Surgical Endoscopy (2019) 33:2114–2120
https://doi.org/10.1007/s00464-018-6482-8

Temporary simultaneous two-arterial occlusion for reducing operative blood loss during laparoscopic myomectomy: a randomized controlled trial

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Received: 3 September 2018 / Accepted: 11 October 2018 / Published online: 17 October 2018

Abstract

Background To evaluate the efficacy and safety of temporary simultaneous two-arterial occlusions (TESTO) in terms of operative blood loss during laparoscopic myomectomy.

Methods A total of 62 patients with symptomatic myomas were randomly assigned to either the experimental group or the control group. In the experimental group, the uterine arteries and utero-ovarian arteries were temporarily occluded with laparoscopic bulldog clamps. The primary outcome measures were operative blood loss and change in hemoglobin.

Results There were no differences in baseline demographics between the two groups. The amounts of operative blood loss (56.3 ± 42.8 mL vs. 138.2 ± 48.8 mL, $p < 0.001$) and change in hemoglobin (1.0 ± 0.5 g/dL vs. 1.7 ± 1.1 g/dL, $p = 0.002$) were significantly lower in the experimental group than that in the control group. The total operative time was not significantly different between the two groups. However, it took less time for myoma enucleation (13.1 ± 14.6 min vs. 17.6 ± 10.4 min, $p = 0.006$) and for uterine suturing (19.5 ± 10.7 min vs. 24.6 ± 8.8 min, $p = 0.006$) in the experimental group than that in the control group. None of patients in both groups developed operative complications.

Conclusion The use of the TESTO procedure is effective in reducing operative blood loss and hemoglobin loss without causing morbidity during laparoscopic myomectomy.

Keywords Myomectomy · Myoma · Bulldog clamp · Operative blood loss · Laparoscopic myomectomy

Uterine myoma is the most common disease of the female genital tract in any age group [1, 2]. Although hysterectomy is the definitive surgical treatment for symptomatic myomas, myomectomy is the treatment of choice for women who want to preserve their uterus and fertility [3]. However, intraoperative bleeding is a major perioperative concern in myomectomy, and can result in the need for blood transfusion, development of hypovolemia, and postoperative anemia [1–3]. Therefore, methods for decreasing operative hemorrhage during myomectomy in women who want to preserve their uteri or plan a future pregnancy are important and warrant investigations.

Although a technique for improved vascular control, namely temporary simultaneous two-arterial occlusions (TESTO) of the uterine and ovarian (or utero-ovarian) arteries, during laparoscopic myomectomy, has recently been reported to minimize operative blood loss [4, 5], this technique may be both time-consuming and technically challenging. Moreover, the efficacy and safety of this technique for its application to clinical practice have not been investigated. Therefore, we conducted this randomized trial to evaluate the efficacy and safety of the TESTO procedure in terms of operative blood loss during laparoscopic myomectomy.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00464-018-6482-8) contains supplementary material, which is available to authorized users.

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Materials and methods

Study design and patients

This TESTO trial was prospectively conducted between May 2016 and July 2018 at Kangbuk Samsung Hospital, Seoul, Republic of Korea. Women with indicated for laparoscopic myomectomy for symptomatic uterine myomas were asked to participate in this study. The inclusion criteria were as follows: symptoms of myomas such as menorrhagia, pelvic pressure/pain, or infertility; plan to undergo laparoscopic myomectomy; number of myomas ≤ 10, with the largest myoma being ≤ 10 cm; regular menstrual bleeding; non-pregnant status at time of surgery; and age between 19 and 48 years. The exclusion criteria were as follows: concomitant complex surgical procedures at the time of laparoscopic myomectomy, such as severe adhesiolysis or resection for severe endometriosis; a dominant pedunculated subserosal or submucosal type of myoma; postmenopausal or climacteric status; history of oophorectomy or salpingo-oophorectomy; any suspicion of malignant uterine or adnexal diseases; major medical comorbidities or psychiatric illnesses, which could affect follow-up and/or compliance; and refusal to participate or provide consent to the procedures.

