

Original Article

Multicenter comparison of the efficacy on prevention of pressure ulcer in postoperative patients between two types of pressure-relieving mattresses in China

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Abstract: Objective: Present study is designed to evaluate the effects of preventing pressure ulcer in surgical patients with two types of pressure-relieving mattresses. Methods: 1074 surgical patients from 12 hospitals in China were divided into A group (static air mattress with repositioning every 2 hours, n = 562) and B group (power pressure air mattress with repositioning every 2 hours, n = 512). The patient was subjected to a pressure-relieving mattress and observed from 0-5 days after surgery. Indications include the Braden scores, hospital-acquired pressure ulcers (HAPU) incidence and stage. Results: The Braden scores between two groups in five days after surgery were no significant ($P > 0.05$). The incidence of HAPU between two groups in same days also was no significant (1.07% vs. 0.98%, $P > 0.05$). The incidence of Stage I and stage II pressure ulcers in group A and B were 1.07% (6/562) and 0.98% (5/512), respectively ($\chi^2 = 0.148$, $P = 0.882$). Conclusion: The effects of preventing pressure ulcer in surgical patients with two types of pressure-relieving mattresses are similar, but the protocol by static air mattress with repositioning every 2 hours is benefit when no power.

Keywords: Support surface, hospital-acquired pressure ulcers, prevention, surgical patients

Introduction

Pressure ulcers (PU) are localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (NPUAP/EPUAP, 2009) [1, 2]. Pressure ulcers in acute care often involve extended hospital stays and additional health service resources. As well as the economic burden, pressure ulcers have a significant impact on patient morbidity (WOCN, 2010) [3]. The postoperative patients are easy to run pressure ulcers due to anesthesia, stayed in operating room more than 4 hours, receiving no nutrition, using many medicines and medical devices like cervical collar, cast, ventilation support, parenteral sedation [4-6].

The incidence of hospital-acquired pressure ulcer (HAPU) is ranging from 14.3% to 23.9% [3, 7]. How to prevent HAPU and to eliminate HAPU in the operating room and beyond become a focused program in many countries [8-10]. Pressure redistribution devices or pressure-relieving devices are one of evidence-based nursing practice criteria to be used as part of the treatment to reduce the pressure on the ulcer, and pressure relieving surfaces have been recommended as a form of pressure ulcer prevention for patients at risk of developing ulcers [11-14]. Pressure ulcer prevention in China represents a major challenge. It required a maximum control of pressure ulcer occurrence in hospitals. The pressure-relieving mattress plays an important role in pressure ulcer

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Table 1. The basic situations of the enrolled patients from 12 participating hospitals (N = 1074)

hospital	N	Male/Female	Age	operation time (min)	Braden score on surgery day
hospital 1	36	18/18	56.28 ± 18.59	156.6 ± 49.8	16.42 ± 3.74
hospital 2	97	48/49	50.14 ± 12.93	350.4 ± 185.4	12.99 ± 2.02
hospital 3	38	24/14	49.08 ± 17.31	297 ± 82.8	12.71 ± 2.38
hospital 4	63	46/17	53.41 ± 14.88	212.4 ± 66.6	13.11 ± 1.78
hospital 5	185	119/66	60.70 ± 15.52	251.4 ± 105.6	14.05 ± 1.56
hospital 6	95	54/41	61.69 ± 13.71	217.2 ± 89.4	12.16 ± 1.57
hospital 7	64	37/27	59.47 ± 15.34	228.6 ± 67.8	11.50 ± 2.48
hospital 8	81	57/24	59.95 ± 10.84	241.2 ± 143.7	12.48 ± 0.96
hospital 9	94	43/51	64.23 ± 12.85	172.2 ± 53.1	13.03 ± 0.86
hospital 10	46	19/27	63.13 ± 14.04	235.2 ± 62.4	12.70 ± 3.11
hospital 11	186	117/69	57.85 ± 16.18	168 ± 37.2	13.52 ± 2.12
hospital 12	89	39/50	52.33 ± 17.24	135 ± 46.2	12.78 ± 2.92
Total	1074	621/453	57.94 ± 15.54	219.6 ± 110.6	13.15 ± 2.25

prevention. De-Laat et al. studied 399 ICU patients on the special pressure-relieving mattress to evaluate the prevention outcomes and discovered that pressure-relieving mattress is the most powerful indicator for pressure ulcer occurrence [15]. Black et al. [13] found the pressure-relieving effect of the low air loss mattress (LALM) was more than the power pressure air mattress (PPAM), especially in decreasing the incidence of pressure ulcers [16].

