Original Article

The analgesic efficacy of ultrasound-guided erector spinae plane block versus ultrasound-guided caudal epidural block for abdominal surgery in pediatric patients – A patient and assessor-blind, randomized controlled study

ABSTRACT

Background: Literature on the efficacy and safety of erector spinae plane block (ESPB) in pediatric patients is limited. Hence, we aimed to compare ESPB versus caudal epidural block (CEB) in children undergoing abdominal surgery.

Methods: In this patient and assessor-blind study, fifty-two ASA I-II patients, between 1 to 9 years of age, were randomized into groups of 26 each. ESPB group received unilateral or bilateral ultrasound (USG)-guided ESPB with 0.5 ml/kg of 0.25% bupivacaine per side. CEB group received USG-guided CEB with 1 ml/kg of 0.25% bupivacaine. The primary objective was to estimate the proportion of patients requiring postoperative rescue analgesia. The secondary objectives were to assess postoperative Face, Legs, Activity, Cry and Consolability (FLACC) scale scores, duration of analgesia, and consumption of rescue analgesic drugs.

Results: More patients in the ESPB group (88.4%), compared to the CEB group (42.3%), required rescue analgesics (*P* value <0.001). FLACC scores in the ESPB group, though satisfactory, were inferior, to the CEB group. The duration of postoperative analgesia was shorter in the ESPB group by 9.54 h (95% CI: 4.51 to 14.57 h, *P* value <0.001). The median (IQR) consumption of rescue paracetamol was significantly higher in the ESPB group (20 mg/kg (10,20) compared to the CEB group (0.0 mg/kg (0.0,10) *P* value <0.001)). No adverse effects were reported.

Conclusion: In children undergoing abdominal surgery, both ESPB and CEB were safe and efficacious. CEB provided a longer duration and better quality of analgesia. ESPB may be considered when CEB is contraindicated or difficult.

Key words: Caudal epidural, erector spinae plane block, pediatric, postoperative pain

Introduction

Erector spinae plane block (ESPB) is being investigated for a wide spectrum of surgeries because of its ease of

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administration and effect on both somatic and visceral pain.[1,2] As the target site of the block, that is the vertebral transverse process (TP), is away from vital structures like the pleura and the spinal cord, it may have enhanced safety over conventional regional techniques like the caudal epidural block (CEB).[2,3]

Though studies on erector spinae plane block (ESPB) in adults have demonstrated its safety and efficacy in a spectrum of surgeries including abdominal surgeries,[4] literature in the pediatric population is limited. Hence, we aimed to compare the analgesic effect of USG-guided ESPB versus USG-guided CEB in pediatric patients undergoing abdominal surgery.

Materials and Methods

This randomized controlled study was conducted in accordance with the revised Declaration of Helsinki. It was approved by the Institutional Human Ethics Committee and was prospectively registered with the Clinical Trial Registry of India. It was conducted at a tertiary care teaching hospital in India from May 2021 to July 2022. Written informed consent was obtained from the parents or guardians of all patients recruited in the study. The primary objective was to determine and compare the proportion of patients requiring rescue analgesics in the initial 24 hours after completion of surgery in the ESPB and CEB groups.

The secondary objectives were to assess and compare the Face, legs, Activity, Cry, Consolability (FLACC) scores,[5] duration of postoperative analgesia, postoperative consumption of rescue analgesics, adverse effects, and parental satisfaction between the two groups.

Children, between 1–9 years of age, with ASA I or II status, undergoing elective abdominal (including inguinal) surgery under general anesthesia were included in our study. Children who had a contraindication to a regional technique, anatomical deformities, progressive neurological disorder, local infection, coagulopathy, sepsis, or known local anesthetic (LA) allergy were excluded.

The study participants were randomized into two groups, of 26 patients each, using a computer-generated random number table. Allocation concealment was performed using the sequentially numbered opaque sealed envelopes technique. The parents/guardians, the anesthesia resident as well as the ward nurses responsible for the assessment of outcomes and postoperative care were blinded to the group allocation. Group E received either unilateral or bilateral (as per surgical need) USG-guided single-shot ESPB in a dose of 0.5 ml/kg of 0.25% bupivacaine per side. Group C received USG-guided single-shot CEB in a dose of 1 mL/kg of 0.25% bupivacaine. The dose of bupivacaine was subject to a maximum dose of 2.5 mg/kg. All procedures were performed either by the consultant or by a trainee with an experience of at least 25 blocks, under the supervision of the consultant.

