minimally

invasive resection surgery to be applied to complex surgical procedures.

On the other hand, although this kind of approach provides obvious advantages on recovery outcomes and recent literature have demonstrated the superiority of a laparoscopic approach to TME [25], oncological radicality of minimally invasive surgery has been recently questioned. It is worth mentioning that recent results advocated the incompleteness of TME after laparoscopic surgery. Indeed, Stevenson and colleagues [5], in the ALaCaRT randomized clinical trial which involved patients with T1–T3 rectal adenocarcinoma, described a successful resection for 194 patients (82%) in the laparoscopic surgery group and for 208 patients (89%) in the open surgery group, with better results on TME completeness (92% vs 87%) in the open approach. Similar evidence was found by Fleshman et al. [6] in the ACOSOG Z6051 randomized clinical trial; also in this case, better results were found in favor of open surgery despite laparoscopy, particularly in terms of complete TME (95% vs 92%) and successful of resection (86% vs 81%).

By this point of view, we can talk of a literature "pre- and post ACOSOG-ALaCaRT" because these two RCTs were a real watershed for the rectal surgery.

In order to obtain an aggregate estimation of safety and efficacy of laparoscopic surgery for rectal cancer, meta-analyses were designed by different authors. Particularly, in the meta-analysis by de' Angelis et al. [26], including 14 studies, it was demonstrated that the rate of noncomplete total mesorectal excision was significantly higher in the laparoscopic group, while no significant differences were found about CRM and DRM involvement when compared with the open surgery group. The most recent meta-analysis, by Creavin et al. [27], including the latest 4 RCTs, showed a higher complete mesorectal excision in open group, while no significant differences were showed in terms of DRM and CRM, confirming the results of de' Angelis; in addiction, this author reported also on the grade of mesorectal excision (intact, superficial and deep mesorectal defects), underlining that it allows assessment of the quality of rectal resection and aids in the prediction of local recurrence risk. Creavin found an acceptable mesorectum (intact or superficial defects only) was present in 95.9% and 96.5% in the laparoscopic and open groups respectively, specifying that superficial mesorectal defects were more common in laparoscopic resections. The author hypothesizes that superficial defects are more common in laparoscopic surgery owing to grasping or traction tears from laparoscopic instruments, ultimately resulting in discrepancies in resection specimens.

Since the introduction of robotic total mesorectal excision (RTME), many reports have shown not only the feasibility but also the safety of this approach; RTME may be advantageous in the dissection of the avascular plane between the presacral fascia and the fascia propria of the rectum without injury to the integrity of the mesorectum in the narrow pelvic cavity. On the other hand, the same studies questioned the efficacy of robotic approach and this conflicting literature made necessary the realization of meta-analysis to compare laparoscopic and robotic rectal cancer surgery. Li [28] and Prete [29], on 17 case–control studies and five trials respectively, conclude that RTME in patients with rectal cancer was associated with a lower rate of conversion, longer operative time, and equivalent long-term oncological and function outcomes than in LTME. Same results were collected by Wang [30] and Xiong [31] in their review with meta-analysis on 8 studies each: they found no significant differences in operation time, estimated blood loss, recovery outcome, postoperative morbidity and mortality, length of hospital stay, and the oncological accuracy of resection and local recurrence between laparoscopic and robotic groups.

All cited literature meta-analyses failed to consider the completeness of mesorectum excision.

Starting from this assumption and considering the lack of a gold standard for rectal cancer surgery, we designed, for the first time, a meta-analysis which included the studies specifically providing the outcome of complete TME in robotic versus laparoscopic approach.

By pooling together 1510 procedures (687 robotic and 823 laparoscopic), we are able to show that robotic surgery could be considered the better way to obtain completeness of total mesorectal excision; our data also underline no differences between laparoscopic and robotic approach in terms of nearly complete and incomplete TME. Furthermore, considering the aggregate date of acceptable TME and non-complete TME, no significant differences were found between the two procedures. The data analysis could carry out the conclusion that laparoscopic approach determines a higher incidence of nearly complete TME.

In details, the studies included in our meta-analysis which express the superiority of robotic surgery in terms of completeness of TME were as follows: Allemann and colleagues [13], who found a better quality of RTME against LTME (complete TME, 95% vs 55%); also Aselmann et al. [14] compared 44 RTME and 41 LTME underlining that the quality of the TME specimen was significantly better in the RTME group and the conversion rate tended to be lower in the RTME group. Same results were obtained by Kim et al. [19], who, in their analysis on 33 RTME and 66 LTME, found that TME quality was complete in 97.0% in the robotic group and 91.0% in the laparoscopic group. The quality of mesorectum was in favor of the robotic approach also in the study of Serin [22] in his work on 65 LTME and 14 RTME (80% vs 100% respectively).

In a single-center analysis of 130 consecutive patients, Valverde and colleagues [24] obtained a complete

mesorectum excision in 88% for RTME vs 82% of LTME, with a greater conversion rate in the laparoscopic group.

Finally, Jayne and colleagues [15], in the ROLARR trial among 471 randomized patients to robotic-assisted ($n = 237$) or conventional ($n = 234$) laparoscopic rectal cancer resection, found a non-inferiority of robotic approach in terms of completeness of TME, postoperative complications, and 30-day mortality.

However, it has to be highlighted that we found a significant heterogeneity among the included studies and this is probably due to the confounding effect of patients' demographic and oncological features of the various populations involved; for this reason, we realized all possible meta-regressions to investigate the influence of patients' and tumors' characteristics on the primary outcome, founding there is no impact of these parameters. Moreover, we can assess that none of patients' and tumors' characteristics (age, male gender, BMI, ASA Score, neoadjuvant chemoradiotherapy, tumor's localization, and AJCC stage) significantly impacted on completeness of TME.

Thus, our results are encouraging to consider that the robotic approach to rectal resection is the better way to obtain a complete TME resection. According to Creavin and considering that robotic instruments are more comfortable, this could be due to the lower amount of grasping and traction required on the tissues which causes shearing of the mesorectal envelope.

However, another limitation of our study is the lack of high-quality studies in literature about the completeness of TME between the two minimally invasive approaches: between the 12 papers included in our analysis, just Jayne et al. [18] realized a randomized controlled trial and this could determine a poor power of the available evidences. Moreover, we have to underline that we recorded a high number of upper rectum treated with TME (from 30.05 to 43.33%) and this can be considered an important patients' selection bias in the analyzed studies.

Basing on the completeness composite outcome, it is mandatory that randomized clinical trials should be performed to assess definitively if robotic minimally invasive surgery is safe and effective as laparoscopic resection.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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