In the present study, we investigated the efficacy of static low air loss mattress (static LALM) and power pressure air mattress (PPAM) in prevention of pressure ulcer, a multicentre randomized controlled trials focused on the postoperative patients and it was the first study in China performed in 12 participating hospitals.

Materials and methods

Research objects

The patients of this study were from 12 general hospitals in 9 cities of 4 provinces in Beijing, Jiangsu, Fujian, and Guangdong. There were 600-1900 beds per hospital, and the total number of beds was 14,240. The inclusion criteria is: age ≥ 18 years, male or female with Braden score ≤ 16 points, general anesthesia for surgery with operating time ≥ 120 min, admitted to the ICU or surgical wards after surgery, clear consciousness, able to express their feelings correctly, had contraindications for using air mattress (doctor's orders: lying on hard-bed or flat-bed), completed informed consent and related inform. The exclusion criteria

is: refused to participate research, in critical condition and repositioning limited by doctor's orders, using ice blanket, shed from intervention less than 72 h, unable to determine the efficacy, incomplete data on the efficacy or safety judgment. 1,074 cases of surgical patients from 12 hospitals were enrolled in for the prevention of pressure ulcers research. The proportion of male and female accounted for 57.82% and 42.18%, respectively. Age was 57.94 ± 15.54 years (18-88 years old). The operating time was 219.6 ± 110.6 min (120-960 min). Braden scoring results on the day of surgery were 13.15 ± 2.25 (6-17 points). 154 cases selected from surgical ICU (SICU) and accounted for 14.34%; 344 cases were from orthopedic wards and accounted for 32.03%, 576 cases were from general surgery wards and accounted for 53.63%. The operation time was calculated under anesthesia records from anesthesia alone to the end of surgery. The selected cases in 12 hospitals are shown in **Table 1.**

Research grouping

We used a random number table to randomize and parallel control design. The observation group, known as static air mattress group (n = 562), was repositioned every 2 hours on that mattress (®WAFFLE static air mattress, EHOB, United States). The control group, known as dynamic air mattress group (n = 512) was repositioned every 2 hours on that mattress (Sanma mattress manufacturing factory, Shanghai in China). Once the selected patients were back from the operating room to the wards or SICU,

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Table 2. Comparison of two baseline datas (N = 1074)

	Static air mattress (n = 562)	dynamic air mattress (n = 512)	t	P
Age	57.81 ± 15.58	58.09 ± 15.52	-0.285	0.776
Operation time (min)	222.8 ± 112.4	216.1 ± 108.7	1.001	0.317
Incision pain (score)	3.29 ± 1.49	3.29 ± 1.48	0.054	0.957
Departments distribution			$\chi^2 = 0.091$	0.763
Surgical ICU (cases)	78	76		
Orthopedic wards (cases)	181	163		
Surgical wards (cases)	303	273		
Sex (male/female)			$\chi^2 = 2.566$	0.109
Male	312	309		
Female	250	203		
Skin before the study (complete or pressure ulcers)			$\chi^2 = 0.916$	0.339
complete	561	512		
pressure ulcers	1	0		

the baseline data were collected until the 5 days after surgery. We used surgical pressure ulcer risk assessment form (Surgical Pressure Ulcer Risk Assessment, SPURA), which was formed (Gerri et al.) from entries through the literature review by reliability and validity testing, including age, sex, operating time, with or without diabetes, anemia, skin edema, mechanical ventilation, end-stage renal disease, hemodialysis, obesity, use of vasopressors, sedation, no protein oral (NPO), excessive moisture (such as incontinence, drainage, sweat) are shown as follows, and meanwhile also used the Braden scale to assess the risk of pressure ulcer, and the visual analogue scale to assess the levels of incision pain (0-10 points, means no pain to serious pain). The two group's baseline data are shown in **Table 2**.

