

Comparison of single absorbable tacker vs. conventional method in fixating the mesh in bilateral inguinal hernia undergoing laparoscopic transabdominal preperitoneal (TAPP): A randomized control trial study

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Background: The current study aims to investigate the superior mesh fixation method, single absorbable tacker versus conventional method, in patients undergoing bilateral inguinal hernia repair through the laparoscopic total abdominal preperitoneal (TAPP) approach. **Materials and Methods:** The current randomized clinical trial has been conducted on 81 patients undergoing bilateral hernia repair through TAPP. The patients were randomly assigned into one of the mesh fixation groups including single absorbable tacker (Group S) ($n = 41$) and conventional method (Group C) ($n = 40$). All patients were assessed during the hospital stay and 1 month postoperatively to assess the surgery-associated complications and days for return to daily activity. Eura-Hs questionnaire was applied to assess the quality of life (QOL) after hernia surgery during 12-month follow-up. **Results:** The duration of bilateral inguinal hernia operation ($P = 0.067$), postoperative urinary catheterization ($P = 0.813$), and hospital stay duration ($P = 0.779$) did not differ between the groups; whereas Group C significantly required a longer time for returning to daily activity ($P < 0.001$). Only a patient in Group C represented hematoma ($P = 0.494$). Seroma incidence was not statistically different between the two groups ($P = 0.712$). Postoperative pain was statistically less in Group S ($P < 0.001$ for all the assessments). Postoperative QOL within a year after hernia repair revealed an insignificant difference between the groups in general ($P > 0.05$); however, a pain subscale was significantly less in Group S ($P = 0.002$). **Conclusion:** Based on the findings of this study, a single absorbable tacker was generally superior to the conventional method considering its less pre- and postoperative complications. However, the two methods did not differ regarding 1-year follow-up QOL.

Key words: Hernia, inguinal, laparoscopy, postoperative complications, quality of life, surgical mesh

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INTRODUCTION

Inguinal hernia repair is the most frequent surgical-associated condition involving primary care physicians. Annually, approximately, 20 million groin hernia repairs are performed worldwide.^[1,2] Inguinal hernia is the fourth-most prevalent condition in the military, which affects medical teams and personnel.^[3]

Surgical procedure is the gold standard treatment for inguinal hernia repair. In recent decades, laparoscopic hernia repair has gained more popularity considering decreased recovery time and less postoperative pain.^[1-4]

The gold standard technique in laparoscopic repair of bilateral inguinal hernia is total abdominal preperitoneal (TAPP). Accordingly, TAPP laparoscopy has been applied in which the peritoneal flap is raised, then the mesh is placed; however, the method of mesh

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fixation remained a matter of debate. Besides, the mesh-type fixation method has been modified in laparoscopic surgery to optimize the outcomes.^[4,5]

Self-fixating mesh is one of the laparoscopic approaches which does not need any fixation instrument, but its placement is intricate and most of the surgeons do not favor it to be applied.^[4,6] The nonfixation method is another technique in this term; however, the major body of evidence opposes it considering the high probability rate of recurrence and mesh migration.^[4,7] The other technique is transfacial sutures to fix the mesh, which requires well-trained laparoscopic surgeons.^[8,9]

Tackers, categorized as absorbable (plastic) versus nonabsorbable (titanium) ones, are helpful and common instruments applied to fixate the mesh. Numerous efforts have been made to compare these two groups regarding postoperative pain, complications, and the patient's quality of life (QOL). Titanium tacks might cause nerve entrapment, erosion into the bowel, and dense adhesion bands.^[4,10,11] Therefore, absorbable tacks have been introduced and led to more promising outcomes.^[12,13]

Absorbable tacks have a lower rate of postoperative pain and fewer doses of analgesics requirement compared to titanium tacks.^[14] Pain is probably the most well-known complication which involves surgeons postoperatively. To decrease postoperative pain, it is essential to use a few tackers to fix the mesh.^[13]

Nevertheless, a paucity of knowledge is available regarding peri and postoperative as well as long-term QOL in patients undergoing groin hernia repair using a single absorbable tack to fix the mesh.

Hence, this study aims to evaluate whether the number of absorbable tackers affects the perioperative and postoperative complications and QOL of bilateral inguinal hernia patients undergoing mesh fixation in TAPP surgery during 1-year follow-up.

