

Use of fibrin glue in groin wound closure after femoral artery exposure: randomized controlled trial

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Objectives

Fibrin glue is supposed to seal tissues, lymphatics, and minor bleeders and close the dead space efficiently. This work was designed to show the effect of fibrin glue on groin wound complications after femoral artery exposure, degree of wound infection, time to wound healing, and need for further patient management.

Patients and methods

It is a prospective randomized controlled study including patients who were submitted to groin incision for femoral artery exposure; patients were randomized into two groups: fibrin-sealant closure group (FS group) or conventional surgery (CS group). FS group patients were submitted to use of fibrin glue sprayed on the femoral sheath before closure of subcutaneous tissue and CS group patients were submitted to conventional surgical closure. The study was conducted from July 2016 to March 2018. The primary outcome was assigned as wound complications like seroma, lymphatic fistula, lymphorrhea, and wound infection. The secondary outcomes were wound-healing time, hospital stay, and need for operative coverage.

Results

In total, 119 patients were included in the study, 60 in fibrin glue group (10 were lost from follow-up) and 59 conventional surgical closure (nine were lost from follow-up). The mean age was 54.95 ± 3.5 in FS group compared with 60.20 ± 3.7 in CS group ($P=0.31$). In FS group, 33 were males and 27 were females, while in CS group, 38 were males and 21 were females ($P=0.42$). Mean BMI was 30.3 ± 0.68 in FS group and 28.63 ± 0.84 in CS group ($P=0.42$). In FS group, 36 were diabetics versus 30 patients in CS group ($P=0.53$). In total, 33 patients were hypertensive in FS group versus 30 patients in CS group ($P=0.10$). In total, six patients were end-stage renal disease in both groups. In total, 30 patients were smokers in FS group versus 32 patients in CS group ($P=0.75$). The mean follow-up time till ensuring wound healing was 22 days, while the median was 27 days. Wound seroma/lymphorrhea was observed in 12 patients of FS group and 30 patients of CS group ($P=0.06$). Wound infection developed in 10 patients in the FS group and 17 patients in CS group ($P=0.48$). Regarding grade-III wound infection, no patient belonged to FS group, while eight patients belonged to CS group; as regards hospital stay, duration/day was 6.15 ± 0.35 in FS group and 10.20 ± 1.2 in CS group ($P=0.005$), time to wound healing was 15.05 ± 10.95 in FS group and 28.40 ± 20.85 in CS group ($P=0.015$), and no patient needed further surgical wound coverage in CS group but seven patients did in CS group.

Conclusion

Application of FS before groin-wound closure seems to be of benefit to reduce wound complications like degree of infection, accelerate time to wound healing, and need for further surgical coverage and hospital stay.

Keywords:

arteries, fibrin tissue adhesive, groin, wounds and injuries

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Introduction

Surgical-site infection (SSI) in vascular surgery is a devastating complication that may lead to limb loss or even life loss [1]. The assumed risks in the situation of deep infection that reaches the graft are mortality rate between 15 and 75% and major amputation rate up to 70% [2]. The most likely infected wound is the groin incisions. Groin incision plays a central

role in various vascular surgical procedures. It is used in bypass procedures, endarterectomies, and thromboembolectomies [3].

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The increased risk for groin infection resides in many factors. The commonly known are disruption of lymphatics, proximity to the perineum, prosthetic graft placement, and lack of direct muscle coverage [4]. Other variables include diabetes and obesity that is proved to have a significant role in initiating groin-wound infection [3]. In addition, redo bypass, female sex, and active infection were associated with a risk of groin-wound infection [5].

Seroma formation or the subcutaneous accumulation of noninfected fluid is one of the most frequent complications following groin incision and thought to predispose to SSI. Also, if accumulated, it leads to increased pressure that may be transmitted to skin flap and causes tissue dehiscence [6].

Besides the general aseptic measures, the known strategy that significantly reduces the incidence of SSI is prophylactic systemic antibiotics administered preoperatively [7]. Some technical modification is sought to reduce groin-wound complications like lateralizing skin wound to create trap-door effect, planning sartorius muscle flap coverage routinely, and focusing on ligating lymphatics excessively [8].

