ORIGINAL ARTICLE

Comparative Study Between Surgical Offloading and Mechanical Offloading in the Treatment of Chronic Plantar Foot Ulcers in Diabetic Patients

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Abstract

Background: ***One of the leading causes of mortality, diabetes mellitus (DM) impacts every part of the body. Both individuals and society bear the brunt of the pain and expense associated with foot disorders. Among the most common health issues, foot ulcers occur at a rate of 2-4% each year in industrialized nations and probably much higher in underdeveloped nations. Peripheral sensory neuropathy, foot abnormalities, and peripheral artery disease are the primary causes of foot ulcers.***

Aim and objectives: ***To evaluate the relative safety and effectiveness of surgical and mechanical unloading techniques for the treatment of diabetic foot patients suffering from chronic plantar ulcers.***

Patients and methods: ***Fifty diabetic patients with chronic plantar ulcers who visited the outpatient clinics of the vascular surgery departments at Al-Azhar University hospitals (AL-Hussein and Said Galal Hospitals) and El-Mabarah Hospital between January 2023 and January 2024 were the subjects of this prospective, non-randomized comparative study.***

Results: ***The purpose of comparing the efficacy of surgical and non-surgical unloading techniques for the management of neuropathic plantar pressure ulcers is to determine .***

Conclusion: ***In order to treat pressure chronic unhealed plantar ulcers, offloading is crucial and works wonders. A personalized approach to unloading ought to be provided to each patient. A more efficient method is surgical unloading.***

Keywords: Surgical offloading; Plantar foot Ulcers; DM

1. Introduction

Developed and emerging countries alike are seeing a rise in the prevalence of diabetes mellitus (DM). Type 2 diabetes affects the vast majority of people with the disease, while type 1 affects just about 5% to 10% of patients. Half of those who have diabetes don't know they have it. People with diabetes can live longer and have a higher quality of life (QOL) if caught and treated early.[1]

Significant patient suffering and societal expenses result from foot complications affecting people with diabetes. Differences in socioeconomic status, footwear, and foot care practices explain in large part why the incidence and severity of foot diseases differ among regions. Approximately 20% of all hospital admissions among people with diabetes are due to diabetic foot ulcers (DFUs), making them a significant cause of morbidity and hospitalization.[2]

Foot abnormalities caused by motor neuropathy, peripheral sensory neuropathy, peripheral vascular disease, and small foot trauma are the main causes of foot ulcers.[3]

Diabetic neuropathic foot ulceration is a condition characterized by peripheral neuropathy and, in certain cases, elevated plantar pressures. It is well-known that while treating neuropathic foot ulcers, inadequate pressure relief causes the wounds to heal more slowly. The majority of research indicates that the primary goal of treating plantar ulcers is to reduce peak pressures.[3]

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In order to avoid and treat pressure ulcers in the plantar areas of the feet caused by diabetes, offloading is essential. The phrase "offloading" refers to pressure modulation, and it is most effective in the treatment of diabetic foot ulcers when applied to areas of high shear or vertical stress. Bed rest, wheelchair, and crutch-assisted gait are common ways to relieve pressure on the foot, but they are impractical because they reduce the patient's independence and quality of life. Patients with diabetes who wear offloading orthotics are able to walk freely. Total contact casts, felted foam, therapeutic shoes, partial shoes, removable cast walkers, and surgical unloading are some alternative techniques.[4]

This study set intended to evaluate the safety and effectiveness of mechanical offloading versus surgical techniques for treating persistent plantar ulcers in patients with diabetes who suffer from foot ulcers.

2. Patients and methods

In this prospective, non-randomized comparative study, fifty diabetic patients with chronic plantar ulcers were studied. The patients were seen at the outpatient clinics of the vascular surgery departments at Al-Azhar University Hospitals (AL-Hussein and Said Galal Hospitals) and Elmabarah Hospital from January 2023 to January 2024. Two groups of patients were formed: Patients in Group A had surgical offloading, whereas those in Group B used non-surgical methods, such as therapeutic foot shoes and an air walker, to alleviate pressure on their joints. Those patients were required to have six months of follow-up care, beginning immediately following the procedure and continuing at one month, three months, and six months thereafter.

