Original Article

Accuracy of non-invasive haemoglobin measurements in patients undergoing transurethral resection of prostate surgery

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ABSTRACT

Background and Aims: The aim of this study was to evaluate the accuracy of non-invasive haemoglobin (SpHb) compared to laboratory venous haemoglobin (tHb) measurements among patients undergoing elective transurethral resection of prostate (TURP) surgery under spinal anaesthesia. **Methods:** In a prospective, observational, outcome-assessor blinded, cohort trial**,** we enroled 50 American Society of Anesthesiologists physical status (ASA-PS) I-II patients with benign prostatic hyperplasia. The primary outcome included SpHb and tHb measurements performed at four perioperative time-points: just before initiating the fluid preload (T1), and at 30 min (T2), 1 h (T3), and 2 h (T4) after starting the prostate resection, respectively. Statistical tool included intra-class correlation (ICC), Bland-Altman plots, and linear regression analysis. **Results:** We collected 200 SpHb/tHb data sets from 50 patients. The SpHb had a non-significant negative bias of –0.83 g/dL, –0.43 g/dL, –0.81 g/dL, and –0.46 g/dL, with limits of agreement of 2.6 g/dL to –4.2 g/dL, 2.4 g/dL to –3.3 g/dL, 1.3 g/dL to –2.8 g/dL, and 1.4 g/dL to –2.3 g/dL, for T1 to T4, respectively. The SpHb/tHb pairs correlated significantly (time-dependent increase in ICC from T1 to T4). The SpHb-tHb difference correlated significantly with corresponding serum sodium (T1 to T3), but not with perfusion index. No correlation existed between % change in SpHb-tHb difference (T1 to T4), and intraoperative blood loss or perioperative weight gain. **Conclusion:** The SpHb exhibited a clinically acceptable negative bias compared to tHb during TURP surgery. Although a wide limit of agreement between the SpHb/tHb pairs is a limitation, the real-time SpHb trends can still serve in clinical judgement.

Key words: Non-invasive haemoglobin monitoring, perfusion index, prostatic hyperplasia, transurethral resection of prostate

INTRODUCTION

Transurethral resection of prostate (TURP) surgery may be associated with significant blood loss and irrigation fluid absorption, that precipitates as fluid overload, electrolyte imbalance, TURP syndrome, cardiovascular instability, cerebral ischemia, and renal failure.[1] Although procedure-related complications have declined dramatically with use of safer equipment and standardised technique, haemorrhage is still a consistent threat, with 7.1% of patients requiring blood transfusion.[2] The complication rate varies significantly with the surgical technique, duration of the procedure, prostate size, and the presence of tumour.[1] One of the anxieties that the anaesthesiologist sometimes faces is to decide on the severity of anaemia, need for blood transfusion, and to ascertain its availability, if required urgently. The laboratory venous haemoglobin (tHb) measurements

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conventionally take an hour even if sent on an urgent basis for decision making. The other issue is the need for repeated venepuncture for obtaining each laboratory measurement. Thus, decision for blood transfusion is commonly subjective, which may lead to inadvertent transfusions.[3]

Non-invasive haemoglobin estimation (SpHb) via pulse CO-oximetry is an emerging technology that enables real-time intraoperative monitoring of haemoglobin through a sensor attached to the patient's finger.[4] Several studies have compared the accuracy of SpHb measurements with tHb values and found it as an acceptable tool for haemoglobin monitoring in procedures like neurosurgery, orthopaedic surgery, and oncosurgery.[5-7] The SpHb values, however, deviated from laboratory measurements in operations like liver transplantation, caesarean section, and emergency settings.[8-10] As SpHb relies on transcutaneous-spectrophotometry principle for haemoglobin estimation, it may get influenced by changes in regional perfusion, major fluid shifts, anaemia, and variation in sympathetic tone, particularly in TURP surgery.[4,5,8] In this study, we hypothesised that if the limits of agreement between the SpHb and tHb measurements are clinically acceptable during TURP surgery for benign prostatic hyperplasia (BPH), then SpHb could be used as an alternative for haemoglobin estimation in patients during prostate surgery. We tested the accuracy of SpHb measurement compared with tHb measurements among patients undergoing TURP surgery for BPH.

