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Long-term oncologic after robotic versus laparoscopic right colectomy: a prospective randomized study

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Abstract

Objective The aim of this study was to compare the long-term outcomes of robot-assisted right colectomy (RAC) with those for conventional laparoscopy-assisted right surgery (LAC) for treating right-sided colon cancer.

Background The enthusiasm for the robotic techniques has gained increasing interest in colorectal malignancies. However, the role of robotic surgery in the oncologic safety has not yet been defined.

Methods From September 2009 to July 2011, 71 patients with right-sided colonic cancer were randomized in the study. Adjuvant therapy and postoperative follow-up were similar in both groups. The primary and secondary endpoints of the study were hospital stay and survival, respectively. Data were analyzed by intention-to-treat principle.

Results The RAC and LAC groups did not differ significantly in terms of baseline clinical characteristics. Compared with the LAC group, RAC was associated with longer operation times (195 min vs. 129 min, $P<0.001$) and higher cost ($12,235 vs. $10,319, $P=0.013$). The median follow-up was 49.23 months (interquartile range 40.63–56.20). The combined 5-year disease-free rate for all tumor stages was 77.4% (95% confidence interval [CI], 60.6–92.1%) in the RAC group and 83.6% (95% CI 72.1–0.97.0%) in the LAC group ($P=0.442$). The combined 5-year overall survival rates for all stages were 91.1% (95% CI 78.8–100%) in the RAC group and 91.0% (95% CI 81.3–100%) in the LAC group ($P=0.678$). Using multivariate analysis, RAC was not a predictor of recurrence.

Conclusions RAC appears to similar long-term survival as compared with LAC. However, we did not observe any clinical benefits of RAC which could translate to a decrease in expenditures.

Trial registry: http://www.ClinicalTrials.gov, number NCT00470951.

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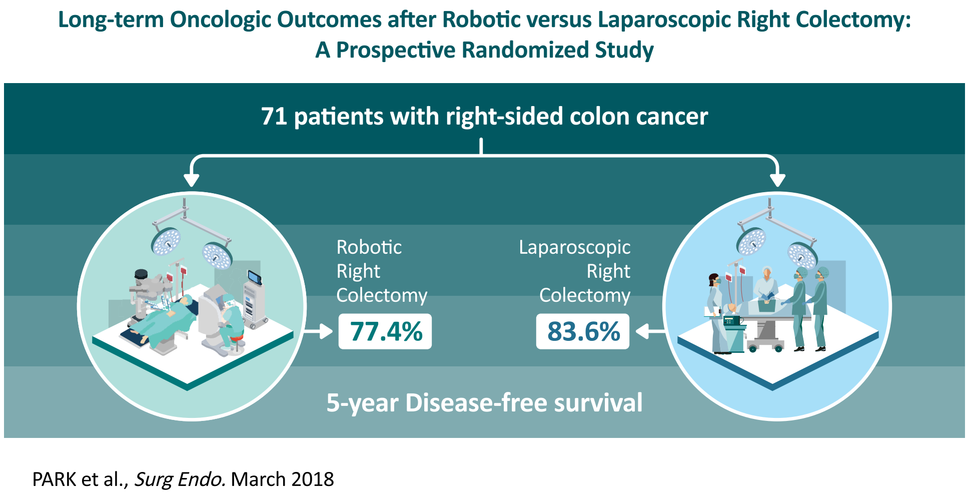
Graphical abstract



Keywords Robotic surgery · Laparoscopy · Survival · Right colon

Robotic surgical systems have a several technological advancement over conventional laparoscopic instrumentations, including a set of articulated instruments, a favorable learning curve and a tri-dimensional high-definition field of view. Following the successful introduction of robotic surgical system to the field of urology, its use gained even more interest among those in the field of general abdominal surgery. Since the first report in 2002, a number of case series and retrospective comparative studies were published showing the feasibility and safety of robot-assisted right colectomy (RAC) [1–4]. However, there have been no long-term results of RAC within a randomized trial.

We previously published the short-term results of a single center randomized clinical trial [5]. In this paper, we presented the results of our trial that assessed the surgical performances and cost efficacy with RAC versus laparoscopy-assisted right colectomy (LAC). Here, we present the data for long-term survival outcome.

