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Bupivacaine improves surgical field and postoperative pain control in endoscopic sinus surgery: a clinical trial

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Abstract

Introduction Endoscopic sinus surgery is often challenging because of bleeding and pain. A variety of techniques have been explored to reduce surgical function and pain, with the sphenopalatine ganglion block showing the most promising results. All of these researches, however, had methodological flaws since saline was used as a placebo injection, which could have irritated the ganglion and produced less-than-ideal results, in accordance with our theory.

Aim and objective To determine the effect of sphenopalatine ganglion block with bupivacaine on intraoperative endoscopic surgical field and postoperative pain.

Patients and methods A prospective double blind, randomized study was conducted in 50 subjects undergoing endoscopic sinus surgery for chronic rhinosinusitis with or without polyp. The case group received 1.5 ml of 0.5% bupivacaine in sphenopalatine ganglion block while control group didn't receive any drug in ganglion. The intraoperative surgical field grade and postoperative pain score was recorded to analyze the effect of the block.

Results We discovered a statistically significant difference in the endoscopic surgical field between the case and control groups. In comparison to the control group, the surgical field was more visible in the sphenopalatine ganglion block group. The case group significantly outperformed the control group in terms of pain visual analogue score throughout the observation period, with the exception of the first day following surgery.

Conclusion Sphenopalatine ganglion block with bupivacaine 0.5% is a straightforward, efficient, and secure way to improve the endoscopic surgical field and lessen postoperative pain in patients undergoing endoscopic sinus surgery.

Keywords Trans-nasal endoscopic surgery, Sinusitis, Bupivacaine, Postoperative pain, Endoscopic hemostasis

Background

Endoscopic sinus surgery (ESS) is becoming a common operation in the field of otorhinolaryngology. Although there is a considerable possibility of orbital and skull base injuries, its occurrence has significantly decreased as a result of better tools and optics. Even yet, a few issues like pain and small bleeding are unavoidable and uncomfortable for both the patient and the physician.

Due to the strong neurovascular supply of the sinonasal area, even small trauma results in significant bleeding and discomfort [1]. Intraoperative bleeding lengthens the procedure and raises the possibility of significant

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consequences. In order to have a better surgical field, the majority of endoscopic procedures are now carried out under hypotensive anesthesia, although this technique has drawbacks in terms of competence, infrastructure, and hazards. Analgesics can also be used to treat postoperative pain, although they too have negative effects. Hemorrhage and pain management are therefore crucial for the best results in ESS.

The sphenopalatine ganglion carries major sensory and autonomic nerves to nasal cavity. Ganglion block with a long-acting local anesthetic agent could provide a better hemorrhage and pain control [1]. Sphenopalatine ganglion block (SPGB) has been used in cluster headache, trigeminal neuralgia, migraine, and cancer palliative care [1]. Randomized controlled trials have been conducted to evaluate the effects of the sphenopalatine block in endoscopic sinus surgery [2–8]. Sphenopalatine ganglion block was found effective in reducing the postoperative pain as compared to placebo. Sphenopalatine ganglion block was found to be safe, simple, noninvasive, and an effective method of short-term pain [2–8]. However; these trials used saline in control group which could stimulate/irritate ganglion. The sphenopalatine ganglion stimulation can have significant side effects like headache, facial pain and swelling [9]. Moreover; sphenopalatine block is not used in routine endoscopic sinus surgery thus placebo injection would cause unnecessary irritation of ganglion leading to a major limitation in assessing the effects of ganglion block through placebo-controlled trials. Based on this hypothesis, we conducted a study to estimate the effect of sphenopalatine ganglion block with bupivacaine without using any placebo in the control group.

Aim and objective

To determine the effect of sphenopalatine ganglion block with bupivacaine on intraoperative endoscopic surgical field and postoperative pain.

Method

This prospective double blind, interventional, randomized study was carried out in 50 subjects over a period of 1 year in the year 2021–2022 after receiving institutional ethical approval and informed written consent from the enrolled subjects.

The predicted sample size was 44 with an expected proportion of 3%, a confidence coefficient of 95%, and an absolute precision of 5%. However, we enrolled 50 subjects with chronic rhinosinusitis (involving all sinuses both sides) with or without polyps in order to prevent any dropouts. Subjects hypersensitive to local anesthetic agents, uncontrolled hypertension, cardiovascular or cerebrovascular diseases, alcohol or opioid consumption, diabetes, and chronic renal disease were excluded. All subjects were put on topical fluticasone furoate one puff (50 μg) each nostril once daily followed by saline spray for 3 weeks and oral prednisolone (0.5 mg/kg/day) for 2 weeks before surgery.

To avoid bias, we randomized the included subject through computer-generated randomization. Subjects were divided into two groups: case (subjects who received sphenopalatine ganglion bupivacaine block) and control (subjects who did not receive sphenopalatine ganglion bupivacaine block). Subject, anesthesiologist, and observer were blinded to the group allocation.

