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CLINICAL TRIAL REPORT

Acupoint Stimulation for Enhanced Recovery After Colon Surgery: A Prospective Multicenter Randomized Controlled Trial

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Purpose: The aim of this study was to evaluate the efficacy of transcutaneous electrical acupoint stimulation (TEAS) in improving bowel function and thus shortening hospital stay after laparoscopic colon surgery within the ERAS pathway.

Patients and Methods: From November 2016 to March 2018, 100 patients who underwent elective colon surgery were enrolled and 94 finished study (n = 47 for each) in three university hospitals. Patients in the TEAS group received TEAS 30 min before surgery and once a day for 3 days after surgery, while those in the Control Group received no stimulation. Primary outcome was the time to discharge.

Results: Compared with standardized postoperative care, TEAS resulted in a shorter time to first flatus (P=0.03) and time to first defecation (P=0.03), as well as a reduction in the length of hospital stay (P=0.02). Median patient-controlled analgesia (PCA) deliveries and PCA attempts at 24h, 48h and 72h after surgery were less in the TEAS group (P<0.01). No evidence of significant advantages in postoperative pain intensity, nausea, vomiting, sleeping quality and expenses was found in the TEAS group.

Conclusion: Perioperative TEAS further shortens the time to meet discharge criteria after laparoscopic colon surgery in patients under ERAS strategy.

Keywords: transcutaneous electrical acupoint stimulation, colon surgery, laparoscopy, ERAS

Plain Language Summary

Recovery of bowel function is important for patients undergoing colorectal surgery. Enhanced recovery after surgery (ERAS) program makes great efforts on improving bowel function. In patients under ERAS program, transcutaneous electrical acupoint stimulation (TEAS) can further shorten the time to first flatus and to first defecation after colon surgery. The length of hospital stay and need of analgesics after surgery were decreased as well.

Introduction

Accumulating evidence supported that the enhanced recovery after surgery (ERAS) pathway and laparoscopic approach benefit patients undergoing colorectal resections by shortening the length of hospital stay and reducing morbidity after surgery.[1–5] For patients undergoing colon surgery, the return of bowel function is especially important for ERAS.[6] Shortening fasting time, early mobilization and early oral intake have been used to facilitate the recovery of bowel

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function.[6] However, postoperative ileus still represents problems in the management.[7] The time to first bowel motion was not satisfied in the laparoscopic arm in many of these trials, which is only about 1 day earlier than that in the open arm.[7–9]

Acupuncture-related techniques have been used to treat bowel function disorders, including irritable bowel syndrome and chronic functional constipation[10–12] Perioperative acupuncture-related techniques including transcutaneous electrical acupoint stimulation (TEAS) have shown benefits including narcotic-sparing effects and fewer complications.[13] Besides, acupuncture has been used to treat gastrointestinal motility disorder.[14–19] Evidence of acupuncture for postoperative gastrointestinal function is accumulating. In patients undergoing major abdominal surgery, Li et al[19] observed shorter time to flatus and to ambulation after TEAS. In patients undergoing laparoscopic surgery, the time to defecation was shortened as well.[20] However, whether the potential benefit of TEAS on gastrointestinal function could shorten the length of stay after surgery is not clear. Therefore, the aim of this multicenter randomized trial was to evaluate whether perioperative TEAS could further improve the gastrointestinal function and shorten the time to meet the discharge criteria in patients undergoing laparoscopic colon surgery with current ERAS approaches.

Materials and Methods

Patients and Randomization

The randomized, prospective, sham controlled study was undertaken in 3 university hospitals in China (Xijing Hospital, Tongji Hospital, and First Affiliated Hospital of Chongqing Medical University). The study was approved by the Institutional Ethics Committee of each participating hospital and has been registered in ClinicalTrials.gov (NCT02921529). Written informed consent was obtained from all patients. Patients scheduled for laparoscopic colon surgery under general anaesthesia were screened. Inclusion criteria included age between 18 and 75 years, a body mass index between 18 and 30, and ASA status of I–III. Patients with contraindications for electrical stimulation, difficulty in communicating, confirmed or suspected drug abuse/addiction or alcohol abuse/addiction, or severe hepatic or renal dysfunction were excluded. Patients were randomly assigned to the TEAS or Control group in a ratio of 1:1 using a computer-generated random allocation sequence. The randomization code for each patient was put in sealed envelope and not opened until allocation.