One of the most frequently thought effective methods for dealing with excess serous discharge is tissue adhesives. They provoke adhesion of the surfaces in many surgical situations that resulted in decreased need for drainage and postoperative seroma [8]. Of tissue adhesives, fibrin glue functions as a tissue sealant through the formation of a fibrin network. The fibrin networks act as a matrix for the migration of fibroblasts and endothelial cells involved in angiogenesis and remodeling of the clot into mature fibrous tissue. The use of fibrin sealants (FS) under the skin flap prior to closure is thought to reduce wound discharge, shut off the lymphatics, and reduce shearing forces of the tissue [1]. The study aims to investigate whether fibrin glue can reduce wound complications or wound infections, as well as subsequent length of hospital stay, time to wound healing, or need for further surgical coverage intervention.

Patients and methods

Study design

This is a prospective randomized controlled study with two groups. A computer-based program was used to randomize patients into either FS group or conventional surgery group or (CS) group. Inclusion criteria: any patient submitted to groin incision for exposure of common femoral artery was included in the

study. Excluded ones were patients with previous groin incision, traumatized patients, and refusal of the consent. The study was conducted in Beni-Suef University Hospital from July 2016 to March 2018. The study was approved by the ethical committee of the Faculty of Medicine, Beni-Suef University, and its assignment number was 178307. The participants were informed of the purpose of the study and its consequences. Written consent was obtained from participating patients. Data recorded: patients' characteristics and demography were obtained, such as age, sex, BMI, smoking, and comorbidities. Preoperative laboratory evaluation, ECG, and cardiac assessment were done for every patient.

Operative procedure

All patients were given prophylactic intravenous antibiotics at induction by the anesthetist. The femoral artery was exposed by vertical incision in the femoral triangle. Incision was directly over the felt pulse or anatomically at the mid-inguinal point if the pulse was not felt. Lateral incision approach was not applied in the study. Lymphostasis was achieved by electrocoagulation of small lymphatic vessels and ligation of larger ones. In FS group, 2–5 ml of fibrin glue was applied to lymphatic structures and subcutaneous tissue prior to closure in order to seal lymphatic vessels and prevent formation of a cavity between dissection layers. The used fibrin glue was tested for validity before use in a test tube (Fig. 1), to assure its proper solidification and binding capacity. The fibrin glue is sprayed over the femoral sheath and adjacent area before closing other layers. In CS group, the wound was closed without application of fibrin glue. Finally, wound closure layer by layer was done for both groups using an interrupted suture line with absorbable material, Vicryl (polyglactin 910) suture for subcutaneous layer and proline 3/0 for the skin. Then, wound irrigation was done with saline followed by povidone iodine and dressing with simple gauze. The main indications of femoral artery exposure in our study were aortofemoral bypass, femoral embolectomy, and femorodistal bypass. Patients' clinical Fountain's description was applied to the patients. Operative time, use of synthetic graft and need for blood transfusion were registered.

Preparation of fibrin glue

Fibrinogen preparation

It is obtained from plasma cryoprecipitate by thawing plasma at 2–4°C, yielding a paste that is recovered by centrifugation. This cryoprecipitate contains fibrinogen, fibronectin, von Willebrand factor, and factor VIII, as well as other plasma components

Figure 1



Fibrin glue is noted sticky to test tube.

(albumin, IgG, IgA, IgM, and vitamin K-dependent clotting factors) entrapped during the centrifugation step.

Thrombin preparation

It was prepared according to the method described by Armand J Quick. This was obtained from fresh frozen plasma of healthy donors screened negative for HIV and hepatitis B. This thrombin solution was stored in deep freeze at less than -20°C to maintain the potency and could be used up to a month. Cold chain was maintained for both components of fibrin glue, till their application. Before use, the syringes containing the two components of fibrin glue were taken out from the deep freeze and thawed to room temperature.

