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ORIGINAL ARTICLE

Robotic-assisted right colectomy versus laparoscopic approach: case-matched study and cost-effectiveness analysis

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Abstract

Aim The aim of this study is to compare clinical and oncological outcomes of robot-assisted right colectomy with those of conventional laparoscopy-assisted right colectomy, reporting for the first time in literature, a cost-effectiveness analysis.

Methods This is a case-matched prospective non-randomized study conducted from October 2013 to October 2017 at Sanchinarro University Hospital, Madrid. Patients with right-sided colonic adenocarcinoma or adenoma, not suitable endoscopic resection were treated with robot-assisted right colectomy and a propensity score-matched (1:1) was used to balance preoperative characteristics of a laparoscopic control group. Perioperative, postoperative, long-term oncological results and costs were analysed, and quality-adjusted life years (QALY), and the cost-effectiveness ratio (ICER) were calculated. The primary end point was to compare the cost-effectiveness differences between both groups. A willingness-to-pay of 20,000 and 30,000 per QALY was used as a threshold to recognize which treatment was most cost effective.

Results Thirty-five robot-assisted right colectomies were included and a group of 35 laparoscopy-assisted right colectomy was selected. Compared with the laparoscopic group, the robotic group was associated with longer operation times (243 min vs. 179 min, $p<0.001$). No significant difference was observed in terms of total costs between the robotic and laparoscopic groups (9455.14 vs 8227.50 respectively, $p=0.21$). At a willingness-to-pay threshold of 20,000 and 30,000, there was a 78.78–95.04% probability that the robotic group was cost effective relative to laparoscopic group.

Conclusion Robot-assisted right colectomy is a safe and feasible technique and is a cost-effective procedure.

Keywords Robotic right colectomy · Cost-effectiveness analysis · Cost analysis · Oncological outcomes

Background

A new development in minimally invasive surgery is the robot-assisted right colectomy (RAC). The advantages of RAC include improved visualization due to a three-dimensional and magnified image with a stable camera platform, the advanced dexterity of instruments, and the possibility of the surgeon solely controlling the camera and assist arm, allowing maximal control [1–3]. These benefits may improve clinical and oncological outcomes in colorectal surgery, but the cost remains the main controversial issue of this approach that may restrict its application [4]. When a new technique is evaluated, not only cost must be investigated, but above all, its financial implications on health performing a cost-effectiveness analysis; cost-effectiveness analysis is the only kind of study that can effectively evaluate the economic differences between two different approaches by including in its analysis the impact on the quality of life of the patient.

The aim of this study is to compare short- and long-term results of RAC with the laparoscopic surgery approach performing a cost-effectiveness analysis.

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Materials and methods

Patient characteristics

We prospectively analysed patients treated at our institution with RAC from June 2013 to June 2017. Inclusion criteria were patients with cecum, ascending or proximal transverse colon adenocarcinoma or adenoma, not suitable for endoscopic resection. We excluded patients with previous other malignancy, patients with distant metastasis and patients with acute emergent cases (i.e., perforation or obstruction). Inclusion in the robotic group depended on authorization of health insurance companies i.e. all patients whose companies authorized the robotic surgery were subjected to RAC.

A 1:1 propensity case-matched study design was used to compare the result of RAC with the result of the laparoscopic right colectomy (LAC). A matched group of patients treated from June 2014 to June 2018 with LAC was extracted from a prospective cohort of patients who underwent surgery in the same centre. Patients were matched by age, gender, body mass index (BMI), American Society of Anesthesiology (ASA) score, malignancy, and tumour size.

The study was approved by the institutional review board and every patient gave signed a consent form.

Surgical technique

The procedures were performed by eight surgeons, all of them with laparoscopic experience. Five of the surgeons had experience with a robotic system and had completed a training program 3 years prior to the initiation of this study. Patients of the beginning of learning curve in the robotic group were included.