Intervention and Blinding

For all patients, electrodes were placed at the bilateral PC6/LI4 and ST36/SP6 and connected to the stimulator (Model No. SDZ-II; Hwato electronic stimulator; Suzhou Medical Appliances Co., Ltd, Suzhou, China) (See Supplemental Digital Content 1). Patients in the TEAS group received stimulation at the bilateral PC6 and ST36 points. The device provided "disperse-dense" waves of alternating frequencies of 2 Hz and 10 Hz for 2 cycles. Increasing electrical stimulation intensity (4 mA to 11 mA) was applied to identify the threshold intensity. Stimulation began 30 min before induction and lasted for 30 min. Then the same stimulation for 30 min was given in the morning once a day for 3 days after surgery. Patients in the Control group received no stimulation.

For logistic reasons, blinding the patients was hard to perform. However, the threshold intensity was identified in all the patients, and they were told that they may or may not feel the electrical stimulation. Interventions were performed by a designated investigator who was not involved in the anaesthesia or the follow-up. The stimulator was placed in an opaque box. Investigators involved in the follow-up were blinded to the group allocation.

Procedures

Anaesthesia was induced with midazolam, propofol and fentanyl. Rocuronium was given to facilitate tracheal intubation. Intraoperative anaesthesia was maintained with a remifentanil infusion and sevoflurane. Patients were managed according to ERAS methods previously reported[21,22] (see Supplemental Digital Content 2) and followed up until discharge.

The primary outcome was the time to meet discharge criteria after surgery that we previously reported[21,22] (Table 1). The secondary outcomes included time to flatus, time to first defecation, and time to first oral intake; pain intensity assessed by visual analogue scale (VAS), attempts and deliveries of patient-controlled analgesia (PCA), postoperative nausea and vomiting (PONV), quality of sleeping (QoS) and quality of recovery (QoR) evaluated at 24h, 48h and 72h after surgery. QoS was assessed using visual sleeping scale and the Richard-Campbell Sleep Questionnaire (RCSQ),[23] and QoR was assessed using

Table 1 Criteria for Discharge

	Content
Criteria 1	Normal body temperature, normal mobilization (off-bed mobilization >6h in 24 h), normal oral diet (oral intake of liquid diet >1000mLin 24h), normal gastrointestinal function (flatus and defecation)
Criteria 2	Pain could be controlled with oral analgesics
Criteria 3	No discomfort complaint, no parenteral nutrition

QoR-15 questionnaire.[24] Higher scores indicate better quality (Supplemental Digital Contents 3 and 4). Postoperative major complications (Supplemental Digital Content 5) and expenses were recorded as well.

Statistical Analysis

We performed all the analyses in a modified intention-to-treat population, which included all the patients who had undergone randomization and all the interventions. All the patients were followed for the duration of the trial.

Based on a previous study, the average time to meet discharge criteria was 5 days for patients undergoing colorectal surgery.[21] A minimum of 43 patients in each group would give 90% power to detect a decrease of 1 day for the time to discharge, with a standard deviation of 1.3 days, at an overall 2-sided $P < 0.05$. The sample size was inflated to 94 patients (n=47 for each) to account for a rate of withdrawals and loss to follow-up by 10%.

Data were analyzed with SAS 9.2 (USA: SAS Institute Inc., 2010). Descriptive statistics were applied to present subjects' characters. Comparison of qualitative data between two groups was done using Chi-square test and Fisher's exact test. And comparison of quantitative data was evaluated by *t*-test. Also, Satterthwaite t' test was applied if the variances were unequal between two groups. Univariate analysis of survival data was estimated using the Log rank test. A two-tailed *P*-value of 0.05 was considered as statistically significant with a 95% confidence interval (95% CI).

Results

From November 2016 through March 2018, a total of 100 patients were enrolled at 3 hospitals. We randomly assigned 50 patients to each group (Figure 1). After randomization, 5 patients were excluded due to procedure converting from laparoscopic to open surgery and 1 patient was excluded due to rejection to TEAS (Figure 1). There was no significant difference between the groups with respect to demographic, anesthetic and surgical characteristics (Table 2), pre-existing diseases and pre-operative laboratory test results including nutritional status (Supplemental Digital Contents 6 and 7). Case numbers in each center were shown in Supplemental Digital Content 8.