Patients and methods

Patients with a diagnosis of cecum, ascending or proximal transverse colon adenocarcinoma were recruited from the colorectal cancer clinics at Kyungpook National Cancer Center (KNCC) between January 2010 and November 2011. The protocol had been approved by the KNUH institutional review board, and registered with http://www.ClinicalTrials.gov (NCT01042743). The reports from this trial follow the CONSORT statement when applicable [6].

Eligible patients were medically cleared for radical right colectomy and aged ≥ 18 year. Diagnosis of colon cancer was confirmed by a colonoscopic biopsy. For evaluation of distant metastasis, an abdominopelvic and a chest computed tomography (CT) were performed. For the purpose of this study, we excluded patients with previous other malignancy, clinical stage T4 or M1, unfitting cases for minimal invasive approach (i.e., en-mass size of the tumor > 8 cm), or acute emergent cases (i.e., perforation or obstruction).

Randomization

All patients provided written informed consent with detailed explanation. Consenting patients were randomly allocated to the robotic or laparoscopic procedure group (1:1) according to a computer-generated random sequence kept concealed by an independent clinical trial coordinator. A single experienced surgical team was made aware of the randomization on the day before surgery, and they performed all the procedures. Patients and clinicians could not be masked to treatment assignments. However, during the follow-up period, radiologists and pathologists were masked to the procedural allocation.

Surgical intervention and follow-up of patients

All patients had a mechanical bowel preparation the day before surgery. Standard procedures including standard or extended right with D3 lymph node dissection were performed depending on the location of tumor. Our standardized technique concerning D3 lymph node dissection was fully specified with some operation figures in the previous report of this trial [5]. A D3 lymph node dissection was considered to be performed when the superior mesenteric vein and the origin of middle colic vessel were entirely exposed in final operative findings. This technique had been applied to all of the 71 patients who participated in this clinical trial. An extended right hemicolectomy with an anastomosis between the ileum and the distal transverse colon had been typically performed for cancer of the hepatic flexure and proximal transverse colon. In the extended right hemicolectomy, the ileocolic, right colic, and middle colic vessels with their contiguous mesentery are divided and removed. Two approached were used for anastomosis creation. In the conventional extracorporeal approach, the specimen was extracted through a periumbilical minilaparotomy, and a traditional extracorporeal side-to-side anastomosis was created using a standard linear stapler. In selected cases, we modified parts of the conventional approach and performed a complete intracorporeal resection and anastomosis of the colon using an endo-linear stapler, as described previously. Postoperatively, all patients were placed on the identical treatment pathway, which is designed for a 5–6 day length of hospital stay. A single surgical team consisting of two surgeons (G.S.C. and J.S.P.) performed all procedures and G.S.C. was colorectal oncology fellowship-trained and had a minimum of 14-year operative experience in practice after fellowship. At trial initiation, he had performed > 400 laparoscopic right colectomy including 40 cases of benign disease and had performed about 30 robotic right colectomy for colon cancer. He underwent certificate training for robotic surgery before clinical trial. All procedures in the RAC group were performed with the da Vinci Si HD™ surgical system (Intuitive surgical Inc., Sunnyvale, CA, USA).

Postoperative adjuvant chemotherapy was recommended for stage III or high risk stage II patients. From week 3–4 after surgery, one of the three adjuvant chemotherapeutic protocols was administrated: (1) 5-fluorouracil and leucovorin (six cycles of an intravenous bolus injection of 5-fluorouracil [400 mg/m^2/day] and leucovorin [20 mg/m^2/day] on days 1–5 every 4 weeks); (2) capecitabine (eight cycles of capecitabine [1250 mg/m^2] twice daily for 14 days, followed by 7 days rest for each cycle); or (3) FOLFOX (12 cycles of oxaliplatin [85 mg/m^2/day] on day 1, 5-fluorouracil intravenous bolus [400 mg/m^2/day] on day 1, leucovorin [400 mg/m^2/day] on day 1, and continuous infusion of 5-fluorouracil [2400 mg/m^2] for 46 h every 2 weeks).

All patients were followed regularly according to a pre-established trial protocol and through an outpatient visit of same hospital. Our surveillance included medical history, physical examination, laboratory studies including serum carcinoembryonic antigen (CEA), and chest-abdominopelvic CT. The regular check-ups were performed at 3-month intervals for the first 2 years and then every 6 months. Colonoscopy was performed 1 year after surgery and every 3 years thereafter. The study coordinator entirely entered the follow-up date to trial data-base at each visit.

