Original Article

To evaluate the effect of quadratus lumborum block on the tramadol sparing effect in patients undergoing open inguinal hernia surgery: A randomised controlled trial

Address for correspondence:
Dr. Vanita Ahuja,
Department of Anaesthesia and Intensive Care, Government Medical College and Hospital Chandigarh, India.
E-mail: vanitaanupam@yahoo.co.in

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Vanita Ahuja, Deepak Thapa, Souvik Nandi, Satinder Gombar, Ashwani Dalal[1], Rajesh Kumar Bansiwal[1]

Departments of Anaesthesia and Intensive Care and [1]General Surgery, Government Medical College and Hospital, Chandigarh, India

ABSTRACT

Background and Aims: An ultrasound-guided quadratus lumborum (QL) block provides both somatic and visceral analgesia in abdominal surgeries. We aimed to evaluate the postoperative tramadol sparing effect of single-shot anterior QL block in inguinal hernia surgery patients. **Methods:** This prospective, randomised controlled trial was conducted in a single tertiary care centre over a period of 1 year. A total of 50 patients, American Society of Anaesthesiologists (ASA) physical status I–II of both sexes aged 18–80 years with body mass index (BMI) ≥20 to ≤35 kg/m^2 undergoing uncomplicated unilateral inguinal hernia surgery under spinal anaesthesia (SA) were randomly allocated to either of the two groups. The block group (n = 25) received single-shot anterior QL block with 20 ml of 0.5% ropivacaine and the control group (n = 25) received no block. Postoperatively, patients received intravenous (IV) paracetamol 1g every 6 h and tramadol patient-controlled analgesia up to 24 h. Primary outcome was total tramadol consumption at 24 h postoperatively. **Results:** The total tramadol consumption mean ± SD [95% CI (range)] at 24 h in the block group was 84.00 ± 37.86 [68.37–99.63 (20–160)] mg versus 93.60 ± 34.99 [79.16–108.04 (20–160)] mg in control group, (p value = 0.36). Postoperative VAS score, haemodynamics, and patient satisfaction score were similar in both the groups. No adverse events were reported. **Conclusion:** A single-shot anterior QL block did not establish a postoperative tramadol-sparing effect at 24 h as compared to no block in patients undergoing inguinal hernia surgery under SA.

Key words: Acute postoperative pain, inguinal hernia mesh, quadratus lumborum block, ropivacaine, spinal anesthesia, tramadol

INTRODUCTION

Inguinal hernia surgeries are associated with moderate intensity nociceptive and neuropathic post-operative pain.[1] There is an overlap and inter-digitation of ilioinguinal, iliohypogastric and genitofemoral nerves in the inguinal area.[2] Inadequate post-operative pain relief causes increased patient stress, cardiopulmonary complications, slower recovery and patient dissatisfaction.[3] Opioids are commonly used as a standard of care for moderate to severe post-operative pain in abdominal surgeries. However, strong opioids cause nausea, vomiting, pruritus, urinary retention, reduction in bowel motility, constipation and at times respiratory depression.[4] Irrational non-steroidal anti-inflammatory drugs (NSAIDs) result in deranged haemostasis, renal dysfunction and gastrointestinal haemorrhage.[5] Epidural analgesia has also been

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associated with many side-effects and complications.[6] The current post-operative pain management involves the use of intravenous (IV) patient-controlled analgesia and regional nerve blocks.

Regional nerve blocks confer excellent site-specific pain relief and reduction in major side effects.[7,8] Newer techniques of regional analgesia, longer acting LA and adjuvants and safety with ultrasound are not only beneficial in adequate management of acute pain but also in preventing development of chronic pain.[9] Ultrasound (US)-guided quadratus lumborum (QL) block is a recently introduced block shown to provide both somatic and visceral analgesia as compared to transversus abdominis plane (TAP) block which prevents somatic pain.[10,11]

So far, the literature is scant regarding the role of anterior QL block in providing postoperative pain relief in inguinal hernia mesh surgery patients. This study aimed to evaluate the post-operative tramadol sparing effect of anterior QL block following inguinal hernia surgery under spinal anaesthesia (SA).

