

482PD Robot-assisted vs laparoscopic vs open abdominoperineal resections for low rectal cancer: Short-term outcomes of a single-center prospective randomized controlled trial

J. Xu, Y. Wei, L. Ren, Q. Feng, J. Chen, D. Zhu, W. Chang, T. Yi, L. Yang, X. Qin
General Surgery Department, Zhongshan Hospital, Fudan University, Shanghai, China

Background: Currently, robotic surgery for rectal cancer using da Vinci System is common. However, there is almost no clinical trial reported. This randomized controlled trial aims to compare the safety and efficacy of robot-assisted, laparoscopic and open abdominoperineal resection (APR) for low rectal cancer.

Methods: From 2013-09 to 2017-03, patients aged from 18 to 75 years, with low rectal cancer within 5 cm from anal verge, clinical T1 to T3, no distant metastases, were randomly assigned to receive either robot-assisted procedures (RAP), laparoscopic procedures (LAP) or open surgery (OS) for APR in 1:1:1 ratio. The primary endpoint was postoperative complication rate.

Results: Totally 506 patients were enrolled in this study, randomly assigned to RAP (n = 169), LAP (n = 169), and OS (n = 168). Actually, 3 patients refused surgery, 173 finished RAP, 176 finished LAP, and 154 finished OS (including 4 convert from LAP to OS). The open conversion rate was 0 in RAP and 2.4% in LAP, with no significant difference (P = 0.123). In per-protocol analysis, no significant difference was observed in tumor location, size, differentiation and pathological TNM stage, among the three groups. RAP had significantly lower postoperative complication rate (10.4%) than both LAP (18.8%, P = 0.027) and OS (26.0%, P < 0.001). Also, RAP reduced intraoperative hemorrhage (median, 100 ml) than LAP (130 ml, P < 0.001) and OS (200 ml, P < 0.001). And RAP promoted postoperative recovery, with shorter days to first flatus (1.0 day) than LAP (2.0 day, P < 0.001) and OS (3.0 day, P < 0.001), shorter days to first automatic urination (2.0 day) than LAP (3.0 day, P < 0.001) and OS (3.0 day, P < 0.001), and shorter days to discharge (5.0 days) than LAP (6.0 days, P < 0.001) and OS (6.0 day, P < 0.001). There was no significant difference in resection margin involvement and number of lymph node harvested. More details are shown in the table.

Conclusions: Robot-assisted APR was safe, and reproduce equivalent surgical quality of conventional laparoscopic and open surgery. Also, it provided less injury and faster functional recovery.

Table: 482PD Study results in per-protocol analysis

	RAP (n = 173)	LAP (n = 176)	OS (n = 154)	P value RAP vs. LAP	P value RAP vs. OS
Operating time, min (median, IQR)	205 (200-220)	195 (160-240)	160 (140-180)	0.002	<0.001
Intraoperative hemorrhage, ml (median, IQR)	100 (90-110)	130 (100-150)	200 (120-220)	<0.001	<0.001
Patients with perioperative transfusion, n (%)	0 (0)	2 (1.1)	3 (1.9)	0.499	0.103
Lymph node harvested, n (median, IQR)	16 (13-20)	16 (12-19)	15.5 (13-19)	0.576	0.748
Circumferential resection margin positive, n (%)	1 (0.6)	3 (1.7)	3 (1.9)	0.623	0.346
Days to first flatus (median, IQR) [#]	1.0 (1.0-2.0)	2.0 (2.0-3.0)	3.0 (2.0-4.0)	<0.001	<0.001
Days to first automatic urination (median, IQR) [#]	2.0 (2.0-3.0)	3.0 (2.0-4.0)	3.0 (2.0-4.3)	<0.001	<0.001
Days to discharge (median, IQR) [#]	5.0 (5.0-5.0)	6.0 (6.0-7.0)	6.0 (5.0-7.0)	<0.001	<0.001
Postoperative mortality, n (%)	0 (0)	0 (0)	0 (0)	–	–
Postoperative morbidity, n (%)	18 (10.4)	33 (18.8)	40 (26.0)	0.027	<0.001
Morbidity of Clavien-Dindo Grade III-IV, n (%)	2 (1.2)	6 (3.4)	5 (3.2)	0.284	0.261

RAP: robot-assisted procedures; LAP: laparoscopic procedures; OS: open surgery. IQR: interquartile range. #: excluded patients with complications.

Clinical trial identification: NCT01985698.

Legal entity responsible for the study: Jianmin Xu

Funding: None

Disclosure: All authors have declared no conflicts of interest.