RAC was performed using a da Vinci Robotic Surgical System Model Si and Xi (Intuitive Surgical, Sunnyvale, CA, USA). Ileocolic vessels were identified and divided at their root close to the superior mesenteric vein. Subsequently, right colic vessels if present were identified and divided. After omentum division, the hepatic flexure was taken down and colon mobilization was completed with incision of lateral peritoneal attachments. In case of cancer of the hepatic flexure and proximal transverse colon, an extended right hemicolectomy was realized dividing the ileocolic, right colic, and middle colic vessels. After colon and ileon division, an intrabdominal ileo colic isoperistaltic biplane anastomosis with four running suture was performed.

The laparoscopic technique was carried out in a manner similar to the robotic technique and ileo colico handsewn biplan anastomosis was performed extracorporeally.

Clinical and oncological outcomes

The main patient demographic characteristics, age, sex, ASA score, BMI preoperative TNM stage were evaluated, and compared between both groups. Perioperative data were evaluated as well as surgical time, intraoperative transfusion and surgical approach. The duration of surgery was calculated as skin-to-skin time.

Postoperative morbidity was stratified according to the Clavien–Dindo classification system [5].,and severe morbidity was identified when grade ≥ III occurred. Anastomosis leakage was diagnosed whenever there existed a clinical suspicion (change in the drainage, fever or abdominal pain) and this diagnosis was always corroborated by the extraluminal presence of a contrast observed during a control CT. Disease-free survival (DSF) and overall survival (OS) were estimated from the time of diagnosis. Postoperative adjuvant chemotherapy was recommended for stage III or high-risk stage II patients. From week 3 to 4 after discharged, the adjuvant chemotherapeutic protocols were administrated. Follow-up consisted in periodic revision every 3 months for the first 2 years, every 6 months for the next 3 years, and yearly thereafter. Physical examination, complete blood test, serum carcinoembryonic and antigen tests and abdominopelvic CT were performed. Colonoscopies were done 1 year after the surgery and once every 2 years thereafter. Recurrent disease was assessed based on the clinical, laboratory, diagnostic imaging, and pathological findings.

Statistical analysis

Data have been recorded in a SPSS Statistics Version 20.0 database. Continuous variables are reported as medium with interquartile range and categorical variables as the absolute frequency and percentage, respectively. Variables are compared with the Wilcoxon rank-sum test and Chi-squared for quantitative and qualitative data, respectively. Disease-free survival and overall survival were calculated with the Kaplan–Meier method and log-rank test.

Cost analysis

The Institute of Validation of Clinical Efficacy (IVEC in Spanish) of the HM Hospitals group calculated the costs ascribed to each patient's treatment. The acquisition or maintenance of the robotic device was not considered. For each patient, cost data were assessed by gathering all costs of care during the hospital stay (including floor, intensive care unit, operating room, pharmaceutical, post-anaesthesia care unit, laboratory and pathology, and radiology costs).

Operating room costs included the costs of operative time (calculated per minute) and equipment (robotic and laparoscopic instruments, energy devices and staplers) calculated by each surgical procedure. Costs were not adjusted for inflation. The overall cost also included any 30-day hospital readmissions. The direct costs of the professionals involved have not been calculated. All costs are expressed in Euro.

QALY analysis

QALYs were estimated at 1 year following the procedure for each patient using the medical outcomes study SF-36 questionnaire (Spanish form) administered by mail to each patient, 1, 3, 6 months and 1 year after surgery. Using the Nichol method, the eight subscales of the SF-36 were used to calculate the Health Utilities Index 2 (HUI2) score [6]. Data were elaborated and scored at a minimum of 1 year post-operatively.

A model-based cost-utility analysis estimating mean costs and QALYs per patient was performed [7].

Cost-effectiveness study

A stochastic cost-utility analysis was undertaken, whereby the incremental cost-effectiveness ratio (ICER) was estimated using overall costs of the RAC and LAC procedures and QALYs derived from patient interviews, to find the incremental cost per QALYs gained [8, 9].

Net monetary benefits (NMBs) were calculated to estimate the maximum willingness to pay (WTP) of decision makers for a QALY gained. The NMB was calculated as the mean QALYs per patient multiplied by WTP threshold minus the mean cost per patient for the treatment. The decision rule is to adopt the treatment if the NMB > 0, and the alternative with the highest NMB represents the best value for money.