Modified SPURA

- Age (≥ 70 years) _____ Male _____ Female _____
- Diabetes Mellitus
- end-stage renal disease (ESRD)
- Hemodialysis
- Anemia (Hct < 25)
- Vasopressors
- Obesity \ddot{y} (Ht _____ Wt _____ BMI _____)
- Ventilator Support

- Sedated (IV narcotics)
- No protein oral (NPO)
- Edema ($>+1$)
- Incontinent, Excessive Moisture
- Decreased Mobility (Bedfast)
- Unable to reposition (hemodynamic instability or clinical status)
- Cast, orthotics, traction, cervical collar
- Operating room (OR) time > 4 hours
- Braden Scale Score _____

Participated researchers' qualifications, training and examination

Qualifications of participants in the research should meet the following criteria: a registered nurse in charge of patients, examination scores ≥ 90 points after the uniform training. Training methods: we used multimedia to teach, watched the operation video and learned operation steps and judgment methods of the Braden scale by one-help-one training model. We trained the updated definition and staging of pressure ulcers (National Pressure Ulcer Advisory Panel, NPUAP 2007) [17]; and trained the operation processes of static and dynamic air mattress and then tested by the analogue examination.

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Observation methods and content

The observation period for each patient was started from the day of surgery and end of the postoperative 5 days. (1) Skin inspection and pressure ulcers assessment: repositioned patients every 2 hrs, checked their skin from head to toes and made a record timely in the observation time. If any skin breakdown was found, we identified whether it developed into a pressure ulcer or not. Next, we determined the pressure ulcers stage, such as suspected deep tissue injury (SDTI) or the unstable pressure ulcers in accordance with the definition of pressure ulcers updated by NPUAP in 2007. The number of pressure ulcers was recorded including the locations and the occurrence time. (2) Assessment for the risk of pressure ulcer: the Braden scale was used to assess and record daily in observation time. The total scores of 6 subscales were 6-23 points.

If the total scores of 6 subscale were 15-16, 13-14 and ≤ 12 points, means patients had low, moderate and high level risk of pressure ulcer occurrence, respectively [18]. (3) The mattress inspection and assessment: we inspected the air mattress by hand checking to find whether it was appropriately inflated, effective and comfortable. Methods: to put one hand underneath the mattress at the patient's hip, if it can easily get in and out and the patient had no complain and felt comfortable suggested that the air mattress had enough air with effective decompression. Otherwise, the air mattress was not used properly, need to do adjustment. (4) Evaluation of the level of patients' comforts: asked patients' feelings after using the mattress in the same words everyday and made a record, 1 = very uncomfortable, 2 = uncomfortable, 3 = just comfortable, 4 = comfortable, 5 = very comfortable. (5) Evaluation of procedure convenience: the participating nurse made an evaluation daily for the procedure convenience and labor-saving during the observation period time, 1 = very inconvenient, 2 = not convenient, 3 = just convenient, 4 = convenience, 5 = very convenient.

All participating nurses in each hospital got the qualification after the unified training in the study by a research group, and implemented the inclusion criteria, exclusion criteria, standard mattress use and observation in accordance with training methods. The results were

recorded on the table in consistence of what had been observed. The outcomes of the study, and all related materials were express mailed to the research group in order to control the bias in the study.

Statistical analysis

SPSS16.0 was used to establish a database for statistical analysis, a paired t-test used for the number of both groups ($\bar{x} \pm S$), and the non-parametric chi-square test for the two groups of non-normal data and hierarchical data, rate and percentage. $P < 0.05$ was considered statistically significant.