METHODS

This prospective randomized control trial (RCT) compared two methods of mesh fixation in TAPP laparoscopy surgery. Group S (single tacker) versus Group C (convention method). Our objectives were to compare perioperative and postoperative complications, and QOL between the two groups.

This study was designed according to the tenets of the Helsinki Declaration and was primarily proposed to the medical ethics committee and approved through code

number IR.AJAUMS.REC.1400.240. Then, it was enrolled in the Registry of Clinical Trials through code number IRCT 20100620004219N1. The study protocol was explained to the patients, and they were informed about the confidentiality of their personal information and were requested to sign written consent of participation in the trial.

Inclusion and exclusion criteria

Patients who were candidates for bilateral inguinal hernia repair aged 18–80 years with no history of previous surgery or emergency hernia surgery (strangulated), those with the American Society of Anesthesiologists (ASA) Grade 1, 2, were enrolled in the study. Those who had a chronic cough or needed additional abdominal wall surgery during the follow-up period were excluded from the study. This study is a parallel RCT with a 1/1 allocation ratio.

Then, the patients were assigned into one of the intervention groups, Group S (single tacker) versus Group C (conventional method) using random envelopes containing a code allocating the patients to one of the interventions. The patients, the physician who followed the patients, and the person who analyzed the data were blinded by the studied groups.

The flow charts of the patients are shown in Figure 1.

Surgical technique

A single dose of the first generation of cephalosporin was given 30 min before the induction of general anesthesia. The abdominal cavity was entered through Hasson's technique under direct vision. The pneumoperitoneum with CO₂ was insufflated through a 10 mm trocar through the supraumbilical incision (15 mmHg). One 10 mm and 5 mm trocars were placed, as shown in Figure 2. The peritoneum was opened at the level of an anterior superior iliac spine and medially dissected to the medial of the umbilical ligament. The hernia sac was isolated and reduced. Mesh 15 × 10 polypropylene (3D MAX light BARD mesh) was applied through the 10 mm trocar.

In Group S, it was fixed with a single tacker against the abdominal wall and Cooper's ligament. In Group C, four tackers were used in the medial and lateral epigastric vessels and Cooper ligament. Taking tacks in the triangle of doom and triangle of pain were explicitly avoided.

The peritoneal flap was closed in a running manner with prolene 2-0. After suturing, the pneumoperitoneum pressure was decreased to 8 mm to check the continuity of the peritoneum. Trocars were removed under direct vision [Figure 3]. If a patient had a Foley catheter during the operation, the catheter was removed from the recovery room.