Inclusion Criteria:

Those who are male or female, diabetic, and have plantar ulcers (which may be caused by pressure) that have not healed after six months and have at least one pulse in the foot (Dorsalis pedis or Posterior tibial).

Exclusion Criteria:

Patients suffering from diabetic foot infections (IDSA grade 2, 3), ischemic foot (non-palpable pedal pulses or ABI less than 0.9).

Pre-Procedural stage:

The following steps were taken after obtaining informed consent: recording demographic data (age and sex), taking a medical history (type of diabetes, presence of co-morbidities; hypertension, ischemic heart disease, chronic kidney disease, or cerebrovascular accident), taking a medical history (emphasizing duration of ulcer, previous treatment, or recurrent ulcers), conducting a general examination (emphasizing height and weight to calculate body mass index), and finally, conducting examinations of the lower limbs and feet. Assessment of the foot and ankle: look for abnormalities such as hallux valgus, pes planus (flat foot), pes cavus (claw toe), hammer toes, claw toes, or the rocker bottom deformity of Charcot.

In order to determine the infection grade using the IDSA system, the ulcer must be examined for inflammation as well as its location, size, form, edge, base, and floor. By feeling the foot, one can detect the ulcer's base, capillary refill, peripheral pulsations, and warmth. A tuning fork test and a pinprick test are two examples of peripheral sensory testing. The X-ray and probe-to-bone test are used to diagnose osteomyelitis. Prior to any intervention, photographs were taken of the wounds. All patients had blood tests that included HbA1C, complete blood count, international normalized ratio, potassium, lipid, and serum albumin. Every single patient had their feet x-rayed. The occurrence of osteomyelitis was the determining factor in the offloading modality. Anaesthesia readiness, Choice of patient.

Post-procedural:

During the first month, the ulcers were measured and photographed once weekly. After that, they were measured and photographed twice monthly until healing took place, and then once monthly until the end of the 6-month follow-up period. At three months post-start, we rechecked the HbA1C and foot x-ray.

During the 6-month follow-up period, all patients had their complications documented and categorized as follows: granulating with continuous healing progress, infection affecting the healing process, non-healing, or recurrence. The dressings were changed based on the wound's condition during the follow-up period.

Primary outcome:

Healing of the plantar ulcers.

Secondary outcome parameters:

Complications of plantar ulcers and duration till healing.

Ethical considerations:

Following a thorough explanation of the study and before to its commencement, participants were asked to provide their written informed consent. Methods used by the Al-Azhar Medical School's Ethical Committee.

Statistical Methods:

The Statistical Package for the Social Sciences (SPSS) version 24 was used for data management and statistical analysis. Medians, ranges, and standard deviations were used to summarize numerical data. In order to summarize the

categorical data, percentages were used. By examining the data distribution and applying the Kolmogorov-Smirnov and Shapiro-Wilk tests, we checked if the data were normally distributed. Using t-tests, we compared the two groups with regard to numerical variables that followed normal distributions. A Mann-Whitney U test was used to compare numerical variables that did not follow a normal distribution. The chi-square (c2) test and, when applicable, Fisher's exact test were used to assess differences for categorical variables. The Bonferroni correction for multiple testing was used to adjust the p-value. Each p-value has two possible outcomes. We regarded p-values≤0.05 to be significant.

3. Results

Table 1. Data about the analyzed cases' demographics.

		GROUP(A) N=25	GROUP(B) N=25	P-VALUE
AGE(YEARS)		42.6±3.82	43.2±3.95	P=0.541
SEX	Male	17(68%)	15(60%)	P=0.556
	Female	8(32%)	10(40%)	
SMOKING	Yes	13(52%)	14(56%)	P=0.777
	No	12(48%)	11(44%)	
DURATION OF DIABETES(YEARS)		6.52±1.36	6.84±1.32	P=0.403
WOUND DURATION (DAYS)		18.2±6.4	17.5±7.19	P=0.749

Data are presented as mean±SD, or frequency (percentage).

Regarding age, sex, smoking, the length of diabetes, and the length of the wound, there were no statistically significant differences between the groups. Patients in group A were 42.6 years old on average, whereas those in group B were 43.2 years old. The study included 17 patients (68%) who had surgery offloading, 8 patients (32%) who had non-surgical offloading, and 15 patients (60%) who had surgical offloading and 10 patients (40%) who had non-surgical offloading.

