

Comparative study between primary fascial closure versus non closure in laparoscopic ventral hernia repair with mesh

Original
Article

Hoda A. Sonbol, Ashraf M. Fawzy, Wadie Boshra Gerges, Tasnim R. Naeem and Mohamed E. Elserafy

Department of General Surgery, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

ABSTRACT

Background: Laparoscopic ventral hernia repair (LVHR) is widely acknowledged to achieve lower rates of recurrence and shorter lengths of hospital stays compared with open repair. However, the surgical community has yet to reach a consensus on the techniques used in LVHR, especially regarding outcomes such as seroma formation, bulging of tissue or mesh (eventration), and hernia recurrence. Our objective was to evaluate the outcomes of LVHR with mesh with primary fascial closure (PFC) and LVHR with mesh, without PFC regarding the aforementioned complication.

Patients and Methods: We randomized two groups of patients (group A and group B), group A underwent LVHR without fascial closure and group B underwent LVHR with PFC. Operative time, hospital stay, hematoma, seroma, early visual analogue scale pain scoring, and chronic pain were measured postoperatively. Recurrence, bulging and patient satisfaction with regard to cosmesis was followed-up for up to 1 year.

Results: A total of 50 patients were included, 25 patients in each group. We reported a recurrence rate of 16% (n=4) in the nonclosure group (group A) in comparison to a recurrence rate of 4% (n=1) in the closure group (group B) with a *P* value 0.157 which was not statistically significant. Patient satisfaction with the cosmetic outcome (using a 10-point Likert-type scale) results were 7.04±2.24 in nonclosure group versus 9.08±1.15, *P* value less than 0.001 and bulging was 40% in group A and 8% in group B, *P* value=0.008, both showing statistically significant difference.

Conclusion: This trial demonstrated that the modification of the classic LVHR technique to include PFC yielded better results about bulging and cosmesis. Lower recurrence rates were reported but confirmation of results warrants Randomized Controlled Trials with larger patient enrollment and longer follow-up periods.

Key Words: Hernia recurrence, laparoscopic ventral hernia repair, primary fascial closure.

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Corresponding Author: Hoda A.A. Sonbol, MBBCh, MS, Department of General Surgery, Faculty of Medicine, Ain Shams University, Egypt. **Tel.:** 01119893103, **E-mail:** hodasonbol@med.asu.edu.eg

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INTRODUCTION

Ventral hernia (VH) is a wide-ranging term used to refer to anterolateral abdominal wall defects. They are generally classified into congenital hernias (i.e. umbilical, paraumbilical, epigastric and Spigelian) and acquired hernias (i.e. incisional). These defects are a common surgical presentation and in most cases are an indications for surgery. The estimated prevalence is about 5% in the general population with ~75% of defects described as primary hernias (epigastric, umbilical, and paraumbilical mainly) and 25% being incisional^[1].

VHs are linked to various complications including pain (both acute and chronic), expanding size, poor cosmesis, deteriorating function, and incarceration. The debate is still ongoing regarding the best surgical technique for their repair^[2].

Laparoscopic ventral hernia repair (LVHR) was initially termed by Leblanc in 1993. It was established upon similar surgical concepts as the open underlay

technique. This led to a decrease in the total rate of hernia recurrence reported to be around 12–32% in open repairs while the rate of recurrence in LVHR ranges from 2.9 to 17.7%. Additionally, it was found to reduce the morbidity linked with open repair i.e. shorter length of hospital stay and better patient outcomes due to decreased complication rates^[2]. LVHR is rapidly gaining acceptance and recently often performed in place of open repair for the following reasons: smaller incisions, better cosmetic results and shorter lengths of hospital stay with a quicker return to normal daily activities^[3].

Laparoscopic surgery has been recognized to be a safe, effective, and less painful technique for many types of surgery and has become the current gold standard for numerous surgical cases. Novel additions, such as intracorporeal closure of a fascial defect brought about new considerations for both the surgeon and the patient^[4].