Outcomes and sample size

The primary outcome was the length of hospital stay. Secondary endpoints were morbidity, operation time, and 3-year disease-free survival (DFS). The hypothesis was that RAC would reduce hospital stay compared with LAC. Based on the authors' data and clinical pathway [7], we estimated a hospital stay for right colectomy to be 7 days and set the superiority margin at 1 day difference. It was calculated that this difference could be detected by a two-tailed test with $\alpha = 0.05$ (power 90%), and 35 patients in each group.

DFS after surgery, defined as the time of randomization to disease relapse, death from any cause, or development of second primary cancer, and assessed by a central independent reviewer. Recurrent disease was assessed based on the clinical, laboratory, diagnostic imaging, and pathological findings. Radiologists and pathologists independently assessed the radiological imaging and pathological specimens.

Statistical analysis

Data were analyzed by intention-to-treat principle. For continuous variables, data were presented as the mean ± standard deviation, and groups were compared using the unpaired *t*-test. The descriptive variables were analyzed by either Chi-squared analysis or Fisher's exact test, as appropriate. The probabilities of DFS and overall survival (OS) were estimated using the Kaplan–Meier method and Cox's proportional hazards model. Comparisons between curves were performed by the log-rank test. Significance was taken at the level of the P value < 0.05. For backward conditional Cox proportional hazards analysis, variables were chosen by $P < 0.05$ in univariate analysis, along with age and sex. All statistical analyses were performed using the SPSS 20.0 (IBM Corp., Armonk, NY, USA) and STATA 13.0 (College Station, TX, USA).

Results

Between September 2009 and July 2011, 86 consecutive patients diagnosed with right-sided colon cancer were assessed for eligibility; of these 15 did not meet the inclusion criteria. A total of 71 patients were subsequently enrolled into the study and randomized to either RAC ($n = 35$) or LAC ($n = 36$) (Fig. 1). One patient was excluded from analysis due to unexpected intraoperative findings; this patient had peritoneal tumor seeding that escaped detection by preoperative

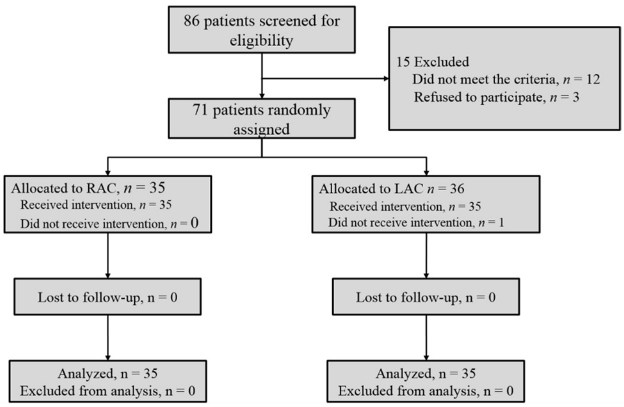


Fig. 1 Trial profile

Table 1 Baseline characteristics

	RAC ($n=35$)	LAC ($n=35$)	*P*
Age (years)[a]	62.8 (10.5)	66.5 (11.4)	0.105
Gender			0.629
Male	14 (40.0%)	16 (45.7%)	
Female	21 (60.0%)	19 (54.3%)	
BMI (kg/m^2)[a]	24.4 (2.5)	23.8 (2.7)	0.331
ASA classification			0.327
I	15 (42.9%)	21 (60.0%)	
II	16 (45.7%)	12 (34.3%)	
III	4 (11.4%)	2 (5.7%)	
Tumor location			0.697
Cecum	4 (11.4%)	4 (11.4%)	
Ascending colon	16 (45.7%)	13 (37.1%)	
Proximal transverse colon	15 (42.9%)	18 (51.5%)	
Postoperative chemotherapy			0.608
Fluropyrimidines alone	16 (45.7%)	17 (48.6%)	
Oxaliplatin-based	5 (14.3%)	6 (17.1%)	
None	14 (40.0%)	12 (34.3%)	
Preoperative serum CEA (ng/ml)[a]	4.5 (6.2)	2.8 (3.5)	0.147

RAC robot-assisted right colectomy, *LAC* laparoscopy-assisted right colectomy, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *CEA* carcinoembryonic antigen

[a]Values are mean (standard deviation)

imaging. The median follow-up time of living patients was 50.40 months (interquartile range 41.83–58.81 months) for the LAC group and 49.33 months (interquartile range 37.05–54.58 months) for the RAC group.