In patients treated by surgical offloading, there were 13 (52%) smokers and 12 (48%) non-smokers; in patients treated by non-surgical offloading, there were 14 (56%) smokers and 11 (44%) non-smokers. In group A, the average duration of diabetes was 6.5 years, but in group B, it was 6.8 years. Group A's mean wound duration was 18 days, whereas Group B's was 17.5 days, (table 1; figures 1&2).

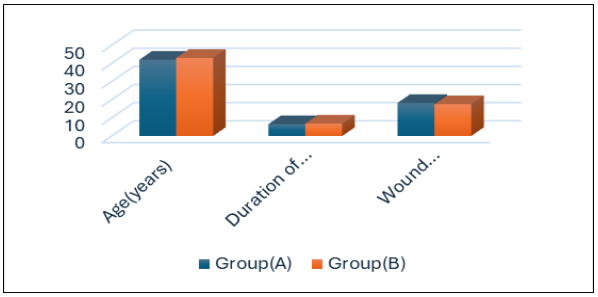

Figure 1. patient characteristics between groups.

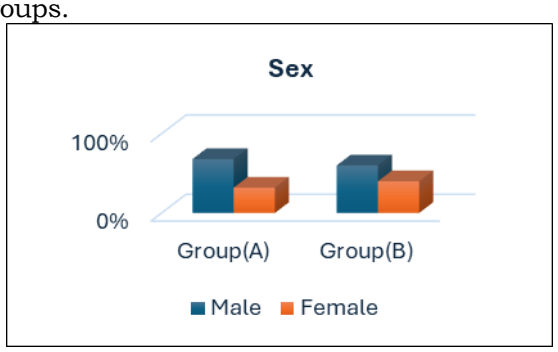

Figure 2. Sex distribution between groups.

Table 2. Characteristics of ulcer between groups.

		GROUP(A) N=25	GROUP(B) N=25	P-VALUE
FOOT DEFORMITY IN ULCERATED FOOT	Yes	20(80%)	22(88%)	P=0.440
	No	5(20%)	3(12%)	
ULCER SIZE(CM^2)	Small(<2.5cm^2)	17(68%)	18(72%)	P=0.758
	Large(>2.5cm^2)	8(32%)	7(24%)	
ULCER AREA AT ENTRY (CM^2)		1.34±.66	1.23±.69	P=0.591

Data are presented as mean±SD, or frequency(percentage).

In terms of foot deformity in ulcerated feet, ulcer size, and ulcer area at entry, there was no statistically significant distinction between the groups. The study composed of 20(80%) patients with food deformity and 5(20%) patients without foot deformity were managed by surgical offloading while non-surgical offloading methods were composed of 22(88%) patients with foot deformity and 3(12%) patients without foot deformity. Group-A composed of 17(68%) patients with small ulcer size and 8(32%) patients with large ulcer size, while group-B composed of 18(72%) patients with small ulcer size and 7(24%) patients with large ulcer size. The mean ulcer area at entry for group-A was 1.34cm2 while group-B was 1.23cm^2 (table 2; figures 3&4).

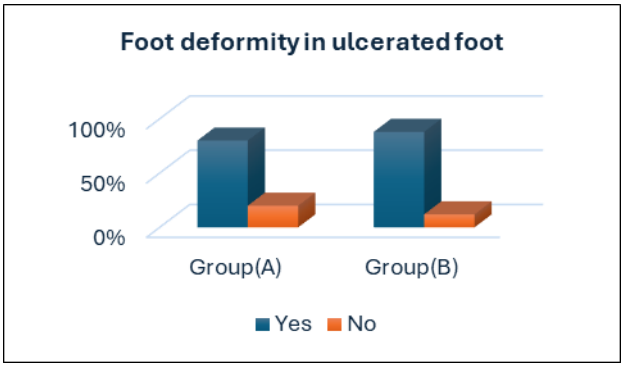

Figure 3. Foot deformity in ulcerated foot between groups.