Typical laparoscopic repair with fascial defect bridging requires the minimum amount of dissection but then the mesh is left unprotected by a musculo-fascial layer and

theoretically more predisposed to infection^[5]. The mesh is often in contact with the skin, chiefly when it comes to larger defects. Primary fascial closure (PFC) then mesh placement is meant to recreate a dynamic and functional anterior abdominal wall while also reducing or completely eradicating the subcutaneous dead space. On the other hand, PFC can often be rather difficult, due to the site of the defect, and time-consuming hence prolonging operative time, especially in large hernias, therefore it is not routinely performed. Few studies are available in existing literature comparing closure of the hernial defect versus not closing it laparoscopically^[6].

Additional benefits proposed by the authors were that by closure of the defect, especially in large hernias, the repair is made more solid and more reliable. Larger mesh overlap and better cosmesis has also been proposed as highly beneficial^[7]. When closure of the defect is performed, the abdominal wall muscles and fascia act as a physical barrier meaning that the mesh is by no means in contact with the skin. This helps prevent friction and erosion of the skin by the mesh and ensuing infections^[8].

PATIENTS AND METHODS:

This was a randomized prospective study that included 50 patients divided into two groups equally and randomly via a closed envelope method. The study took place at Ain Shams University Hospital. We compared a group of patients who underwent LVHR with mesh without PFC (group A) to a group who underwent LVHR with mesh with PFC (group B) after approval of the ethical committee and obtaining an informed consent from all patients participating. During the follow-up period, four patients dropped out in group A, and three patients in group B. One patient in group B was excluded due to conversion to open surgery because of extensive adhesions. These patients were replaced with others to complete the sample size.

Our inclusion criteria included patients 18–65 year old patients, capable of understanding and giving signed informed consent, with VHs (including umbilical, paraumbilical, port site, epigastric, and incisional) between 3 and 10 cm (so that repair was achieved without tension). Our exclusion criteria were patients whose operations were converted to open surgery intraoperatively, patients with parastomal hernias, hernias defects less than 3 and greater than 10 cm, or patients with contraindications to laparoscopic surgery, incarcerated or strangulated hernias.

All patients underwent the following preoperatively: Careful history taking, including age, weight, BMI, occupation and special habits mainly alcohol consumption and smoking. History of present illness, past medical history: such as diabetes, hypertension, drug allergies, blood transfusion and previous operations especially in cases of port site hernias and incisional hernias.

Clinical examination of the hernias was done focusing on size and location of the hernia defect, reducibility, and signs of incarceration.

Routine preoperative laboratory tests were withdrawn for all patients (complete blood picture, liver and kidney function tests, coagulation profile, fasting blood sugar, and chest radiography). Specific complaints were further investigated such as pulmonary function tests for patients with chronic obstructive airway disease, Echocardiogram for patients above 50 years old and ECG for patients above 40 years old. Radiological preoperative investigations such as pelvi-abdominal ultrasound and pelvi-abdominal computed tomography (CT) (in cases where the defect size could not be accurately evaluated by ultrasound).

Surgical intervention

Preoperative prophylactic antibiotics (second-generation cephalosporins) were given 1 h before induction of anesthesia. All 50 cases were done under general anesthesia. The position of trocars was placed as follows: generally, 3–4 trocars were placed on the lateral side of the abdomen (the camera port was placed in the lumbar region at the level of the umbilicus, left hypochondrial and left iliac fossa working ports), an additional port was placed in the right upper abdomen when needed. Adhesiolysis and hernia content reduction were done in all cases.

In the case of group A (nonclosure): The hernial defect was measured and a dual-sided composite mesh was chosen to circumferentially overlap the defect by at least 5–7.5 cm. The mesh was placed in the intraperitoneal position (inlay) and was fixed to the parietal abdominal wall at its four corners by polypropylene-0 stitches using an endoclose device. It was further serially secured to the abdominal wall in two rows using 5 mm tackers. The first row was placed just lateral to the defect. The second row of tackers was applied to the outer margin of the mesh (Fig. 1).

In the case of group B (Closure): The primary approximation of the fascial edges and closure of the defect was done using polypropylene-0 intracorporeal continuous sutures before mesh placement. As in group A, a dual-sided composite mesh was chosen to circumferentially overlap the defect by at least 5–7.5 cm. The mesh fixation and tackers placement were done in the same technique as group A (Fig. 2). No drains were placed in any the patients.