Baseline characteristics were similar between treatment groups (Table 1). Perioperative results, morbidity, and operative cost are summarized in Table 2. No patient in both groups required conversion to laparotomy. Estimated blood loss, mean length of hospital stay, and morbidity were similar in both groups, but operating time and the fashion of anastomosis (intracorporeal vs. extracorporeal) differed significantly (Table 2). A modified technique, involving an intracorporeal anastomosis followed by extraction of the specimen via off-the midline (i.e., Pfannenstiel or trans-vaginal incision), were conducted in seven patients in the LAC group and 30 in the RAC group ($P<0.001$). An extended right colectomy was performed in 14 patients in laparoscopic group, and 11 patients in robotic group ($P=0.454$). Neither late hospital readmissions nor late reoperations were significantly different for the RAC versus LAC group. Reoperation was necessary in one patient in the RAC group and LAC group due to anastomotic stenosis and incisional hernia, respectively. Pathologically, no differences were observed between the two groups in terms of tumor size, specimen length, and number of retrieved lymph nodes.

Table 3 shows the rates of DFS, and OS for the two groups. No significant difference was seen in 3-year and 5-year DFS (Table 3; Fig. 2). The hazard ratio (HR) for 3-year DFS for the RAC versus the LAC group, stratified by sex and age, was 1.21 (95% confidence interval [CI] 0.42–4.13). Three-year OS rate likewise did not differ significantly. The between group HR was 1.58 (95% CI 0.27–10.49) for 3-year OS. Stage-specific analysis showed no difference in disease-free and OS between treatment groups. Specifically, the 5-year DFS for stage III tumor was 76.8% (95% CI 50.6–99.9%) in the LAC group and 70.6% (95% CI 40.9–98.3%) in the RAC group ($P=0.753$ by log-rank test).

Seven patients in the RAC group experienced tumor relapse (three liver metastases, two peritoneal metastases, one lung metastases, and one supraclavicular lymph node metastases) compared with five in the laparoscopy group (two liver metastases, one lung metastases, one bone metastases, and one peritoneal metastases). No port site recurrence was noted with a median follow-up of 49 months.

In univariate analysis of the prognostic factors affecting DFSs, RAC, and LAC had similar DFS ($P=0.237$). With a multivariate analysis, positive lymphovascular invasion, elevated preoperative CEA levels and positive lymph node metastasis were independent prognostic factors affecting DFS.

Discussion

Since the mid 2000s, robotic surgery has been performed in some institutions as a helpful alternative to a conventional surgery in a variety of colorectal procedures. Indeed, several studies have shown that RAC was feasible and safe techniques compared with LAC. However, most previous studies of robotic right colectomy focused on short-term outcomes, such as technique feasibility, morbidity,

Table 2 Postoperative and pathological data

	RAC (*n* = 35)	LAC (*n* = 35)	*P*
Skin-to-skin time (min)[a]	195 (41.0)	129.7 (43.2)	< 0.001
Estimated blood loss (ml)[a]	35.8 (36.3)	46.8 (31.3)	0.311
Conversion to laparotomy (%)	0 (0)	0 (0)	1.000
Type of anastomosis (%)			< 0.001
Intracorporeal	30 (85.7)	7 (20.0)	
Extracorporeal	5 (14.3)	28 (80.0)	
Hospital stay (days)[a]	7.9 (4.1)	8.3 (4.2)	0.130
No. of Lymph nodes removed	29.9 (14.7)	30.8 (13.3)	0.265
Pathological stage (%)			0.747
I	9 (25.7)	10 (28.6)	
II	16 (45.7)	16 (45.7)	
III	10 (28.6)	9 (25.7)	
Perioperative morbidity (%)	6 (17.1)	7 (20.0)	0.500
Wound infection	2 (5.6)	2 (5.6)	
Anastomosis leakage	1 (2.8)	0 (0)	
Intraabdominal abscess	0 (0)	1 (2.8)	
Bleeding	1 (2.8)	3 (8.5)	
Ileus[b]	1 (2.8)	1 (2.8)	
Direct total cost (US$)[a]	12,235.0 (1907.9)	10,319.7 (1607.7)	0.013
Late hospital readmission[c] (%)	1 (2.8)	2 (5.6)	0.888
Late reoperation[c] (%)	1 (2.8)	1 (2.8)	1.000