Sensitivity analysis

For the cost-effectiveness analysis, a sensitivity analysis was carried out to propagate the uncertainty of the estimations to the results of the model. A multivariate and stochastic sensitivity analysis was performed by 5000 Monte Carlo simulations. The cost-effectiveness plane was used to represent all pairs of solutions of the model. The results of the one-way sensitivity analysis are shown in the tornado diagram, and graphically depicts how variations in each input affect the outcome. The 95% confidence intervals around the base case values were derived using the 2.5 and 97.5 percentiles calculated from the sensitivity analysis.

The tornado diagram is stacked in order of decreasing width, indicating that variations in inputs near the top (Total Costs RDP) have the greatest effect on the outcome, while variations in inputs near the bottom (QALYs discount rate) have a relatively small effect on the outcome.

Acceptability curve

We also computed a cost-effectiveness acceptability curve which plots the probability that the RAC was cost-effective relative to LAC over a reasonable range of levels of willingness-to-pay.

Although in Spain, there is no defined willingness-to-pay threshold in healthcare, according to the National Institute for Health Care Excellence (NICE), we used a willingness-to-pay of 20,000 € and 30,000 € per QALY as a threshold to recognize which treatment was most cost effective [9].

Results

During the study period time, a total 35 RAC were performed at our centre and were matched with 35 LAC; preoperative patients' characteristics were similar in the two groups and are shown in Table 1.

As shown in Table 2, the mean operative time was significantly higher in the RAC group compared to the LAC (243 min vs. 179 min; $p = 0.01$) and there was no significant difference in terms of intraoperative transfusion and conversion rate.

With respect to the surgical specimen, the margin rate that was found to be negative in all patients and the number of retrieved lymph nodes was similar in the two groups as shown in Table 2. Regarding the postoperative results, no differences were found in terms of postoperative complication and length of stay. Finally, we observed a statistical difference in the postoperative transfusion rate which was inferior in the robotic group (Table 3).

With a median follow-up of 30, 4 months (range 7–70 months), DFS and OS were similar in the RAC and LAC groups (Figs. 1 and 2).

Cost-effectiveness analysis

A summary of costs is shown in Table 4. The incremental cost of the RAC approach vs LAC was 1227.64 € and the incremental utility was 0.105 QALYs. The estimated ICER for patients was 11,691.81 € per QALY gained in favour of RAC.

Operative costs were higher in the RAC group but hospitalization, radiological and laboratory costs were lower than LAC. Total costs of the robotic and the laparoscopic

Table 1 Patient characteristics

	Robotic group ($n=35$)	Laparoscopic group ($n=35$)	p
Sex			
Male	23	20	0.31
Female	12	15	
Age, years, mean (range)	69.6 (55-83)	68.2(32-84)	0.21
ASA score			
I	4	4	0.52
II	24	233	
III	3	8	
IV	0	0	
BMI Kg/m^2, mean (range)	23 (19-31)	25 (20–34)	0.11
CEA ng/ml, mean (range)	5.2 (0.72-28.32)	2.4 (0.88–6.21)	0.1
Histopathological data			
Adenocarcinoma	32	32	1
Adenoma	3	3	
Tumour size, cm, mean (range)	3.3 (2.4-8)	3.2(0.3-10)	0.95

Table 2 Operative results and histopathology

	Robotic group ($n=35$)	Laparoscopic group ($n=35$)	p
Operative time, min, mean (range)	243 (140–380)	179 (120–270)	0.01
Conversion	28	29	0.36
Intraoperative	2	1	
Transfusion, ml, mean (range)	80 (0–1600)	80 (0–800)	0.95
Total nodes	15.8	15.4	0.42
Positive nodes	0.5	1	0.98
pTNM			
Stage I	9	7	0.51
Stage II	17	18	
Stage III	6	7	
Perineural invasion			
Present	3	4	0.36
Absent	22	21	
Differentiation			
G1	7	5	0.37
G2	20	24	
G3	5	3	

approaches showed no statistical difference (9455.14 € vs 8227.50 € respectively, $p=0.21$). Probabilistic sensitivity analysis, estimated by Monte Carlo simulations, demonstrated that the probability that the robotic approach was cost-effective at a WTP threshold of 20,000 € and 30,000 € per QALY gained was 78.78% and 95.04%, respectively (Fig. 3).