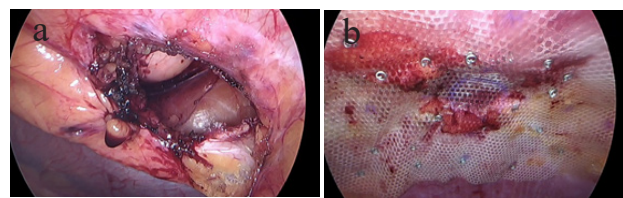


Fig. 1: Laparoscopic ventral hernia repair with mesh without primary fascial closure, (a) hernia defect after reduction of content, (b) after fixation of mesh.

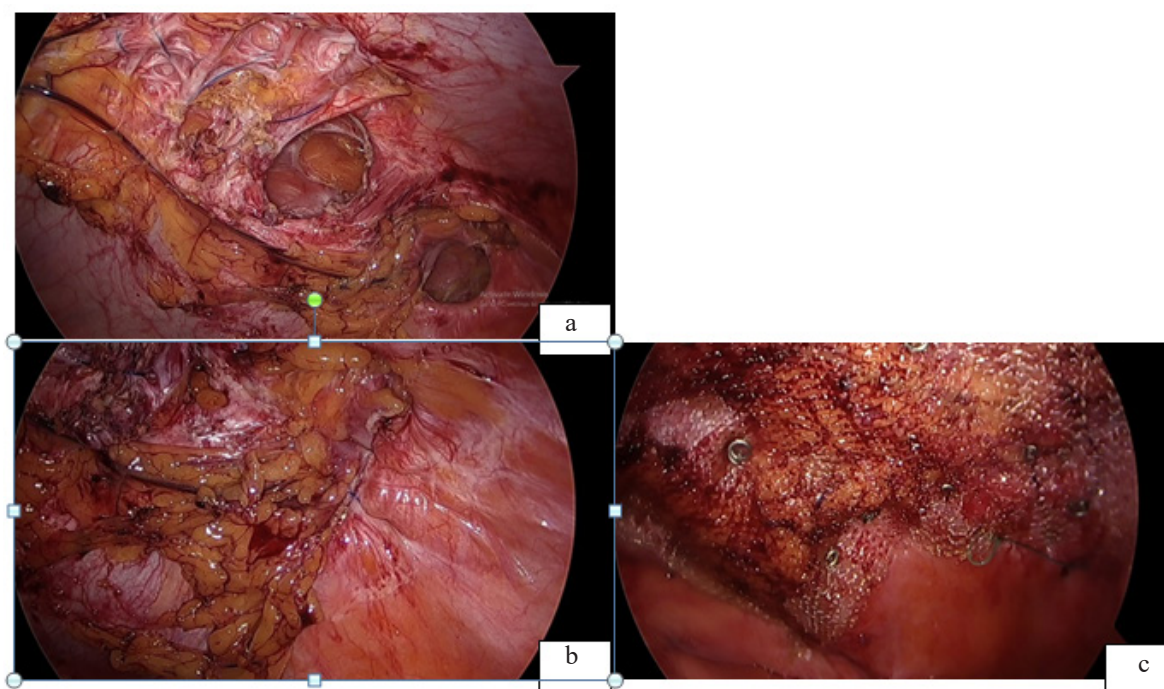


Fig. 2: Laparoscopic ventral hernia repair with mesh with primary fascial closure, (a) hernia defect preoperative, (b) after completion of primary fascial closure, (c) after fixation of mesh.

Postoperative care and follow-up

Early mobility was encouraged for all patients and most of them were discharged on the next postoperative day after the return of normal bowel movement. Patients were assessed regarding operative time, hospital stay, early postoperative pain (first 48 h) via the visual analogue scoring (VAS), wound complications such as hematoma (collection of subcutaneous clotted blood), seroma (collection of subcutaneous serous fluid) that were confirmed via ultrasound. Recurrence, clinical bulging (differentiated from recurrence by abdominal CT scan) and cosmetic results were assessed at follow-up visits serially at 1, 3, and 6 months up to 1 year.

Data collection and statistical analysis

The following data were assembled: age, sex, BMI, Hernia characteristics (location and size), operative time, hospital stay, early VAS pain scoring, wound complication, chronic pain, recurrence, clinical bulging and cosmetic satisfaction and follow-up to 1 year.