A standardized anesthesia technique was followed in all patients. Premedication with 0.5 mg/kg oral midazolam was administered 10–15 minutes before shifting the patient to the operating room (OR). On arrival of the patient to the OR, standard ASA monitors (pulse oximetry, electrocardiography, and non-invasive blood pressure as tolerated) were placed using a Primus^{R} (Drager, Germany) anesthesia workstation. General anesthesia was induced with IV propofol 2–3 mg/kg or incremental sevoflurane in 100% O_2 using a face mask. IV fentanyl 2 μg/kg and atracurium 0.5 mg/kg were administered to all children followed by the insertion of an appropriately sized endotracheal tube or a supraglottic device as per the choice of the consultant anesthesiologist. Anesthesia was maintained with O_2:N_2O (50%:50%), intermittent atracurium and sevoflurane (1.5%–2.0%) to maintain a minimum alveolar concentration (MAC) of 1–1.3. Under all aseptic precautions, either CEB or ESPB, as per the randomization code, was performed under USG guidance. After 10 minutes of administering the block, the surgeons were allowed to proceed with the surgical procedure.

Intraoperatively, if the mean arterial pressure or heart rate increased to more than 30% above the baseline, despite a MAC of at least 1.5 and remained sustained for at least 3 minutes, 0.5 μg/kg IV bolus of fentanyl was administered. A bolus of fentanyl was repeated in case of persistent tachycardia after 10 more minutes. At the end of the surgery, 15 mg/kg of IV paracetamol (PCM) was administered. Following extubation, the patients were shifted to the recovery room and observed for at least 1 hour. If the FLACC score was ≥6 in the immediate postoperative period (within 30 minutes of extubation), an IV fentanyl bolus of 0.5 μg/kg was administered again.

Postoperative analgesia protocol

Further monitoring was done in the ward by the nursing staff with periodic visits by the anesthesia resident. IV PCM 15 mg/kg, 8 hourly was given to all patients postoperatively. If the FLACC score of the patient was between 3 and 4, additional rescue IV PCM 10 mg/kg was administered (subject to a maximum standard dose of up to 75 mg/kg in 24 hours). If the FLACC score was >4, rescue analgesia in the form of IV diclofenac 1 mg/kg was given.

Block technique

For the ESPB, the patient was placed in the lateral decubitus position with a semi-prone tilt with the side of the block-oriented upwards. Under aseptic precautions, a 13-6 MHz high-frequency linear transducer of a SonoSite M-Turbo^{R} (Fujifilm, USA) USG machine was placed ipsilateral to the block side, 1–2 cm lateral to the spinous processes, in a parasagittal orientation. The transducer was placed at the T10 to T12 vertebral level, counting downwards from the first rib after identifying it with ultrasound. After identifying the erector spinae muscles and the vertebral TP, a 22 G 5 cm Stimuplex^{R} A needle (B Braun, Germany) was inserted using an in-plane technique in the cranio-caudal direction to hit the TP of the desired vertebral level as per the planned surgical incision. Hydro-dissection with 1–2 ml of normal saline was used to confirm accurate needle placement and proper spread. After negative aspiration, the LA was administered slowly.

In the CEB group, in the lateral decubitus position, the high-frequency linear transducer was first placed transversely at the midline to obtain a "frog eye" sign view of the sacral cornu, the sacro-coccygeal ligament, the sacrum, and the sacral hiatus. At this position, the USG transducer was rotated by 90° to obtain a longitudinal view. The needle was inserted in-plane into the sacral canal and the LA was injected under real-time visualization.

