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Efficacy of ultrasound guided erector spinae plane block compared to wound infiltration for postoperative analgesia following laparoscopic living donor nephrectomy: a double-blinded randomized controlled trial

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Abstract

Background Postoperative pain remains a significant problem in patients undergoing donor nephrectomy despite reduced tissue trauma following laparoscopic living donor nephrectomy (LLDN). Inadequately treated pain leads to physiological and psychological consequences, including chronic neuropathic pain.

Materials and methods This randomized controlled double-blinded trial was conducted in sixty-nine ($n=69$) participants who underwent LLDN under general anesthesia. Participants were randomized into Group B ($n=34$) and Group C ($n=35$). Group B received ultrasound-guided bilateral erector spinae plane block (ESPB) with bupivacaine 0.125% 20 ml on the surgical side and 10 ml on the contralateral side before extubation, while Group C received wound infiltration with bupivacaine 0.125% 15 ml. The primary objective of the study was to compare cumulative 24-hour morphine consumption postoperatively. The secondary objectives were time to first rescue analgesia, visual numeric rating scale (VNRS) pain scores at rest and during movement, incidence of postoperative nausea and vomiting (PONV), and complications associated with ESPB.

Results Participants in Group B required significantly less median (IQR) 24-hour morphine compared to Group C [6 (6–9) mg vs. 15 (12–15) mg; median difference 9; 95% CI in median difference 6–12; $p<0.001$), longer median (IQR) time to first rescue analgesia [6 (6–8) hours vs. 1 (1–2) hours; $p<0.001$], and lower VNRS at rest and during movement at baseline, 0.5, 1, 2, 4, 6, 8, 12, 24 hours.

Conclusion Ultrasound-guided ESPB provided effective pain relief compared to wound infiltration with local anaesthetic in patients who underwent LLDN.

Trial registration INT/IEC/2021/SPL-514; CTRI/2021/07/045909.

Keywords Acute postoperative pain, Nephrectomy, Analgesia, Erector spinae block, Regional anaesthesia, Pain management, Donor nephrectomy, Wound infiltration

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Background

Laparoscopic Living Donor Nephrectomy (LLDN) is considered the gold standard procedure for kidney donation. It reduces postoperative morbidity and length of hospital stay, resulting in a more aesthetically pleasing scar than open surgery [1]. However, postoperative pain remains a problem for many donors despite the reduced tissue trauma following LLDN. The reasons attributed are extensive tissue dissection, visceral manipulation, pneumoperitoneum, traction on neurovascular structures, relatively a large skin incision required to retrieve the graft kidney, and heightened pain sensitivity of healthy voluntary donors. Inadequately treated postoperative pain discourages potential donors and leads to physiological and psychological consequences, including chronic neuropathic pain [2, 3]. It is imperative that adequate postoperative pain control measures should be integral part of successful transplantation program.

Pain after LLDN surgery can be managed using a multimodal approach that includes parenteral opioids and local anaesthetics. Non-steroidal anti-inflammatory analgesics (NSAIDs) are generally avoided due to their potential for nephrotoxicity [4]. Opioids provide effective pain relief but can cause side effects such as nausea, vomiting, sedation, constipation, pruritis, and respiratory depression. Local anaesthetics can be administered via port site infiltration, central neuraxial blocks and regional nerve blocks. In recent years, regional nerve blocks have gained popularity over central neuraxial blocks due to their targeted action, minimal or no impact on hemodynamics, and shorter hospital stay after surgery [5]. The erector spinae plane block (ESPB) was invented by Forero et al. [6]. Although ESPB has been successfully used in various thoracic and abdominal surgeries, its role in LLDN is not yet studied. This study aimed to investigate the analgesic efficacy of ESPB compared to wound infiltration with local anaesthetic in patients undergoing LLDN. The primary objective was to compare cumulative morphine consumption postoperatively in the first 24 h. The secondary objectives included the time to first rescue analgesia, pain scores using the visual numerical rating score (VNRS) at rest and during movement at different time intervals, the incidence of postoperative nausea and vomiting (PONV) and complications associated with the block procedure, if any.

