Original Article

Thoracic spinal anaesthesia – An effective alternative to general anaesthesia in breast surgeries: A randomised, non-blinded study

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ABSTRACT

Background and Aims: General anaesthesia (GA) is the preferred modality for breast surgeries; however, neuraxial anaesthesia can be performed in cases where GA poses a significant risk. We hypothesise that neuraxial blockade is a safe and effective alternative to GA in short-duration breast surgeries. **Methods:** This randomised study included 30 patients of the American Society of Anesthesiologists physical status I and II, who were scheduled for elective breast surgeries of a duration of less than 90 min. Group I received thoracic spinal anaesthesia, while in Group II, standardised GA was administered. The primary outcome was the time to the first rescue analgesic, and the secondary outcomes were time to recovery, patient satisfaction and the cost incurred. **Results:** The demographic characteristics of both groups were comparable ($P > 0.05$). The time to first rescue analgesic in Group I was more than in Group II ($P = 0.001$). Patient satisfaction score was superior in Group I compared to Group II ($P = 0.002$). The average cost was lower in Group I compared to Group II ($P = 0.002$). Recovery was quicker in Group I than in Group II ($P = 0.001$). There were no significant haemodynamic disturbances or major complications in either group. **Conclusion:** Thoracic spinal anaesthesia is an excellent alternative to GA in terms of analgesic efficacy, patient satisfaction, recovery and cost-effectiveness for short-duration breast surgeries.

Keywords: Anaesthesia, breast surgery, cost-effectiveness, general anaesthesia, spinal block, subarachnoid block, thoracic spinal anaesthesia

INTRODUCTION

General anaesthesia (GA) is currently the standard technique used for breast surgeries. Certain constraints of GA, like inadequate pain control secondary to lack of residual analgesia, higher incidence of nausea and vomiting, and increased length of hospitalisation and cost, have revolutionised the demand for neuraxial anaesthesia.[1] While not being routinely used, thoracic spinal anaesthesia (TSA) has advantages, including fewer respiratory and cardiac complications, a more pronounced suppression of the neuroendocrine stress response, a lower incidence of deep vein thrombosis, quality postoperative analgesia and a lower incidence of nausea and vomiting.[2] In TSA, the sympathetic block is restricted to fewer dermatomes with minimal involvement of lower limbs, resulting in a smaller reduction in preload and blood pressure.[3] Early recovery and ambulation are boons in short-duration breast surgeries.

Levobupivacaine is a potent, longer, longer-acting local anaesthetic. Fentanyl causes less cephalad effects due to its rapid clearance and potentiates the effects of local anaesthetics.[4,5] This study was conducted with the aim of exploring the role of TSA

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for anaesthesia for breast surgeries as compared to GA. We hypothesise that TSA is a safe and effective alternative to GA in short-duration breast surgeries. The primary objective was to compare the time to first rescue analgesic between patients receiving TSA versus patients receiving GA posted for short-duration breast surgeries. The secondary objectives were time to recovery, patient satisfaction score and the cost incurred.

METHODS

This randomised, non-blinded, comparative study was conducted from December 2022 to May 2023 after obtaining approval from the institutional ethical committee (vide no. IEC/59/2022, dated 10 October 2022). The trial was registered at the Clinical Trials Registry – India (vide no. CTRI/2022/11/047467; URL: https://ctri.nic.in/Clinicaltrials). This study was carried out in accordance with the principles of the Declaration of Helsinki (2013) and good clinical practice. Written and informed consent was obtained from patients for participation in the study and use of their data for research and educational purposes. Patients satisfying the following inclusion criteria were recruited: age between 20 and 60 years, belonging to the American Society of Anesthesiologists (ASA) physical status I and II and scheduled for elective short-duration breast surgeries. Patients with a history of allergy to local anaesthetics, patients with mental disorders, coagulopathy, morbidly obese patients, patients with infection at the site of the procedure, advanced renal, hepatic and cardiorespiratory diseases and patients who refused to participate were excluded.

