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ORIGINAL ARTICLE

# Laparoscopic versus open repair for inguinal hernia in children: a retrospective cohort study

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## Abstract

**Purpose** We compared the outcomes of laparoscopic surgery (LS) with those of open surgery (OS) for unilateral and bilateral pediatric inguinal hernia.

**Methods** Using a nationwide claim-based database in Japan, we analyzed data from children younger than 15 years old, who underwent inguinal hernia repair between January 2005 and December 2017. Patient characteristics, incidence of reoperation, postoperative complications, length of hospital stay, and duration of anesthesia were compared between LS and OS for unilateral and bilateral hernia.

**Results** Among 5554 patients, 2057 underwent LS (unilateral 1095, bilateral 962) and 3497 underwent OS (unilateral 3177, bilateral 320). The incidence of recurrence was not significantly different between OS and LS (unilateral: OS 0.2% vs. LS 0.3%, $p=0.44$, bilateral: OS 0.6% vs. LS 0.6%, $p=1.00$). The incidence of metachronous hernias was significantly higher in the OS group than in the LS group (4.8% vs. 1.0%, $p<0.001$). The surgical site infection rate was significantly lower after OS than after LS for unilateral surgeries (0.9% vs. 2.2%, $p=0.002$). There was no difference between OS and LS in the length of hospital stay.

**Conclusion** Both OS and LS had a low incidence of recurrence in children; however, the incidence of metachronous hernias was lower for LS, which may influence operative technique decisions.

**Keywords** Laparoscopic hernia repair · Pediatric inguinal hernia · Contralateral metachronous inguinal hernia · Pediatric surgery

## Introduction

Inguinal hernia is common in infants and children and hernia repair is one of the most frequently performed pediatric operations [1, 2]. The incidence of inguinal hernia in pediatric patients ranges from 0.8 to 4.4% [3-5], being highest in infants, especially premature infants, and decreases with age [4].

For over 50 years, the standard method of repair for pediatric inguinal hernia repair has been open surgery (OS) because of its low rate of complications and recurrence [6]. Recently, however, several large case studies have reported a low rate of complications and recurrence for laparoscopic surgery (LS) [7-13]. The advantages of LS are its cosmetic merit, shorter length of hospital stay, faster recovery, and ability to prevent metachronous contralateral hernia [14-18]. Therefore, the use of LS in pediatric patients has been increasing in recent years.

Interestingly, some studies, including randomized control trials, do not show clear advantages for LS [19, 20]. These previous randomized control studies were based on a small number of patients (41–179), with an insufficient follow-up period to evaluate recurrence and metachronous contralateral hernia (3.5–24 months). Additionally, most retrospective studies were reported from experienced high-volume

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centers. Therefore, there is no proven superiority of either of these surgical methods. The purpose of the present study was to assess the outcomes of LS vs. OS using a nationwide database in Japan.

## Methods

This study was conducted according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [21]. The study was approved by the Ethics Committee of the Graduate School and Faculty of Medicine, Kyoto University (approval number: R1583, June 15, 2018). The requirement for informed consent was waived due to the anonymous nature of the data.

### Data sources

We performed a non-interventional, retrospective nationwide cohort study of pediatric inguinal hernia repair. The medical claims database was provided by JMDC, Inc. (Tokyo, Japan) and included information from approximately 100 health insurance associations in Japan, covering approximately 3.0% of the Japanese population. The database contained the claims data for the employees of companies and their family members and could track patients even when they visited other hospitals. The present study cohort comprised mainly employee family members. Such patients could be followed until the patient changed from their family health insurance to their own insurance or the family insurance changed; for example, if the employee changed jobs or quit, or if the family insurance changed from father to mother. The database contained the following information: age, sex, medical and pharmacy claims data (inpatient and outpatient), diagnoses coded according to MEDIS-DC (The Medical Information System Development Center, Tokyo, Japan) [22], medication information coded according to the World Health Organization Anatomical Therapeutic Chemical (ATC) classification, and procedural information defined using Japanese standardized procedure codes (K codes).