Postoperative care

All patients received prophylactic antibiotics at induction of anesthesia and continued parentally for 1 day postoperatively. Patients were advised to minimize their ambulation in the early postoperative period (4 days) and then they were allowed to ambulate gradually with caution. Dressing was started after 2 days, unless the dressing was soaked, followed by daily-once dressing. The groin wounds were examined at 1, 2, and 6 weeks after surgery at the ward or at the outpatient clinic. That is applied to patients with

peaceful groin. However, if the groin was not peaceful, readmission or frequent outpatient clinic visits were asked. Next, the patient was managed either by close observation and frequent wound dressing or operatively by flap coverage. If evidence of wound infection was shown on follow-up visits, the patient would be readmitted with frequent daily dressing (two to three times), close wound observation, and empiric systemic antibiotic. In cases with grade-III wound infection, proceeding to flap coverage was considered. In cases of wound serous discharge or lymphorrhea, repeated dressing with wound compression was done. This protocol of ambulation and wound care was applied for both groups. Wound infection was diagnosed mainly clinically, but confirmatory or adjunctive investigations may be asked.

End points and assessment

Primary outcome was assigned as wound complications. That included wound serous discharge, wound infection, wound lymphorrhea, lymphocele, skin bruises, and wound dehiscence. The secondary outcomes were time to wound healing, hospital stay in days, and need for operative wound coverage. These variables were assumed to be influenced by FS.

Definitions used in investigating the patients

Lymphorrhea was defined as perfusion of clear lymphatic fluid at the operative wound site. Lymphatic fistula was defined as the production of more than 30 ml of clear fluid per day at the operative wound site, lasting more than 3 days following the procedure, or persistent lymphatic leakage for more than 5 days after the procedure, regardless of the amount of fluid. Lymphocele was defined as subcutaneous collection of clear fluid without infection or hematoma. If a lymphocele was suspected, the groin was examined using ultrasound. Wound infections were graded according to Szilagyi's classification of vascular wound infection [2] as follows:

- (1) Grade I, dermis intact (cellulitis, seroma, and serous leak).
- (2) Grade II, dermis not intact (necrosis, dehiscence, and abscess).
- (3) Grade III, graft exposed.

Hospital stay: calculated by days the patient stays at the hospital till his discharge. However, if a patient was readmitted in the hospital due to wound complication, the days of new admission till discharge were added to the days of his/her first stay.

Statistical analysis

Data were analyzed using SPSS 18 for Windows (Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp). Data were explored for normality using Kolmogorov–Smirnov test of normality and Levene test for homogeneity of variance. The results of Kolmogorov–Smirnov test and Levene test indicated that some data were normally distributed, so parametric tests were used for comparisons. Categorical data were compared using χ^2 test or Fisher’s exact test. Group data with a normal distribution were compared using two-tailed Student’s *t* test. All statistical tests were performed at a significance level of 5% ($P=0.05$). The significance of the results was assessed in the form of *P* value that was differentiated into nonsignificant when *P* value more than 0.05 and significant when *P* value less than or equal to 0.05. Median, interquartile range (IQR), and power were calculated for some continuous variables like age, BMI, and hospital stay. Lower values of the power indicate more homogeneous variables and vice versa. Age and BMI represent patients’ demography, while hospital stay represents one of the study outcomes (end points).