The primary outcome was the proportion of patients requiring rescue analgesia in the initial 24 hours after surgery. The secondary outcomes were the FLACC scores (at 0, 30 minutes, and 2, 6, 12, and 24 hours after surgery), the duration of postoperative analgesia defined as either the time of the first pain complaint from verbal children or a FLACC score >3 within the initial 24 hours from the time of completion of the surgery. Other outcomes were the intraoperative and postoperative opioid (fentanyl) consumption, cumulative doses of postoperative rescue analgesics (paracetamol and diclofenac) required, adverse effects (postoperative nausea and vomiting, urinary retention, itching, etc.) and parental satisfaction score (on a 0-10 numerical scale, with 0 representing the lowest possible, and 10, the highest possible parental satisfaction) in both groups.[6]

Sample size estimation

A recent study reported 55% of pediatric patients undergoing inguinal surgery, required rescue analgesia in the initial 24 hours postoperatively after CEB.[7] Another recent study reported that 18% of patients undergoing lower abdominal surgery, required rescue analgesia postoperatively after ESPB.[8] Using this data and assuming an α error of 0.05, a β error of 0.20 with a power of 80%, a sample size of 50 patients was calculated.

Statistical analysis

The collected data was entered on a computer-based spreadsheet. The data was cleaned and anonymized before the analysis. Analysis was carried out using R software (version 4.2.1) with tidyverse,[9] gtsummary[10] survival and survRM2 packages.[11] Continuous variables have been summarized as median with interquartile range. Categorical variables have been summarized as frequency and percentages and analyzed using the Fischer exact test. Box and whisker plots were generated to explore the distribution of numerical variables and the Wilcoxon rank sum test was used to compare the difference in their distribution.

To analyze the duration of analgesia, the reverse Kaplan-Meier survival curves of the two groups were plotted using the survfit function, and the log-rank test was used to compare them. Restricted mean survival time (RMST) which represents the average survival time up to a pre-specified time point, and the difference in RMST between the two groups was estimated.[11,12] The between-group contrast was calculated to compare the RMST estimates using the contrast.rms function from the rms package. The results of this analysis are reported as estimates with corresponding standard errors, 95% confidence intervals, and *P* values. For all statistical tests, a *P* value <0.05 was taken to indicate statistical significance.

Results

In the study duration, 60 patients were assessed for recruitment, out of which five patients were excluded due to inability to palpate anatomical landmarks and three due to the presence of a sacral dimple. The remaining 52 were randomized equally into two groups. Table 1 depicts the general characteristics and the distribution of the surgical procedures in the two groups.

Intraoperatively, patients in both groups remained stable with no significant hemodynamic response at the time of the surgical incision. There was minimal consumption of additional fentanyl intraoperatively [Table 2]. In the initial 24-hour postoperative period [Table 2], 23 (88.4%) patients in the ESPB group and 11 (42.3%) patients in the CEB group required additional rescue PCM, producing a statistically significant difference (*P* value <0.001) between the two groups. The median (interquartile range) 24-hour cumulative PCM consumption, apart from the scheduled doses as per protocol, in the ESPB group, on the first postoperative day

was also significantly higher at 20 mg/kg (10, 20) as compared to the CEB group (0.0 mg/kg (0.0, 10), *P* value <0.001)). A similar proportion of patients belonging to both groups required diclofenac in the initial 24 hours after surgery, with a low median (interquartile range) cumulative dose requirement [Table 2].

The observed FLACC scores at various time intervals in the initial 24 hours postoperatively are illustrated on the box and whisker plot [Figure 1]. Overall, the FLACC scores were statistically inferior in the ESPB group for the first 6 hours (*P* value <0.05 at all time points up to 6 hours).

Table 1: General characteristics of the study patients

Characteristic	Group ESPB[1] (*n*=26)	Group CEB[1] (*n*=26)	*P*[2]
Age (years)	5.0 (3.0, 6.0)	4.5 (2.0, 6.0)	0.592
Sex			0.734
Male	20 (76.9%)	21 (80.8%)	
Female	6 (23.1%)	5 (19.2%)	
ASA grade			0.455
I	23 (88.4%)	24 (92.3%)	
II	3 (11.5%)	2 (7.7%)	
Weight (kg)	15.0 (12.4, 17.0)	15.5 (11.1, 21.0)	0.978
Surgery			0.548
Inguinal herniotomy	12 (46.2%)	14 (53.8%)	
Orchidopexy	2 (7.7%)	4 (15.4%)	
Pyeloplasty	4 (15.4%)	4 (15.4%)	
Others	8 (30.8%)	4 (15.4%)	
Surgical duration (hours)	2.0 (1.0, 3.0)	2.0 (1.0, 2.0)	0.254

[1]Data is expressed as number (percentage) or median (interquartile range). [2]Wilcoxon rank sum test or Fisher's exact test. CEB - Caudal epidural block, ESPB - Erector spinae plane block