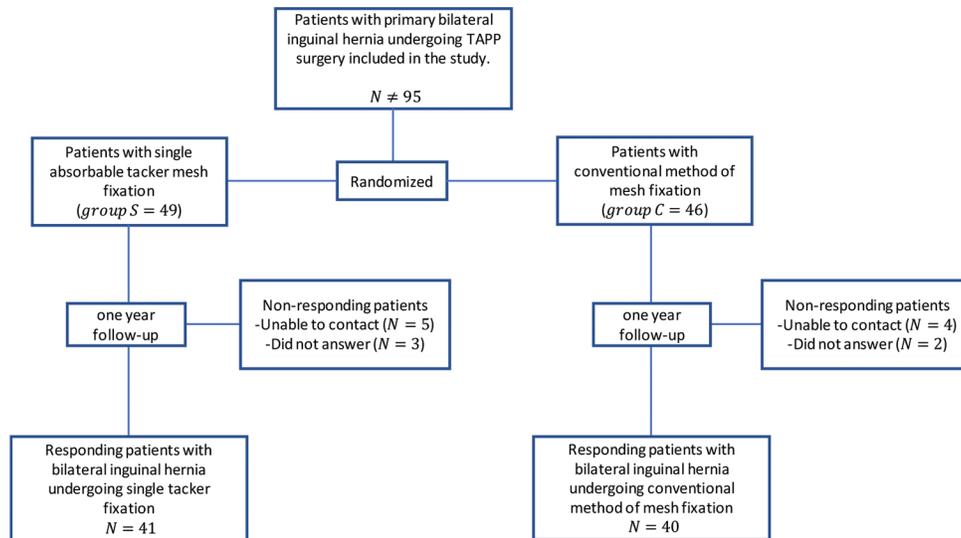


Figure 1: Flow chart of patients included in the study

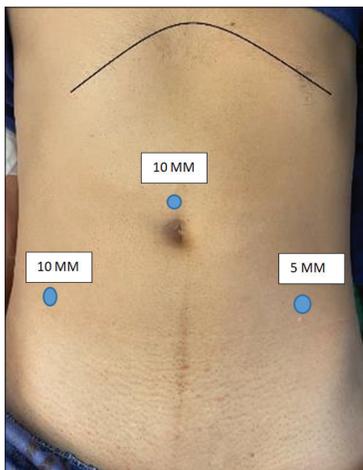


Figure 2: Trocars placement

A standard analgesia regimen was used for all patients during the hospital stay (pethidine 25 mg, TDS, I. M., and sup diclofenac 100 mg, TDS.). If a patient experienced urinary retention during the hospital stay, Nelaton or Foley catheters were used.

Patients were discharged if they had tolerable pain and urinated during the in-hospital stay. The standard discharge regimen included tablet paracetamol (500 mg q8 h), supp diclofenac (100 mg TDS), and cap cephalixin (500 mg q6 h). The wound dressing was changed every 2 days.

Data collection

Patients’ demographic data, such as age, gender, weight, body mass index (BMI), and American Anesthesia Class (ASA), were recorded. Perioperative data, including intraoperative events, length of hospital stay, duration of operation, and early postoperative complications (seroma, hematoma, in-hospital catheterization, and early postoperative

pain (under 6 months after surgery), were recorded. Pain in the early postoperative period was measured by the Visual Analog Scale (VAS).

Primary outcomes

All patients were visited during the hospital stay and 1 month postoperatively to assess the surgical site infection, seroma, hematoma, days to return to work and pain.

Patients were monitored by telephone follow-up in 6 months and 12 months after surgery regarding seroma, hematoma, recurrence, neuralgia, and pain. If a patient stated a complication in telephone follow-up, an in-person examination was done. All data were recorded in a checklist consisting of 32 multiple-choice questions filled out by an investigator.

Eura-Hs questionnaires were used to assess the QOL after hernia surgery.^[15,16] An investigator has filled out these two by asking patients, 12 months after surgery.

Statistics and analysis

The obtained data were entered into the Statistical Package for the Social Sciences (SPSS Inc., Chicago, Illinois, USA) version 24. Categorical data were presented in absolute numbers and percentages. For the analysis of qualitative variables, the Chi-square test was used. The normal distribution of the data was evaluated using the Kolmogorov–Smirnov test. If the data complied with normal distribution, they were reported in mean and standard deviation. The independent sample *t*-test was applied to compare quantitative variables. If the distribution was not normal, the Mann–Whitney test was used.

The generalized estimating equation was utilized to estimate the generalized linear model with a possible

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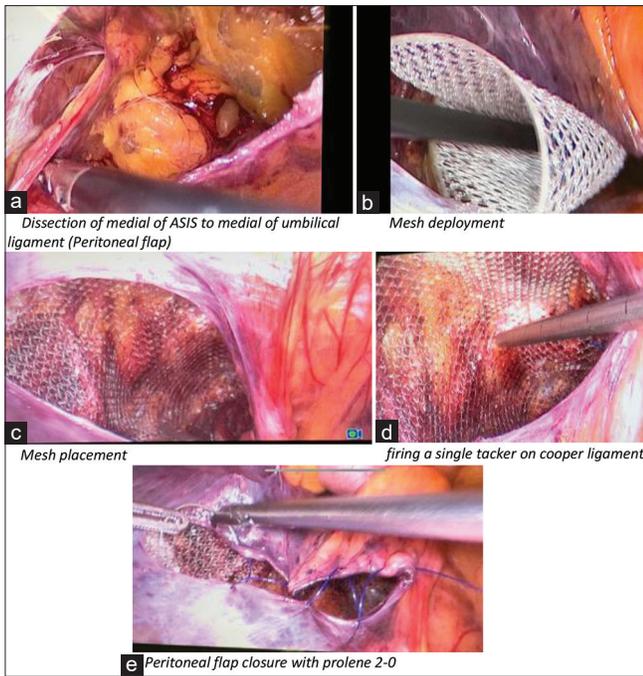


Figure 3: (a-e) Surgical technique of Mesh fixation in single tacker group

correlation between observing groups from different time points concerning postoperative pain. $P < 0.05$ was considered statistically significant.