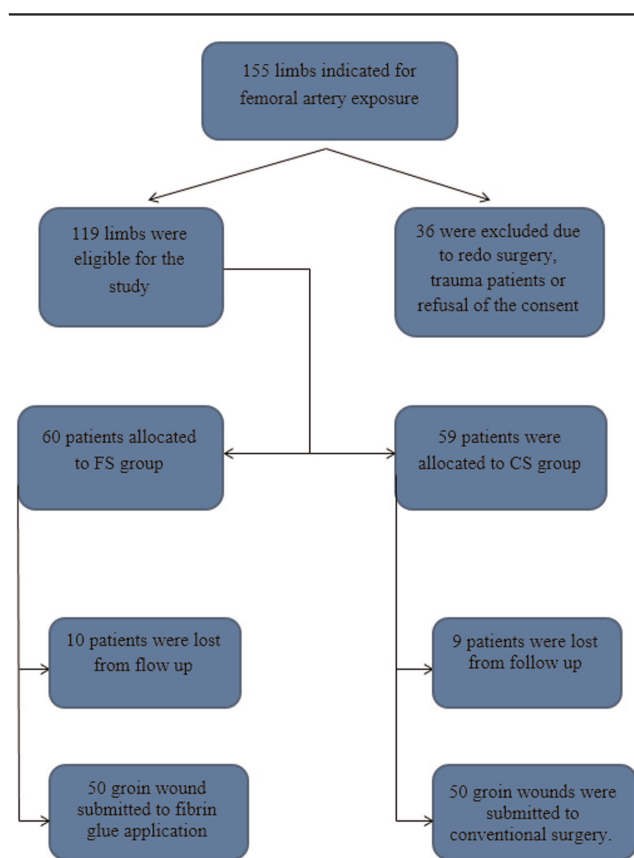
Results

In total, 155 limbs were indicated for femoral artery exposure. In total, 36 patients were excluded according to the aforementioned exclusion criteria or refusal of the consent. The remaining 119 patients were enrolled randomly into both groups. In total, 60 patients were allocated to FS group, however, 10 of them were lost from follow-up and the outcome was analyzed for the remaining 50 patients. In total, 59 patients were allocated into CS group, of them nine were lost from follow-up and 50 were analyzed for their outcome (Fig. 2). The mean follow-up time till ensuring wound healing was 22 days, while the median was 27 days.

Patients’ characteristics

Table 1 shows the demographic features of both groups with statistical comparison between them, including patients lost from follow-up later on. The mean age was 54.95 ± 3.5 in FS group compared with 60.20 ± 3.7 in CS group ($P=0.31$). In FS group, 33 were males and 27 were females, while in CS group, 38 were males and 21 were females ($P=0.42$). Mean BMI was 30.3 ± 0.68 in FS group and 28.63 ± 0.84 in CS group ($P=0.42$). In FS group, 36 were diabetics versus 30 patients in CS group ($P=0.53$). In total, 33 patients were hypertensive in FS group versus 30 patients in CS group ($P=0.10$). In

Figure 2



Patients’ flowchart.

Table 1 The demographic features of patients in both groups

	Fibrin glue group [n (%)] of patients (total=60)	Control group [n (%)] of patients (total=59)	<i>P</i> value
Age	54.95±3.5	60.20±3.7	0.314
Sex			
Males	33 (55)	38 (64)	0.417
Females	27 (45)	21 (36)	
BMI	30.3±0.68	28.63±0.84	0.124
Diabetes	36 (60)	30 (50)	0.525
Hypertension	33 (55)	30 (50)	0.100
End-stage renal disease	6 (10)	6 (10)	1.00
Smoking	30 (50)	32 (55)	0.752

total, six patients were end-stage renal disease in both groups. In total, 30 patients were smokers in FS group versus 32 patients in CS group ($P=0.75$). Reviewing these results, there was no statistically significant difference between both groups regarding their demography and comorbidities.

Presentation and operative features

Patient presentation is represented in Table 2 in addition to some operative features. In total, 36 patients presented with acute ischemia, while 24 patients presented with chronic ischemia in FS

group. That is compared with 36 patients presented with acute ischemia and 23 patients presented with chronic ischemia in CS group ($P=1$). Grade of ischemia was assessed using Fontaine classification system and declared that 13 patients were grade III and 47 patients were grade IV in FS group. That is compared with 10 patients' grade III and 49 patients' grade IV in CS group ($P=0.9$). In total, 18 patients were submitted to aortobifemoral bypass in FS group compared with 13 patients in CS group. In total, 30 patients were submitted to femoral embolectomy in FS group compared with 34 patients in CS group ($P=0.75$). Operative time of less than 3 h was found in 39 patients in FS group compared with 42 patients in CS group. Operative time more than 3 h was found in 21 patients in FS group compared with 17 patients in CS group ($P=0.72$). Use of synthetic graft was done in

24 patients in FS group versus 27 patients in CS group ($P=0.52$). Blood transfusion was needed in 12 patients in FS group and also in 12 patients in CS group. By reviewing the table, both groups were similar regarding their presentations and operative features.