Methods

After the approval of the Institute Ethics Committee (INT/IEC/2021/SPL-514) PGIMER Chandigarh, this randomized controlled double-blind trial was conducted in eligible voluntary kidney donors belonging to American Society of Anesthesiologists (ASA) physical status 1 and 2, aged 18 years or older, and underwent LLDN under general anesthesia from March 2021 to August 2022. Participants with a local infection at the block site, allergy to local anesthetic agents, poor ultrasound window for ESPB, and refusal to consent to participate in the study were excluded from this study. This study was prospectively registered (CTRI/2021/07/045909) in the Clinical Trial Registry of India and followed the principles of the Declaration of Helsinki. A Written informed was obtained from all the study participants before enrolment in the study.

Group allocation and blinding

The study participants were randomly allocated to either of the interventional group (Group B and Group C) using a block randomization method, with a block sizes of 4. Within each block, participants were randomly allocated to one of the two groups using a computer-generated random number. Group B received ultrasound-guided bilateral ESPB after surgery and before extubation at the T9-10 level in lateral position. Group C received general anesthesia along with local wound infiltration) before extubation. Participants were blinded to their group allocation and the anesthesiologist who followed up with them postoperatively was also unaware of their group allocation.

Anaesthesia technique

All the study participants were evaluated in the pre-anaesthesia checkup clinic and reviewed a day prior by the attending anesthesia team. They were informed about the both interventional procedures and the VNRS for pain (0 to 10, with 0 representing no pain and 10 representing the worst pain). Participants were instructed to follow standard fasting guidelines and were advised to take oral ranitidine 150 mg and alprazolam 0.25 mg tablets the night before and two hours before surgery. Participants in both the groups underwent LLDN under general anaesthesia. Anaesthesia was induced with intravenous fentanyl 2–5 µg/kg followed by intravenous propofol 2 mg/kg. Atracurium 0.5 mg/kg was used to facilitate endotracheal intubation. Anaesthesia was maintained with 50% air-oxygen mixture and isoflurane (minimum alveolar concentration [MAC] 1-1.3) with the patient on positive pressure mechanical ventilation to maintain end-tidal carbon dioxide ($EtCO_2$) between 32 and 36 mm of Hg. Fentanyl bolus of 1–2 µg/kg was intermittently administered to maintain the mean arterial blood pressure and heart rate within 20% of the baseline value.

Intervention

In group B, under aseptic precautions, ultrasound-guided bilateral ESPB was performed at the end of surgery while the participants were in the lateral position at T9-10 vertebral level. A high-frequency linear ultrasound probe (5–10 MHz) (Sonosite, Inc. Bothell. WA 98021 USA) was placed 3 cm lateral to the spinous process in the sagittal plane. After identifying the hyperechoic transverse process, the paraspinal muscles were visualized. A 9 cm 20 G Quinke's spinal needle was advanced until its tip was located between the transverse process and the erector spinae muscle. The correct tip location was confirmed by plane hydro-dissection with normal saline. Bupivacaine 0.125% (20 ml on the side of surgery and 10 ml on the contralateral side) was then administered in this plane between the erector spinae muscle and the vertebrae transverse process. Participants in the Group C received general anesthesia along with local anesthetic wound infiltration of laparoscopic port site and Pfannenstiel incision with bupivacaine 0.125% 15 ml total volume (maximum dose 2 mg/kg) before extubation.

Intravenous Ondansetron 0.1 mg/kg and paracetamol 15 mg/kg were given at the end of surgery. Neuromuscular blockade was reversed using intravenous neostigmine (50 µg/kg) and glycopyrrolate (10 µg/kg) and the participants were extubated. Participants were then transferred to the postoperative recovery unit. If participants report a VNRS exceeding 4/10, intravenous morphine 3 mg was administered. The following were recorded at different time intervals (Baseline, 0.5, 1, 2, 4, 6, 8, 12 and 24 h): pain scores (VNRS) at rest and during movement, time to first rescue analgesia, and incidence and severity of PONV as per 4-point PONV scale (0- none, 1- mild nausea, 2- severe nausea, 3-vomiting episodes).