RESULTS

This RCT was conducted on 81 patients undergoing TAPP laparoscopy surgery assessing the outcomes of different mesh fixation techniques, within the 1-year follow-up period. Accordingly, 40 patients underwent single tacker fixation (49.4%). The studied population had a mean age of 49.58 ± 15.48 years old and predominantly consisted of males (90.1%).

Demographics

The two assessed groups were statistically matched in terms of age ($P = 0.586$), gender ($P = 0.630$), and BMI distribution ($P = 0.728$), as shown in Table 1.

Perioperative data

The majority of the patients in both groups had ASA 1 classification which was not statistically different (85% in Group S and 90% in Group C) ($P = 0.519$).

The mean duration of operation was higher in the convention group, but the difference was not statistically significant (63.87 ± 13.42 vs. 69.02 ± 11.48 , $P = 0.067$).

The studied population had no intraoperative adverse events such as intestinal perforation, vascular injury, or nerve damage. The need for in-hospital catheterization was higher in Group C (convention), but the difference

Table 1: Demographic data

Groups	Group S (n=40)	Group C (n=41)	P
Sex, n (%)			
Men	36 (90)	37 (90.2)	0.630
Women	4 (10)	4 (9.8)	
Age, mean±SD	48.62±15	50.51±16	0.586
Weight, mean±SD	74.47±9.97	77.04±14.28	0.351
BMI, mean±SD	25.16±3.17	25.44±4.04	0.728

BMI=Body mass index; SD=Standard deviation

was not statistically significant ($P = 0.813$). The mean time for hospital stay was higher in the convention group, but it was not statistically significant ($P = 0.779$).

Postoperative data

There was no recurrence of groin hernia, surgical site infection, and postoperative neuralgia in any of the groups, and only a patient in the conventional group experienced hematoma which was controlled medically ($P = 0.494$). Seroma incidence was not statistically different between the two groups ($P = 0.712$). The mean time to back to work was shorter in Group S (14.30 ± 7.35 , 22.39 ± 9.3 , $P < 0.001$). The above data are shown in Table 2.

The mean pain score according to VAS in postoperative 1 was remarkably lower in Group S (2.07 ± 0.65 vs. 3.21 ± 1.01 , $P < 0.001$). The mean for pain was lower in 1 month, 6 months, and 12 months after surgery ($P < 0.001$). The above data are shown in Table 3.

Quality of life

Postoperative QOL after hernia repair was evaluated using the Eura-Hs questionnaire within 12 months after the interventions. The mean of pain in Group S was significantly lower compared to Group C (0.67 ± 0.47 , 1.04 ± 0.89 , $P = 0.002$). Restriction, cosmetic, and total QOL between the two groups were not statistically different Table 4.

DISCUSSION

The current trial tried to explain the outcomes of a single tacker versus the conventional method in fixing the mesh during bilateral TAPP inguinal hernia surgery. Accordingly, perioperative variables, early postoperative complications, and postoperative QOL in a period of 1-year follow-up were evaluated. To the best of our knowledge, the current study is the first one assessing single tacker versus conventional technique in the fixation of mesh for bilateral inguinal hernia repair.

Pain

Pain is a common postoperative complication of inguinal hernia surgery. To date, finding the best methods for reducing postoperative pain is a matter of debate. Regardless of the techniques applied to repair the

Table 2: Perioperative and postoperative data

	Group S (n=40)	Group C (n=41)	P
Past medical history, n (%)			
Diabetes mellitus	5 (12.5)	6 (14.63)	0.616
Hypertension	2 (5)	5 (12.19)	
Hypothyroidism	3 (7.5)	4 (9.75)	
ASA, n (%)			
1	34 (85)	37 (90)	0.519
2	6 (15)	4 (10)	
Duration of operation (min), mean±SD	63.87±13.42	69.02±11.48	0.067
Hospital stay (days), mean±SD	1.17±0.38	1.21±0.47	0.779
Seroma, n (%)	4 (10)	3 (7.3)	0.712
Hematoma, n (%)	0	1 (2.5)	0.494
Need for catheterization, n (%)	7 (17.7)	8 (20)	0.813
Time to return to work (days), mean±SD	14.30±7.35	22.39±9.3	<0.001