METHODS

After institutional ethical approval and written informed consent, we included all consecutive American Society of Anesthesiologists physical status I-II males, aged 50 to 70 years, undergoing elective TURP surgery for BPH under spinal anaesthesia, with prostatic volume up to 80 cm^3 and an expected operative time <90 min, in this prospective, outcome-assessor blinded, observational, cohort trial, conducted in between March 2019-February 2020 (Clinical Trial Registry-India: CTRI/2019/02/017528). Those with any contraindication to spinal anaesthesia, cardiopulmonary disease, haematological disease, hyperbilirubinaemia, cerebral vascular disease, peripheral vascular disease, smokers or inability to give consent were excluded. All procedures done in the study followed the ethical guidelines of declaration of Helsinki. The anaesthesia procedure was supervised by an anaesthetist blinded to the outcome variables. A study investigator not involved in patient care collected the venous blood samples and recorded the outcome parameters. Another investigator, unaware of other outcome variables gathered the tHb report.

Patients were shifted to the preoperative area. An SpHb probe (Masimo Radical 7 CO-oximetry device) was attached to the index finger of their non-dominant hand and wrapped in a black plastic shield, to minimise the optical interference. For obtaining the venous blood samples, intravenous (IV) access was obtained in the non-dominant hand, and the baseline sample was sent. Premedication included ranitidine (50 mg IV), metoclopramide (10 mg IV), and Lactated ringer preload (5 mL/kg IV over 20 min), administered through an IV access in the dominant hand. On arrival to the operating room, a standard multiparameter monitor and SpHb probe were placed. Under aseptic precautions, spinal anaesthesia was induced with hyperbaric bupivacaine 0.5% (2 mL) and fentanyl (25 μg) at the L3-L4 or L4-L5 interspinal space, in sitting position. All patients were then turned supine, and initiated on maintenance IV fluid (Lactated Ringer). Once a D10-dermatomal block-level (loss of sensation to pinprick) was achieved, the patients were switched to lithotomy position and surgery was allowed to proceed. The maintenance fluid was administered at the discretion of supervising anaesthetist. Glycine (1.5%) was used as an irrigation fluid. Any intraoperative hypotension (systolic blood pressure <90 mm Hg or <20% of baseline) was treated with phenylephrine (50–100 mg IV) and additional rapid infusion of maintenance fluid. Bradycardia (heart rate <50 beats/min) was treated with atropine (0.5 mg). Hypoxaemia (oxygen saturation <94%) was treated with free-flow oxygen via a facemask at 4 L/min. At the end of the surgery, patients were shifted to the post-anaesthesia care unit and kept on maintenance fluid at 100 mL/h IV. A sample (4 mL) was obtained from the irrigation fluid bucket (after stirring properly) and sent for haemoglobin (Hb) estimation.

The primary outcome included the SpHb and tHb values, measured at four perioperative time points: at baseline (T1) just before initiating the fluid preload, and at 30 min (T2), 1 h (T3) and 2 h (T4) after starting the prostate resection, respectively. The SpHb values were recorded through a Masimo Radical 7 device (Rev E, Masimo Medical Technologies India Pvt. Ltd., Bangalore, India). This monitor also provided the perfusion index (PI) measurements, recorded at the same time points. The tHb values were measured from a venous blood sample (1 mL, heparinised syringe) collected at the same time points, and analysed by a blood gas analyser (Radiometer ABL800 Flex, Radiometer India, Mumbai, India). This equipment was calibrated regularly, as per manufacturer instructions. The sodium levels were also recorded from the blood analyser reports at the same time points. The perioperative weight gain (estimated by the gravimetric method) compared to baseline, was measured at T4. Data regarding the volume of intraoperative irrigation fluid used, intraoperative IV fluid infused, intraoperative blood loss, duration of surgery, preoperative ultrasound-estimates of prostate size, and intraoperative untoward events, were also collected. The intraoperative blood loss was estimated by using the formula: [Hb concentration in irrigated fluid (mg/dL) x Volume of irrigated fluid (L)]/[Preoperative blood Hb (g/dL) $\times 10^3$].[11]

The sample size was calculated by Medcalc software 19.0.7 (Acacialaan, Belgium). Based on a previous study,[9] for detecting a mean difference of ± 0.47 g/dL between the tHb and SpHb values, with a maximum allowable difference of 2.97 g/dL, and standard deviation difference of 0.92 g/dL, we calculated a sample size of 45 patients, at a 95% confidence interval (CI). Considering a 10% dropout rate, we required a minimum of 50 patients. The statistical analysis was performed with Statistical Package for the Social Sciences (SPSS) 23.0 (International Business Machine Corp., Armonk, NY, US). The results were presented as descriptive statistics and analysed by intra-class correlation (ICC), Bland-Altman plots, linear regression, bivariate correlation, and Kolmogorov–Smirnov test. A P value < 0.05 was considered significant.