The results of NMB analysis are shown in Table 5. RAC showed increased costs and increased QALYs compared to LAC, resulting in a higher NMB.

The acceptability curve (Fig. 4) shows that RAC had a higher probability of being more costeffective than LDP when a WTP more than 11,912 €/QALY was accepted.

Table 3 Postoperative results

	Robotic group ($n=25$)	Laparoscopic group ($n=25$)	*p*
Length of stay	8.3	8.7	0.43
Postoperative complication			
Present	8	9	0.76
Absent	27	26	
Clavien > 3			
No	32	31	0.76
Yes	3	4	
First flatus, days (range)	2.7 (2–4)	3 (1–7)	0.21
Postoperative blood transfusion	0	100 (0-300)	0.041

The results of the tornado diagram are shown in Fig. 5. This demonstrates a significant uncertainty in the input cost, but not especially in the input of health status (QALYs).

Discussion

The methodology of this study was designed to compare two different operative modalities and techniques: the robotic versus laparoscopic approach for patients with right colon cancer. We believe that this comparison would be much more effective in assessing the logic behind using the robotic technique in clinical practice, which has been evolving to reduce the limitations of the laparoscopic approach.

Indeed the laparoscopic approach has several limitations, such as tremor, a two-dimensional view, an inability to perform high-precision suturing, poor ergonomics, fixed tips, and limited movement dexterity. For these reasons, the possibility of performing an intra-abdominal anastomosis using the robotic approach is more feasible, safer and easier than the laparoscopy approach, with the same outcomes. Several studies show that robotic colorectal surgery is associated with better short-term outcomes than laparoscopy surgery, and the benefits include reduced postoperative pain and reduced duration of ileus, as well as a shorter hospital stay [1–3, 10]. According to the results in the literature, in our study, patients who underwent RAC received fewer postoperative transfusions and present a similar length of stay and the same rate of postoperative complications compared with LAC.

Moreover, several studies confirm that disease-free survival and overall survival do not differ between RAC and LAC. In 2010, D'Annibale et al. evaluated the survival rates in 50 patients who underwent robotic right colectomy, with a median follow-up of 36 months, with a DFS and OS of 90% and 92%, respectively [11]. Kang et al. reported similar results among the open, laparoscopic and robotic surgery in the management of right-sided colon cancer (87.7%, 84%