All patients were subjected to a detailed pre-anaesthetic evaluation. Routine and specific investigations were conducted based on the patient's profile. Patients were explained the procedure and informed about the visual analogue scale (VAS) (ranging from 0 to 10, with 0 being perceived as 'no pain' and 10 as the 'worst pain'). The verbal rating for patient satisfaction score between 1 and 5, in terms of satisfied to dissatisfied, was also considered. Premedication was given with oral alprazolam and ranitidine 150 mg the night before surgery. Fasting guidelines were maintained (nil by mouth for 6 h for solids and 2 h for liquids).

This was a non-blinded study. Randomisation was performed using a computer-generated random number table, and allocation concealment was accomplished using a sequentially numbered, opaque, sealed envelope that was unsealed on the day of surgery 1 h before surgery. Patients were assigned to one of two preset groups (groups I and II) of 15 patients each. Group I received TSA, whereas Group II received GA.

On the patient's arrival to the operating room, standard ASA monitors were attached, and baseline parameters, including heart rate (HR), non-invasive blood pressure, oxygen saturation (SpO_2) and electrocardiogram (ECG), were recorded. An intravenous (IV) line was secured with an 18G cannula. Ringer's lactate was administered at 10 ml/kg/h. Subsequently, patients in Group I were placed in sitting positions, and under aseptic conditions, the skin and underlying tissues were infiltrated with 2 ml of 2% lignocaine solution at the site. The T5–T6 space was anatomically identified by palpation from the lower border of the scapula corresponding to T7, which was also confirmed by ultrasound. A thoracic puncture was performed at the T5–T6 interspace in all patients with a 26G Quincke Babcock spinal needle. After slowly piercing and negotiating the structures, the needle's stylet was removed and the hub was observed for the free flow of cerebrospinal fluid (CSF). Once the flow of clear CSF was noted, 1.2 ml of isobaric levobupivacaine 0.5%, along with 25 μg fentanyl (total volume 1.5 ml), was administered. The patients were then placed in the supine position. The upper and lower sensory blockades were checked, and their extent was noted. Patients whose block failed to act or a satisfactory level was not achieved within 10 min were excluded from the study. These patients were administered GA. TSA was administered by an experienced anaesthesiologist using a paramedian approach, limiting the number of attempts to less than three.

The sensory block was assessed by using a pinprick method. Upper limb motor involvement was assessed by handgrip, elbow flexion, wrist flexion and extension. Motor block in the lower limbs was evaluated by a modified Bromage scale, which was assessed as follows: 1- complete block (unable to move the feet or knees), 2- almost complete block (able to move the feet only), 3- partial block (just able to move the knees), 4- detectable weakness of hip flexion, 5- no detectable weakness of hip flexion while supine (full flexion of knees) and 6- able to perform partial knee bend.

During the intraoperative period, haemodynamic parameters were noted every 5 min during the first 15 min and then every 15 min throughout the surgery [Figure 1]. Adverse effects like