RESULTS

All 50 eligible patients completed the study successfully [Figure 1]. The demographics and perioperative parameters are summarised in Table 1. All patients achieved the desired block level. The mean duration of the surgical procedure was 72.23 min. The PI values remained above 0.75% mark in all 200 perioperative SpHb measurements (as recommended). The mean intraoperative IV fluid infused was 736 mL, while the volume of intraoperative irrigation fluid required was 18.02 Litres. The mean intraoperative blood loss was 127.76 mL, with no requirement of blood transfusion [Table 1]. On bivariate analysis, the baseline SpHb-tHb difference (T1) had a weak negative correlation with body mass index (BMI) (r = –0.283, P = 0.04), but no relationship existed with that of age [Table 2].

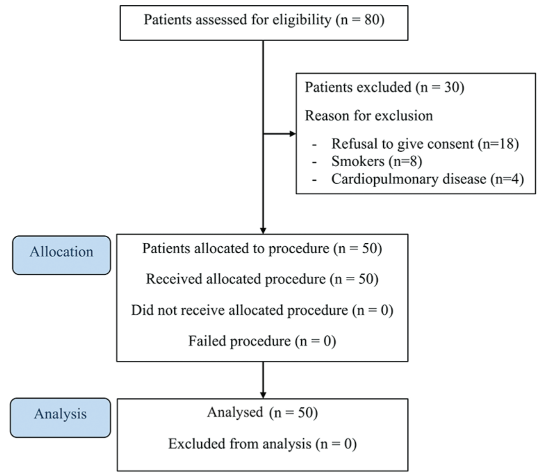

Figure 1: STROBE flow chart of patient studied

In total, we collected 200 outcome data sets from 50 patients. The mean SpHb-tHb difference was –0.63 g/dL, including all the data pairs. Considering individual time points, the SpHb exhibited a non-significant negative bias (linear regression analysis) of –0.83 g/dL, –0.43 g/dL, –0.81 g/dL, and –0.46 g/dL, compared to corresponding tHb values at T1 to T4, respectively [Table 3]. The limits of agreement (Bland Altman plot at 95% CI) between the SpHb/tHb pairs were 2.6 g/dL to -4.2 g/dL for T1, 2.4 g/dL to -3.3 g/dL for T2, 1.3 g/dL to -2.8 g/dL for T3, and 1.4 g/dL to -2.3 g/dL for T4 [Figure 2]. The 37% SpHb-tHb difference values were <0.5 g/dL, 23% were <1 g/dL, 23% were 1-2 g/dL, and 17% were >2 g/dL, respectively. The SpHb/tHb pairs correlated significantly at all time points, with a time-dependent increase in ICC from T1 to T4 [Table 4].

We also analysed a correlation between the SpHb-tHb difference and the corresponding venous sodium values or PI. But none of the above showed any correlation for 200 data pairs [Table 2]. However, on a subgroup analysis, we observed a significant negative correlation (r = –0.239; P = 0.017) between the SpHb-tHb difference and the serum sodium pairs for the first 100 values (T1 and T2), and a weak correlation (r = –0.164; P = 0.045) for the first 150 values (T1-T3). But no correlation was observed with that of PI. We found no correlation in between % change in SpHb-tHb difference (from T1 to T4) and the intraoperative blood loss or perioperative weight gain at 2 h [Table 2]. There was also no correlation

Table 1: Description of baseline and intraoperative parameters (*n*=50)