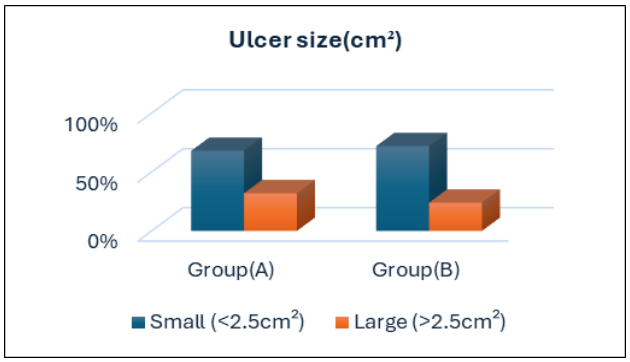

Figure 4. Ulcer size between groups.

Table 3. Clinical outcomes of studied cases.

		GROUP(A) N=25	GROUP(B) N=25	P-VALUE
REDUCTION IN ULCER AREA IN FIRST 4 WEEKS %		77.9±10.41	50.2±4.95	P=0.001
ULCER HEALING	8 weeks	8(32%)	7(28%)	
	12 weeks	6(24%)	5(20%)	P=0.883
	20 weeks	8(32%)	8(32%)	
	28 weeks	3(12%)	5(20%)	
COMPLICATIONS	No	15(60%)	10(40%)	
	Abrasion due to device	2(8%)	2(8%)	P=0.243
	Blister due to device	1(4%)	2(8%)	
	Falls due to device	2(8%)	2(8%)	
	New ulcer	1(4%)	4(16%)	
	Pressure points due to device	3(12%)	2(8%)	
	SAE	1(4%)	3(12%)	

Data are presented as frequency(percentage).

Regarding to percentage of reduction in ulcer area in first 4-weeks there was statistically significant difference in group-A compared to group-B. At 8-weeks a total of 8(32%) cases from group-A showed complete ulcer healing in comparison to 7(28%) cases from group B. At 12-weeks a total of 6(24%) cases from group-A showed complete ulcer healing in comparison to 5(20%) cases from group-B. At 20-weeks a total of 8(32%) cases from group-A showed complete ulcer healing in comparison to 8(32%) cases from group-B. At 28-weeks a total of 3(12%) cases from group-A showed complete ulcer healing in comparison to 5(20%) cases from group-B. Additionally, these findings revealed no statistically significant group differences.

Both groups experienced the same kinds of complications during the trial, including SAE, blisters, falls, new ulcers, pressure points, and abrasions brought on by the device. As stated by group-A Two instances (8%) involved abrasions caused by the device, one case (4%) involved blisters, two cases (8%) had falls caused by the device, one case (4%) involved new ulcers, three cases (12%) involved pressure points caused by the device, and one case (4%) involved SAE.

In line with group-B Three cases (12%) were complicated with SAE, four (16%) cases were complicated with new ulcers, two (8) cases were complicated with blisters, two (8) cases were complicated with falls, and two (8) cases were complicated with abrasions caused by the device. Regarding problems, there was no statistically significant difference between the groups, (table 3; figures 5&6).

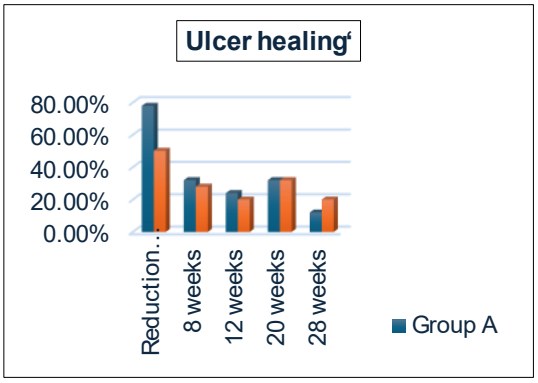

Figure 5. Ulcer healing between groups.

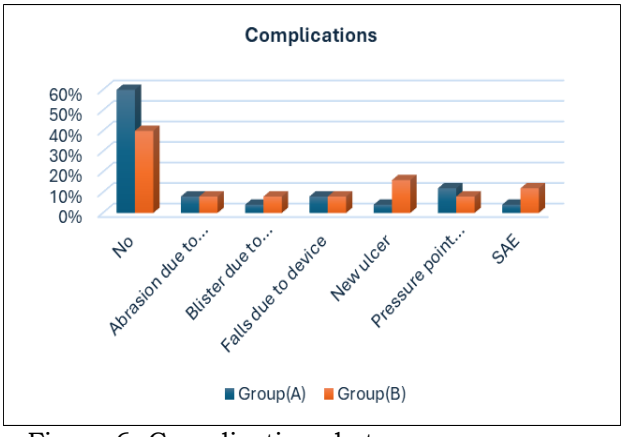

Figure 6. Complications between groups.