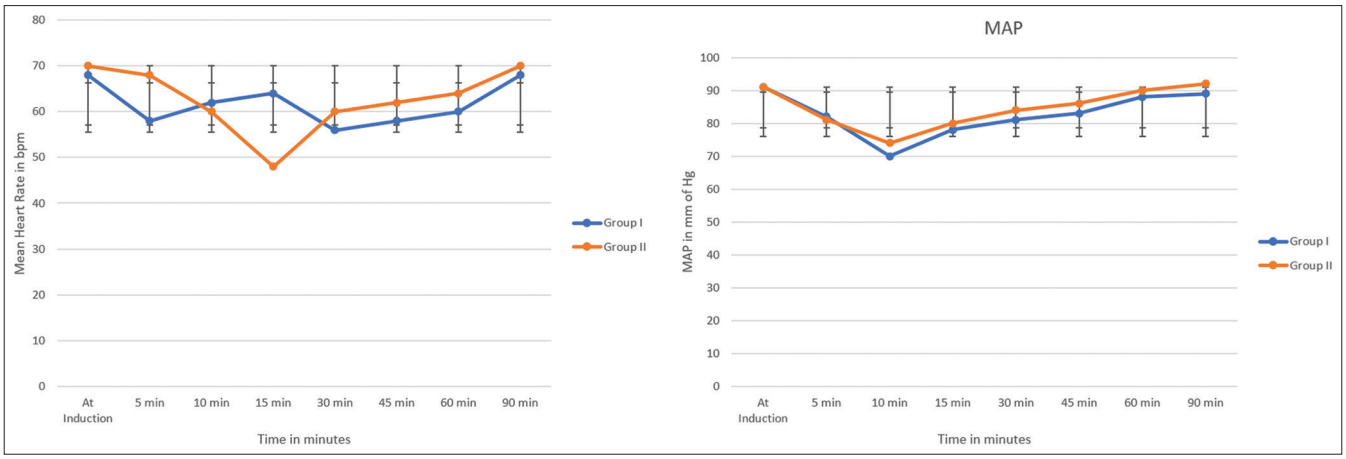

Figure 1: Intraoperative comparison of haemodynamic parameters (heart rate and MAP). MAP = mean arterial pressure

hypotension (i.e., 20% decrease relative to baseline), bradycardia (HR <50 beats/min), nausea, vomiting, hypoxaemia (SpO_2 <90%), subjective breathing difficulty and any other complications were noted. Any additional medications given intraoperatively were recorded.

Patients were asked to note the subjective recovery of sensation and pain score, which was then certified by an anaesthesiologist in the postoperative period. Pain was assessed using VAS (0- no pain, 1–3- mild pain, 4–6- moderate pain and 6–10- severe pain). IV paracetamol (1 g) was given as rescue analgesia once VAS was equal to or more than 4. The need for rescue analgesia, time to first rescue analgesia, time to recovery (Aldrete ≥9), the total dose of postoperative analgesia required in 24 h, patient satisfaction score and the total cost of drugs used were noted.

All patients in Group II were preoxygenated and premedicated with IV glycopyrrolate (0.01 mg/kg), midazolam (0.05 mg/kg) and fentanyl (1–2 μg/kg). Anaesthesia induction was done with IV propofol (2 mg/kg). Tracheal intubation was facilitated by IV atracurium (0.5 mg/kg) using an appropriately sized cuffed endotracheal tube, which was then secured after bilateral equal air entry was confirmed. Based on predicted body weight, lungs were mechanically ventilated with a 5–6 ml/kg tidal volume. The respiratory rate was adjusted to maintain end-tidal carbon dioxide of 35–40 mmHg. Anaesthesia maintenance was done with inhalational gas mixtures comprising isoflurane, oxygen, nitrous oxide and intermittent doses of IV atracurium. All haemodynamic parameters were monitored. During the end of the procedure, residual neuromuscular block was antagonised with IV neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) and the trachea was extubated. Incidences of nausea, vomiting, headache and respiratory depression were recorded postoperatively. The time to first rescue analgesic, time to recovery, patient satisfaction score and the total doses of postoperative analgesic required in 24 h were assessed. The total cost of medications used in both groups was calculated from the hospital invoice.

The time to first rescue analgesic is when patients seek rescue analgesia following surgery in the postoperative period. It was determined after emergence and transfer to the recovery room. All patients were interviewed and asked to rate if they were satisfied or dissatisfied with the anaesthetic they received. Patient satisfaction was assessed using a 6-point Likert scale, which comprised 'very dissatisfied', 'dissatisfied', 'slightly dissatisfied', 'slightly satisfied', 'satisfied' and 'very satisfied' with a score ranging from 0 to 5, respectively.[6] Reasons for patient dissatisfaction were analysed. Postoperatively, as described above, pain was assessed using VAS. The number of doses of paracetamol used in 24 h was also documented.

Bradycardia was defined as an HR less than 50 beats/minute and treated with IV atropine (0.01 mg/kg). Hypotension was defined as a decrease in blood pressure by more than 20% of the baseline value and was treated by rapid fluid bolus administration and IV ephedrine in diluted concentrations.