The data was then tabulated and statistically analyzed. Quantitative variables were described as mean and standard deviation and qualitative data as frequency. The results were considered significant (S) with *P value* less than 0.05 and highly significant (HS) with *P value* less than 0.01. *P value* greater than or equal to 0.05 were considered nonsignificant (NS). Statistical analysis was done using IBM SPSS statistics for windows, Version 21.0. Armonk, NY: IBM Corp.

RESULTS:

There was no statistically significant difference regarding the baseline characteristics of patients in both group A and group B regarding age, sex, BMI, comorbidities and defect size (Table 1).

Regarding operative time, group A mean time was 47 ± 17.79 min and group B mean time was 64.56 ± 14.63 min with a *P value* less than 0.001 which showed a statistically significant difference. Regarding postoperative assessment data i.e. length of hospital stay, hematoma, seroma, and chronic pain there was no statistically significant difference between the two groups. The hospital stay ranged from 1 to 2 days in group A and 1 to 3 days in group B. There was only one case of postoperative hematoma that occurred in group B, the patient complained of pain with signs of skin ecchymosis, and confirmation of diagnosis was done via ultrasound. This case was managed conservatively with a resolution of the hematoma on follow-up ultrasound. Seroma occurred in 3 (12%) cases in group A and in only 1 (4%) case in group B. Patients were diagnosed with ultrasound when subcutaneous bulging was noted. All patients were managed conservatively with complete resolution on follow-up ultrasound (Table 2).

Regarding operative events, one patient suffered from a small bowel serosal tear injured during adhesiolysis that was repaired using one suture (vicryl 3-0) with no postoperative complications on follow-up. One patient's operation was converted to open repair due to extensive adhesion, this patient was excluded from the study.

There was a statistically significant difference regarding the early postoperative VAS pain scoring (*P value* 0.031) (Table 2) with a median score 2 (1–2) in group A and a median score 3 (1–3) in group B.

At 1 year follow-up, our recurrence rate of 16% (n=4) in the nonclosure group (group A) in comparison to a recurrence rate of 4% (n=1) in the closure group (group B) with a *P value* 0.157 which was not statistically significant. Patient satisfaction with the cosmetic outcome (based

upon 10 points Likert-type scale with 1 representing least satisfied and 10 most satisfied) was as follows: 7.04±2.24 in nonclosure group versus 9.08±1.15, *P value* less than 0.001, showing statistical significance. Bulging (or clinical eventration) was 40% in group A and 8% in group B (*P value* 0.008 which shows a highly statistically significant difference. There was chronic pain (past 6 months) in 2 cases in group A (8%) and only one case in group B (Table 3).

Table 1: Baseline characteristics of the studied groups

	Group A N= 25	Group B N= 25	Test value	<i>P value</i>	Significance
Age (years)					
Mean±SD	44.52±9.87	43.24±9.74	0.462*	0.646	NS
Range	23–64	27–60			
Sex					
Female	19 (76)	20 (80)	0.117*	0.733	NS
Male	6 (24)	5 (20)			
BMI (kg/m ²)					
Mean±SD	33.78±2.89	35.22±3.55	-1.572*	0.123	NS
Range	28–38.9	28.2–42			
Comorbidities					
No	12 (48)	16 (64)	1.299*	0.254	NS
Yes	13 (52)	9 (36)			
HTN	8 (32)	7 (28)	0.095*	0.758	NS
DM	4 (16)	1 (4)	2.000*	0.157	NS
Hypothyroid	1 (4)	0	1.020*	0.312	NS
BA	2 (8)	2 (8)	0.000*	1.000	NS
Defect size (cm)					
Mean±SD	4.7±1.42	4.36±1.25	0.899*	0.373	NS
Range	3–8	3–7			

Table 2: Comparison between group A and group B regarding early postoperative data of the studied patients

	Group A N=25	Group B N=25	Test value	<i>P value</i>	Significance
Operative time (min)					
Mean±SD	47±17.79	64.56±14.63	-3.811	<0.001	HS
Range	25–78	48–95			
Hospital stay (days)					
Mean±SD	25–78	38–85	0.911*	0.367	NS
Range	1–2	1–3			
Hematoma (postoperative)					
No	25 (100)	24 (96)	1.020*	0.312	NS
Yes	0	1 (4)			
Seroma					
No	22 (88)	24 (96)	1.087*	0.297	NS
Yes	3 (12)	1 (4)			
VAS pain Scoring (early post-op)					
Median (IQR)	2 (1–2)	3 (1–3)	-2.154#	0.031	S
Range	1–7	1–7			