The patients were randomly assigned to either the experimental group or the control group in a 1:1 ratio, by using a random permuted-block randomization algorithm via an interactive Web-based response system (http://www.randomization.com). A study nurse called the coordinating center just before the induction of general anesthesia on the day of surgery for the purpose of randomization. The protocol was approved by the Institutional Review Board of Kangbuk Samsung Hospital and registered with ClinicalTrials.gov (identifier: NCT02747550). The study was performed in accordance with the protocol, and all patients provided written informed consent before participation.

To control for the variability of surgical skill, all surgical procedures were performed by one surgeon (Song), with experience of > 500 procedures of laparoscopic myomectomy. All patients underwent the same standard preparation before surgery. The laparoscopic port (or trocar) placement was determined according to each patient's condition and needs. General anesthesia was induced with endotracheal intubation, with the patients placed in the deep Trendelenburg position. After the creation of a pneumoperitoneum following insufflation with carbon dioxide, a 5-mm or 10-mm laparoscope was inserted through the umbilical port. In patients allocated to the experimental group, the uterine arteries and utero-ovarian arteries were simultaneously temporarily occluded during myomectomy. In the control group, no intervention for TESTO was made during myomectomy.

TESTO procedure

In the experimental group, the retroperitoneum was opened using a Harmonic scalpel (Ethicon Endo-surgery, Cincinnati, OH, USA) along the infundibulopelvic ligament, and the ureter was identified at the level of the pelvic brim that crosses the external iliac artery. After the dissection, the ureter was extended distally and downward, and the uterine arteries were skeletonized and temporarily occluded with laparoscopic bulldog clamps (Aesculap, Tuttlingen, Germany) at the level where they originate from the internal iliac artery. Then, utero-ovarian arterial anastomoses were also transiently occluded at the utero-ovarian pedicle (between the ovary and the uterus) through placement of laparoscopic bulldog clamps (Supplementary surgical clip).

Laparoscopic myomectomy

Except for the TESTO procedure in the experimental group, the remaining surgical procedures, such as myoma enucleation, uterine defect suturing, and myoma morcellation, were identical between the two groups and were performed as previously described [6, 7]. Briefly, a longitudinal myometrial incision was made using a Harmonic scalpel over the myoma. After identifying the cleavage plane, the myoma was enucleated by applying adequate traction with a laparoscopic myoma screw or forceps. Uterine defect closure after myoma enucleation was performed with 1–0 unidirectional barbed sutures (V-Loc; Covidien, Boulder, CO, USA) in a single or double layer. The myomas, which were placed into the specimen retrieval endopouch, were removed transumbilically with knife morcellation. After completing the laparoscopic procedure by washing the pelvic cavity and absorbing any clots that had formed, the laparoscopic port was removed. The transumbilical fascia and skin were approximated using a 1–0 Vicryl running suture (Ethicon, Somerville, NJ, USA), and the skin was closed subcuticularly using a 4–0 V-Loc suture (Covidien) or a Stratafix suture (Ethicon). The patients were discharged from the hospital under the following conditions: after restoration of bowel activity, after successful ambulation, in the absence of postoperative fever, and when narcotic analgesics were no longer needed. All patients were scheduled for follow-up examinations at 1 week and 3 months after surgery.

Outcome measures

The primary outcome measures were operative blood loss and change in hemoglobin. Operative blood loss was calculated by the anesthesiology unit as the difference between the total amount of suction and irrigation plus the difference between the total gauze weight before and after surgery. The

change in hemoglobin was defined as the difference between the preoperative hemoglobin level and the hemoglobin level on postoperative day 1. The secondary outcome measures were the presence of regular menstrual bleeding (defined as cycle length between 21 and 45 days) and operative complications. Intraoperative complication was defined as major vessel injury, bowel injury, urinary tract injury, or any other severe unplanned adverse events. Postoperative complication was defined as grade III or higher complication occurring within 3 months after surgery according to the Clavien–Dindo classification [8]. Grade III complication was defined as any complication requiring surgical, endoscopic, or radiological intervention.