RAC robot-assisted right colectomy, *LAC* laparoscopy-assisted right colectomy

[a]Values are mean (standard deviation)

[b]Requiring a nasogastric drainage before discharge

[c]Total number of patients suffered from postoperative complication more than 30 days after discharge

Table 3 DFS and OS

	RAC (*n* = 35)	LAC (*n* = 35)	*P*[†]
DFS (%)[a]			0.442
3 years	88.1 (77.1–99.1)	91.1 (81.4–99.9)	
5 years	77.4 (60.6–92.1)	83.6 (72.1–97.0)	
OS (%)[a]			0.678
3 years	96.8 (90.6–99.9)	94.0 (86.0-99.9)	
5 years	91.1 (78.8–99.9)	91.0 (81.3–99.9)	

RAC robot-assisted right colectomy, *LAC* laparoscopy-assisted right colectomy

[a]Values are mean (95% confidence interval)

[†]Log rank test

and pathological quality [8–12]. Survival comparisons between the robotic approach and other more commonly used minimal invasive procedures, such as laparoscopy-assisted colectomy, remain still largely undetermined. To our knowledge, these are the first data comparing oncologic outcomes between RAC and LAC within a randomized controlled trial.

To date, there have been only two retrospective studies to assess the oncologic outcome of robotic colectomy. D'Annibale et al. evaluated the survival rates in 50 patients who underwent robotic right colectomy and, with a median follow-up of 36 months (range 6–96 months), the DFS and OS were 90% (45/50) and 92% (46/50), respectively [8]. In another comparative study designed by Kang et al. 5-year DFS was similar among the open, laparoscopy, and robotic surgery in the management of right-sided colon cancer (87.7%, 84%, and 89.5%, respectively) [13]. Of note, no significant difference was observed between the three groups in terms of specimen length, number of metastatic and retrieved lymph nodes, and pathologic stage. Similarly, our study also confirmed that the oncological clearance in terms of pathological radicality and 3-year survival rate was not adversely affected by the robotic approach.

A major drawback of robot surgery is the great expenses caused by operation room charges. In view of the worldwide increasing concern about exploding costs in health care, the decision process for adopting new surgical modalities should be verified through cost-benefit analysis of clinical trial. Multiple studies have showed the cost inefficiency of robotic surgery in the treatment of colorectal cancer [5,

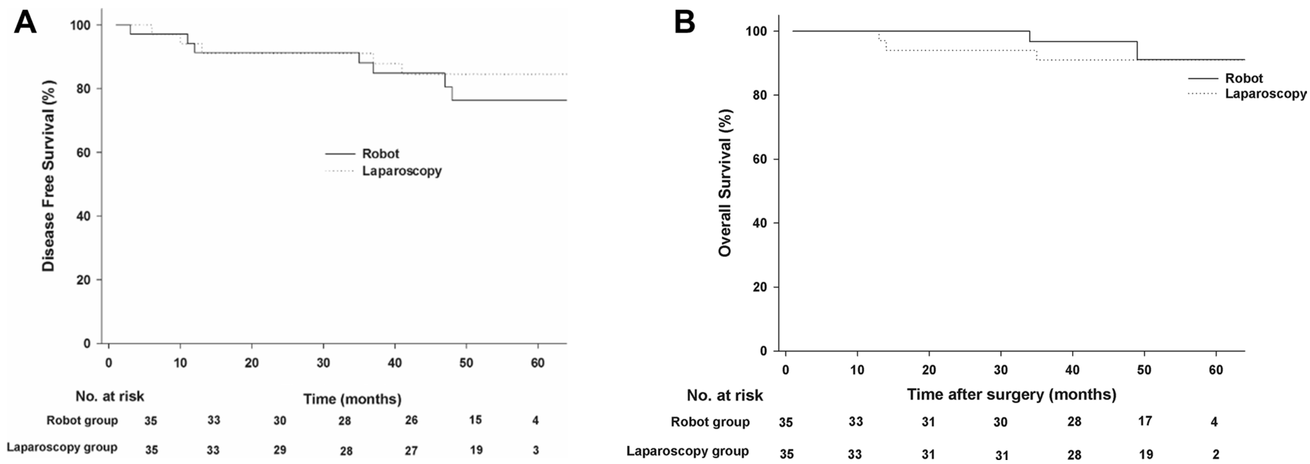


Fig. 2 Kaplan–Meier survival curve showing DFS (**A**) and OS (**B**)