### Study cohort

We identified patients aged less than 15 years, who underwent LS or OS for primary inguinal hernia between January 2005 and December 2017. We excluded children who were hospitalized for other diseases; those who underwent other operations simultaneously, with the exception of umbilical hernia repair, orchidopexy, and other minor surgeries such as resection of an accessory ear or a benign skin tumor, and frenotomy; patients who underwent emergency surgery; and patients who underwent prior inguinal hernia repair. The included patients were classified into the following four groups: unilateral LS, unilateral OS, bilateral LS, and bilateral OS.

### Outcome measures

The main outcome measure was the incidence of reoperation, which included recurrence and metachronous hernia (MH). The secondary outcome measures were the incidence of recurrence and MH (as the number per 1000 person-years), postoperative complication rate, length of hospital stay, duration of anesthesia, and proportion of those who changed hospitals at the second surgery.

We collected data on complications, using MEDIS-DC codes, which correspond to ICD-10 codes (Online Resource 1). Data on surgical site infections (SSI), pain, bleeding, edema, urinary tract infection, vas deferens injury, and intestinal injury within 1 month after primary hernia repair were collected. Data on fever during the same hospitalization were collected, as various reasons for a fever are possible after hospitalization, such as flu and otitis media. We also collected data on antibiotic administration to establish the severity of SSIs. We defined recurrence as the preoperative diagnosis of recurrent hernia or reoperation after bilateral hernia repair. We defined MH as reoperation after primary unilateral hernia repair without a diagnosis of recurrent hernia. We also examined the patient number, laterality, MH rate, and follow-up rate for each year during the period from 2005 to 2017.

### Statistical analysis

Continuous variables are presented as the median (interquartile range, IQR) or the mean (standard deviation, SD), according to distribution of the data, and categorical variables are presented as a number and percentage (%). We used the Mann–Whitney *U* test to compare continuous variables and the chi-squared test to compare categorical variables. Because of the exploratory nature of this study, a $p$ value of $< 0.05$ was considered significant. All statistical analyses were performed using SAS software (Version 9.4; SAS Institute, Cary, NC).

## Results

Figure 1 shows the patient selection flow diagram and Table 1 summarizes the patient characteristics. We identified 5676 patients from 516 hospitals who met the inclusion criteria and excluded 122 (58 who were hospitalized with other diseases, 44 who underwent other operations on the same day, 8 who underwent emergency surgery, and 12 with prior inguinal hernia repair). Thus, the number of eligible patients was 5554, with 2057 patients in the LS groups (unilateral

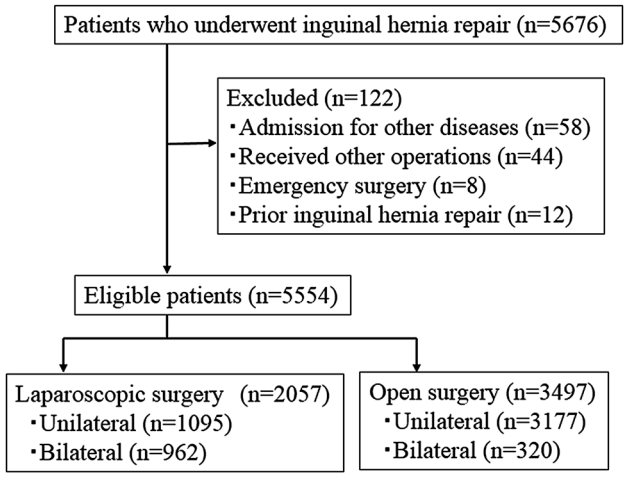


**Fig. 1** Patient selection flowchart

1095, bilateral 962) and 3497 patients in the OS groups (unilateral 3177, bilateral 320). Significantly more boys underwent unilateral hernia repair in the OS groups (59% vs. 52% for the OS vs LS groups, respectively). The patients who underwent bilateral hernia surgery were significantly younger in the OS group than in the LS group (median age, 33.5 months vs. 49 months, respectively; $p < 0.001$). The follow-up period was significantly longer in the OS group than in the LS group for both unilateral (46 months vs. 25 months, respectively; $p < 0.001$) and bilateral hernia surgery (41 months vs. 25.5 months, respectively; $p < 0.001$).