METHODS

This prospective, randomised, controlled trial was conducted per the Declaration of Helsinki in the Department of Anesthesia and Intensive care in collaboration with the Department of Surgery between March of 2018 and August of 2019. After approval from the Hospital Ethics Committee and registration with Clinical Trial Registry India (CTRI/2018/02/012011), 50 patients scheduled for unilateral open inguinal hernia surgery were enrolled. The study included patients of American Society of Anaesthesiologists (ASA) physical status I-II of both sexes aged 18 to 80 years with body mass index (BMI) ≥20 to ≤35 kg/m^2 and scheduled for uncomplicated unilateral inguinal hernia surgery.

Exclusion criteria for the study were patient refusal, history of substance abuse, any contraindication to spinal anaesthesia, allergy to local anaesthetic (LA) and tramadol, pregnant and lactating women, inability to understand the functioning of patient-controlled analgesia (PCA) pump and VAS (visual analogue scale) and local infection at QL block site.[12]

Upon fulfilling the inclusion and exclusion criteria, patients were enrolled and a written informed consent was taken. Patients were instructed regarding the use of PCA pump and VAS for pain assessment, a day prior to the surgery and also after surgery. In paper VAS on a 10-cm line for pain assessment, 0 stands for no pain and 10 stands for the worst imaginable pain. Patients were kept fasting after midnight and were pre-medicated with tablet alprazolam 0.25 mg and tablet pantoprazole 40 mg orally, a night before surgery and 2 h before surgery, respectively.

In the operating room, the haemodynamics of patients were monitored using multichannel monitors (Aespire View, Datex-Ohmeda, Madison, USA) and 500 ml of 0.9% normal saline was infused via IV access. A standard technique of subarachnoid block was used for all the patients. A total of 3.5 ml (3 ml of 0.5% bupivacaine heavy and 25 μg fentanyl) of drug was injected through the L_2–L_3 or L_3–L_4 interspace in the subarachnoid space. After completion of the surgery, all patients received IV paracetamol 1 gm and IV tramadol 50 mg. The patients were shifted to post-anaesthesia care unit (PACU) and randomisation of the patients was done using computer-generated random number table. Patients were randomly allocated to one of the following two groups of 25 each.

Block group (n = 25) Patients received single shot anterior QL block with 20 ml of 0.5% ropivacaine and dressing was done at block site.

Control group (n = 25) Patients received dressing at the block site for patient blinding.

Group allocation concealment was performed by placing the details of group allocation in an opaque-coloured sealed envelope. Blinding was done by using similar dressing at block site in all the patients. Patients were enrolled by an anaesthesia junior resident in the ward, randomisation was done in the post-operative area after the completion of surgery, allocated envelop was opened by the nurse who did not participate in the assessment of patient and the procedure was performed by an anesthesiologist who was later not involved in patient assessment. The patient and assessor were blinded to group allocation.

Patient was placed in the lateral position with operative side up. After sterile preparation a low frequency (3–7 MHz) curved (40 mm ray of curvature) array probe (MyLabOne, Esaote, Europe B.V, Philipsweg 1 6227 AJ Maastricht, Netherlands) covered by sterile plastic sleeve was placed horizontally on the umbilicus and moved laterally. Both rectus abdominis

and three muscle layers of the abdominal wall were identified and traced posterior to the point where the deep fascia of the transversus abdominis merges with the thoracolumbar fascia at L4 level. A 22-gauge 10-cm echogenic US needle (Braun Medical, Melsungen, Germany) was inserted in plane with the probe until between the psoas major and QL muscle. Needle positioning was confirmed after negative aspiration and hydro dissection with 5 ml of normal saline. After confirmation, 20 ml of 0.5% ropivacaine was injected and a sterile dressing was done at the block site.

All the patients received IV paracetamol 1g every 6 h, IV ondansetron 8 mg every 12 h and tramadol PCA (tramadol concentration of 10 mg/ml, bolus dose of 2 ml, lock out interval of 20 minutes, maximum dose limit of 350 mg over 24 h) up to 24 h postoperatively. If any patient consumed the maximum dose of tramadol and had VAS >4 then, IV diclofenac 75 mg was administered as rescue analgesia.