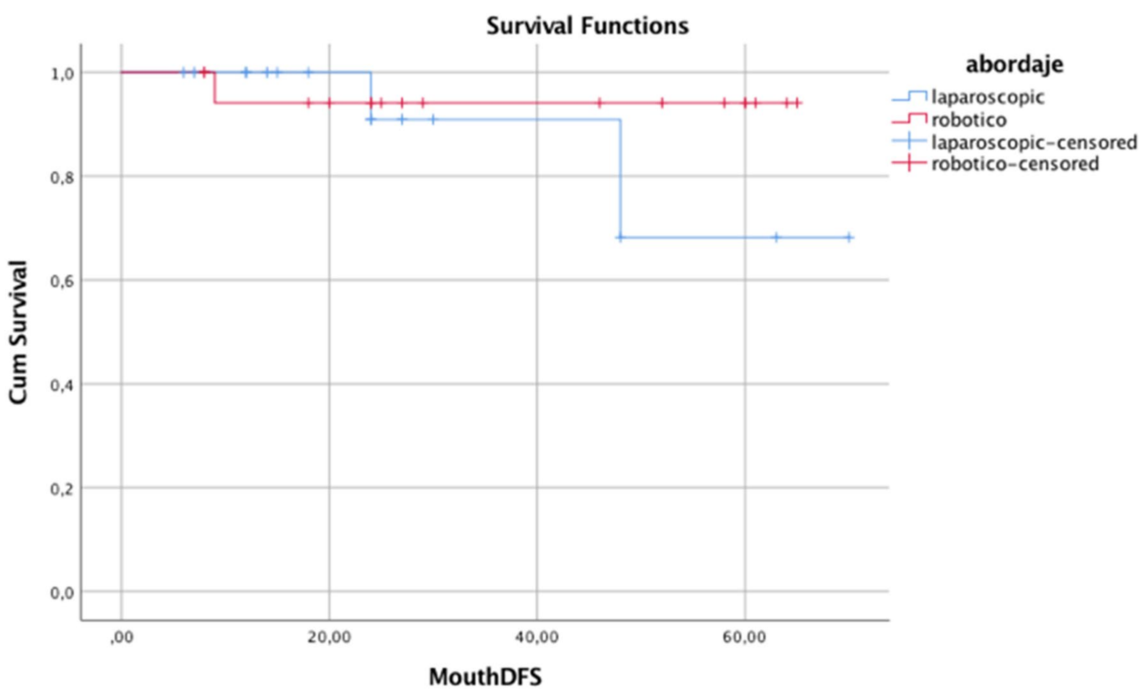

Fig. 1 DFS between RAC and LAC (Log rank = 0.696)

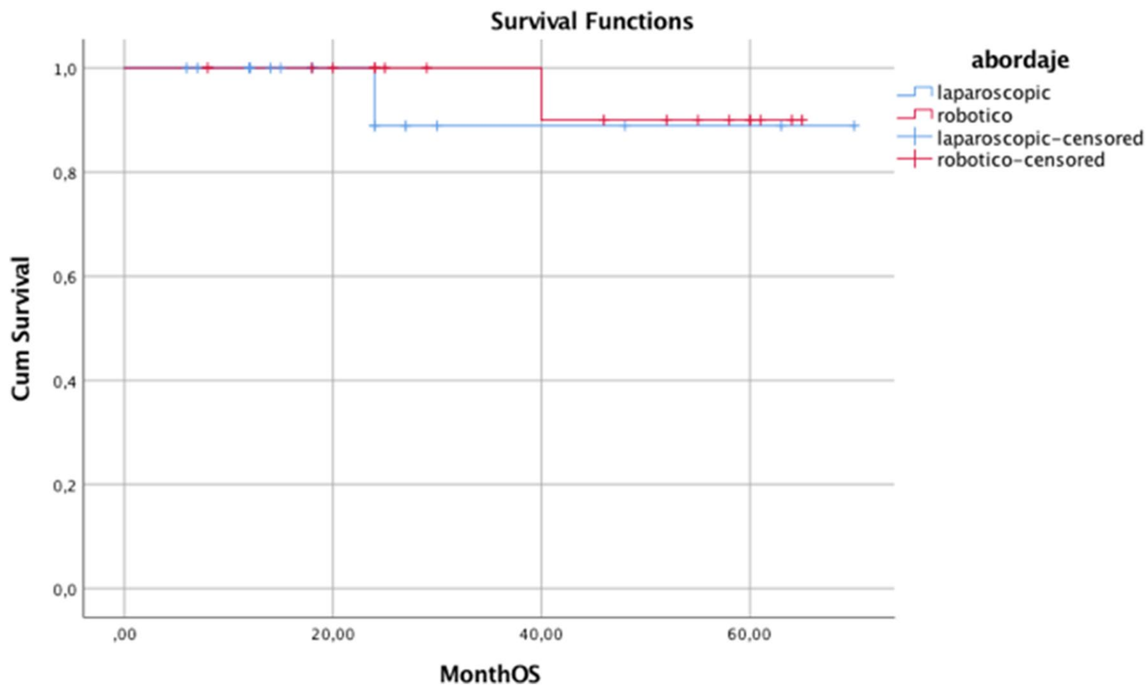

Fig. 2 OS between RAC and LAC (Log rank = 0.377)