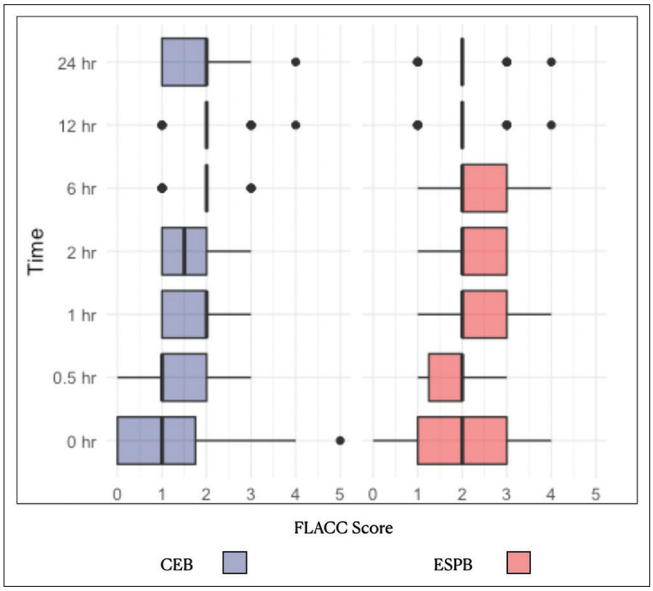

Figure 1: Box and whisker plot showing the comparison of postoperative Face, legs, Activity, Cry, Consolability scale (FLACC) scale scores between the erector spinae plane block (ESPB) group and the caudal epidural block (CEB) group

However, in both groups, median FLACC scores remained between 1 and 2. This represents that there was no significant pain in patients of both groups in this time duration.

The reverse Kaplan-Meier survival curve [Figure 2] shows that the percentage of patients requiring rescue analgesia within the initial 24 hours after surgery in the ESPB group was significantly higher than the CEB group (log-rank <0.001). The duration of analgesia [Table 2] represented by the restricted mean survival time in the ESPB group was significantly shorter compared to the CEB group (6.73 hours versus 16.27 hours). The between-group contrast analysis confirmed that the ESPB group patients had a significantly shorter duration of analgesia by 9.54 hours (95% CI: 4.51 to 14.57 hours, *P* < 0.001).

The median (interquartile range) parental satisfaction scores were statistically superior in the CEB group at 24 hours (8.0 (7.0, 8.0) versus 7.0 (6.0, 7.8) in the ESPB group, *P* value 0.043) [Table 2]. However, parents of both groups were satisfied with the pain relief with the median parental satisfaction score ranging between 7 and 8 in both groups at the timelines tested. No complications like PONV, itching, weakness, delayed return of bowel function or urinary retention were reported among the study patients.

Discussion

This randomized study revealed that single-shot USG-guided ESPB along with multi-modal analgesia provided effective postoperative analgesia for pediatric patients undergoing abdominal surgeries. But its analgesic efficacy was inferior to

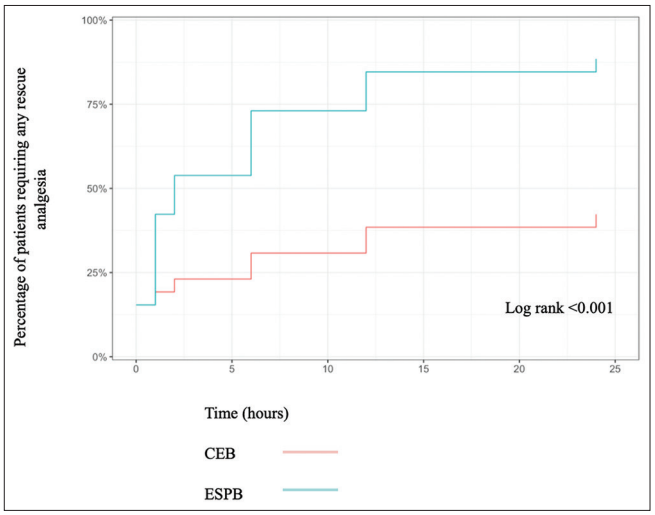

Figure 2: Reverse Kaplan-Meier survival curve illustrating the percentage of patients requiring rescue analgesia over the initial 24 hours postoperatively in the erector spinae plane block (ESPB) group and the caudal epidural block (CEB) group