ASA=American Society of Anesthesiologists; SD=Standard deviation

Table 3: Mean of pain score (Visual Analog Scale) during 1-year follow-up

	Group S (Single)*	Group C (Convention)*	P
Pain			
At the time of discharge	2.07±0.65	3.21±1.01	<0.001
Postoperative 30 days	1.67±0.72	2.24±1.09	<0.001
Chronic pain			
Postoperative 6 months	0.59±0.36	1.12±1	<0.001
Postoperative 12 months	0.36±0.08	0.79±0.59	<0.001

*Mean±SD. SD=Standard deviation

Table 4: Quality of life

Eura-Hs	Group S (Single)*	Group C (Convention)*	P
Pain	0.67±0.47	1.04±0.89	0.002
Restriction	1.70±1.66	2.31±1.86	0.101
Cosmetic	0.97±0.67	0.72±0.34	0.073
Total	2.85±2.43	4.07±3.12	0.080

*Mean±SD. SD=Standard deviation

hernia, some studies in the literature have represented a critical role in mesh fixation and its method to reduce postoperative pain complaints.^[1,2,4] Our investigation was accompanied by remarkably less pain complaints in both early postoperatively and in different intervals assessments done in a year follow-up in the single tacker mesh fixation compared with the conventional technique.

A randomized clinical trial was done with 98 inguinal hernia patients who underwent mesh fixation with a single absorbable versus nonfixation method. The mean VAS score at discharge was 2.43 in the single tacker versus 2.19 in the nonfixation group.^[17] In another RCT 30 unilateral inguinal hernia, male patients compared four titanium tacks mesh fixation versus nonfixation. The mean VAS score was lower in the nonfixation method.^[18]

The above studies showed the superiority of absorbable versus nonabsorbable tackers. Despite the lower rate of postoperative pain in the nonfixation method, which is comparable to our study, the probability of mesh migration is higher in them. A large body of the literature suggests mesh fixation in TAPP surgery to prevent mesh migration.^[5,15]

Some scholars discussed the benefits of suturing to fix the mesh in comparison to tacks. In Kleidari *et al.* RCT study, early postoperative complications regarding mesh fixation were compared between tacker and Vicryl suture groups. Each group contains 35 patients. Mesh was fixed with three nonabsorbable tacks. The mean postoperative pain at discharge in the tacker and suture groups, respectively, was (5.54 vs. 4.63, $P=0.002$). Interestingly, in our study, the mean of pain at discharge was lower in comparison with both groups of tacker and suture groups.^[8]

Aziz *et al.* study compared Vicryl suture to tacker in fixing the mesh in TAPP inguinal hernia surgery. Three titanium tacks were used. The mean of post 1 was 4.63 in the suture group versus 5.54 in the tacker group. Notably, the mean for pain in our study was significantly lower than the Aziz *et al.* study.^[19]

Some surgeons used self-fixating mesh to reduce postoperative pain. An RCT study was conducted on 101 patients who underwent unilateral TAPP inguinal hernia surgery with Pro-grip self-fixating mesh. The mean of postoperative pain at 6 h is 2.6. Interestingly, the mean of postoperative pain in our study compared with pro-grip self-fixating mesh was lower in the single tacker group.^[15]

Some articles used single mesh instead of double mesh in bilateral inguinal hernia surgery to reduce the pain after surgery. In Nagaty's study, 40 patients with bilateral primary inguinal hernia were included in the study. Patients were randomized into two groups of double mesh fixation and single large mesh. Mesh was fixed with four titanium tacks. Each group contains 20 patients. The mean for postoperative pain at discharge in the double and single mesh fixation groups, respectively, was 3.62 versus 2.17.^[20]

In our study, we used two meshes for repairing the inguinal hernia. The mean for post-op pain in this study was significantly lower not only on double mesh but also in the single large mesh of Nagaty study.^[20]

Duration of operation

The mean duration of operation was about 6 min shorter in the single fixation method than in the conventional technique; however, the difference between the groups was not statistically significant. We assume that the increased number of tackers to fixate the mesh was responsible for the elongation of the surgical procedure.