Primary outcome was total PCA tramadol consumption at 24 h postoperatively. The secondary outcomes were tramadol consumption at each time point, pain at rest and on movement were measured using VAS, haemodynamics, nausea/vomiting and any adverse effects. Nausea/vomiting was assessed using a four-point scale, where 0 stands for none, 1 stands for slight, 2 stands for moderate and 3 stands for severe.[13] Data collection was done at baseline and then 5, 10 and 15 minutes and 1, 4, 8, 12, 18 and 24 h after the placement of QL block. Patient satisfaction score was done at 24 h.[14] Pain assessment and patient satisfaction score was done at three months postoperatively (over telephonic interview). All these observations were recorded in the proforma attached. Decoding was done at the end of the study and data was analysed using appropriate statistical tests.

Statistical analysis

Continuous data was written as either in the form of its mean and standard deviation or in the form of its median and interquartile range, as per the requirement. Discrete categorical data was presented as *n* (%). The normality of the quantitative data was checked by the measures of Kolmogorov–Smirnov tests of Normality. For normally distributed data, t-test was applied for statistical analysis of the two groups. For skewed data or nonparametric data, Mann–Whitney *U*-test was used for the statistical analysis of the two groups. The categorical data comparisons were done by Pearson Chi-square test or Fisher's exact test as appropriate. For time-related variables of scores, Wilcoxon Signed rank test was applied. For normally distributed data, analysis of variance (ANOVA) followed by Post hoc Multiple Comparisons test (Dunnet t-test) was carried out. All the statistical tests were two-sided and were performed at a significance level of $\alpha = 0.05$. Analysis was conducted using International Business Machine Statistical Tests for Social Packages (IBM SPSS) STATISTICS (version 22.0). A $P < 0.05$ was considered statistically significant.

Sample size was calculated on the basis of pilot cases conducted prior to study. The formula for the sample size (n) = (Zα/2 + Zβ)2 *2*σ2/d2, where Zα/2 is the critical value of the normal distribution at α/2 (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the normal distribution at β (e.g., for a power of 80%, β is 0.2 and the critical value is 0.84), σ2 is the population variance and d is the difference in study likely to detect (20% difference of mean 110 mg). It was observed that the mean tramadol consumption in control group was 110 mg with a standard deviation of 25.8 mg. Using the above formula, with a confidence interval of 95%, the required sample size came out to be 22 patients per group at a power of 80%. To compensate for dropouts, we decided to include 25 patients per group. So, the total sample size of our study was 50 patients.

RESULTS

In the present study, 60 patients were assessed. Out of these, 10 patients were excluded and finally 50 patients were enrolled and randomly allocated into either of the two groups [Figure 1]. The demographic characteristics were similar in both the groups [Table 1].

The Q-Q plot of PCA patient tramadol consumption was normally distributed. No patient took PCA tramadol before 60 min postoperatively. After 24 h of surgery, the mean ± SD [95% CI (range)] of total tramadol consumption at 24 h in the block group was 84.00 ± 37.86 [68.37–99.63 (20–160)] mg and in the control group, the mean total tramadol consumption in patients was 93.60 ± 34.99 [79.16–108.04 (20–160)] mg. The difference in the mean tramadol consumption between both the groups at 24 h was not significant, (p value = 0.356) [Table 2]. VAS scores at rest and movement were similar with non-significant differences at all time points [Figures 2 and 3].