The total operative time, which was electronically recorded, was defined as the time from skin incision to skin closure. The times required for performing each phase, including the enucleation time for all myomas, the suturing time for all uterine wall defects, and the morcellation times, were measured and calculated using a digital time counter. The procedure time for TESTO (defined as the time from the opening of the retroperitoneum to the positioning of the bulldog clamp) and the occlusion time (defined as the time for occluding the bilateral uterine and utero-ovarian vessels using bulldog clamps) were also collected. Failure of the intended operation was defined as the use of one or more additional ports and conversion to laparotomy. At the end of each operation, the degree of surgical difficulty was evaluated by the operator based on a 10-point scale varying from 1 (low difficulty) to 10 (high difficulty), as described by Vassiliou et al. [9]. Additional procedures that influence the operative time and the amount of operative blood loss included labioplasty, posterior colporrhaphy, and urinary incontinence surgery. The length of hospital stay was defined as the time from the operation day to the day of discharge.

Statistical analysis

This trial was designed as a non-equality test, with the hypothesis that myomectomy with the TESTO procedure is not equal to myomectomy without the TESTO procedure in terms of operative blood loss. Therefore, the sample size was calculated based on the difference in operative blood loss, collected retrospectively from 30 consecutive patients who underwent conventional laparoscopic myomectomy without the TESTO procedure at Kangbuk Samsung Hospital before this study, showing an operative blood loss of 148.4 ± 50.4 mL (unpublished data). We assumed that the equivalence was clinically significant if the difference in operative blood loss between the two groups was ≤ 25% (37.1 mL). With a type I error of 0.05, a power of 80%, and a predicted dropout rate of 5%, the estimated sample size required was 31 patients in each group. No interim analysis was planned or performed.

SPSS 20.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. All analyses were performed according to the intention-to-treat principle. Data were presented as mean ± standard deviation or median (interquartile range) for quantitative variables, and frequency (%) for qualitative variables. Student's t test or the Mann–Whitney test was used to compare means or medians, and the χ^2 or Fisher's exact test was used to compare the frequency distributions between categorical variables, as appropriate. A p value of < 0.05 was considered to indicate statistical significance.

Results

Enrollment was performed from June 2016 through June 2018, and the 3-month follow-up was concluded in September 2018. Of 91 patients who were invited to participate in the study, 29 patients were ineligible based on the exclusion criteria because of declining to participate ($n = 5$), having concomitant complex surgical procedures ($n = 13$), being > 48 years old or having a postmenopausal status ($n = 5$), having > 10 myomas or a largest myoma diameter of > 10 cm ($n = 4$), and having a dominant pedunculated subserosal myoma ($n = 2$). Therefore, 62 patients were randomized, 31 each to the experimental and control groups (Fig. 1). After randomization, none of the patients changed groups or stopped participating in the study.

The baseline characteristics of the two groups are described in Table 1. The mean age and body mass index of the study patients were 39.8 ± 5.7 years and 22.9 ± 3.3 kg/m^2, respectively, with no statistical difference between the two groups. Other baseline characteristics including parity, history of abdominal surgery, preoperative hemoglobin, preoperative anti-Mullerian hormone level, laparoscopic approach, main indication of myomectomy, number of uterine myomas, diameter of the largest myoma, weight of extracted myomas, location of the largest myoma, and adhesiolysis also did not statistically differ between the two groups.

Table 2 shows the primary and secondary outcomes in the two groups. The amount of operative blood loss was significantly lower in the experimental group than in the control group (56.3 ± 42.8 mL vs. 138.2 ± 48.8 mL, $p < 0.001$). The amount of change in hemoglobin was also significantly lower in the experimental group (1.0 ± 0.5 g/dL vs. 1.7 ± 1.1 g/dL, $p = 0.002$). Although there was no statistical significance, blood transfusion during the operation or at the postoperative period was needed in only two patients of the control group. All patients of both groups had regular menstruation within 3 months after surgery. None of the patients in both groups developed operative complications.

The other surgical outcomes are summarized in Table 3. The total operative time was not significantly