Table 4. Peak pressure(kPa) in both groups.

	GROUP(A) N=25	GROUP(B) N=25	P-VALUE
IN PATIENT'S OWN SHOE (KPA)	280.52±79.16	334.78±93.62	P=0.032
POST INTERVENTION (KPA)	95.35±27.46	158.84±64.11	P=0.001
PEAK PRESSURE REDUCTION IN DEVICE	185.16±87.04	175.93±79.42	P=0.697
PEAK PRESSURE REDUCTION %	62.76±15.79	51.23±16.05	P=0.014

Data are presented as mean±SD.

When comparing group A to group B, there was a statistically significant increase in the percentage of ulcer area decrease in the first four weeks (P<0.001). Group-A's offloading device pressure (kpa) was substantially lower than Group-B's (P<0.001). Furthermore, Group-A's pressure in the patient's own shoe (kpa) was considerably lower than Group-B's (P=0.032).

Furthermore, there was no statistically significant difference in the device's peak pressure reduction across the groups. However, Group-A experienced a considerably greater peak pressure drop in device percentage than Group-B (P=0.014), (table 4; figure 7).

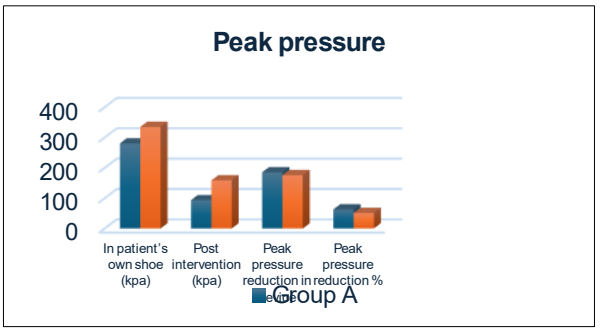

Figure 7. Peak pressure between groups.

Case presentation

Male patient 50 years old, DM type 2 on OHD, post CABG 2 years ago, post right 3rd and 4th toes amputation 1 year ago. Right Chronic non-ischemic ulcer about 7 months ago, measuring 2.5*1.5 cm2. Surgical offloading was done to this case.

Figure 8. Right NIDF, chronic planter unhealed ulcer.

Figure 9. X-ray film shows 2nd metatarsal head osteomyelitis.

Procedure:

Excision of the hyperkeratotic edges, then 2nd metatarsal head was excised,
then wound debridement under complete aseptic technique.

Post-procedure:

A follow-up X-ray was taken before to release, and the second metatarsal head was excised. Shoes (foot print) offloaded the case after it was instructed not to be weight bearing. Complete healing occurred within 4-5 weeks without any complication. Dressing was used in covering (Saline, zymalge gel).

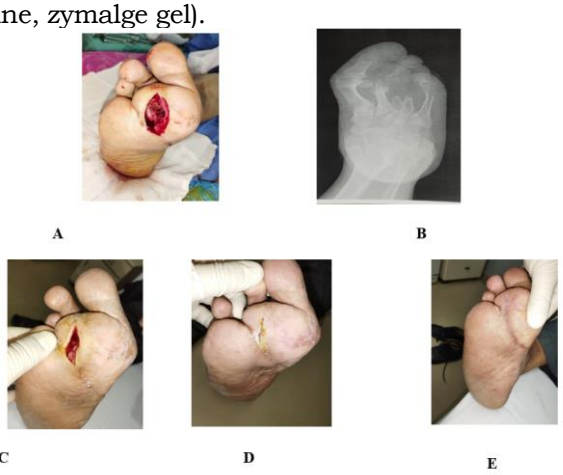

Figure 10. postoperative follow up.

A: Excision of the hyperkeratotic edges then 2nd metatarsal head was excised then wound debridement.
B:2nd metatarsal head was excised (X-Ray post operative).
C:Wound follow up (healing progress).
D: Wound post 3 weeks.
E:Complete healing post 5 weeks.