Results

We selected 1074 cases and completed the 5 days of observation period after surgery without any loss. During the observation period, there were 11 cases of pressure ulcers (nine cases of stage I pressure ulcers, two cases of stage II). The locations of pressure ulcers: six cases of the sacral, four cases of the heels, one case of the left trochanter. The incidence of HAPU was 1.02% (11/1074). The incidence of HAPU occurred in different departments as follows: the SICU was 1.95% (3/154) > surgical wards with 1.22% (7/576) > orthopedic wards with 0.29% (1/344). HAPU incidence of Static air mattress group was 1.07% (6/562), dynamic air mattress was 0.98% (5/512). The difference was not statistically significant ($\chi^2 = 0.148$, $P = 0.882$). Two cases occurred HAPU on the day of surgery and accounted for 18.18%; 5 cases occurred on the first day after surgery and accounted for 45.46%; 3 cases occurred on the second day after surgery and accounted for 27.27%; and 1 case occurred on the third day after surgery and accounted for 9.09%. Occurrence period was as follows: 7 cases occurred from 6:00 pm to 8:00 am, accounted for 63.64% and 4 cases occurred from 8:00 am to 6:00 pm, accounted for 36.36%. Comparison of the Braden score results and preventive effects within 5 days are shown in **Table 3**.

The further analysis of the parameters between 11 HAPU patients and the patients without pressure ulcers is shown in **Table 4**.

Conveniences of evaluation results on mattresses used by nurses participated in the

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Table 3. Comparison of Braden scores and prevention effects (N = 1074)

	Static air mattress (n = 562)		dynamic air mattress (n = 512)		t	P
	(x ± S)		(x ± S)			
Braden scores results						
Surgery day	13.15 ± 2.18		13.14 ± 2.32		0.076	0.939
Postoperative 1 d	14.35 ± 2.09		14.60 ± 2.17		-1.915	0.056
Postoperative 2 d	15.37 ± 2.19		15.62 ± 2.22		-1.840	0.066
Postoperative 3 d	16.16 ± 2.35		16.34 ± 2.37		-1.215	0.225
Postoperative 4 d	16.98 ± 2.54		17.05 ± 2.55		0.413	0.680
Postoperative 5 d	17.40 ± 2.68		17.40 ± 2.63		0.575	0.986
PU risk	yes (≤ 16)	no (> 17)	yes (≤ 16)	no (> 17)	χ ²	P
Surgery day	533	29	486	26	0.018	0.894
Postoperative 1 d	494	68	429	84	2.442	0.118
Postoperative 2 d	416	146	358	154	3.357	0.067
Postoperative 3 d	342	220	290	222	1.612	0.204
Postoperative 4 d	232	330	205	307	0.273	0.601
Postoperative 5 d	174	388	162	350	0.007	0.931
Titles of nurses for observation and care					0.152	0.696
Nurse	70		59			
Advanced Nurse	347		318			
Supervisor nurse	145		135			
Preventive effects	n (%)		n (%)			
Pressure ulcers	6 (1.07%)		5 (0.98%)		0.022	0.882
No pressure ulcers	556		507			
Numbers of pressure ulcers	6		5		0.022	0.882
Departments distribution					3.330	0.189
ICU	2 (2.56%)		1 (1.32%)		0.312	0.576
Surgical wards	4 (1.32%)		3 (1.10%)		0.058	0.809
Orthopedic wards	0 (0%)		1 (0.61%)		1.110	0.292

Table 4. Comparison of the parameters between pressure ulcer patients and patients without pressure ulcers

	patients with pressure ulcer (n = 11)	patients without pressure ulcer (n = 1063)	t	p
Age	51.27 ± 18.47	58.01 ± 15.51	1.432	0.153
Operation time (min)	340.80 ± 196.20	218.40 ± 108.60	4.013	0.000*
Insicion pain (score)	3.77 ± 0.88	3.30 ± 1.42	1.114	0.266
Braden score on surgery day	13.82 ± 2.40	13.14 ± 2.24	0.995	0.320
Postoperative 1 d Braden score	15.45 ± 1.81	14.46 ± 2.13	1.550	0.121
Postoperative 2 d Braden score	16.55 ± 2.16	15.48 ± 2.20	1.599	0.110
Postoperative 3 d Braden score	17.00 ± 2.15	16.24 ± 2.36	1.060	0.289
Postoperative 4 d Braden score	17.45 ± 2.16	17.01 ± 2.55	0.579	0.563
postoperative 5 d Braden score	15.00 ± 2.83	17.40 ± 2.65	1.282	0.200
Sex			χ ² = 2.096	0.148
Male	4	617		
Female	7	446		