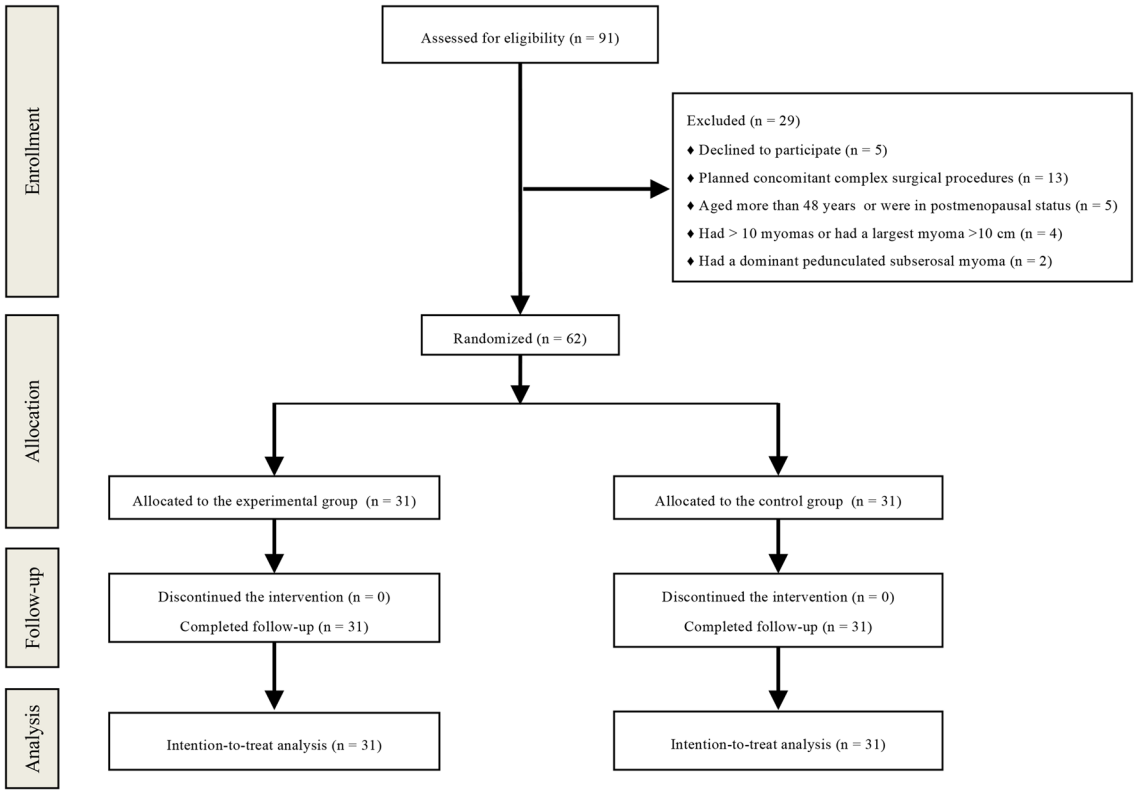

Fig. 1 Enrollment, randomization, and follow-up of the study subjects

different between the experimental and control groups (87.9 ± 35.3 min vs. 81.5 ± 27.8 min, $p = 0.725$). However, it took less time for myoma enucleation (13.1 ± 14.6 min vs. 17.6 ± 10.4 min, $p = 0.006$) and for uterine suturing (19.5 ± 10.7 min vs. 24.6 ± 8.8 min, $p = 0.006$) in the experimental group than in the control group. The times required for skin incision, skin closure, and morcellation were similar between the two groups. In the experimental group, the procedure for TESTO took more time, with an average of 14.4 ± 3.2 min, and the average vascular occlusion time with the bulldog clamps was 29.0 ± 7.0 min. The degree of surgical difficulty was significantly lower in the experimental group than in the control group (3.9. ±1.2 vs. 5.6 ± 1.4, $p < 0.001$). Failure of the intended surgery occurred in one case of the experimental group. The length of hospital stay was not significantly different between the two groups.

Discussion

The main finding of this study was that operative blood loss and change in hemoglobin were significantly lower in the experimental group than that in the control group. We also observed that no complication related to the vascular control technique (bulldog clamp placement) occurred in the experimental group. To the best of our knowledge, this is the first randomized controlled trial to evaluate the efficacy and safety of TESTO during laparoscopic myomectomy. Considering that operative bleeding is a major concern of surgeons in laparoscopic myomectomy, our results will potentially benefit all surgeons interested in performing minimally invasive surgical procedures.