Primary Outcome

The median follow-up time was 7 days in each group. The median time to discharge was 6.0d±1.8d (95% CI, 5.5–6.5) in the TEAS group compared with 7.0d±2.4d (95% CI, 6.3–7.7, P =0.02) in the Control group (Table 3). Log rank test showed a P value of 0.02 between the two groups (Figure 2). Subgroup analysis based on type of surgery showed same results concerning time to discharge (Supplemental Digital Content 9).

Secondary Outcomes

The mean time to flatus and mean time defecation were 34.5 h±16.7h (95% CI, 29.6–39.4) and 42.0h±25.0h (95% CI, 34.7–49.3) respectively in the TEAS group, compared with 42.4h±22.9h (95% CI, 35.6–49.1, P =0.03) and 55.4h±29.7h (95% CI, 46.7–64.1, P=0.03) respectively in the Control group (Table 3). Log rank test of the two outcomes showed P values of 0.03 and 0.03 respectively between the two groups (Supplemental Digital Contents 10 and 11).

Incidences of PONV, the VAS at rest and at cough, and score of sleeping quality in 3 days after surgery were not different between the groups (all P >0.05). However, median PCA deliveries and PCA attempts at 24h, 48h and 72h after surgery were less in the TEAS group than in the Control (P<0.01). Median QoR-15 scores[22] in the TEAS group were not different to the Control group at 48 h and 72h after surgery, but lower at 24h after surgery 50.5 (IQR 42.3–61.8) vs 44.5 (IQR35.0–57.0), P =0.04. Postoperative morbidity of infection and major complications were not different between the

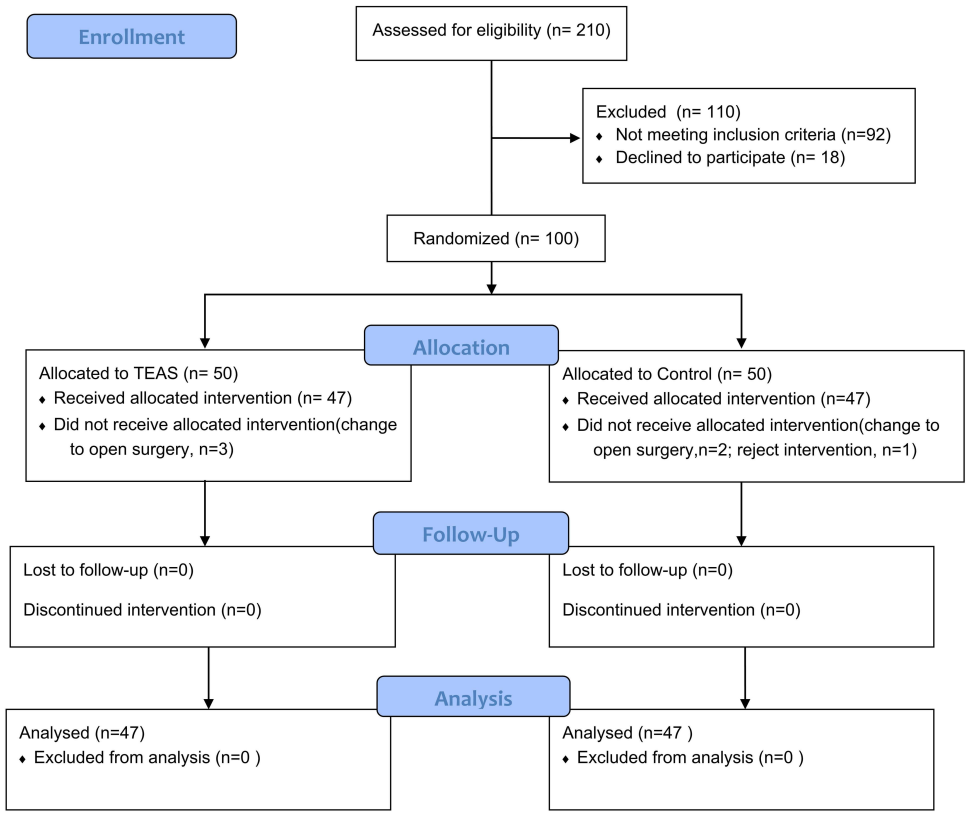

Figure 1 Trial profile.

two groups. Mean postoperative expense was 62962±28001CNY in the TEAS group and 84,218±115 027 CNY in the Control group, with no significant difference (P=0.22, Table 3).