Table 3: Comparison between group A and group B regarding long term postoperative data of the studied patients

	Group A N=25	Group B N=25	Test value	P value	Significance
Patient satisfaction to cosmosis					
Mean±SD	7.04±2.24	9.08±1.15	-4.042*	<0.001	HS
Range	3–10	5–10			
Bulging					
No	15 (60)	23 (92)	7.018*	0.008	HS
Yes	10 (40)	2 (8)			
Recurrence (1 year)					
No	21 (84)	24 (96)	2.000*	0.157	NS
Yes	4 (16)	1 (4)			
Chronic pain					
No	23 (92)	24 (96)	0.355*	0.552	NS
Yes	2 (8)	1 (4)			

DISCUSSION

LVHR has been described as having a considerably shorter length of hospital stay, reduced recurrence rates, and fewer complications in comparison to open repair. However, even with improved surgical outcomes with LVHR techniques, postoperative seroma formation, mesh or tissue eventration or bulging, and recurrence are still common complications. PFC during LVHR with mesh shows promising results^[9].

Many benefits have been suggested with PFC. Authors have suggested that the repair is made stronger and more reliable by closing the defect. Additionally, it is hypothesized that by fascial edge approximation, the abdominal wall function is restored to a more physiological and therefore functional state^[10,11].

Supporting this theory the laparoscopic bridging technique without defect closure tends to cause bulging of the mesh through the defect^[8,12]. In addition to the cosmetic disadvantage, notably in larger defects, the mesh may be in contact with the skin. Conversely, when the defect is closed, the mesh is certainly not in contact with the skin due to the presence of a physical barrier. This often helps avert mesh erosion of the skin due to friction, and ensuing infections^[10].

In our study, we altered the standard LVHR to assess whether the incidence of recurrence could be reduced further. We performed primary closure of VHs (hernias that met our inclusion criteria) by continuous intracorporeal sutures before placement of a composite mesh. Before the placement of mesh, we ensured that the anterior abdominal wall tension through the defect was not increased substantially.

Regarding the baseline characteristics in our study, the mean age is 44.52 years in group A and 43.24

years in group B, males are 24% in group A and 20% in group B while females were 76% in group A and 80% in group B. Co-morbidities were 52% in group A and 36% in group B, with no statistically significant difference.

Hernia recurrence was the primary outcome of our study, with a follow-up period of 12 months. Our results showed a recurrence rate of 16% (n=4) in the Non-closure group (group A) in comparison to a recurrence rate of 4% (n=1) in the closure group (group B) (*P value* 0.157, not statistically significant). We hypothesize that as we started this study less than 2 years ago, we ultimately could not attain a patient sample size large enough to achieve statistical significance despite observing a reduction in hernia recurrence in the closure group.

Comparable randomized control trials conducted were very few. Of those, Bernardi *et al.*^[13] evaluated clinical recurrence by supplementing this with a Pelvi-abdominal CT scan at 2 years follow-up period. Recurrence rates were 3.2% for the nonclosure group versus 9.8% for the closure group (*P=0.131*, not significant). The type of mesh used in their study was not stated. Another randomized control trials, Christoffersen *et al.*^[14] reported recurrence of five out of 36 (13.8%) patients in the closure group versus 12 out of 37 (32.4%) patients in the nonclosure group (*P=0.047*), a statistically significant difference.

Zeichen *et al.*^[7] (a retrospective study) compared nonclosure patients (n=93) to primary fascia closure patients (n=35). The patient's mean follow-up period was 26 months (1–108 months). In the nonclosure group, the recurrence rate was 19% while the closure group had a recurrence rate of 6.25%. These results did not find a statistically significant difference in recurrence rates between closure and nonclosure groups.

Banerjee *et al.*^[2] (A retrospective observational study) observed a recurrence rate of 3% with the primary repair group in comparison with 4.8% associated with mesh alone. ($P=0.54$, Not significant). They also reported the rate of recurrence in the recurrent hernia group, which was 10.5% in the mesh-only group ($n=4$) compared with 4.8% ($n=1$) in the primary repair then mesh fixation group. Clapp *et al.*^[3] (A retrospective review of 176 patients) reported significantly fewer recurrences in the Closure group (0.0% vs 16.7%; P value=0.02, statistically significant).