Table 4 Financial data stratified by approach

	Robotic ($n = 20$)		Laparoscopic ($n = 20$)	
	Mean (€)	CI 95% (lower; upper) (€)	Mean (€)	CI 95% (lower; upper)
Hospitalization cost	2446.87	1963.07; 2930.65	2940.6	1952.90; 3928.45
Operative cost	6423.77	5267.42; 7580.11	4415.2	3849.35; 4981.04
Laboratory cost	529.48	327.04; 731.90	780.06	359.28; 1200.84
Radiology cost	55.02	22.14; 87.89	91.56	31.22; 151.88
Total cost	9455.14	7868.44; 11,041.82	8227.5	6437.86; 10,017.13
Utility				
Qaly	0.826	0.769; 0.883	0.721	0.663; 0.779
Incremental results				
Incremental cost (€)	1227.64 (95% CI 1200.14–1255.13)			
Incremental utility (Qaly)	0.105 (95% CI 0.1044–0.10,555)			
ICER (€/Qaly)	11,691.81			

and 89.5%, respectively) [12]. Our study confirmed these results with a DFS of 90% and 85% and an OS of 95% and 95% for the robotic and laparoscopic groups, respectively.

The major limitations of the robotic approach remain the operative time and, above all, an increase in cost.

First, the problem of the long operation time was widely reported for robotic colorectal surgery [4]. As we described in our series, operative time was superior in the robotic group (243 min) with respect to the laparoscopic one (179 min). Many factors influence operation times, and these factors include setup time, docking time, the fact that RAC group included patient in the beginning of the learning curve, and the type of anastomosis. However, these are all factors in the phase of improvement, in particular for the technical system, which is a subject of study in the new technology fields. The learning curve, according several authors, is reduced in comparison to the laparoscopic approach, and the robotic approach should reduce the time taken for intra-abdominal anastomosis [12, 13].

Second, this study analyses the problem of costs, and the most important results of the analysis is that in our series, the costs are comparable between the laparoscopic and the robotic approaches. All data were submitted to a multivariate analysis considering the following: diagnostic costs