## Efficacy

Table 2 summarizes the outcomes of each type of surgery. The incidences of recurrence did not differ between OS and LS for both unilateral (0.2% vs. 0.3%, respectively; $p = 0.44$) and bilateral hernia repairs (0.6% vs. 0.6, respectively; $p = 1.00$). The incidence of recurrence per 1000 person-years was 0.38 for unilateral OS, 1.05 for unilateral LS, 1.50 for bilateral OS, and 2.38 for bilateral LS. There was a significant difference in the incidence of MH between the OS and LS groups (4.8% vs. 1.0%, respectively; $p < 0.001$). The incidence of MH per 1000 person-years was 11.42 for unilateral OS and 3.84 for unilateral LS. Table 3 shows the incidence of MH for each year. Although there were variations, the incidence of MH was lower in the LS group than in the OS group in the short follow-up period.

There was a significant difference in the incidence of SSIs after OS vs. LS for unilateral hernia with vs. without antibiotics (0.4% vs. 0.9%; $p = 0.033$ vs. 0.9% vs. 2.2%; $p = 0.002$, respectively). Postoperative pain (7% vs. 4.9%, respectively; $p = 0.017$) and fever (0.9% vs. 0.1%, respectively; $p < 0.001$) were significantly lower after LS than after OS. Although the median duration of anesthesia was significantly shorter for OS than for LS for unilateral hernia repair (63 min vs. 75 min, respectively; $p < 0.001$), it was significantly longer for OS than for LS for bilateral hernia repair (83 min vs. 75 min, respectively; $p < 0.001$). However, there was no difference in the length of hospital stay between OS and LS for unilateral or bilateral hernia repair (unilateral: 2.7 days vs. 2.7 days, respectively; $p = 0.25$ and bilateral: 2.9 days vs. 2.7 days, respectively; $p = 0.060$). Eleven patients in the unilateral OS group and four patients in the unilateral LS group underwent second surgery for recurrence of MH in different hospitals. None of the patients with bilateral hernias, who needed second surgery, changed hospitals.

**Table 1** Patient characteristics

| | Unilateral ($n = 4272$) | | | Bilateral ($n = 1282$) | | |
|---|---|---|---|---|---|---|
| | Open ($n = 3177$) | Laparoscopic ($n = 1095$) | $p$ | Open ($n = 320$) | Laparoscopic ($n = 962$) | $p$ |
| Sex (male), $n$ (%) | 1860 (59) | 572 (52) | < 0.001 | 144 (45) | 405 (42) | 0.36 |
| Age (months), median (IQR) | 47 (19–74) | 49 (22–72) | | 33.5 (13–63) | 49 (22–75) | < 0.001 |
| Age < 9 months, $n$ (%) | 375 (12) | 95 (9) | 0.0043 | 56 (18) | 103 (11) | 0.0014 |
| Additional surgery, $n$ (%) | | | | | | |
| Umbilical hernia repair | 35 (1.1) | 20 (1.8) | 0.067 | 5 (1.6) | 11 (1.1) | 0.56 |
| Orchidopexy | 18 (0.6) | 2 (0.2) | 0.11 | 1 (0.3) | 1 (0.1) | 0.41 |
| Other minor surgery | 20 (0.6) | 4 (0.4) | 0.31 | 2 (0.6) | 5 (0.5) | 0.82 |
| Follow-up period (months), median (IQR) | 46 (21–74) | 25 (11–45) | < 0.001 | 41 (19–75) | 25.5 (12–46) | < 0.001 |