Endpoints

In Table 3, statistical difference is observed between both groups as indicated by P value in some variables. Wound-infection rate was similar in both groups. Grade-I wound infection was seen in two patients in each group. Also, grade-II wound infection (Fig. 3) was seen in two patients in each group. However, grade-III wound infection (Figs 4 and 5) was observed conclusively in CS group in eight patients and they all were submitted to operative wound coverage. The mean length of hospital stay was 6.15

Table 2 Clinical presentation of patients in both groups and operative features

	Fibrin glue group (number of patients)	Control group (number of patients)	P value
Indications of intervention			
Acute embolic ischemia	36	36	1
Chronic limb ischemia	24	23	
Fontaine classification			
Grade III	13	10	0.9
Grade IV	47	49	
Type of surgery			
Aortobifemoral bypass	18	13	0.75
Femoral embolectomy	30	34	
Femorodistal bypass	12	12	
Operative time			
Less than 3 h	39	42	0.723
More than 3 h	21	17	
Use of synthetic graft	24	27	0.52
Blood transfusion	12	12	1.00

Table 3 Comparison between both groups regarding their outcome

	Fibrin glue group [n (%)] of patients (total=50)	Control group [n (%)] of patients (total=50)	P value
Wound seroma and/or lymphorrhea	12 (24)	30 (60)	0.06
Lymphatic fistula	10 (20)	17 (34)	0.440
Infection	10 (20)	18 (36)	0.480
Grade of infection			
Grade I	5 (10)	5 (10)	0.115
Grade II	5 (10)	5 (10)	
Grade III	0	8 (16)	
Grade III infection	0	8 (16)	
Hospital stay in days	6.15±0.35	10.20±1.2	0.005
Lymphocele	3 (6)	2 (4)	0.9
Skin bruises	10 (20)	10 (20)	1
Time to wound healing in days	15.05±10.95	28.40±20.85	0.015
Management of wound infection			
Conservative (repeated dressing)	10 (20)	10 (20)	0.072
Surgical (sartorius flap)	0	8 (16)	

± 0.35 in FS group versus 10.20 ± 1.2 in CS group ($P=0.005$). Mean time to wound healing was 15.05 ± 10.95 in FS group compared with 28.40 ± 20.85 in CS group ($P=0.015$). Wound seroma and/or lymphorrhea was seen in 12 patients in FS group compared with 30 patients in CS group ($P=0.06$). Lymphatic fistula was shown in 10 patients in FS group versus 17 patients in CS group ($P=0.44$). The rate of development of lymphatic fistula showed no statistical significant difference. Lymphocele was observed in three patients in FS group versus two patients in CS group ($P=0.9$). Skin bruises were seen in 10 patients in each group. Table 4 represents median, IQR, and power calculation for age and BMI variables of patients' characteristics. The observed powers of these variables are low (16.9 and 33.5%), indicating that the patients were homogeneous. While Table 5 represents median, IQR, and power calculation of hospital stay, variables of the study endpoint, where the observed power of this variable is high (86%), indicating the observed effect of adding FS.

Discussion

By analysis of the obtained results, both groups were similar regarding their demography, presentation, and operative features. However, FS group showed superior

outcome as regards grade-III wound infection, shorter hospital stay ($P=0.005$), and shorter time to wound healing ($P=0.015$). It is also observed that 25% of FS group showed fewer incidences of wound seroma and/or lymphorrhea versus 60% of CS group, even

Figure 4



Grade-3 wound infections with exposed synthetic graft.

Figure 3



Wound dehiscence with serous discharge/lymphorrhea.

Figure 5



Groin-wound dehiscence that responded to conservative management with formation of granulation tissue covering the blood vessels.

Table 4 Median, interquartile range, and observed power for some continuous variables of patients' characteristics

	Fibrin glue group	Control group	Observed power (%)
Age			
Median	56	30	16.9
Interquartile range (IQR)	25	29	
BMI			
Median	30.5	28.3	33.5
IQR	6	7	

Table 5 Median, interquartile range and observed power for hospital stay variable

	Fibrin glue group	Control group	Observed power (%)
Hospital stay/days			
Median	6	7.5	86
IQR	3	10	

IQR, interquartile range.