The present study shows that transient occlusion of uterine and utero-ovarian arteries is an effective surgical technique for reducing operative blood loss that can be performed during laparoscopic myomectomy. Our finding was consistent with previous studies investigating the effect of temporary vascular control of uterine artery during laparoscopic myomectomy. Dubuisson et al. conducted a literature review to define the role of preventive uterine artery occlusion during laparoscopic myomectomy [10]. They reported that six of eight comparative studies showed a substantial decrease in operative blood loss in patients who underwent preventive uterine artery occlusion during surgery [10]. However, these vascular clamping techniques with bulldog clamps or vascular clips require the surgeon to undergo a learning curve for operative skills, such as opening the retroperitoneum and identifying the pelvic vasculature. This approach can be an attractive option for selected patients, if performed by an experienced laparoscopist, as it can reduce

Table 1 Baseline characteristics

	Experimental group ($n=31$)	Control group ($n=31$)	p value
Age (years)	39.7 ± 5.5	39.9 ± 5.9	0.724
Body mass index (kg/m^2)	22.6 ± 3.2	23.2 ± 3.5	0.554
Parity			0.607
Nulliparous	14 (45.2%)	12 (38.7%)	
Parous	17 (54.8%)	19 (61.3%)	
History of abdominal surgery	13 (41.9%)	8 (25.8%)	0.180
Preoperative hemoglobin (mg/dL)	12.5 ± 1.9	12.2 ± 1.8	0.434
Preoperative AMH level	2.2 ± 2.2	2.0 ± 3.1	0.258
Laparoscopic approach			0.130
Single-port laparoscopy	25 (80.6%)	29 (93.5%)	
Multi-port laparoscopy	6 (19.4%)	2 (6.5%)	
Main indication for myomectomy			0.853
Pelvic pain or pressure	4 (12.9%)	4 (12.9%)	
Abnormal uterine bleeding	9 (29.0%)	11 (35.5%)	
Rapid growing	18 (58.1%)	16 (51.6%)	
Number of uterine myomas	3.3 ± 2.2	2.6 ± 2.0	0.087
Diameter of largest myoma (cm)	7.1 ± 1.6	6.6 ± 1.6	0.278
Weight of extracted myomas (g)	162.6 ± 81.7	144.2 ± 100.5	0.289
Location of largest myoma			0.700
Anterior	17 (54.8%)	13 (41.9%)	
Posterior	8 (25.8%)	10 (32.3%)	
Lateral	2 (6.5%)	4 (12.9%)	
Fundal	4 (12.9%)	4 (12.9%)	
Adhesiolysis	4 (12.9%)	3 (9.7%)	> 0.999

AMH anti-Müllerian hormone

Table 2 Primary and secondary outcome measures

	Experimental group ($n=31$)	Control group ($n=31$)	p value
Operative blood loss (mL)	56.3 ± 42.8	138.2 ± 48.8	< 0.001
Change in hemoglobin (g/dL)	1.0 ± 0.5	1.7 ± 1.1	0.002
Need for blood transfusion	0	2 (6.5%)	0.492
Return to regular menstruation	31 (100.0%)	31 (100.0%)	–
Operative complications	0	0	> 0.999
Intraoperative complications	0	0	
Postoperative complications[a]	0	0	

[a]Postoperative complications were defined as grade III or higher complications occurring within 3-month post-surgery according to the Clavien–Dindo classification

blood loss and potentially decrease the need for transfusion. Further experience and technical refinements will continue to improve the operative results.

The main concern about mechanical occlusion of the blood supply to the uterus is that prolonged ischemia may result in potential damage to the uterine endometrium and myometrium. In a randomized controlled trial, Taylor et al. investigated the impact of triple tourniquets during open myomectomy. In this trial, patients randomized to the treatment group ($n=14$) had triple tourniquets (one to occlude the uterine arteries and two to occlude the left and right ovarian vessels) [11]. This trial found a significant decrease in operative blood loss in the tourniquet group (489 ± 362 mL vs. 2359 ± 1241 mL, $p<0.001$) and a significantly lower transfusion requirement (1 patient vs. 11 patients, $p<0.001$) compared with the control group in which tourniquets were not used. No adverse event related to mechanical occlusion of the uterine and ovarian blood