4. Discussion

Chronic consequences from diabetes mellitus include secondary neuropathy and vascular damage. Diabetic foot ulcers (DFUs) are among the most serious complications that have a significant impact on health expenses, morbidity, and mortality. The most common site for these ulcers is thought to be the forefoot.[5]

DFUs are frequently treated using topical dressings, non-surgical unloading, and in-office debridement as part of a standard of care (SC) strategy. The use of innovative topical agents and vacuum-assisted wound care has recently seen a sharp increase in popularity. On the other hand, surgery has traditionally been saved for patients whose DFU management with SC failed.[6]

According to our findings, there were no statistically significant differences between the groups in terms of age, sex, smoking, wound duration, or diabetes duration.

Consistent with our findings, Amr et al.,[7] conducted a prospective non-randomized comparative analysis on 30 patients who underwent offloading; 15 of them underwent surgery, and 15 did not (using shoes or walkers). Following up for six months, they demonstrated that, in terms of demographic data, there were no statistically significant differences among surgical and non-surgical unloading techniques.

Moreover, Assaed et al.,[8] included 30 diabetic

patients with chronic non-ischemic non-healed plantar pressure ulcers in their prospective non-randomized comparative study; 15 of them were treated with surgical offloading techniques, and 15 of them with non-surgical (air walker and therapeutic foot shoes) techniques. The results indicated that there was no statistically significant difference between the surgical and non-surgical offloading techniques in terms of demographic data.

Our results demonstrated that there was no statistically significant difference in foot deformity in ulcerated feet, ulcer size, or ulcer area at entry across groups.

Providing evidence for our findings, Amr et al.[7] demonstrated that the characteristics of ulcers, such as foot deformities in ulcerated feet, ulcer size, and ulcer area at entrance, did not significantly differ between the surgical and non-surgical offloading groups.

Also, Assaed et al.,[8] found that the features of ulcers in diabetic patients did not alter statistically significantly between the surgical and non-surgical offloading groups.

According to our findings, there was no statistically significant variation in complications between the groups.

In line with our findings, Amr et al.,[7] found that in diabetic individuals with plantar ulcers, there was no discernible difference in the complications between the surgery and non-surgical groups.

As for the complications, Assaed et al.,[8] revealed that there was no discernible difference in the problems experienced by the surgical and non-surgical groups of diabetic patients with plantar ulcers.

Moreover, Yammine and Assi,[9] demonstrated that in diabetic cases with ulcers, there was no discernible difference in the complications between surgical offloading techniques and the conventional standard of care (SC).

According to our results, group A's reduction in ulcer area over the first four weeks was statistically significantly higher than group B's.

In contrast to our findings, Amr et al.,[7] revealed that the percentage decrease in ulcer area over the first four weeks wasn't statistically significantly different between the surgical and non-surgical offloading groups. The varying sample size may be the cause of the disparity in the results.

Moreover, Yammine and Assi,[9] demonstrated that in diabetic patients with ulcers, the healing time after surgical offloading techniques was noticeably less than that of standard of care (SC).

According to our findings, Group A's offloading device pressure (kpa) was noticeably lower than Group B's.

According to our results, Amr et al.,[7] showed that, in comparison to the non-surgical group, the surgical offloading group's offloading device pressure (kPa) was much lower.

According to this study, Group A's patient shoe pressure (kPa) was noticeably lower than Group B's.

However, Amr et al.,[7] found that the pressure in the patient's own shoe (kPa) did not differ statistically significantly between the surgical and non-surgical offloading groups. Our results also showed that there was no statistically significant difference between the groups in the peak pressure reduction in the device. Bus et al.,[10] demonstrated that, in comparison to alternative treatment methods, surgical techniques might considerably lower foot pressure.

According to the current investigation, Group A experienced a substantially greater peak pressure drop in device percentage than Group B.

Similar outcomes were attained by Amr et al.,[7] who demonstrated that the surgical group's peak pressure drop was noticeably greater than that of the non-surgical group.

4. Conclusion

When treating pressure chronic unhealed plantar ulcers, offloading is crucial and successful. Each patient should have a customized unloading technique. Offloading surgically is a quicker method.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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