There was no statistically significant difference in time

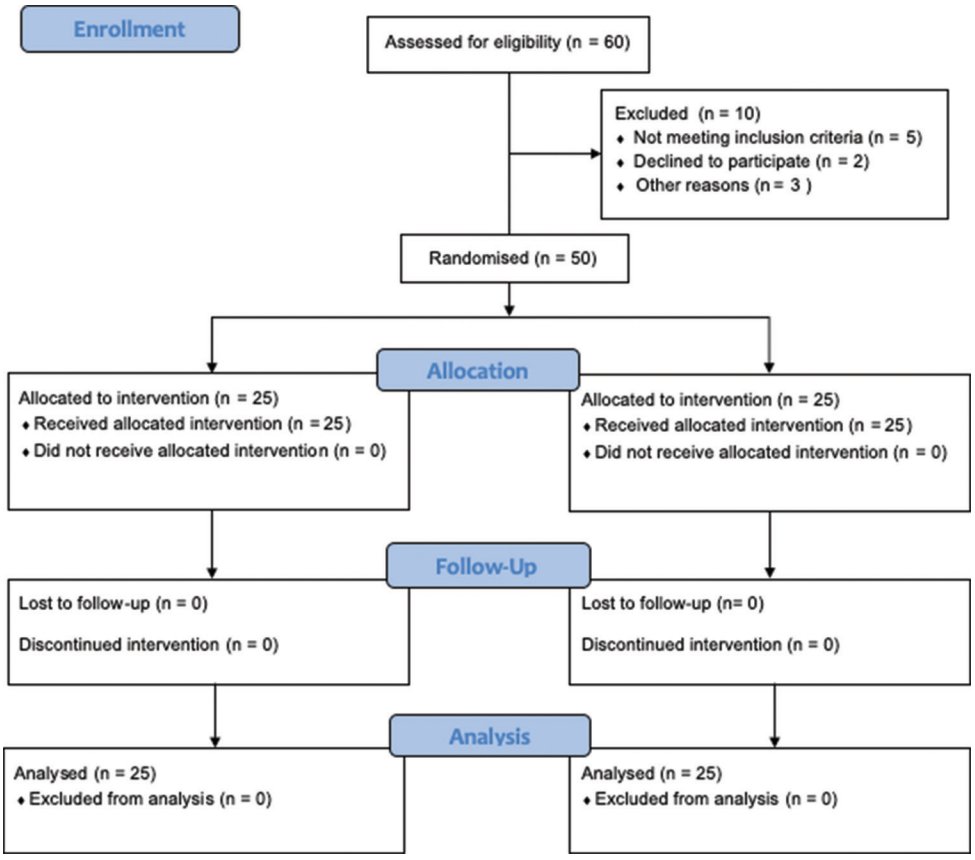

Figure 1: Consort diagram

Table 1: Patient demographic characteristics

Variables	Block group (*n*=25)	Control group (*n*=25)	*P*
Age (year)	43.36±14.06	47.88±18.86	0.342
Weight (kg)	66.76±13.03	67.72±12.66	0.793
Height (cm)	171.36±8.09	173.24±8.83	0.436
ASA I/II	20 (80%)/5 (20%)	22 (88%)/3 (12%)	0.200
Gender (Male)	25 (100%)	25 (100%)	1.000

Values are represented as mean±SD or number of patients (%)

for the first tramadol PCA dose, total consumption of diclofenac as rescue analgesia and postoperative passage of urine. The haemodynamic parameters were within the normal physiological range at all time intervals in both the groups. None of the patients reported nausea, vomiting, sedation, pruritus or shivering at any time interval in the study. Patients reported similar PSS at 24 h in both the groups. No serious adverse effects were reported in any patient during the entire study period.

At three-month follow up, similar VAS at rest, VAS on movement and PSS were found in both the groups.

DISCUSSION

Intra-abdominal surgeries require visceral pain relief as cephalad as T6 and as caudal as L1. The application of QL in abdominal surgeries provided wider analgesic distribution ranging from T12–L4 dermatomes.[15-19] Initially, lateral (QL block 1) and posterior (QL block 2) were described. Thereafter, anterior (trans-muscular, QL block 3) QL block was described as an alternative route using a local anaesthetic injection administered between the QL and the psoas muscle.[10,15-19] In the present study, total tramadol consumption at 24 h was compared in patients receiving single shot anterior QL block versus no block in patients undergoing inguinal hernia surgery under SA. We found that the postoperative tramadol PCA consumption at 12, 18 and 24 h was reduced in patients receiving single shot anterior QL block but not greater than 20% at 24 h as compared to no block. These results were probably due to the lower volume of ropivacaine rather than dose effect.