Statistical methods

Data were analyzed using International Business Machine (IBM) Statistical Package for the Social Sciences (SPSS) version 25.0 computer software and Microsoft Excel 2015. Data were presented as mean with standard deviation (± SD) or median with interquartile range (IQR). Normality was assessed using the Kolmogorov–Smirnov test. For normally distributed continuous data, Student's t-test was used, and for categorical variables with two categories, the chi-squared ($\chi 2$) test was applied. The 24-hour cumulative median morphine consumption was compared using Mann-Whitney U test. Time to first rescue analgesia was analyzed using Kaplan Meier survival analysis. Postoperative resting and dynamic VNRS [median (IQR)] were analyzed using Mann-Whitney U test. This study had a 95% confidence interval and a p-value of less than 0.05 was considered statistically significant. A minimum of 30 participants in each group was required assuming that this would allow the detection of $\geq 30\%$ difference in the postoperative morphine requirements for first 24 h postoperatively with a power of 90% and alpha error of 0.05.

Results

Eighty ($n=80$) voluntary kidney donors who underwent LLDN were screened for eligibility. Five ($n=5$) participants were declined to consent for participation. Seventy-five participants ($n=75$) were randomized into Group B ($n=37$) and Group C ($n=38$). Six participants ($n=6$) did not receive allocated intervention and results were analyzed for 69 participants [Fig. 1]. In group B, the mean (SD) age of the study participants was 48 (10) years and 45 (10) years in group C. The majority of participants (>75%) in both groups were female. Both the groups were comparable in terms participant's body weight and ASA physical status [Table 1].

The median 24-hour morphine consumption in Group B was 6 (6–9) mg and 15 (12–15) mg in Group C which was statistically significantly higher (median difference 9 mg; 95% CI in median difference 6 to12; $p<0.001$) (Fig. 2). The participants in the Group C had a significantly shorter median time to the first rescue analgesia compared to Group B [1 (1–2) hours vs. 6 (6–8); $p<0.001$] (Table 2) and (Fig. 3). The VNRS pain scores were lower in Group B as compared to Group C at all-time points after surgery, both at rest and during movement (Fig. 4). The incidence and severity of PONV is listed in Table 3. There were no complications observed related to the block procedure.

Discussion

The present study demonstrated the analgesic efficacy of ESPB in patients who underwent LLDN for postoperative pain relief compared to local anesthetic wound infiltration. ESPB had significantly reduced the 24-hour cumulative morphine consumption and pain scores as measured by VNRS at all time points during the 24 h follow-up both at rest and during movement.

The management of postoperative pain is crucial for the early recovery of voluntary kidney donors. Pain following LLDN is multifactorial in origin [1]. Though the laparoscopic port site incisions are smaller than open surgeries and associated with shorter recovery time, the lower abdominal Pfannenstiel incision made to retrieve graft kidney causes significant pain and discomfort to the donors. Additionally, surgical dissection of abdominal and pelvic structures during the surgery