*IQR* interquartile range

**Table 2** Open vs. laparoscopic repair of inguinal hernia in children

| | Unilateral ($n=4272$) | | | Bilateral ($n=1282$) | | |
|---|---|---|---|---|---|---|
| | Open ($n=3177$) | Laparoscopic ($n=1095$) | $p$ | Open ($n=320$) | Laparoscopic ($n=962$) | $p$ |
| Duration of anesthesia (min), median (IQR) | 63 (50–80) | 75 (55–96) | < 0.001 | 83 (65–107) | 75 (58–95) | 0.006 |
| With umbilical hernia repair (min), median (IQR) | 120 (95–141) | 99 (83.5–124) | | 113 (109–116) | 119 (98–142) | |
| Data missing, *n* (%) | 1737 (55) | 809 (74) | | 187 (58) | 690 (72) | |
| Complications | | | | | | |
| Surgical site infection, *n* (%) | 29 (0.9) | 24 (2.2) | 0.002 | 6 (1.9) | 17 (1.8) | 1.00 |
| With antibiotics, *n* (%) | 12 (0.4) | 10 (0.9) | 0.033 | 3 (0.9) | 7 (0.7) | 0.71 |
| Pain, *n* (%) | 222 (7.0) | 54 (4.9) | 0.017 | 16 (5.0) | 62 (6.4) | 0.35 |
| Bleeding, *n* (%) | 5 (0.2) | 1 (0.1) | 0.61 | 0 (0) | 1 (0.1) | 0.56 |
| Edema, *n* (%) | 14 (0.4) | 3 (0.3) | 0.45 | 0 (0) | 2 (0.2) | 0.41 |
| Fever, *n* (%) | 30 (0.9) | 1 (0.1) | < 0.001 | 2 (0.6) | 3 (0.3) | 0.44 |
| Urinary tract infection, *n* (%) | 2 (0.1) | 3 (0.3) | 0.078 | 2 (0.6) | 3 (0.3) | 0.44 |
| Vas deferens injury | 0 (0) | 0 (0) | – | 1 (0.3) | 0 (0) | 0.083 |
| Intestinal injury | 0 (0) | 1 (0.1) | 0.089 | 0 (0) | 0 (0) | – |
| Length of hospital stay (days), mean (SD) | 2.7 (0.9) | 2.7 (1.0) | 0.25 | 2.9 (1.1) | 2.7 (1.0) | 0.060 |
| Recurrence (ipsilateral), *n* (%) | 5 (0.2) | 3 (0.3) | 0.44 | 2 (0.6) | 6 (0.6) | 1.00 |
| Recurrence (per 1000 person-years) | 0.38 | 1.05 | | 1.50 | 2.38 | |
| Metachronous hernia, *n* (%) | 151 (4.8) | 11 (1.0) | < 0.001 | – | – | |
| Metachronous hernia (per 1000 person-years) | 11.42 | 3.84 | | | | |
| Time between primary and second surgery (months), mean (SD) | 11 (6–22) | 9 (5–18) | | | | |
| Change in hospital for second surgery, *n* (%) | 11 (0.4) | 4 (0.4) | 0.93 | 0 (0) | 0 (0) | – |
| Subsequent umbilical hernia repair, *n* (%) | 15 (0.5) | 1 (0.1) | 0.075 | 3 (0.9) | 3 (0.3) | 0.16 |

*SD* standard deviation, *IQR* interquartile range

## Discussion

The results of the present study, which analyzed a nationwide database, revealed no significant difference in the incidence of recurrence between OS and LS, but a significant difference in the incidence of MH between OS and LS.

OS is the worldwide standard for pediatric inguinal repair because of its safety and low rate of recurrence [6, 20]. Moreover, the cost of OS is less than that of LS in Japan (60,000 yen vs. 229,600 yen), as OS can be performed without expensive laparoscopic instruments. However, LS has gained popularity because of its good clinical outcomes [8, 10, 11, 23]. Although six previous randomized controlled studies compared LS and OS [15, 19, 24-27], an obvious advantage of either method is still debatable. According to a recent report, pediatric surgeons still tend to prefer OS to LS [28]. From 2009 to 2014, only 13% of hernia repairs in children were performed as LS in the United States [28]. In Japan, about 27% of children with inguinal hernias underwent LS between 2010 and 2016 [29]. In the present study, approximately 37% of the patients underwent LS between 2005 and 2017, with the proportion of LS increasing year by year (Table 3). Over the last 2 years of the study period, LS was performed for over 50% of the patients.