S. No.	Parameters		Values
1.	Age (Years)		61.80±5.63
2.	BMI (kg/m^2)		24.67±4.62
4.	ASA Grade	I/II	8/42
5.	Preoperative Prostate size (cc)		49.71±15.69
6.	Duration of surgery (min)		72.23±15.53
7.	Volume of intraoperative irrigation fluid (Litre)		18.02±10.08
8.	Intraoperative IV fluid infused (mL)		736.00±382.53
9.	Intraoperative blood loss (mL)		127.76±43.22
10.	Venous sodium levels at different time points (meq/Litre)	T1	137.23±4.24
		T2	137.06±4.13
		T3	135.80±3.93
		T4	136.50±4.17
11.	Perfusion Index at different time points (%)	T1	2.43±0.82
		T2	1.85±0.84
		T3	1.55±0.67
		T4	1.60±0.64

Data are presented as mean±standard deviation, number. BMI indicates body mass index; ASA American Society of Anesthesiologists; T1: baseline just before initiating the fluid preload; T2: 30 min, T3: 1 h, and T4: 2 h after starting the prostate resection, respectively. A *P*<0.05 considered statistically significant

Table 2: Correlation analysis between SpHb-tHb difference and other parameters at different time points (*n*=50)

S. No.	Correlation variables	CC	*P*
1.	SpHb-tHb difference (T1) and Age	0.168	0.244
2.	SpHb-tHb difference (T1) and BMI	-0.283	0.046
3.	Percentage change in SpHb-tHb difference (from T1 to T4) and Intraoperative blood loss	0.035	0.808
4.	Percentage change in SpHb-tHb difference (from T1 to T4) and Perioperative weight gain	-0.048	0.742
5.	Perioperative SpHb-tHb difference and Venous sodium levels (including all 200 data pairs)	-0.121	0.089
6.	Perioperative SpHb-tHb difference and Perfusion index (including all 200 data pairs)	-0.041	0.566

SpHb indicates Non-invasive haemoglobin; tHb: venous haemoglobin; BMI: Body mass index; CC: Correlation coefficient; T1: baseline just before initiating the fluid preload; T4: 2 h after starting the prostate resection. A *P*<0.05 considered statistically significant

Table 3: Difference in the measured haemoglobin values by two methods at various time points (*n*=50)

S. No.	Timepoints	Mean difference SpHb-tHb (g/dL)	Lower CI	Higher CI	*P*
1.	T1	-0.83	-1.32	-0.34	0.549
2.	T2	-0.43	-0.85	-0.01	0.879
4.	T3	-0.81	-1.14	-0.48	0.923
5.	T4	-0.46	-0.73	-0.19	0.482

SpHb indicates Non-invasive haemoglobin; tHb: venous haemoglobin; CI: Confidence Interval; T1: baseline just before initiating the fluid preload; T2: 30 min, T3: 1 h, and T4: 2 h after starting the prostate resection, respectively. A *P*<0.05 considered statistically significant

Table 4: Correlation between measured haemoglobin values by two methods at different time points (*n*=50)

S. No.	Time points	SpHb (g/dL)	tHb (g/dL)	ICC (95% CI)	*P*
1.	T1	12.86±2.00	13.70±2.36	0.78 (0.57-0.88)	<0.001
2.	T2	12.57±2.12	13.01±2.31	0.86 (0.76-0.92)	<0.001
4.	T3	12.28±2.05	13.10±2.14	0.88 (0.64-0.94)	<0.001
5.	T4	12.43±2.02	12.90±2.18	0.93 (0.85-0.96)	<0.001

Data are presented as mean±standard deviation. SpHb indicates Non-invasive haemoglobin; tHb: venous haemoglobin; ICC: Intraclass correlation coefficient; CI: Confidence Interval; T1: baseline just before initiating the fluid preload; T2: 30 min, T3: 1 h, and T4: 2 h after starting the prostate resection, respectively. A *P*<0.05 considered statistically significant

in between % change in SpHb (from T1 to T4), and intraoperative blood loss (r = –0.110, P = 0.447) or perioperative weight gain (r = –0.154, P = 0.285). The % change in tHb from T1 to T4 had a weak correlation to the intraoperative blood loss (r = –0.243, P = 0.089), but no association was observed with that of perioperative weight gain (r = 0.098, P = 0.500). None of the patients had any untoward event.