Discussion

This multicenter prospective randomized trial suggests that in patients being managed by the current ERAS protocol, perioperative TEAS (30 min before anaesthetic induction, and 30 min once a day for 3 days after surgery) provided additional benefit in enhanced recovery after laparoscopic colon surgery. Patients needed less opioid after surgery, and the time to meet discharge criteria and recovery of bowel function were shortened significantly.

Our study was the first multicenter randomized controlled trial on the role of TEAS for postoperative hospital stay and bowel function in laparoscopic colon surgery. There has been limited randomized controlled trials published in the English literature that examined the role of acupuncture in preventing postoperative ileus after laparoscopic colorectal surgery. In a single-center trial, Ng et al[25] observed that electroacupuncture once a day for 4 days postoperatively decreased the time to flatus by 0.6 d and shortened the length of hospital stay from 8.5 to 6d. In our study, with TEAS, a non-invasive technique, we achieved enhanced recovery as well time to flatus decreased by 7.9h and time to discharge decreased by 1d. Additionally, we did TEAS both preoperatively (30min before anaesthesia induction) and postoperatively (once a day for 3 days). Previous studies have found that preoperative acupuncture-related technique potentially provided additional benefits including alleviating anxiety and decreasing anaesthetic consumption.[13]

The shortening of time to discharge or to flatus varied in different trials. In a trial in open colorectal surgery, Zhang et al[26] found that electroacupuncture decreased the time to flatus by 9 hours, close to the 7.9 hours in our study. But Ng's study and Li's study found stronger effect of bowel function acceleration.[19,25] And the time to first oral intake was not shortened in our study, while in Ng's study the time to normal diet decreased by 0.8d. A possible explanation is that in our study patient were managed with ERAS protocol which encourages early oral intake and mobilization. The benefits of TEAS maybe overlapped by ERAS strategy. Ng et al acknowledged that one of the limitations of their study was that

Table 2 Demographic and Surgical Characteristics of the Patients

	TEAS (n=47)	Control (n=47)	*P* value
Age, years	56.2±9.0	55.6±9.9	0.75
Gender (male/female), n	26/21	23/24	0.54
BMI (kg/m^2)	22.5±2.6	22.8±2.8	0.63
ASA (I/II/III)	0/45/2	1/43/3	0.68
NRS 2002 score	2(0, 5)	2(0, 4)	0.62
Type of surgery (left/right/sigmoid)	6/18/23	5/18/24	0.95
Duration of surgery, min	163.7±49.2	160.1±50.3	0.73
Duration of anaesthesia, min	200.2±48.6	199.2±52.3	0.92
Fluid input, mL	1930.9±459.9	1996.8±529.3	0.52
Crystalloid, mL	1462.8±428.8	1437.2±543.2	0.80
Colloid, mL	446.8±214.5	553.2±238.5	0.05
Output, mL	434.8±273.5	430.0±236.0	0.93
Blood loss, mL	72.8±135.9	62.9±44.0	0.65
Use of vasoactive agents, n (%)	12 (25.5)	13 (27.7)	0.82

Note: Data are presented as mean±SD, n or median (min, max).
Abbreviations: BMI, body mass index; ASA, American Society of Anaesthesiologists; NRS, nutritional risk screening.