*On surgery day when patients were back to ward or SICU, trained nurses read the anesthesia records from anesthesia alone to the end of surgery and calculated the operation time (min).

study were shown in **Table 5**. The statistically analyzed results were showed in the table, on

the only postoperative 1d two groups of mattresses operation was very convenient, whose

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Table 5. Conveniences of evaluation results on mattresses

	Evaluation time static air mattress (n = 562, median = 4)			dynamic air mattress (n = 562, median = 4)			χ^2	P
	N > median (cases)		≤ median (cases)	N > median (cases)		≤ median (cases)		
	N > median (cases)	≤ median (cases)		N > median (cases)	≤ median (cases)			
Surgery day	562	91	471	512	64	448	2.958	0.085
Postoperative 1 d	562	104	458	512	72	440	3.860	0.049
Postoperative 2 d	562	109	453	511	78	433	3.174	0.075
Postoperative 3 d	556	107	449	508	83	425	1.528	0.216
Postoperative 4 d	536	107	429	495	80	415	2.504	0.114
Postoperative 5 d	484	85	399	464	79	385	0.048	0.827

Table 6. Evaluation of comforts on two kinds of mattresses by surgical patients

	Evaluation time static air mattress (n = 562, median = 4)			dynamic air mattress (n = 562, median = 4)			χ^2	P
	N > median (cases)		≤ median (cases)	N > median (cases)		≤ median (cases)		
	N > median (cases)	≤ median (cases)		N > median (cases)	≤ median (cases)			
Surgery day	562	62	500	512	61	451	0.206	0.650
Postoperative 1 d	562	76	486	512	69	443	0.000	0.982
Postoperative 2 d	560	76	484	511	66	445	0.100	0.750
Postoperative 3 d	553	80	473	507	68	439	0.245	0.621
Postoperative 4 d	536	78	458	494	64	430	0.551	0.458
Postoperative 5 d	482	68	414	462	68	394	0.071	0.789

percentage (accounted for 18.51% and 14.06% respectively), convenience and below (accounted for 81.49% and 85.94% respectively), the difference was statistically significant ($P < 0.05$), the rest differences were not statistically significant ($P > 0.05$). The subjective evaluation of comfort on two kinds of mattresses by surgical patients is shown in **Table 6**.

Discussion

Air mattress on pressure ulcers prevention research and choose basis and research purposes

Domestic air mattress to prevent pressure ulcers research focuses on the dynamic aspects of the application effect air mattress. The dynamic air mattress applied the principle of drying skin and relieving body's pressure to prevent pressure ulcers. The surface of the mattress has opened a number of micropores, where the gas is ejected to take away body fluids and reduce humidity, thereby maintaining the skin dry, inhibiting the growth of bacteria, and dispersing patient's body pressure on the mattress to play the role of prevention. Most Chinese hospitals use such mattress due to the relatively cheaper price (about 800-1000 RMB per mattress) and the effective preven-

tion on pressure ulcers. The static air mattress with static air technology, which was based on the principle of buoyancy, Boyle's law, Newton's third law, Pascal principle, made the body into a air chamber of the static air mattress, then compressed and extruded the volume of air out of the chamber until the air pressure in the chamber was sufficient to support the weight of the body and relieve surface pressures on the unit area of skin in the vertical, non-gradient manner. Studies have demonstrated that the effects in the prevention of pressure ulcers as well as in treatment. Leen et al. studied that 83 patients at risks were randomly divided into a group of foam mattresses and a group of foam mattresses plus static air mattresses, the results showed the group of foam mattresses plus static air mattresses was better to prevent pressure ulcers and improve healing rate than the foam mattresses alone (100% vs. 28.57%). Keen et al. suggested that the static air mattress without the electric drive cost less than the dynamic air mattress in the prevention and treatment [19]. Newly domestic Haiying Liu et al. researched 200 cases of bedridden patients with the Braden score ≤ 16 , age ≥ 18 years on the static and dynamic air mattresses to observe the effects by using a computer pressure sensor (Xsensor manometry blanket made in Canada), found that the static air mattress

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was better than the dynamic air mattress in reducing pressure and pressure areas. But there were no multicenter randomized controlled studies with larger samples on pressure ulcers prevention of the static air mattress and the dynamic air mattress.