14, 15]. Although the payment system is variable between the countries and different institution, robotic colorectal surgery costs approximately two- to threefold greater than conventional laparoscopic surgery. Furthermore, there is an approximate $2.5 million cost of robot acquisition, and an annual service cost of $200,000 in addition to the cost of the limited-use instrument arms [16]. In our trial, we could not find patient-specific benefits followed by robotic colectomy, which narrow the impact of robot surgery on economic burden, both in terms of perioperative results and long-term outcomes. Expected improvements both in the technology and the supply system according to the more industry competitions may contribute to the improved cost-effectiveness of robotic colectomy in the future.

There remain some technical issues to implementing robotics in colectomy because most robotic platforms currently being used are designed to work in only one quadrant. Repeated docking and undocking of the robot are sometime needed when using the robot to perform surgical procedure in different compartments in the abdominal cavity [17]. Notably, the manipulation of redundant organ such as small bowel or colon may be more challenges than manual laparoscopy instruments because arm's reach, range of motion, and tactile feedback are limited. In addition, the separation of surgeon and operating bed can be a source of interrupting the flow of the operation. In the remote console, robotic surgeon has been more dependent on a skilled bedside assistant for counter-traction, suction, and change of instrument. Indeed, Studies including our trial have generally shown that robotic colectomy takes longer time than their laparoscopic counterparts, in part due to time setting up, docking, and time spent communicating with bedside assistant [3, 11, 18, 19].

A potential benefit of the intracorporeal anastomosis with right colectomy is the ability to remove the specimen through any type of incision. In our series, totally introacorporeal procedures were performed more often in the NOSE than in the CL groups. These results may be explained by the fact that our port system of the RAC was different from laparoscopic technique which usually used peri-umbilical incision. We placed 12 mm of robotic camera port in the left lower quadrant or suprapubic region of the abdomen. In such port system, our practice has been modified to only perform Pfennelstiel incisions or Mcverney incisions for specimen extraction after RAC, without the need of an unnecessary mobilization and manipulation of the transverse colon and under direct visualization of the mesentery.

Although random patient assignment allowed control for unbalanced factors among the two study cohorts, this study was subject to the limitations inherent in any small clinical study. The sample size calculation of our trial was based on short-term outcomes such as hospital stay, so our long-term oncological data were inconclusive. Admittedly, the sample size of this study was not adequate for comparing DFS. It is estimated that approximately 1000 colon cancer patients will be required to make any robust decision in oncological outcomes. Considering that there is a major difference in operative cost between two surgical modalities, it will be a challenging target for a future trial.

In conclusion, this prospective randomized trial demonstrated that oncological clearance and long-term survival are seemingly not jeopardized by the robotic approach. However, robotic right colectomy is pertaining to the enormous costs and the prolonged operation time without providing clear benefits in oncological outcomes or postoperative recovery. A more widespread use of RAC might be upheld by the decrease of its costs (installation, maintenance, and disposable devices) and by the evidence of an improved surgical outcomes according to future optimization of robotic platform for colorectal procedures.

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Author contributions Analysis and writing of manuscript are attributed to Jun Seok Park and In Teak Woo. Responsibility to correspondence and study proposal are attributed to Gyu-Seog Choi. Enrollment of patients, statistical analysis, and study proposal are attributed to Hye Jin Kim Hyun Kang, In Teak Woo, In-Kyu Par,k and Soo Yeun Park.

Compliance with ethical standards

Disclosures Jun Seok Park, Hyun Kang, Soo Yeun Park, Hye Jin Kim, In Teak Woo, In-Kyu Park, Gyu-Seog Choi have no conflicts of interest or financial ties to disclose.

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