Table 3 Recovery Parameters of the Patients

	TEAS (n=47)	Control (n=47)	*P* value	Difference, 95% CI
Time to discharge, d	6.0±1.8[a]	7.0±2.4	0.02	−0.98(−1.82,-0.14)
Time to flatus, h	34.5±16.7[a]	42.4±22.9	0.03	−7.90(−12.35,-3.66)
Time to first defecation, h	42.0±25.0[a]	55.4±29.7	0.03	−13.42(−23.62, −6.80)
Time to first oral intake of water, h	33.5±22.3	28.9±17.5	0.28	/
PONV, n (%)				
24 h after surgery	30(63.83)	22(46.81)	0.17	/
48h after surgery	10(21.28)	9(19.15)	0.76	/
72h after surgery	8(17.02)	4(8.7)	0.23	/
VAS at rest/at cough, median (min, max)				
24 h after surgery	2.2(0.0, 10.0)/5.8(0.4, 10.0)	1.2(0.0–8.1)/ 5.5(1.4–10.0)	0.41/0.94	/
48h after surgery	1.2(0.0, 6.7)/ 5.0(0.3, 10.0)	1.6(0.0–6.0)/ 5(0.7, 10.0)	0.80/0.98	/
72h after surgery	0.6(0.0, 5.0)/ 3.5(0.1, 10.0)	1.0(0.0, 6.2)/ 4.0(0.3, 10.0)	0.05/0.33	/
PCA attempts/deliveries, median (min, max)				
24 h after surgery	8.0(3.0, 18.0)/5.0.0(2.0, 12.0)	16.5(8.0, 38.0)/12(6, 22.0)	0.001/0.001	/
48h after surgery	13.0(5.0, 22.0)/7.0(3.0, 14.0)	26.0(11.5, 45.5)/16.5(8.0, 35.0)	0.002/0.001	/
72h after surgery	13.0(5.0, 24.0)/7.0(3.0, 20.0)	24.5(13.0, 46.0)/16.5(10.0, 36.0)	0.002/0.003	/

(*Continued*)

Table 3 (Continued).

	TEAS (n=47)	Control (n=47)	*P* value	Difference, 95% CI
QoR −15 score, median (min, max)				
24 h after surgery	54.5(15.0, 92.0)	59.0(27.0, 136.0)	0.01	/
48h after surgery	59.0(35.0, 104.0)	62.0(0.0, 130.0)	0.35	/
72h after surgery	67.0(31.0, 113.0)	67.0(11.0, 136.0)	0.75	/
VSS score, median (min, max)				
24 h after surgery	69.0(0.0, 100.0)	60.0(0.0, 96.0)	0.29	/
48h after surgery	44.5(0.0, 96.0)	52.5(1.0, 89.0)	0.27	/
72h after surgery	30.5(2.0, 82.0)	40.5(1.0, 93.0)	0.48	/
RCSQ score, median (min, max)				
24 h after surgery	61.4(18.7, 100.0)	57.0(19.0, 85.0)	0.26	/
48h after surgery	38.5(6.3, 91.0)	45.0(12.9, 85.1)	0.39	/
72h after surgery	34.0(5.0, 81.6)	39.9(8.0, 77.4)	0.44	/
Major complications, n (%)	0(0)	0(0)	1.00	/
Post-surgery expense, CNY	62962±28,001	84,218±115,027	0.21	/

Note: Data are presented as mean±SD, n (%) or mean (min, max).
Abbreviations: PONV, postoperative nausea and vomiting; VAS, visual analogue scale; PCA, patient-controlled analgesia; QoR, quality of recovery; VSS, visual sleeping scale; RCSQ, Richard–Campbell Sleep Questionnaire; CNY, Chinese Yuan.

they did not use a fast-track perioperative program. They also suggested that possible combined effects of EA and the fast-track program on the clinical outcomes after laparoscopic colorectal surgery will be an important area for further research.