DISCUSSION

We observed a non-significant variable bias in SpHb, with wide limits of agreement between the SpHb and tHb measurements, at different perioperative timepoints in patients undergoing TURP surgery. Though SpHb underestimated the tHb values, their correlation increased in a time-dependent fashion from baseline to 2 h after initiating the prostate resection.

The SpHb values had a mean negative bias of –0.63 g/dL, compared to tHb. It was lower at 30 min (–0.43 g/dL, T2) and 2 h (–0.46 g/dL, T4) after initiating the prostate resection. The mean tHb values were also lower at these timepoints. Previous studies have shown that SpHb tends to be higher at lower tHb values.[5,12] Thus, if SpHb overestimates the tHb measurements,

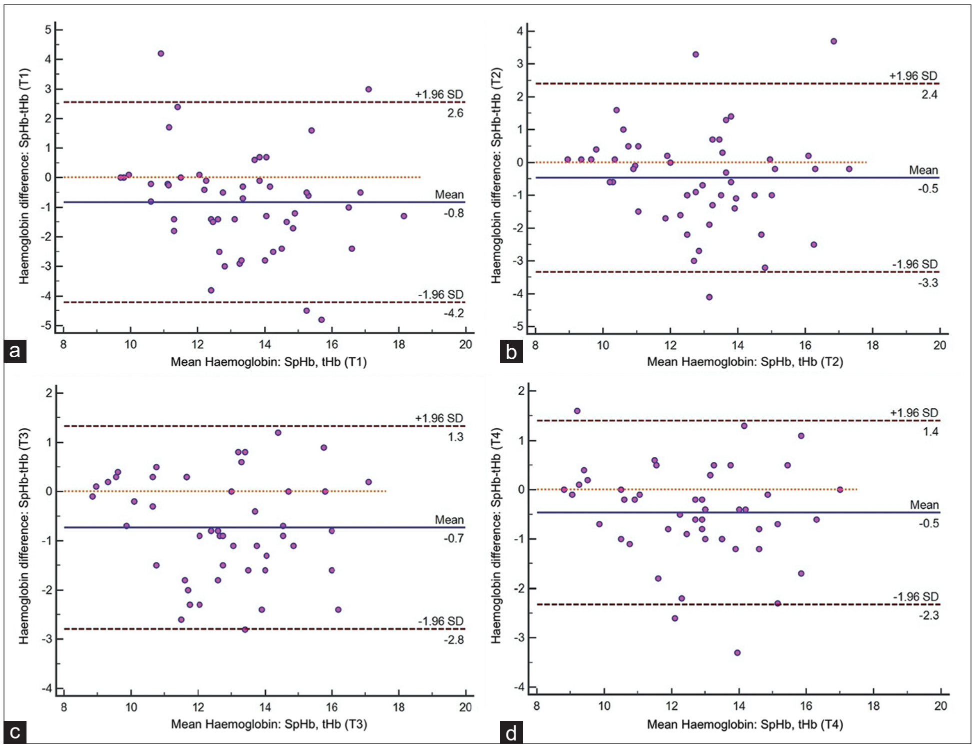

Figure 2: Bland and Altman analysis comparing SpHb and venous tHb at different perioperative time points. (a) at baseline (T1), and (b) at 30 min (T2), (c) at 1 h (T3), and (d) at 2 h (T4) after initiating the prostate resection, respectively. The solid horizontal line corresponds to mean value, while the dashed horizontal lines show upper and lower limits of agreement

the resultant SpHb-tHb difference rises at lower tHb values. We observed a decreased SpHb-tHb difference at lower tHb values, as SpHb underestimated the tHb values. Previous studies have also shown a negative biasness <1 g/dL in SpHb values on different surgical subsets.[13,14] Considering the magnitude of SpHb-tHb difference, 60% values fall within 1 g/dL, 23% were between 1 and 2 g/dL, and 17% were >2 g/dL, respectively. Butwick *et al.* observed an SpHb-tHb difference of <1 g/dL and 1-2 g/dL, in 40% and 36% patients, while Miller RD *et al.* observed a difference of <1.5 and >2.0 g/dL, in 61% and 22% patients, respectively.[6,9]