There are several different LS procedures and the outcomes differ depending on the method [30, 31]. The incidence of recurrence after laparoscopic intraperitoneal simple Z-type or purse-string sutures has been reported as 3.1%, 3.4%, and 4.1% [9, 32, 33]. In Japan, the most common laparoscopic procedures are percutaneous extraperitoneal closure (LPEC) and single-incision LPEC (SILPEC), both of which are associated with low incidences of recurrence (0–0.9%) [7, 8, 11, 12, 34, 35]. As the present study analyzed information from a medical claims database, we could not differentiate between intraperitoneal simple closure and the LPEC procedure because the same reimbursement code

**Table 3** Surgical techniques, laterality, metachronous hernias, and patients lost to follow-up per year

| Year | Number of patients | Laparoscopic surgery ($n=2057$) | | | | Open surgery ($n=3497$) | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | $N$ (%)[a] | Bilateral, $n$ (%)[b] | Metachronous hernia, $n$ (%)[c] | Lost to follow-up, $n$ (%)[b] | $N$ (%)[a] | Bilateral, $n$ (%)[d] | Metachronous hernia, $n$ (%)[e] | Lost to follow-up, $n$ (%)[d] |
| 2005 | 113 | 5 (4) | 3 (60) | 0 | 1 (20) | 108 (96) | 10 (9) | 4 (4.1) | 16 (15) |
| 2006 | 117 | 8 (7) | 4 (50) | 0 | 2 (25) | 109 (93) | 8 (7) | 4 (4.0) | 19 (17) |
| 2007 | 109 | 11 (10) | 1 (9) | 0 | 0 | 98 (90) | 13 (13) | 3 (3.5) | 10 (10) |
| 2008 | 128 | 9 (7) | 2 (22) | 0 | 3 (33) | 119 (93) | 11 (9) | 11 (10.2) | 14 (12) |
| 2009 | 163 | 27 (17) | 12 (44) | 1 (6.7) | 7 (26) | 136 (83) | 13 (10) | 4 (3.3) | 34 (25) |
| 2010 | 274 | 58 (21) | 25 (43) | 1 (3.0) | 12 (21) | 216 (79) | 19 (9) | 12 (6.1) | 46 (21) |
| 2011 | 377 | 95 (25) | 41 (43) | 2 (3.7) | 7 (7) | 282 (75) | 22 (8) | 13 (5) | 35 (12) |
| 2012 | 457 | 124 (27) | 69 (56) | 0 | 12 (10) | 333 (73) | 29 (9) | 12 (3.9) | 54 (16) |
| 2013 | 649 | 190 (29) | 92 (48) | 2 (2.0) | 21 (11) | 459 (71) | 33 (7) | 24 (5.6) | 49 (11) |
| 2014 | 695 | 292 (42) | 138 (47) | 1 (0.6) | 20 (7) | 403 (58) | 38 (9) | 23 (6.3) | 50 (12) |
| 2015 | 777 | 349 (45) | 165 (47) | 3 (1.6) | 33 (9) | 428 (55) | 42 (10) | 16 (4.1) | 35 (8) |
| 2016 | 855 | 440 (51) | 209 (48) | 1 (0.4) | 22 (5) | 415 (49) | 44 (11) | 16 (4.1) | 20 (5) |
| 2017 | 840 | 449 (53) | 201 (45) | 0 | 7 (2) | 391 (47) | 38 (10) | 9 (2.5) | 6 (2) |

*n* number

[a] *n*/number of patients each year

[b] *n*/number of laparoscopic procedures each year

[c] *n*/number of unilateral laparoscopic procedures each year

[d] *n*/number of open procedures each year

[e] *n*/number of unilateral open procedures each year

is assigned to both procedures in Japan. However, the outcomes of LS in the present study were similar to those of LPEC or SILPEC. Further studies should be conducted to compare laparoscopic surgical procedures.

The incidence of recurrence in the present study was similar to that in a previous nationwide database study in Japan (OS 0.3% vs. LS 0.4%) [29]. In a recent report from the United States, the incidence relative to the follow-up period was 3.46 per 1000 person-years [36]. The present study had a better incidence of recurrence per 1000 person-years. Furthermore, OS was associated with a lower incidence of recurrence relative to the follow-up period than LS (unilateral: OS 0.38 vs. LS 1.05; bilateral: OS 1.50 vs. LS 2.38, respectively). The reason for this difference between studies from Japan and the United States is unclear. As the concept of the OS procedure is almost the same, the difference among studies may be attributed to differences in patient characteristics, including ethnicity. Consistent with this, other studies from Asia have also shown a low incidence of recurrence after LS and OS (0–0.7%) [37-40]. The follow-up rate and period may be another reason for the differences in results. About 10% of the patients in the present study were lost to follow-up (Table 3). Further studies are necessary to clarify the reasons for the difference in these results.