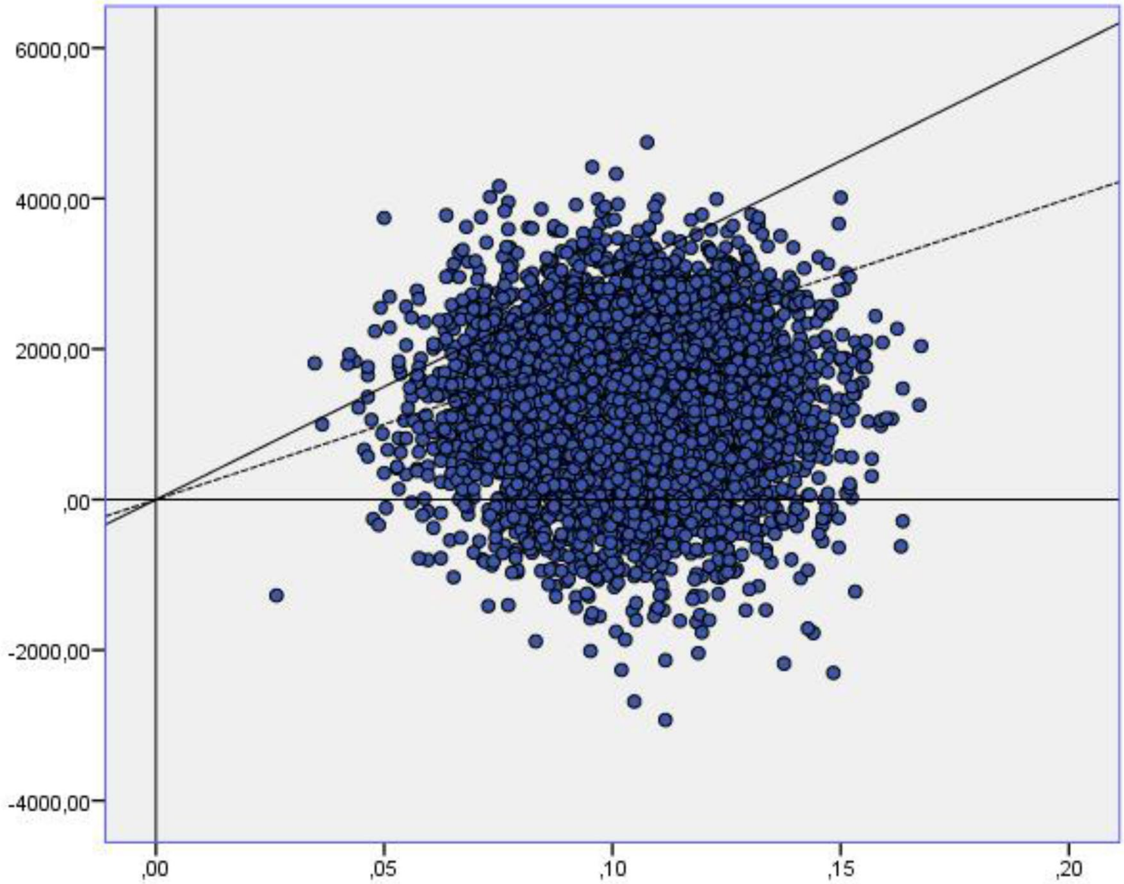

Fig. 3 Cost-effectiveness plane

Table 5 Net monetary benefit

Treatment	Cost	Qalys	Net monetary benefit (€)	
			20,000	30,000
Robotic	9455.14 (95% CI 7868.44–11,041.82)	0.826 (95% CI 0.769–0.883)	7064.86 (95% CI 6618.18–7511.56)	15,324.86 (95% CI 15,201.56–15,448.18)
Laparoscopic	8227.50 (95% CI 6437.86–10,017.13)	0.721 (95% CI 0.663–0.779)	6192.50 (95% CI 5562.87–6822.14)	13,402.5 (95% CI 13,352.87–13,452.14)
Incremental	1227.64 (95% CI 1200.14–1255.13)	0.105 (95% CI 0.1044–0.10555)	872,36 (95% CI 855,87–887,86)	1922.36 (95% CI 1911.37–1922.36)

(laboratory and radiological costs), costs of surgical procedure and hospital stay. Analysis of cost effectiveness lead by an independent company reveals similar outcomes.

However, the simplistic overall cost of an operation can only provide limited information on the benefits of a new technique. Only a cost-effectiveness analysis can help to understand the real difference between two operations. To our knowledge, this is the first study reporting cost-effectiveness analyses between robotic and laparoscopic right colectomy.

This cost-utility analysis showed that RAC resulted in similar costs compared to LAC and an increase in QALY (0.105 QALY per patient). In fact, the majority of the replications obtained with the bootstrap method were found in the northeast quadrant of the cost utility plot (uncertain quadrant). To explore the acceptability of RAC cost, we also calculated the ICER in relation to willingness-to-pay thresholds, generally used in the UK as a reference in Europe, per QALY gained.