The limits of agreement for SpHb/tHb pairs at all the three perioperative time points (T2-T4) were lower than the baseline (T1), with no significant difference between the variables. The observed bias and limits of agreement may get affected by perioperative variation in peripheral vascular perfusion, blood loss and the sympatholytic effects of neuraxial anaesthesia.[4] On comparing the SpHb-tHb difference and the PI pairs, however, no correlation was observed for any of the perioperative time points at a mean PI range of 1.60-2.43%. The % change in SpHb-tHb difference at T4 from T1 was also correlated with intraoperative blood loss and perioperative weight gain, but no correlation was observed between the above variables. Although we attempted to calculate the total blood loss during the study period of 2 h, data for the postoperative period could not be accounted for, as the laboratory reports could not estimate the haemoglobin values of irrigation fluid used during the postoperative period (due to its low haemoglobin content). Other factors like minor spillage of irrigation fluid on the OT floor might also have affected the results. Previous studies on different subsets also have reported a similar limit of agreement between the two methods for haemoglobin estimation.[6,9] Until more validated methods for estimating such factors come into place, confirming such an association may remain a tedious job.

As of correlation between the SpHb and tHb values, the ICC was calculated as 0.78 (T1), 0.86 (T2), 0.88 (T3) and 0.93 (T4), respectively. These values are higher than that of previous trials analysing the effect of fluid, colloid or red blood cell (RBC) transfusion in children undergoing neurosurgery (0.58, 0.56, 0.54), or during the steady and dynamic state of major liver resection surgery (0.45, 0.42).[5,14] In a study on human volunteers undergoing haemodilution, the degree of precision for the above variables was 0.92 g/dL.[15] Though all these trials involved a significant fluid shift, the inherent difference in other unaccounted factors like study population, mode of anaesthesia, BMI, and methodology of analysis could influence the results. We also plotted the baseline SpHb-tHb difference (T1) against age and BMI and observed a significant, although weak correlation with BMI values. It would be interesting to test such an association in obese patients.

Since wide fluid shifts are expected across the body compartments during TURP surgery (due to ongoing blood loss and irrigation fluid absorption), we wondered whether a change in vascular volume would have created biasness in SpHb measurements compared to tHb values. Since the majority of absorbed irrigation fluid remains in the extracellular compartment for the first 30 min of TURP surgery, the effect of haemodilution on the blood sodium levels is predominant during this phase.[16] The net impact, however, depends upon the ongoing natriuresis and blood loss through the urine. As the osmotic gradient rises, water gets progressively extravasated to intracellular compartment, to the extent that venous sodium level reaches its minimum at a point where irrigation is discontinued.[16] On subgroup analysis of data pairs for the first hour of surgery, we observed a significant correlation between the SpHb-tHb difference and venous sodium levels, which reflects their association. The venous sodium level, however, is an inaccurate marker of extracellular hydration during the postoperative period.[16] It was visible in the bivariate analysis of all 200 data sets (T1-T4), showing no correlation between the above variables. A larger sample may, however, better delineate their relation in such settings. The effect of mode of anaesthesia, variation in SpHb with a change of measurement site, and comparison with arterial tHb are other factors that may affect the results. We considered venous tHb samples taking into account its precision as reported by previous studies.

Our study had several limitations. We could not analyse biasness in SpHb at lower haemoglobin values, as no patient experienced significant intraoperative blood loss to transfusion thresholds. Such limits, however, become exigent during a prolonged surgery for larger prostate size/tumours or under inexperienced hands. Although SpHb is higher at lower tHb values, a homologous biasness may still define its transfusion thresholds at such haemoglobin levels. Dedicated studies are required to establish SpHb and tHb relationship at transfusion thresholds. The body temperature may also affect the peripheral perfusion, and thus the measured SpHb values. As we maintained the operative room temperature as per standard norms and the measured PI remained higher than recommendations (>0.75%), we believe that body temperature would not have affected the SpHb values.

CONCLUSION

The continuous non-invasive haemoglobin estimation via Pulse CO-oximetry exhibited a clinically acceptable negative bias compared with tHb values during TURP surgery. Although a wide limit of agreement between the SpHb/tHb pairs is a limiting factor, the real-time SpHb trends may still assist in patient monitoring. Further calibration of the device taking note of unaccounted factors may improve its consistency.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the legal guardian has given his consent for images and other clinical information to be reported in the journal. The guardian understands that names and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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