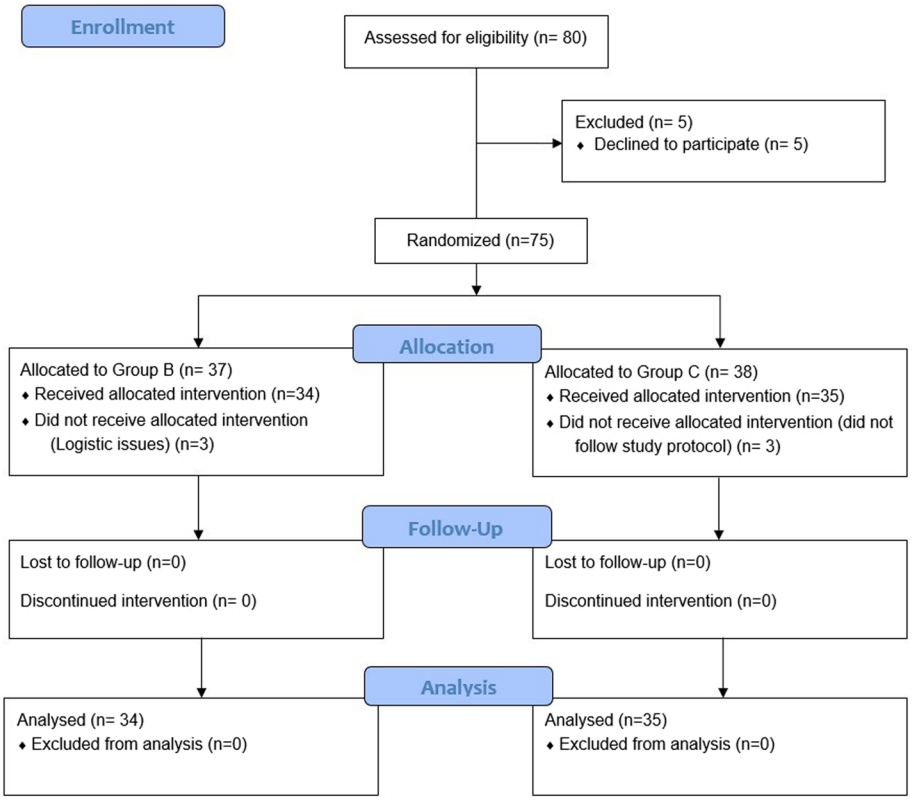

Fig. 1 CONSORT flow diagram

Table 1 Demographic characteristics of the study participants

	Group B ($n=34$)	Group C ($n=35$)	*P* value
Age (years)	48 (10)	45 (10)	0.528
Sex (Female)[a]	26 (76)	31 (89)	0.218
Weight (Kg)	63 (9)	62 (6)	0.372
ASA physical status[a]			
1	29 (85)	27 (77)	0.540
2	5 (15)	8 (23)	

Data is presented as mean (SD)

Group B Erector spinae plane block group, *Group C* Control group, *ASA* American society of anesthesiologists

[a] number (%)

p value < 0.05 is considered as statistically significant

lead to significant postoperative visceral pain which may require multimodal therapy for adequate analgesia [7]. Moreover, the fear of postoperative pain deters potential donors psychologically which could discourage them from donating organs.

ESPB has been used successfully in various thoracoabdominal open and laparoscopic surgeries for intraoperative and postoperative pain management [8–14]. In ESPB, local anesthetic is injected into the fascial plane between the erector spinae muscle and vertebral transverse process [6]. This provides both visceral and somatic analgesia through direct blockade of dorsal, ventral ramus of the spinal nerve and sympathetic ganglion resulting from the spread of local anaesthetic to paravertebral space. Onay et al., in a small randomized controlled trial found ESPB resulted in similar postoperative pain scores and morphine consumption during the postoperative period compared to ultrasound-guided quadratus lumborum block for open nephrectomy surgery [15]. ESPB given at T9 level provided effective intraoperative and postoperative effective pain relief in patients who underwent retroperitoneal laparoscopic nephrectomy surgeries [16].

In 2023, Fan et al. in their randomized controlled trial conducted in 61 patients found that ESPB provided non-inferior analgesia in patients who underwent laparoscopic nephrectomy surgery compared to thoracic paravertebral block [17]. In another randomized controlled trial in 186 patients who underwent laparoscopic nephro-ureterectomy, Xu et al. reported the median (IQR) 24 h cumulative sufentanyl equivalent dose was 15 (5–30) microgram and the median (IQR) time to first patient controlled analgesia demand

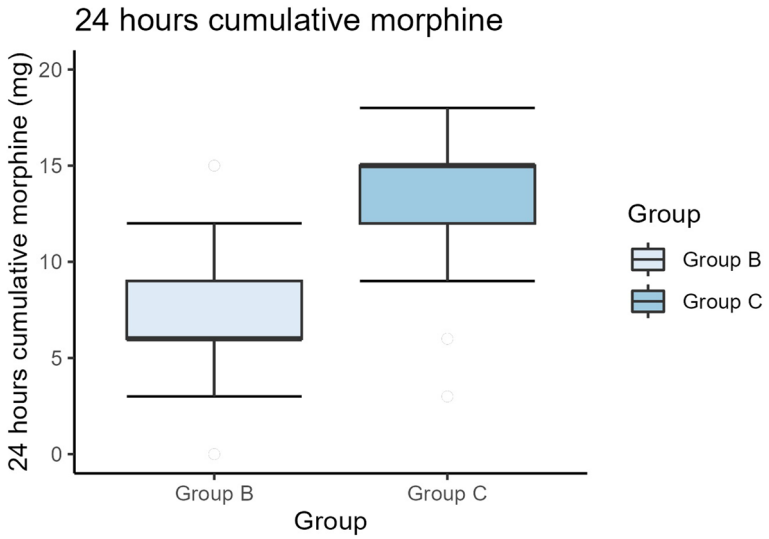

Fig. 2 24-hours cumulative morphine consumptions among the study participants

Table 2 Details of rescue morphine for analgesia in the study participants and various time points in the post-operative period