Table 3 Other surgical outcomes

	Experimental group ($n=31$)	Control group ($n=31$)	p value
Total operative time (min)	87.9 ± 35.3	81.5 ± 27.8	0.725
Skin incision time	4.2 ± 2.0	3.5 ± 1.8	0.189
Skin closure time	12.4 ± 4.7	12.3 ± 4.3	0.740
Myoma enucleation time	13.1 ± 14.6	17.6 ± 10.4	0.006
Uterine suturing time	19.5 ± 10.7	24.6 ± 8.8	0.006
Morcellation time	16.2 ± 14.6	13.3 ± 9.5	0.530
Procedure time for TESTO (min)[a]	14.4 ± 3.2	–	
Vascular occlusion time (min)	29.0 ± 7.0	–	
Degree of surgical difficulty[b]	3.9 ± 1.2	5.6 ± 1.4	< 0.001
Failure of intended surgery	1 (3.2%)	0	> 0.999
Insertion to additional trocars	1 (3.2%)	0	
Conversion to laparotomy	0	0	
Length of hospital stay (days)	2.1 ± 0.3	2.2 ± 0.6	0.654

TESTO, temporary simultaneous two-arterial occlusion

[a]Procedure time for TESTO was defined as the time needed to put the vascular clamps (the time from the opening of the retroperitoneum and the positioning of the bulldog clamp)

[b]The degree of surgical difficulty was evaluated subjectively by the operator using a 10-point scale ranging from 1 (low difficulty) to 10 (high difficulty)

supply occurred in the tourniquet group. Al-Shabibi et al. conducted a randomized trial comparing operative blood loss with triple tourniquets to occlude the uterine blood supply against preoperative treatment with gonadotrophin-releasing hormone analogues in open myomectomy [12]. They reported that triple tourniquets were significantly more effective than preoperative treatment with gonadotrophin-releasing hormone analogues in reducing operative blood loss during open myomectomy, and that no complication related to uterine perfusion occurred in the tourniquet group. To their knowledge, none of the women who in the last 7 years in whom tourniquets were routinely used became menopausal unexpectedly, thus, they concluded that mechanical occlusion of the blood supply to the uterus is a safe option for reducing operative blood loss. In this study, we set 60 min as the maximal time for a safe occlusion, allowing 30 min for each occlusion period separated by a 5-min reperfusion interval to minimize the negative influence of controlled ischemia on uterine perfusion. Although the uterine arteries are the major source of blood supply to the uterus and its derived myomas, the collateral circulation will be established from the vaginal artery and small pelvic arteries to supply blood for the uterus if the uterine and utero-ovarian arteries are occluded by vascular clamping.

The procedure time for TESTO in our study (14.4 ± 3.2 min) was consistent with that of a previous study, showing that, on average, the surgeon needed 15 min for bilateral bulldog clamping of the uterine arteries [13]. Surprisingly, although the TESTO procedure took more time for the experimental group, the total operative time was not significantly different between the two groups. We believe that the significant decrease in operative blood loss decreasing the times required for myoma enucleation and uterine suture, thus compensating for the additional time of the TESTO procedure. Decrease in operative blood loss may also contribute to less surgical difficulty in the experimental group than in the control group.

This study has some limitations. First, the main limitation of this study is that the procedures were performed by a single experienced surgeon. Thus, our results may not be applicable to other surgeons. Second, we did not measure the postoperative uterine perfusion parameters, such as the uterine artery resistance index and pulsatility index by using transvaginal color Doppler ultrasonography before and after surgery [14]. However, comparative studies of Doppler vascularization before and after occlusion of uterine arteries in patients who underwent laparoscopic myomectomy did not show significant differences in the resistance index of the uterine arteries and the homogeneity of the myometrial vasculature [13, 15]. Third, the postoperative ovarian reserve was not evaluated in this study. Future studies measuring the postoperative serum anti-Müllerian hormone levels are required to ensure the safety of the TESTO procedure during laparoscopic myomectomy.

In conclusion, this study demonstrates that the use of the TESTO procedure is statistically significantly effective in reducing operative blood loss and hemoglobin loss during laparoscopic myomectomy. No conspicuous complication occurred in any group. However, for the safe performance of TESTO, an adequate learning curve is needed, and careful attention should be given to the risk of injury to the pelvic vasculatures and organs during laparoscopic myomectomy.

More randomized studies with a larger number of patients with symptomatic myomas are required to address the efficacy and safety of this procedure in terms of operative outcomes.

Compliance with ethical standards

Disclosures Drs. Hwa Cheong Kim and Taejong Song have no conflicts of interest or financial ties to disclose.

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