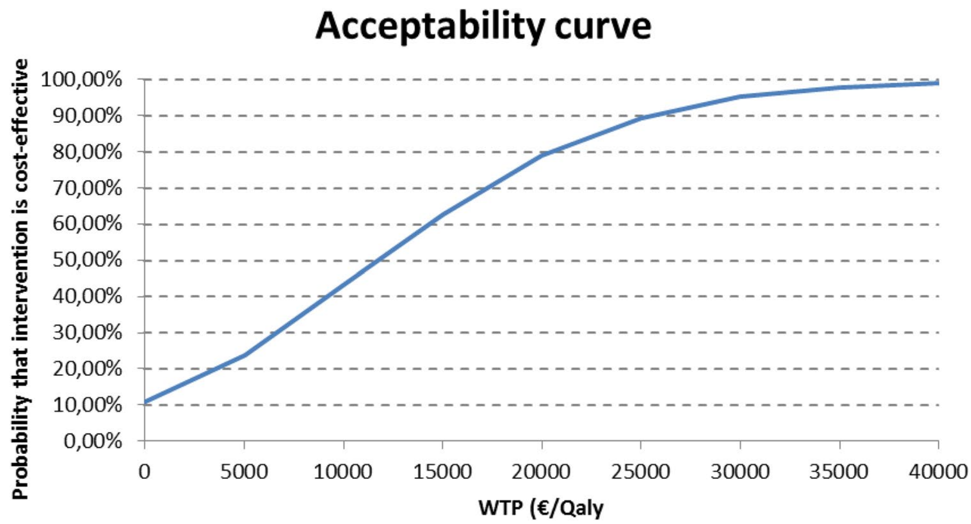

Fig. 4 Cost-effectiveness acceptability curve

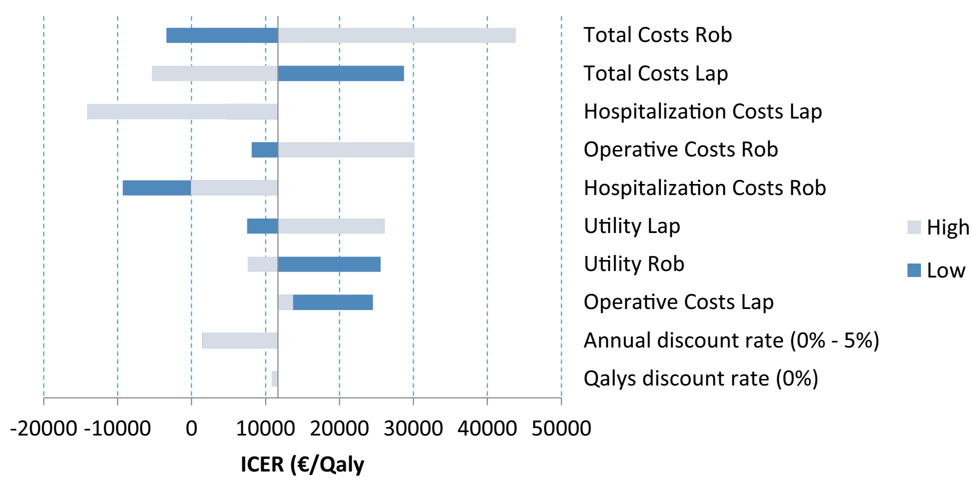

Fig. 5 Sensitivity analysis

The probability of RAC being cost effective compared to LAC was 78.78% and 95.04%, for a WTP of 20,000–30,000 €, respectively, which is the specific acceptability European threshold.

According to the acceptability curve depicted in Fig. 4, RAC starts to have a higher probability of being more cost effective than LAC when a WTP more than 11,912 €/QALY is accepted. The results of this study underline that RAC is a cost-effective procedure compared to LAC.

Our study shows similar clinical results in the robotic and laparoscopic approach, with no cost savings but, for the first time, there is an apparent improvement in the quality of life of the patients in favour of the robotic group.

The small number of patients represent the main limitation of this study. The unicentric nature of our study and the small number of surgeons who performed all of the procedures guarantee the homogeneity of the two groups analyzed. In our opinion, studies that use costs from a single hospital system may be more informative for a detailed cost analysis and cost-effectiveness analysis than multicenter studies. Moreover, in our study, an independent company performed the financial analysis, thus eliminating the risk of an observer bias.

Conclusion

In conclusion, results from our study suggest that the robotic approach for the RAC represents a technically feasible and safe procedure that yields comparable short- and long-term outcomes in terms of short-term morbidity compared to the LAC. Furthermore, this paper is the first cost-effectiveness study regarding robotic right colectomy, and highlights that RAC is acceptable in terms of cost effectiveness in health care. Future prospective randomized trials are needed to define its role for the treatment of right colectomy, as the surgical management of right-sided colonic disease is evolving.

Compliance with ethical standards

Conflict of interest Author declares no conflict of interest.

Ethical approval This study was approved by the Ethics Committee of the Sanchinarro Hospital, San Pablo University. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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