In our study, operative time showed a statistically significant difference between the two groups with longer operative time reported in the Closure group. Zeichen *et al.*^[7] reported a mean operative time of 75.04 (18–215) in the nonclosure group and 88.96 (45–143) in the Closure group. Bernardi *et al.*^[13] reported a nonsignificant statistical difference about operative time (The nonclosure group mean time was 75.4 min and in PFC group it was 88.3 min). In Christoffersen *et al.*^[14], the mean operative time in the nonclosure group was 34 min and 47 min in the Closure group with a P value of 0.005. As hypothesized the time added for PFC prolongs the operative time considerably.

Regarding the postoperative bulging rate in our study, the results were 40% in group A and 8% in group B (P value 0.008 which is highly significant). Similarly, Clapp *et al.*^[3] reported results similar to ours with 69.4% bulge rate in the nonclosure group and 8.3% in the closure group, $P=0.0001$ which is also highly significant. Bernardi *et al.*^[13] however reported similar rates of clinical eventration in both groups with seven (11.5%) in the PFC group and nine (14.5%) in the nonclosure group, P value 0.616 (not significant). In Christoffersen *et al.*^[14], upon pelvi-abdominal CT, one patient in the closure group showed bulging of the mesh while two in the no-closure group showed bulging of the mesh 2 years later, P value 0.539 (not significant).

In our study, regarding patient-centered outcomes, we reported on patient satisfaction to cosmosis utilizing a 10-point Likert-type scale (1 representing least satisfied and 10 most satisfied) with the results as follows: 7.04 ± 2.24 in non-closure group vs 9.08 ± 1.15 , P value <0.001 , showing statistical significance difference. Similarly, Clapp *et al.*^[3] also utilized a 10-point Likert-type scale and reported that mean patient satisfaction and functional status rates were higher in the closure group than in the nonclosure group: 8.8 ± 0.4 versus 7.1 ± 0.5 and 79 ± 2 versus 71 ± 2 , respectively. Bernardi *et al.*^[13] used the modified Activity Assessment Scale, a quality of life (QoL) survey which is a validated hernia specific survey, where both groups reported a rise in their QoL scores

following repair which was higher in those who underwent PFC reporting on average a 12-point higher improvement in their QoL scores (41.3–31.5 vs. 29.7–28.7, P value 0.047). Christoffersen *et al.*^[14] used both a Verbal Rating Scale (VRS) for satisfaction regarding cosmosis and a Carolinas Comfort Scale for QoL assessment where there was no significant difference between the groups. There is a need for standardization of a method to assess patient satisfaction and cosmosis enabling accurate comparisons between different studies.

In our study, the seroma formation rate was 12% in the nonclosure group and 4% in the closure group. In Clapp *et al.*^[3] rate of seroma formation was 27.8% in the nonclosure group and 5.6% in the closure group. $P=0.02$, statistically significant). At 30 days follow-up, Christoffersen *et al.*^[14] reported seroma formation as 14 of 40 (35%) in the closure group versus 22 of 38 (58%) in the nonclosure group ($P=0.043$, statistically significant).

We also reported a statistically significant difference between the incidence of recurrence and that of defect size (P value 0.005) and postoperative seroma formation (P value <0.001).

CONCLUSION

Despite the limited comparative literature available, PFC with LVHR appears to be a rather promising technique. Its use appears to yield lower eventration (bulging) rates, seroma formation, and recurrence rates. Patients also appear to be more content with the results, especially from a cosmetic point of view, and have enhanced functional status compared with the bridging repair.

Further randomized controlled trials, with larger patient enrollment and longer follow-up periods, are necessary to confirm the benefit of this technique over the traditional repair. This will assist in reaching a consensus and help produce widely accepted medical practice guidelines. Additionally, we need to study the maximum defect size that can be closed without exerting excess tension on the anterior abdominal wall and still produce considerable benefits. Another proposed technique is the combination of defect closure with endoscopic component separation that may be applicable to larger defects.

CONFLICT OF INTEREST

There are no conflicts of interest.

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