In anterior QL block, the LA is targeted between the QL and psoas major muscle, which allows cephalad spread via the posterior pathway to the median and lateral arcuate ligaments (of the diaphragm) and into the thoracic paravertebral spaces.[20] There

Table 2: Postoperative comparison of total tramadol consumption in mg in the first 24 h following open inguinal hernia surgery under spinal anesthesia

Tramadol consumption	Block group (*n*=25)	Control group (*n*=25)	*P*
Baseline	0.00±0.00 [0.00-0.00 (0-0)]	0.00±0.00 [0.00-0.00 (0-0)]	1.000
5 min	0.00±0.00 [0.00-0.00 (0-0)]	0.00±0.00 [0.00-0.00 (0-0)]	1.000
10 min	0.00±0.00 [0.00-0.00 (0-0)]	0.00±0.00 [0.00-0.00 (0-0)]	1.000
15 min	0.00±0.00[0.00-0.00 (0-0)]	0.00±0.00 [0.00-0.00 (0-0)]	1.000
60 min	16.00±18.26 [8.46-23.54 (0-80)]	16.80±16.00 [10.20-23.40 (0-60)]	0.870
4 h	36.00±24.49 [25.89-46.11 (0-80)]	41.60±24.44 [31.51-51.69 (0-80)]	0.422
8 h	49.60±30.07 [37.19-62.01 (0-100)]	56.00±24.49 [45.89-66.11 (0-80)]	0.413
12 h	60.00±30.00 [47.62-72.38 (20-120)]	71.20±27.13[60.00-82.40 (20-120)]	0.173
18 h	74.40±32.41 [61.02-87.78 (20-120)]	80.00±31.62 [66.95-93.05 (20-120)]	0.539
24 h	84.00±37.86 [68.37-99.63 (20-160)]	93.60±34.99 [79.16-108.04 (20-160)]	0.356

Values are represented as mean±SD [95% CI (range)]. Independent sample *t*-test for the inter-group comparisons

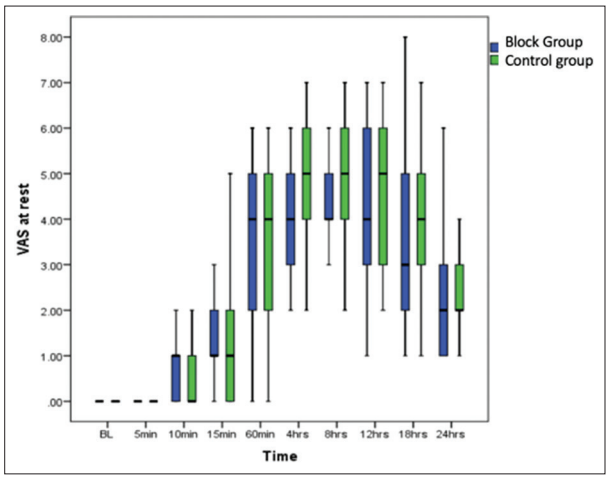

Figure 2: Box and Whisker plot for showing the post-operative comparison of VAS score at rest in the first 24 h following the open inguinal hernia surgery under spinal anaesthesia. Values are represented as median (IQR [range]). The line inside the box signifies the median, box signifies the interquartile range (IQR), and the whiskers describe the range

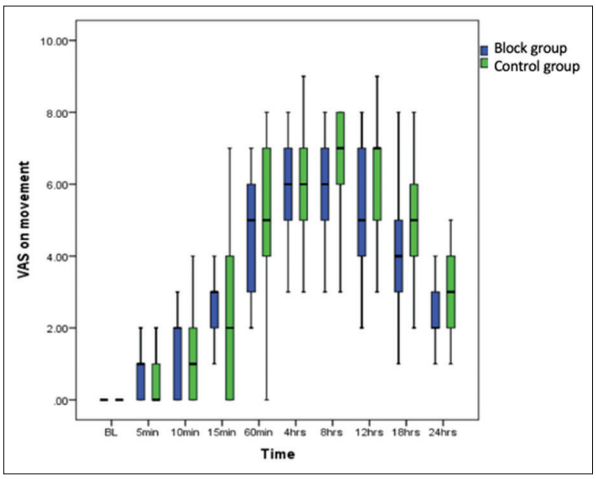

Figure 3: Box and Whisker plot for showing the post-operative comparison of VAS score on movement in the first 24 h following open inguinal hernia surgery under spinal anaesthesia. The values are represented as median (IQR [range]). The line inside the box signifies the median, box signifies the interquartile range (IQR), and the whiskers describe the range