The mean time in Nagaty study applying double mesh fixation was fixed with four titanium tacks and accounted for 72 min which was similar to our study;^[20] whereas, Patel *et al.* conducted a relatively similar study on 23 patients and represented 2–3 h duration of surgery.^[5]

Intraoperative complications

There were no intraoperative complications in our study. This finding is similar to Kleidari *et al.* investigation,^[8] while injuries to epigastric vessels, vas deferens, and copious bleeding due to metal tacker fixation have been reported in other studies.^[21]

None of the procedures were converted to open surgery in the current study; whereas, the other studies have reported the potential requirement for open surgery in 0.3% of all laparoscopic inguinal hernia repairs.^[21] We assume that despite the extended time of operation, it is worth placing a tacker for mesh fixation and reducing intraoperative and postoperative complications.

Hospital stay

In the current study, both groups were discharged in a relatively similar period after the procedure. This period is similar to that of most of the other studies in the literature;^[20] however, some investigations are representing longer periods of hospital stay ranging from 3 to 5 days, as well.^[10,22-24]

Seroma and hematoma

In the current study, seroma was presented by four patients in the single tacker group (10%) and three patients in the convention group (7.3%). Only a patient in the conventional group was referred with hematoma (2.5%). Seroma was managed conservatively, and the hematoma was resolved within 2 weeks after the surgery.

The incidence rate of seroma after TAPP of inguinal hernia surgery is 2.5%–25% which mostly resolves approximately within 4–6 weeks after the surgery.^[25,26] A retrospective cohort study was done on 167 patients who underwent TAPP for an inguinal hernia. In this study, the mesh was fixed with 4–5 titanium tackers and the seroma and hematoma incidence rates were 14.7% and 6.7%, respectively, which were higher than our study.^[6]

Infection, neuralgia, and recurrence

Fortunately, none of the cases in our study represented surgical site infection, neuralgia, or recurrence.

The current study did not report surgical site infection, neuralgia, or recurrence. The recurrence rate in TAPP inguinal surgery is from 0% to 4%.^[27] The surgical infection rate in TAPP surgery is 0%–0.2%.^[28] The neuralgia incidence rate in TAPP surgery is from 0% to 4.2%.^[29]

Time to return to work

The time to return to work was statistically significant between the two groups in our study. In a study on 180 patients with bilateral inguinal hernia patients, the time to return to work in the TAPP group was statistically lower in comparison to open preperitoneal and Lichtenstein technique groups (12.30 ± 1.47 , 19.85 ± 1.06 , $P < 0.001$). In a study on 154 TAPP patients without mesh fixation, the time to return to work was 22.7 days which was longer than our study.^[30]

Quality of life

The European Hernia Society introduced this questionnaire assessing hernia surgery in three domains: pain, restriction, and cosmetics. In this study, we used Eura-Hs QOL for 1 year postoperatively.^[16] To the best of our knowledge, it might be the first study using Eura-Hs QOL comparing the QOL between the two methods of mesh fixing using a single absorbable tacker. We found that the pain score between the two groups was statistically significant. In a study on 101 patients undergoing TAPP hernia surgery with Pro-grip self-fixating mesh, the Eura-Hs score was used preoperatively and in 13-month follow-up. The pain, restriction, and cosmetic in 1-year follow-up were, respectively, 0.9, 0.91, and 0.90.^[15] The Eura-Hs pain score in our study was lower, in restriction was higher, and the cosmetics were the same.

Limitations

We suggest further studies regarding single absorbable tacker in fixing the mesh with a more extended population and longer follow-up period to evaluate the recurrence rate and postoperative neuralgia.

CONCLUSION

We showed that fixing the mesh with a single absorbable tacker has less postoperative pain, a shorter duration of return to normal activity, and shorter hospital stays than the conventional method of mesh fixation. The QOL did not generally differ between the two groups; however, postoperative pain within a year after the surgical procedure was still less in the single tacker group.

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Conflicts of interest

There are no conflicts of interest.

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