Table 2: Comparison of hemodynamic parameters and analgesic consumption between erector spinae plane block (ESPB) and caudal epidural block (CEB) groups

Intraoperative	**Group ESPB (*n*=26)[1]**	**Group CEB (*n*=26)[1]**	***P*[2]**
HR baseline (b/min)	118.0 (105.5, 130.8)	120.0 (104.2, 136.8)	0.819
SBP baseline (mm Hg)	96.0 (92.0, 100.5)	101.0 (98.0, 104.0)	0.017
HR incision (b/min)	117.5 (99.8, 134.5)	113.5 (98.8, 121.5)	0.355
SBP incision (mm Hg)	91.0 (88.0, 93.0)	89.0 (83.0, 92.8)	0.389
Additional fentanyl consumption (μg/kg)	0.0 (0.0, 0.4)	0.0 (0.0, 0.0)	0.253
Postoperative			
Fentanyl consumption (μg/kg)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.168
Patients requiring rescue paracetamol (*n* %)	23 (88.4%)	11 (42.3%)	<0.001
Rescue paracetamol consumption (mg/kg)	20 (10,20)	0.0 (0.0, 10)	<0.001
Patients requiring rescue diclofenac (*n* %)	9 (34.61%)	6 (23.07%)	0.541
Rescue diclofenac consumption (mg/kg)	0.0 (0.0, 1.5)	0.0 (0.0, 0.0)	0.197
Parental satisfaction score at 6 h	8.0 (7.0, 8.0)	8.0 (7.2, 8.8)	0.121
Parental satisfaction score at 24 h	7.0 (6.0, 7.8)	8.0 (7.0, 8.0)	0.043
Duration of analgesia	**ESPB (*n*=26)[3]**	**CEB (*n*=26)[3]**	***P*[4]**
Restricted mean survival time (hours)	6.731 (1.612) (3.57 to 9.89)	16.269 (1.998) (12.35 to 20.19)	
Restricted mean time lost (hours)	17.269 (1.612) (14.11 to 20.43)	7.731 (1.998) (3.814 to 11.647)	
Restricted mean survival time difference (hours)	9.538 (95% CI 4.506 to 14.571)		<0.001

[1]Data is expressed as median (interquartile range) or *n* (%). [2]Wilcoxon rank sum test or Fischer's exact test. [3]Estimate (standard error) (95% CI). [4]Log-rank test.
CEB - Caudal epidural block, ESPB - Erector spinae plane block, HR - Heart rate, b - Beats, SBP - Systolic blood pressure

that of USG-guided CEB indicated by a greater proportion of patients requiring rescue analgesics, inferior FLACC scores, higher cumulative rescue PCM consumption in the initial 24 hours after surgery, and a shorter duration of postoperative analgesia.

Randomized studies on ESPB comparing it with other well-established blocks are limited in number, which has been highlighted in a recent meta-analyses on this topic.[4,13] A meta-analysis on the analgesic effect of ESPB in children included only 7 randomized controlled trials out of which 5 had a control group of patients receiving either no block or a sham block.[13] There were only 2 studies that compared ESPB with other established techniques, like quadratus lumborum block and ilioinguinal block for abdominal and inguinal surgeries, respectively, and have reported safe and effective analgesia.[7,14] The authors have emphasized that the benefit of ESPB over other blocks has not been established due to the paucity of evidence. This has also been recently highlighted by Lonnqvist *et al*.[15] in an editorial who have reiterated that though case reports, case series and studies with placebo or systemic analgesia (instead of other established techniques) in the control group indicate benefit, the analgesia could in part be due to high plasma levels of LA which is common and expected in inter-fascial blocks. Thus, randomized studies comparing ESPB with other established blocks are needed.