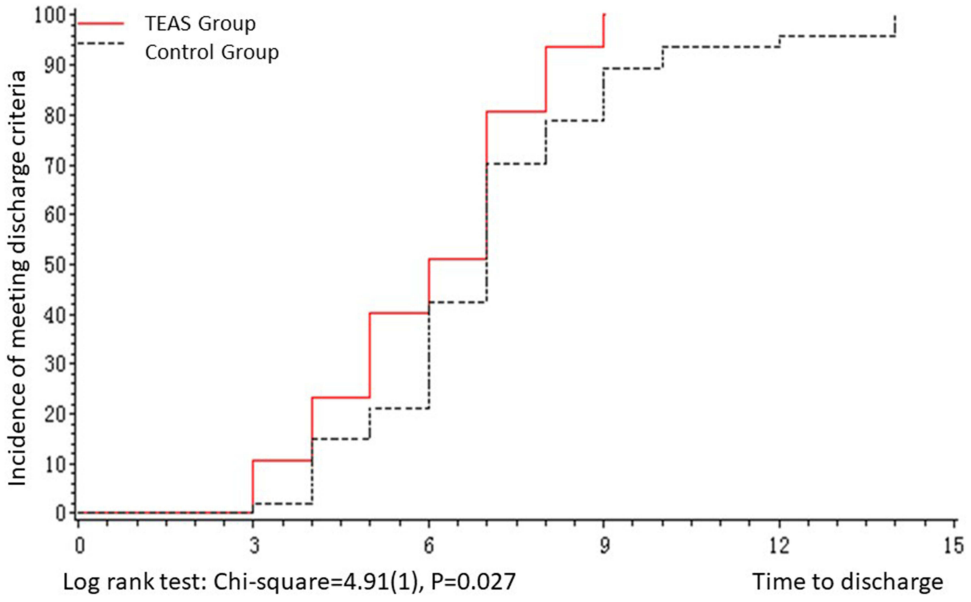

Figure 2 Kaplan–Meier estimation of incidence of meeting discharge criteria.

In our study, the cost after surgery was not different between the two groups (P=0.22). However, it should be prudent to conclude that TEAS has no cost-effective benefit. In our study, the time to meet discharge criteria was reduced by 1 day in patients receiving TEAS. It is estimated that a reduction of the length of hospital stay by 1 day may reduce the annual health care system costs in the United States by approximately US$1 billion.[27] The cost-effective effect of TEAS may be shown in the hospital and overall health care system.

Mechanisms of acupuncture-related techniques improving gut function have been studied in animal and clinical studies. In patients undergoing open colon surgery, Meng et al[28] failed to prove any benefit of electroacupuncture on time to first bowel movement when the patients received epidural anaesthesia, which blocked the afferent and efferent pathway. This highlights the role of neural pathway during action of acupuncture. It was also reported that vagal nerve system-induced anti-inflammatory effect may be the underlying mechanism of acupuncture improving gut function. Electroacupuncture may suppress intestinal manipulation-induced inflammation via activation of the cholinergic anti-inflammatory pathway in macrophages.[29,30] Besides, in our study, the postoperative analgesics consumption was fewer during the first 3 days after surgery. The use of opioid-based analgesia is usually thought to exacerbate postoperative ileus.[31–33] The decreased opioid use in our study may contribute to the better bowel function recovery.

In our study, frequency of stimulation was set at 2Hz/10Hz, which is a low frequency. Both low frequency and high frequency of electrical acupoint stimulation have been used in the prevention and treatment of postoperative ileus. In Li et al[19] and Wang et al[20] trials, 2/100Hz was used. While Yang et al found that 10 Hz and 30Hz are more effective in increasing the gastrointestinal motility and attenuating peripheral inflammation.[34] Besides, our previous studies showed that TEAS at 2/10Hz induces opioid-sparing effect,[35] which may decrease opioid-related postoperative ileus. The optimal frequency for improving gut function still needs further investigation.

The present trial has some limitations. First, investigators could not administer TEAS in a patient-blinded manner. The patient may tell the investigator who did the follow-up that he/she felt a stimuli. We tried to minimize the potential bias by applying electrodes at acupoints and testified stimulation threshold for all patients. We told the patients that they may not feel the stimulation during treatment. The stimulators were put in opaque box to blind the medical staff in the OR and in the ward. Second, flatus is sometimes regarded as an insensitive index, and the time to resume oral intake can be influenced by the patient's perception and the clinician. We therefore adopted time to meet discharge criteria as primary endpoint and time to defecation as one secondary endpoint, because they are more objective and can be recorded by the assessor without bias. Third, though we followed ERAS approaches and encouraged the patients to resume oral intake as early as 6h after surgery, the time to oral intake was longer than 24h in both groups. Adherence to ERAS protocols should be paid attention in future studies.

Conclusion

In conclusion, this multicenter randomized controlled study suggests that TEAS could further enhance short-term recovery and shorten hospital stay after laparoscopic colon surgery in patients being managed by ERAS program. Further studies are warranted to generalize our findings.

Data Sharing Statement

Data related to the specific manuscript will be made available upon reasonable request in adherence with transparency conventions in medical research and through requests to the corresponding author (xlzmzk@163.com).

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Disclosure

The authors declare no conflicts of interest in this work.

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