is controversial spread related to QL block as per cadaveric studies which have demonstrated that following transmuscular or anterior QL block, the injectate spread either only to lumbar paravertebral space or in single cadaveric model, no spread to paravertebral space.[19-21] In a recently published study, Ahmed *et al.* compared the two different techniques of QL block for duration of analgesia in patients undergoing inguinal hernia surgery. 40 patients were randomised to receive either transmuscular or posterior US-guided QL block with 20 ml of 0.25% ropivacaine at the end of the general anesthesia before extubation. The authors reported a longer duration of block in transmuscular QL block group as compared to posterior QL block group (20.1 ± 6.2 versus 12.0 ± 4.8 h, respectively) with a *P* value of <0.001. Although the authors concluded that total morphine consumption was reduced in the posterior QL group (1.9 ± 0.6 mg versus 1.1 ± 0.9 mg) than in the transmuscular QL group over 24 h,[22] it does not satisfy a clinically meaningful difference. The present study as compared to that of Ahmed *et al.* has a few differences. Firstly, in the present study, the anterior QL block was compared with no block and, secondly, the surgeries were performed under SA which itself causes post-operative analgesia, masking the initial benefits of a single shot anterior QL block. There are also a few similarities of the present study with Ahmed *et al.* In both the studies, a similar volume of 20 ml of LA was used and both studies reported a clinically insignificant reduction in opioid consumption over 24 h post surgery.

Failure to show difference in post-operative analgesic sparing as found in the present study draws its support from the published literature.[23,24] Tamura *et al.* demonstrated that 20 ml of LA did not result in the spread to paravertebral space (PVS) via intramuscular

QL block and hence may cause suboptimal sensory effect in the lower abdomen.[23] Tamura *et al.* in an another study, used higher volume of LA in intramuscular QL block in a crossover volunteer study. In five healthy men, intramuscular QL block with 0.2% ropivacaine 0.7 ml/kg of LA did not spread into the PVS and the sensory effect was present in lateral abdominal wall only.[24]

On the contrary, Stuart Green *et al.* performed a pre-operative US-guided transmuscular QL block with 30 ml of 0.5% ropivacaine in 10 cases of total hip arthroplasty. The length of hospital stay was shorter in patients receiving QL block (2.9 days) versus patients not receiving QL block (5.1 days) (p-value = 0.015). The intra-operative use of fentanyl was also lower in patients receiving QL block (183.5 μg) versus patients not receiving QL block (240 μg) (p value = 0.038).[25] Diwan *et al.* in a case series of five patients described contrast spread in high and low QLB with the initial needle placement at upper-mid or mid-lower part of the kidney. The authors described the analgesic benefit of high QLB for visceral pain and low QLB was for non-visceral pain. Diwan *et al.* emphasised that the spread of LA is governed by multiple factors such as the path of least resistance by LA, speed of injection, catheter tip, and volume of LA injection in QLB and hence dermatomes involved may be unpredictable.[26] The present study failed to demonstrate a greater difference in 24 h tramadol consumption due to single shot block with a lower volume of 20 ml of LA for anterior QL block and the continuity of analgesic benefit of spinal anaesthesia in the initial post-operative period.

The use of 20 ml volume of LA was planned for single shot anterior QL block in the present study, as patients of mesh hernia surgery are discharged on the following day. Published literature describes complications with larger volume of LA in a single shot QL block. Fujimoto *et al.* used 30 ml of 0.25% ropivacaine on each side and reported numbness in their lower limbs at awakening in bilateral posterior QL block, whereas no patient in the control group experienced numbness. In all five patients out of 31 patients who received QL block and experienced numbness, the symptoms improved by 24 h after surgery. The authors suggested that the patients should be informed of the possibility of both numbness and weakness as the potential side-effects in their preoperative consent.[27] In the present study, no patient reported any adverse events. Similarly, the pain assessment and patient satisfaction score done at three months postoperatively were similar in both the groups.

There are a few limitations of the present study. Firstly, a sensory assessment of anterior QL block after the wearing off effect of SA was not included in methods. Secondly, the duration of the surgery of uncomplicated inguinal hernia was not recorded. In future, the US-guided anterior QL block with catheter techniques should be planned as randomised controlled trials for patients undergoing inguinal hernia mesh surgery.

In conclusion, a single shot QL block did not establish the postoperative tramadol-sparing effect at 24 h as compared to no block in patients undergoing inguinal mesh hernia surgery under SA.

Declaration of patient consent

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

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Conflicts of interest

There are no conflicts of interest.

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