A previous systematic review reported that a hernia will develop on the opposite side in approximately 7% of the patients who undergo unilateral inguinal hernia and 12.5% of such patients with a minimum follow-up > 5 years [41]. Moreover, MH is associated with contralateral patent processus vaginalis (CPPV) and CPPV repair prevents future MH. We could not identify the proportion of CPPV cases or the number of CPPV repairs in the present study; however, it has been reported that 40–60% of children with unilateral inguinal hernia have CPPV, and when CPPV is detected, it is usually repaired [8, 11, 12, 14, 34]. As with the incidence of recurrence, the incidence of MH also depends on the follow-up rate and period. In the present study, the incidence of MH in the unilateral OS group was 4.8%, but the true incidences of recurrence and MH are probably higher because of incomplete follow-up.

The difference in the incidence of MH between the present study and the previous nationwide cohort study in Japan (3.4% for OS and 0.3% for LS) may result from the characteristics of the databases [29]. In Japan, patients can select their hospital and some patients change hospitals after their first surgery, resulting in missing information about the second surgery from the DPC (Diagnosis Procedure Combination) database, but not from the database of the present study, which had the ability to track the data of each patient, even when the patient

visited other hospitals. In the present study, the proportion of patients who changed hospitals for a second operation for recurrence or MH was 11/156 (7%) for unilateral OS, 4/14 (29%) for unilateral LS, and 0 for bilateral OS/LS. This might be one reason for the higher incidence of MH in the present than in the previous large cohort study in Japan [29]. A complete long-term follow-up study would be required to reveal the true incidence of MH.

The findings of previous studies on SSIs after hernia repair have varied widely [11, 16, 29]. In the present study, the incidence of SSI was significantly higher after LS than after OS for unilateral hernia repair, with or without antibiotics. Another large cohort study from Japan reported a lower incidence of SSI; however, the database used lacked post-discharge data [29]. In the present study, 18% of SSIs were diagnosed during hospitalization.

The duration of anesthesia was significantly longer for LS than for OS for unilateral hernia repair, but shorter for LS than for OS for bilateral hernia repair. This is consistent with the findings of the previous large cohort study [29]. The operative time varies widely, depending on the surgical team experience, operative technique, and patient characteristics. Six randomized control studies comparing the operative times for OS and LS reported various results as follows: two favored OS, two reported no significant difference, and two favored LS [15, 19, 24-27]. The present study may show the trend of anesthesia time in Japan for pediatric inguinal hernia repair; however, further research is necessary to confirm this result.

The present study has several limitations. First, some critical data were unavailable; for example, left- or right-sided hernia, body weight, height, hernia size, conversion data, operative technique details, and severity of complications. This is important as the incidence of MH has been reported to be higher in left-sided inguinal hernia than in right-sided inguinal hernia [14] and the size of the hernia defect is a risk factor for recurrence [42]. Moreover, the conversion rate has been reported to range from 0 to 1.7%, with most studies reporting a 0% conversion rate [43]. There were no technique details in the database. In Japan, the OS technique is usually simple high ligation and the LS technique is usually LPEC or SILPEC [29]. We used antibiotic administration data to improve the reliability of the diagnosis of SSI, but there was no additional operation for SSIs. Second, about 45% of the patients underwent surgery in the three most recent years of the 13-year study period. Therefore, the observation period may have been insufficient for many patients and about 10% were lost to follow-up. Thus, the incidences of recurrence, MH, and complications found in this study are likely to be lower than the actual proportions. Additionally, the database lacked data on the duration of anesthesia for many patients. Depending on the timing of the operation, data about the time of anesthesia were limited or missing.

## Conclusion

In the present study, both OS and LS had similarly low incidences of recurrence, of > 0.3% for unilateral hernias and 0.6% for bilateral hernias. Both methods have advantages and disadvantages; therefore, the choice of operative technique depends on the patient, their family, and the doctor's preference. For unilateral hernia, a lower incidence of MH for LS than for OS should be considered during decision -making.

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### Compliance with ethical standards

**Conflict of interest** K.K. received research funding from Olympus Corporation. M.N. and K.I. have no conflicts of interest to declare.

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