According to the research reported in the literature, this study chosen the static air mattress and the dynamic air mattress widely used in clinical. We cooperated with 12 general hospitals, and selected patients staying in the general wards and SICU after general surgery and orthopedic surgery as the research object. We conducted a multicenter randomized controlled study on two different air mattresses to further verify the effects of operating convenience, patients' comfort on pressure ulcers prevention, providing the basis for selecting air mattress with good clinical applicability and functions.

Research results analysis

1,074 cases of surgical patients were selected from 12 hospitals, they were randomly divided into static air mattress group and dynamic air mattress group, the baseline information on the two groups was no statistically significant (**Tables 1 and 2**, $P > 0.05$). During the observation period (postoperative 0-5 d) occurred 11 cases of Stage I-stage II hospital-acquired pressure ulcers (HAPU), the incidence was 1.02%, which was higher than the cross-sectional survey results of HAPU (0.63%) in 12 hospitals [15], much higher than HAPU incidence of 0.39% in surgical wards. The reasons may be associated with the following factors: (1) different observation time: 12 hospitals in the cross-sectional research chosen one day in the month as a research day 13 [17], the selected patients were only observed in the time point, the statistical results of HAPU, also known as point incidence. However, the observation time of the study was a period of time (after 0-5 d), the results are the incidence of pressure ulcers in this period time. (2) different selected objects: the cross-sectional survey selected patients hospitalized for at least 24 h, ≥ 18 years of age on the research day, surgical inpatients included the patients waiting for surgery and all patients after surgery, and no special requirements on the surgical time and anesthesia, but the selected objects in this study required the general anesthesia, operation

time ≥ 120 min (**Table 3**), the abroad study proved [7, 20] general anesthesia, operative time ≥ 120 min patients with risk factors for pressure ulcers occur. (3) Difference on the proportions of pressure ulcers population at risk: the surgical patients with Braden score ≤ 16 points in the cross-sectional survey accounted for 9.71% (1776/18288), but in this study, patients with Braden score ≤ 16 points on the day of surgery accounted for 94.88% (**Table 4**, 1019/1074), patients with Braden score ≤ 16 points after 5 days accounted for 31.28% (336/1074). Studies have shown that patients with low Braden score increased the risk of suffering from pressure ulcers [7, 18, 21, 22], for which pressure ulcers guidelines require preventive measures. One of those is the pressure-relieving. In this study, pressure ulcers still occurred after risk assessment, reposition and pressure-relieving mattress, dynamic monitoring and adjustment for preventive measures, which was in consistent with statement on the inevitable pressure ulcers published in 2009 by WOCN. After the further analysis on HAPU incidences of two groups, we could find that the incidence of static air mattress was slightly higher than the dynamic air mattress group (**Table 3**, 1.07% vs. 0.98%), but the difference was not statistically significant ($P > 0.05$). The distribution of departments had shown that ICU was the highest (**Table 3**, 2.56% vs. 1.32%), then the surgical wards (**Table 3**, 1.32% vs. 1.10%), the lowest was the orthopedic wards (**Table 3**, 0.61%). The difference between two groups was not statistically significant ($P > 0.05$). Therefore we concluded that the effects on two air mattresses on pressure ulcers prevention were similar. From the nurses' operating convenience (**Table 5**) and patients' comforts (**Table 6**), there was no significant difference ($P > 0.05$) between two air mattresses. The incidence of HAPU in this study was lower than the incidence of pressure ulcers after taking the follow-up visiting from the postoperative 7 d to 12 weeks reported by Margareta, and the incidence of HAPU in SICU reported by Gerri's (the Surgical, intensive care unit, SICU). The reasons would be related to the different race and different prevention interventions, including mattress [17].

In summary, static air mattresses and dynamic air mattresses can be used both for surgical patients to prevent pressure ulcers, if the

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power is taken into account, the static air mattress is artificially inflated without power, which is more beneficial for pressure ulcers prevention during the wounded transition under the disaster scene, battle field aids and more complex conditions.

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Disclosure of conflict of interest

None.

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