Rescue analgesia with morphine (mg)	Group B	Group C	*P* value
0 min	0	0	0.160
30 min	0	0	0.003
1st hour	0	3(0–3)	< 0.001
2nd hour	0	3(3–3)	< 0.001
4th hour	0	6(3–6))	< 0.001
6th hour	3(0–3)	6(6–6))	< 0.001
8th hour	3(3–3)	9(9–9))	< 0.001
12th hour	6(3–6)	12(12–12)	< 0.001
24th hour	6(6–9)	15(12–15)	< 0.001
24 h cumulative	6	13	< 0.001
Mean time to first rescue analgesia (hours)	6 (1–2)	2 (6–8)	< 0.001

Data is mentioned as median (IQR)

Group B Erector spinae plane block group, *Group C* Control group

p value < 0.05 is considered statistically significant

was 7 (4–18) hours in the ESPB group [18]. In our study, ESPB was administered after surgery but before extubation to prevent any unexpected hemodynamic instability that could potentially affect the outcome of the graft.

Very recently, Özlem Özkalayci et al., in a randomized controlled trial, in 52 patients who underwent, hand assisted-laparoscopic living donor nephrectomy, reported no significant difference in the intravenous morphine equivalent consumption (ESPB group 33.3 ± 21.4 mg vs. no block group 37.5 ± 18.5 mg; $P = 0.27$). They administered pre-induction, ultrasound ESPB block on the side of nephrectomy with 30 ml of Bupivacaine 0.25%. Based on a preliminary study Özlem Özkalayci et al., ESPB administered at T8/10 did not produce adequate analgesia in the lower abdomen where the hand port was placed hence, they decided to give the block at T12 level in the study. And they concluded that, augmenting the block intensity using bi-level or bilateral block techniques covering all-surgical sites. In our study, ESPB was administered after surgery but before extubation to prevent any unexpected hemodynamic instability that could potentially affect the outcome of the graft.

LLDN with Pfannenstiel incision to retrieve graft kidney is a common practice in our center. Since the Pfannenstiel incision (10–12 cm) crosses the midline, we gave bilateral block, with reduced volume on the dependent side. We did not come across any complications during the block procedure and in the postoperative period.

Our study has potential limitations that should be noted. Firstly, we could not use patient-controlled analgesia due to resource limitations. Secondly, preoperative anxiety and depression were not measured in our study which can affect pain perception and pain scores, although all potential donors underwent preoperative screening for any major psychological concerns related to organ donation. Thirdly, we did not evaluate the extent of dermatomal sensory block following the procedure. Fourthly, the dose of local anesthetic used in wound infiltration is lower than that used in ESPB. However, the rate of local anesthetic absorption from these sites may not be the same, and the NRS difference between the groups cannot be attributed to the dose difference alone.