though *P* value is still not statistically significant (0.06). Also, it could be observed that need for surgical wound coverage was more in CS group where seven patients were submitted versus no patients in FS group. The incidence of wound complications at the groin done for arterial exposure varies between 2.8 and 44% [9]. Predisposing factors for groin-wound infection include close proximity to genitalia, the superficial position of femoral vessels covered only by skin and fascia, and abundant lymphatic, which would be severed during dissection of the vessels [10]. Various methods were tried to reduce groin-wound complication like avoiding electrocautery, using an ultrasonic wave device in vessel dissection, and modifying the site of groin incision. However, none of these procedures was proved to be effective in reducing wound complication [11]. Some additional procedures were suggested to avoid groin-wound complication. For example, muscle flap (sartorius muscle flap) was proposed as an effective method to avoid groin-wound complications and has promising results [12]. Also, negative wound dressing is proved to be effective in controlling lymphorrhea and aiding wound healing [13]. By looking around, FS was used effectively to reduce wound complication after axillary lymph-node dissection and abdominoplasty [14]. In addition, some findings suggest that fibrin glue reduces wound complication through participating in closure of the wound dead space, sealing bleeding or oozing from operative bed, and sealing open lymphatics. Wound infection subsequently would not follow. Such wound complications in vascular surgery are very dangerous

as it heralds vascular reconstruction and may precipitate fatal secondary hemorrhage.

Consequently, the current prospective randomized controlled study was designed, in which two groups were compared. FS group patients were submitted to groin-wound closure after adding fibrin glue over the femoral sheath. CS group patients were submitted to conventional groin-wound closure. Giovannacci *et al.* [5] declared that application of fibrin glue is associated with significant reduction in lymphatic wound complications. Giovannacci *et al.* [5] showed that the incidence of lymphatic complications was 19% in control group and 10% in fibrin group ($P=0.027$), with a relative risk of 1.4 for group A versus group B. That is exactly what was reached in the current study. As regards to other wound complications, Giovannacci *et al.* [5] showed that nonlymphatic wound complications like infection were similar in both groups. That is also approved by this study. But the current study showed the difference in the degree of wound infection and subsequently its management, need for surgical coverage, and hospital stay. So the study looked at wound infection in a different manner, considering its degree and further management. In 2014, Weldrick *et al.* [11] results did not show a significant difference between FS and standard closure (SC), with 43/133 patients who developed wound infection in the FS group, compared with 45/130 patients in the SC group indicated by *P* value of 0.74. An interesting point of discussion is analysis of diabetic and obese patients. For example, eight patients got grade-III wound infection exclusively in CS group. On notice, five of them share to be diabetic, BMI more than 30, and submitted to synthetic graft infection. Concerning grade-II wound infection, five patients were found in each group: four were diabetics, four were with BMI more than 30, and three were submitted to synthetic graft insertion. Regarding grade-I wound infections, five patients were found in each group: three diabetics, three with BMI more than 30, and two were submitted to synthetic graft insertion. However, a larger number of patients is needed to do multivariate analysis and gives us statistical association. There is observed high number of wound complications in the current study. Some explanations are attributing that to overchecking, which could touch some variables like seroma, skin bruises, and grade-I wound infection. However, the other endpoint was solid and cannot be confused like grade-III wound infection, hospital stay, and time to wound healing. A future plan to focus on the association of wound complication on one side

to diabetes, obesity, and synthetic graft on the other should be designed. Finally, assessment of the risk of amputation (the WIFI classification scoring system) is dependent on the three primary factors that constitute the risk to limb: wound (W), ischemia (I), and infection (FI) [15]. A point of view suggests that surgical wound infection in vascular surgery is the fourth factor that contributes to limb loss. Also, exercise is suggested to have an influence on the outcome of surgery as it affects the cardiovascular system in general [16]. The limitations faced in the study were mainly the small sample size. Another concern was about fibrin glue preparation and saving. However, this point could be dealt with by checking it in vitro before use. Patients of redo surgery are needed to be investigated, who were excluded from the study. At the end, the current evidence needs to be potentiated by a larger number of patients. Especially with the added costs of FS products, more and larger randomized controlled studies are needed to give enough evidence to change the traditional groin-wound closure. Also, cost analysis is recommended in the future studies. In spite of the cost of FS, the cost of wound care in CS group till it healed may exceed the initial cost of the sealant.

Conclusion

The preliminary findings of this randomized controlled study show that application of fibrin glue during closure after exposure of the femoral artery in the femoral triangle leads to a significant reduction in the incidence of wound seroma, lymphorrhea, grade-III wound infection, hospital stay, time to wound healing, and need for further surgical coverage. Strict and close surveillance is needed for all patients.

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Conflicts of interest

There are no conflicts of interest.

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