Based on our hospital data of short-duration breast surgeries suitable for an ambulatory setting and assuming the time to first rescue analgesic as the

primary outcome with a significant difference of 30 min between the two groups, for 95% confidence level and 80% power with an acceptable margin of error along with an absolute precision of around 2%, the sample size was derived to be a total of 30 patients (15 in each group) including a possible 10% dropouts. As the variance decreases, sufficient power is achieved with a smaller sample.[7]

Data was tabulated and entered into MS Excel. The results were analysed using Statistical Package for the Social Sciences (SPSS) statistics software version 21.0 (IBM Corp, Armonk, NY, USA) statistical software. Descriptive statistics were presented in terms of numbers. Categorical variables like ASA and patient satisfaction score were expressed in frequency and percentage. The comparison of categorical variables between the groups was carried out by using the Chi-square test/Fisher's test. The distributions of continuous and discrete variables like age, height, weight, duration of surgery, time to first rescue analgesic, VAS score, Aldrete score, cost incurred and number of doses of rescue analgesics were expressed in terms of mean (standard deviation) [95% confidence interval (CI)]. They were compared using an independent Student's *t*-test or Mann–Whitney test. Results were statistically significant if the *P* value was <0.05 and were highly significant if the *P* value was <0.001.

RESULTS

The study included 30 patients who were analysed [Figure 2]. Both groups were comparable in terms of demographic characteristics, ASA class and duration of surgery [Table 1] ($P > 0.05$). TSA was administered to Group I patients, providing a sensory block of T2–T8 levels. The time to first rescue analgesic request was significantly longer in Group I than in Group II ($P = 0.001$) [Table 2]. Analgesia was better achieved in Group I. Rescue analgesic requirement was also significantly higher in Group II ($P = 0.006$) [Table 2]. The mean pain VAS score was significantly better in Group I than in Group II during the observation period at all time intervals ($P < 0.001$) [Table 2]. This led to significantly lower consumption of rescue analgesics in Group I. Patients in Group I had quicker recovery than those in Group II, as evidenced by better Aldrete score ($P = 0.001$) [Table 2]. The HR and mean arterial pressure were comparable in both groups [Figure 3]. The cost incurred in Group I was less when compared to Group II ($P = 0.002$) [Table 2]. The cost included all disposables, drugs and gases used in anaesthesia. Patient satisfaction score was superior in patients who received TSA ($P = 0.002$) [Table 2]. None of the patients in Group I had motor blockades in both upper and lower limbs. Two patients in Group I were administered IV atropine 0.6 mg for bradycardia [Figure 1]. During

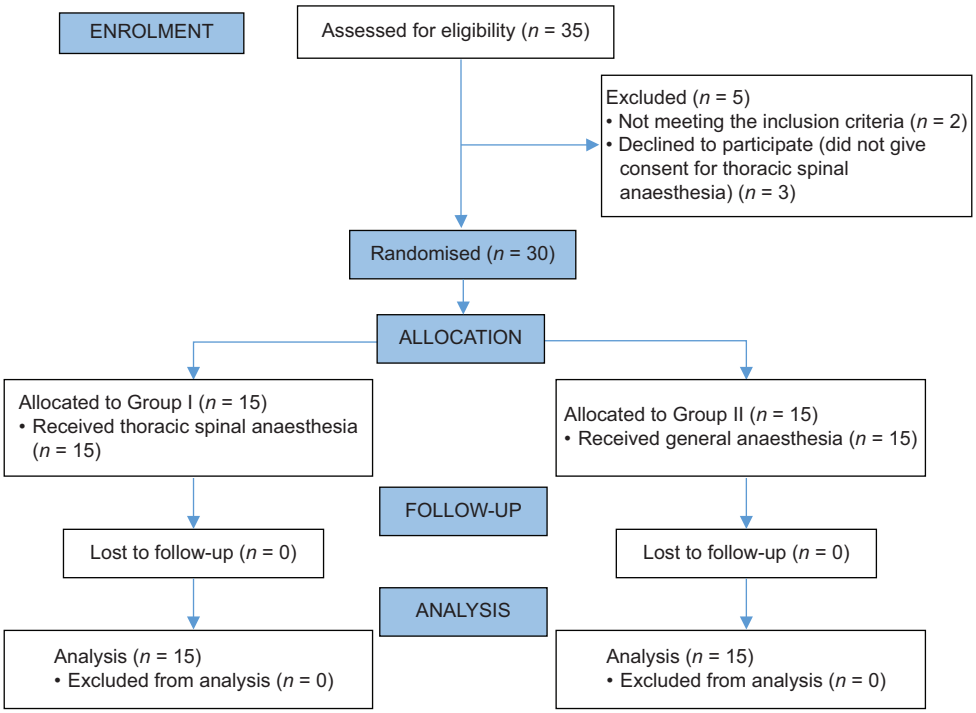

Figure 2: CONSORT flow chart of the study groups. CONSORT = Consolidated Standards of Reporting Trials, n = number of patients