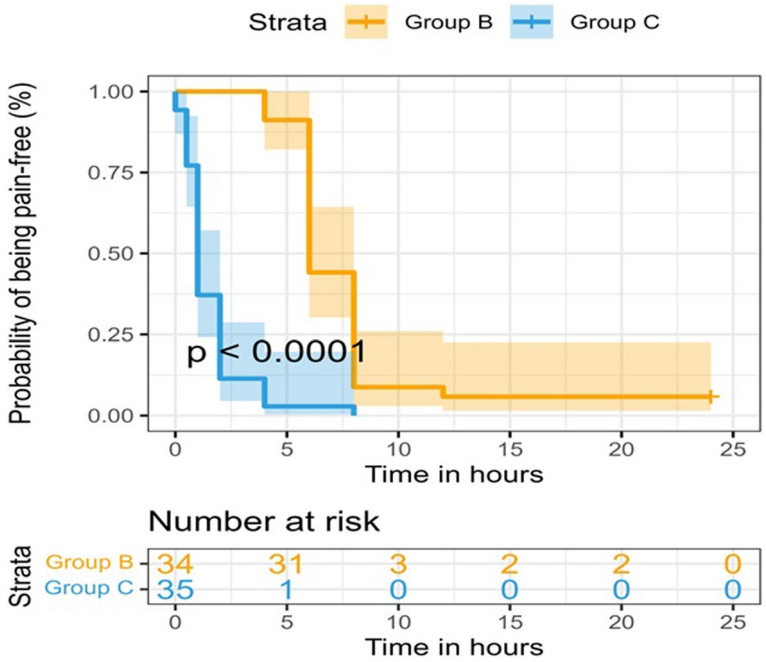

Fig. 3 Kaplan-Meier curve for probability of being painfree in the study groups

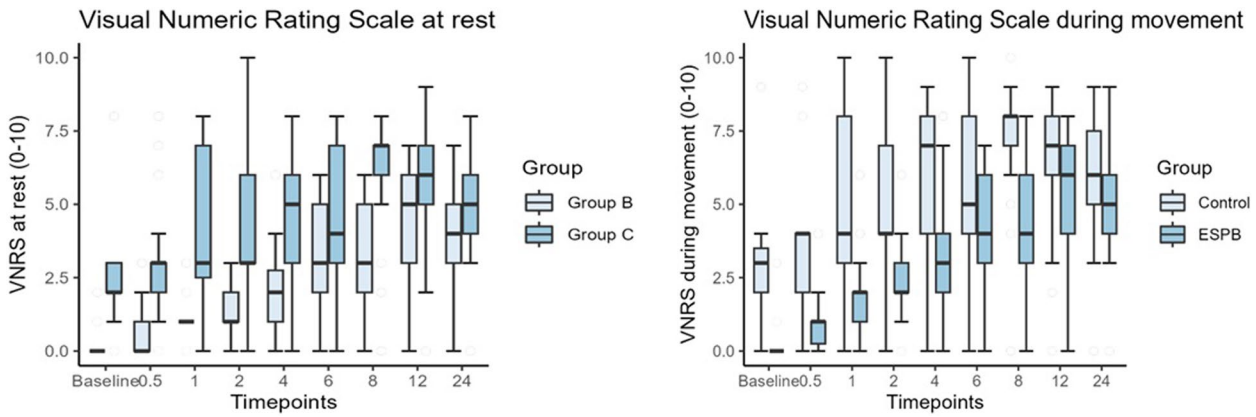

Fig. 4 Visual numeric rating scale during rest and at movement in the post-operative period

Table 3 Incidence and severity of PONV in the first 24 post-operative hours

	Group B ($n=34$)				Group C ($n=35$)				*P* value
Severity of PONV	0	1	2	3	0	1	2	3	
0–4 h	22 (65)	10 (30)	2 (6)	0 (0)	13 (37)	21 (46)	6 (17)	0 (0)	0.058
4–12 h	33 (97)	1 (3)	0 (0)	0 (0)	33 (91)	2 (9)	0 (0)	0 (0)	0.317
12–24 h	34 (100)	0 (0)	0 (0)	0 (0)	35 (100)	0 (0)	0 (0)	0 (0)	-

Data presented as number (%)

Severity of PONV 0- none, 1- mild nausea, 2- severe nausea, 3- vomiting

PONV Post-operative nausea and vomiting, *Group B* Erector spinae plane block group, *Group C* Control group

p value < 0.05 is significant

Further investigation is needed to determine the optimal injection level and volume required to provide analgesia for the Pfannenstiel incision on the opposite side of the surgery.

Conclusion

Ultrasound-guided ESPB provided effective pain relief with lower opioid consumption and fewer episodes of postoperative nausea and vomiting compared to wound infiltration with local anaesthetic in participants who underwent LLDN.

Abbreviations

ESPB	Erector spinae plane block
LLDB	Laparoscopic live donor nephrectomy
NSAIDS	Non-steroidal anti-inflammatory drugs
PONV	Post-operative nausea and vomiting
VNRS	Visual numeric rating scale
IQR	Interquartile range

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None.

Authors' contributions

SL- helped in all aspects of the study, including design, research implementation, and manuscript writing. KK- helped in all aspects of the study, including design, research implementation, and manuscript writing. KG-helped in all aspects of the study, including design, research implementation, and manuscript writing. SS- helped in conceiving the original concept and supervised the project. DBK-helped with computation and formal analysis. AS- helped in the design and implementation of the research. AA- helped in data collection and critical review. VM- helped in performing the procedure and data collection. NBN- helped in methodology and resource management. RKK- helped in data collection and resource management. This manuscript has been read and approved by all of the authors.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Institute Ethics Committee PGIMER Chandigarh approval was obtained wide ref no: INT/IEC/2021/SPL-514. A written informed consent was obtained from all the study participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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