Similarly, there are limited studies on the comparison of ESPB with neuraxial blocks for different types of surgeries and have reported mixed results with some favoring ESPB and some neuraxial techniques[1,16] Only 2 randomized studies in pediatric patients were found which revealed contrasting results. Singh *et al*.[17] reported continuous ESPB to be equivalent to thoracic epidural analgesia in children undergoing thoracotomy. On the other hand, Elshazly *et al*.[18] reported single-shot ESPB to be inferior to CEB for femur and hip surgeries. We could identify only two studies (either on children or adults) on neuraxial techniques versus ESPB for inguinal or abdominal surgeries. Our results favoring the neuraxial technique were similar to a study comparing spinal anesthesia to ESPB in adults undergoing inguinal hernia, which revealed that the analgesic efficacy of spinal anesthesia was superior, albeit with more adverse effects.[19] Our results were not in agreement with that of Abdelrazik *et al*.[20] who reported the quality of analgesia with ESPB to be superior in comparison to CEB in pediatric patients undergoing lower abdominal surgeries, though both techniques provided adequate analgesia in their study. However, the results of this study are difficult to interpret as the authors have not detailed their postoperative analgesia protocol. Moreover, the authors have used a very small dose of LA (approximately 0.16 ml/kg of 0.25% bupivacaine) in their ESPB group so their result of prolonged analgesia with such low doses of LA does not seem reproducible.

Our results are consistent with the earlier studies on the radiological and cadaveric spread of LA after ESPB.[21] It is believed to act via diffusion into the paravertebral and

epidural spaces at the origin of the spinal nerves. Preliminary studies indicate that ESPB anesthetizes not only the spinal nerve roots but also the rami communicantes carrying sympathetic fibers, leading to the relief of visceral pain. We hypothesize that the need for the LA diffusion in ESPB, in contrast to direct deposition of the drug near the effect site in CEB, may account for the difference in the analgesic efficacy of the two blocks.

Literature on the choice of LA dose in ESPB is also limited. We chose a dose of 0.5 ml/kg of bupivacaine per side because of previous literature supporting this dose. The T10-T12 level was chosen on account of studies reporting the extensive dermatomal spread of more than five levels cranio-caudally when the block is performed at this level, thus providing adequate analgesia for abdominal surgeries.[2,3] Most early literature has described the ESPB in the prone position using the parasagittal technique.[3] We performed the block in the lateral decubitus position with a semi-prone tilt because of the needless difficulty of prone positioning after general anesthesia especially with supra-glottic devices *in situ*. Likewise, most authors have described a transverse approach when performing the block in the lateral decubitus position. We chose the parasagittal approach because of our familiarity and experience with this technique.

To contextualize our results, ESPB was found to be effective and safe in our patients undergoing surgeries with moderate surgical trauma. However, as compared to the time-tested gold standard, it was found to be inferior, especially in the first few hours after surgery. Thus, ESPB may be useful, along with multi-modal analgesia, in surgeries with mild to moderate severity of expected pain, particularly where the ease and superficial nature of the block would be particularly advantageous over epidural anesthesia, for example in coagulopathic patients or in cases where an epidural is contraindicated or difficult. Despite the low reported rate of complications, we emphasize that it is prudent to be as cautious as for all other invasive procedures. Uppal *et al*. have also recently advised judgment while choosing this block, because of unproven efficacy, for procedures where moderate to severe pain is expected and other gold-standard options are available.[22]

The strengths of our study are that it was a single-blind randomized study with blinding of outcome assessors. This study design minimizes selection and confounding bias. USG guidance for both blocks validated the comparison of the two techniques. We acknowledge the limitations of our study. First, since all our blocks were performed under general anesthesia, dermatomal evaluation of the block effect could not be done. Second, the assessment of postoperative analgesia was based on subjective (though validated) pain scores. A child can also show a higher FLACC score because of factors other than pain like hunger or ambient temperature. Third, our sample size was relatively small with a heterogeneous nature of surgeries. Larger studies comparing ESPB with other regional blocks are needed. Moreover, the different approaches of ESPB may be explored further in future studies.

We conclude that, in pediatric patients undergoing abdominal surgery, though both ESPB and CEB were safe and effective in providing adequate intraoperative and postoperative analgesia, ESPB was inferior to CEB with a greater proportion of patients requiring postoperative rescue analgesics, inferior FLACC scores, greater postoperative PCM consumption and a shorter duration of postoperative analgesia. ESPB may be considered in preference to CEB in pediatric patients undergoing abdominal surgery when CEB is contraindicated or difficult.

Ethical approval

Institutional Human Ethics Committee 2020/PG/July/01 dated 24.2.2021.

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Conflicts of interest

There are no conflicts of interest.

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