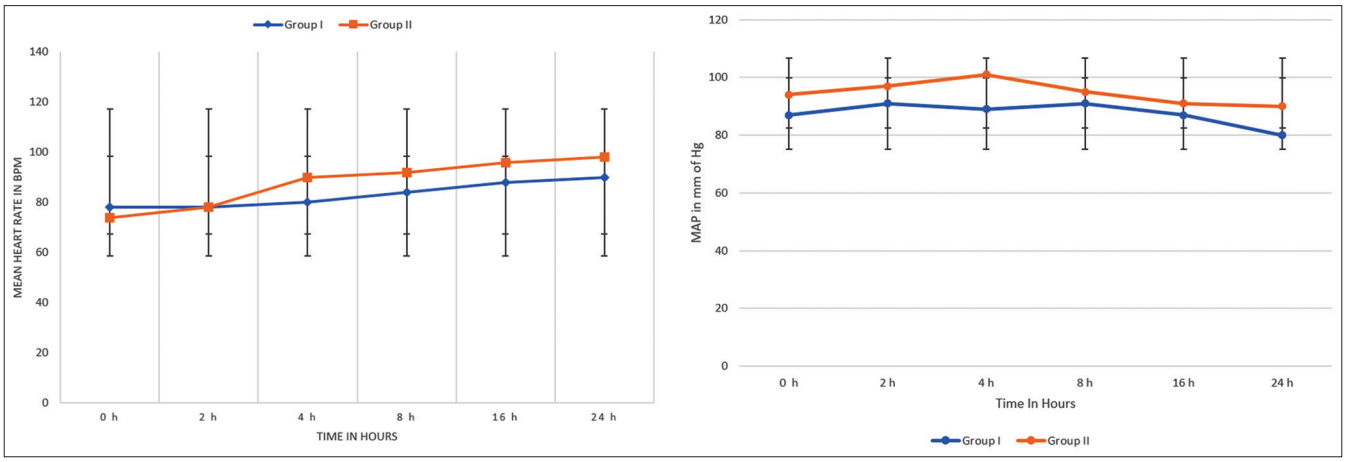

Figure 3: Postoperative heart rate and MAP. MAP = mean arterial pressure

Table 1: Comparison of the demographic and operative data between the two groups

Parameters	Group I (*n*=15)	Group II (*n*=15)
Age (years), mean (SD)	40.07 (6.66)	40.07 (15.3)
Height (cm), mean (SD)	161.13 (172.12)	158.13 (11.987)
Weight (kg), mean (SD)	60.2 (8.62)	61.23 (7.6)
Duration of surgery (min), mean (SD)	67 (4.2)	68 (3.1)
ASA physical status I/II, *n*	14/1	11/4

Data expressed as mean (SD) or numbers. *n*=number of patients.
ASA=American Society of Anesthesiologists, SD=standard deviation

the intraoperative period, three patients in Group I had hypotension [Figure 1], which was successfully managed with rapid IV fluid transfusion and ephedrine 6 mg boluses. In Group II, two patients experienced vomiting in the postoperative period and were treated with IV ondansetron 8 mg.

DISCUSSION

In our study, patients receiving TSA had early recovery with lower analgesic requirements than those in the GA group, as evidenced by their delayed time to first rescue analgesic requirement.

Concerns associated with TSA were spinal cord injury and cephalad spread of the drug, resulting in haemodynamic compromise and respiratory arrest.[8] However, none of these complications were noted in our study. Many studies have proven that surgeons are satisfied with the abdominal relaxation achieved with TSA in abdominal surgeries.[9] Studies have demonstrated that the depth of subarachnoid space was greater at the mid-thoracic region (T5). In addition, this region has a relatively more posterior separation of the spinal cord. Hence, T5–T6 space was chosen for our study.[9,10]

Khan *et al.*[9] postulated that segmental TSA is a feasible, safe and economical anaesthetic technique for various thoracic and abdominal surgeries. le Roux *et al.*[1] also concluded that TSA has been a promising tool for an increasing number of anaesthetists worldwide.

Our study corroborated with the observations made by Chandra *et al.*[8] Their findings revealed that TSA is practically feasible for laparoscopic cholecystectomy cases with minimal intraoperative complications and no evidence of neurological deficits. Non-opioid adjuvants like midazolam and ketamine have also been used as adjuvants to local anaesthetics in TSA.[11] We used fentanyl as an adjuvant owing to its rapid onset and lower incidence of respiratory depression in comparison to other opioids.[12,13]

The use of continuous opioid-based TSA has been described to provide superior postoperative analgesia compared to single-dose TSA in major abdominal surgeries.[14] Since we were dealing with short-duration breast surgeries, the option of using a catheter in the subarachnoid space was not considered.

Mehta *et al.*[15] indicated that thoracic combined spinal epidural anaesthesia with low-dose anaesthetics in laparoscopic cholecystectomy is associated with early ambulation without significant postoperative complications. Mazy *et al.*[16] have also compared TSA with a thoracic paravertebral block in breast cancer surgery. They observed that TSA administered at the T5 level was associated with less haemodynamic instability and had a high patient satisfaction rate, which could be correlated with our observations.

The use of isobaric levobupivacaine ensured that there was no spread of local anaesthetic rostrally or

Table 2: Comparison of various study characteristics between the two groups

Parameters	Group I (*n*=15)	Group II (*n*=15)	*P*
Time to first rescue analgesia (min), mean (SD) (95% CI)	336 (121.8) (274, 397.62)	45 (11.4) (39.231, 50.769)	0.001
Aldrete score, mean (SD) (95% CI)	9.00 (0) (0, 0)	6.62 (0.506) (6.364, 0.876)	0.001
Cost (rupees/Indian currency), mean (SD) (95% CI)	1004.73 (188.80) (909.18, 1100.27)	1928.85 (91.92) (1882.32, 1975.37)	0.002
Number of doses of rescue analgesia, mean (SD) (95% CI)	2.1 (0.22) (1.98, 2.21)	3.2 (0.80) (2.79, 3.60)	0.006
Patient satisfaction score (5/1), *n*	15/0	3/12	0.002
VAS at 0 h, mean (SD) (95% CI)	3.26 (0.42) (3.05, 0.47)	5.48 (0.76) (5.095–5.865)	<0.001
VAS at 2 h, mean (SD) (95% CI)	4.46 (0.54) (4.19, 4.73)	7.23 (0.63) (6.91, 7.54)	<0.001
VAS at 4 h, mean (SD) (95% CI)	4.22 (1.16) (3.63, 4.81)	6.26 (1.28) (5.61, 6.91)	<0.001
VAS at 8 h, mean (SD) (95% CI)	3.24 (0.96) (2.75, 3.73)	5.78 (1.26) (5.14, 6.42)	<0.001
VAS at 16 h, mean (SD) (95% CI)	3.66 (0.26) (3.53, 3.79)	4.92 (0.48) (4.68, 5.16)	<0.001
VAS at 24 h, mean (SD) (95% CI)	6.47 (0.52) (6.21, 6.73)	7.23 (0.73) (6.86, 7.60)	0.003

Data expressed as mean (SD) (95% CI) or numbers. *n*=number of patients. CI=confidence interval, SD=standard deviation, VAS=visual analogue scale

caudally.[17] None of the patients had desaturation, headache, pruritus, respiratory depression, shivering or urinary retention.

Open-label studies have several advantages. They provide valuable insights into patient experiences and treatment preferences. Unblinding allows access to information about the assigned interventions. Our study had limitations. This study, being non-blinded and labelled, includes the potentiality for bias. We did not try TSA in patients with severe comorbidities. The onset and duration of sensorimotor blockade were not assessed. The feasibility of TSA needs further evaluation for longer duration and high-risk surgeries. A larger sample size would have generated a more comprehensive range of observations and better conclusions. Some of the controversies in this study include the duration of anaesthesia provided by the thoracic spinal in case of unanticipated prolongation of the surgical procedure. This may require conversion to GA.

CONCLUSION

We conclude that the analgesic requirement was lower in the TSA group. Patient satisfaction was high, and the cost incurred was lower for patients receiving thoracic spinal anaesthesia than for GA.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared upon request.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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