All subjects underwent endoscopic sinus surgery of maxillary, ethmoid, frontal, and sphenoid on both sides under general anesthesia with 2.5 mg/kg of 1% propofol and 2 mg/kg of 2% fentanyl, with tracheal intubation. Isoflurane (1–2.5%) was administered as the maintenance dose. A sphenopalatine ganglion block was performed with 1.5 ml of 0.5% bupivacaine using a 22-gauge needle. Cases with nasal polyposis, leading to an inability to visualize the sphenopalatine foramen through the nasal endoscope, were subjected to sphenopalatine ganglion block through the pterygoid-maxillary-palatal approach. The subjects in the control group were infiltrated with 5 ml of 2% lignocaine with adrenaline (1:2,00,000) in each nostril as per the standard local infiltration technique for endoscopic sinus surgery. All endoscopic sinus surgeries were performed with an endoscopic shaver under orotracheal intubation. The intraoperative surgical field was graded according to the 6-point endoscopic surgical field grading system (0: No bleeding; 1: slight bleeding with no suction required; 2: slight bleeding with occasional suctioning; 3: Slight bleeding with frequent suctioning with surgical field gets filled up by blood few seconds later; 4: Moderate bleeding, surgical field filled up with blood just after suction; 5: Severe bleeding, suction doesn't clear the surgical field and surgery is not possible) [10]. The postoperative pain of patients was measured by a blinded observer according to the visual analogue scale (VAS 0–10; 0 being no pain and 10 being severe, intolerable pain) after just full recovery from general anesthesia, 4, 8, and 24 h of surgery. During the observation period, no analgesics were given to any of the patients before or after surgery. Anyone with a pain VAS of 8 or higher, or who refused to continue with the study, received rescue analgesia in the form of oral or parental diclofenac.

The data was calculated as mean with standard deviation. The surgical grades and pain score were compared between groups while intra-operative hemodynamic parameters were compared to find their effect on surgical field score. Statistical analysis was done by applying ANOVA (Analysis of Variance) for repetitive observations while chi-square test was used for

non-repetitive observation. *P* value of less than 0.5 was considered significant.

Results

No complications occurred either during surgery or afterward in the study group.

The study had 25 subjects each in case and control group with mean age of 45.24 ± 13.97 years and 35.64 ± 15.19 years respectively. These groups had significant difference in the age of the enrolled subjects. The study constituted of 32 subjects with chronic rhinosinusitis with polyp (13 case group and 19 control group as per the randomization).

The case group's intraoperative systolic and diastolic blood pressure was 133.46 ± 9.95 mmHg and 73.50 ± 8.43 mmHg respectively, with heart rate of 83.66 ± 12.48 beats per minute. The control group's intraoperative systolic and diastolic blood pressure was 137.15 ± 9.69 mmHg and 74.86 ± 10.67 mmHg respectively while heart rate was 82.2 ± 11.76 beats per minute. Statistical analysis did not show any significant difference ($p > 0.05$).

Surgical field view during surgery

The 6-point endoscopic surgical field grading scale was used to evaluate the intraoperative surgical field. There were statistically significant differences between the case and control groups (Table 1). Grade 2 surgical field was present in 56% of the case group's participants.

Table 1 Endoscopic sinus surgical field

Surgical field grade	Case (number/percentage of subject)	Control (number/percentage of subject)
Grade 1	6 (24%)	0 (0%)
Grade 2	14 (56%)	8 (32%)
Grade 3	4 (16%)	11 (44%)
Grade 4	1 (4%)	6 (24%)
Overall surgical field grade (Mean ± SD)	2.0 ± 0.76*	2.92 ± 0.76

* Statistically significant ($p < 0.05$)

Surgical field and association with intraoperative parameters

The impact of intraoperative blood pressure and heart rate on the surgical field was investigated (Table 2). When patients with surgical field grade 4 and lower surgical field grades were compared with each other, those with the highest intraoperative pulse rates exhibited a statistically significant difference ($p < 0.05$). Furthermore, subjects with surgical grade 4 had significantly higher systolic blood pressure than those with lower grades ($p < 0.05$). Similarly, participants in grade 4 had higher intra-operative diastolic blood pressure, although this was not found statistically significant.

Pain score

By measuring pain with a visual analogue score, there was a substantial difference between the case and control. Although both groups saw a progressive increase in discomfort, the case group experienced significantly less pain over the course of 24 h than the control group (Table 3). On the second postoperative day, there was no apparent difference in the pain scores between the two groups. The control group had more subjects with higher visual analogue scores than the case group during the observation period (Figs. 1, 2, 3, and 4). Rescue analgesia was not used throughout the study period by either the case group or the control group.

Table 3 Pain visual analogue scale in case and control groups

Time	Case	Control	*P* value
0 h	2.68 ± 1.75	4.64 ± 1.38	0.001
4 h	2.08 ± 1.22	3.60 ± 1.73	0.000
8 h	1.60 ± 1.29	2.72 ± 1.72	0.006
24 h	0.76 ± 1.13	1.20 ± 1.00	0.076

Table 2 Effect of pulse rate and blood pressure on surgical field

Surgical field grade	Pulse rate (in beat per minute)*	Systolic blood pressure (in mmHg)*	Diastolic blood pressure (in mmHg)
Grade 1	73.50 ± 10.29	131.67 ± 7.84	74.83 ± 7.38
Grade 2	80.59 ± 11.82	129.18 ± 10.64	71.55 ± 8.20
Grade 3	87.67 ± 12.58	137.20 ± 7.98	74.0 ± 7.77
Grade 4	93.43 ± 6.07	140.43 ± 7.11	77.43 ± 11.16

* Statistically significant ($p < 0.05$)

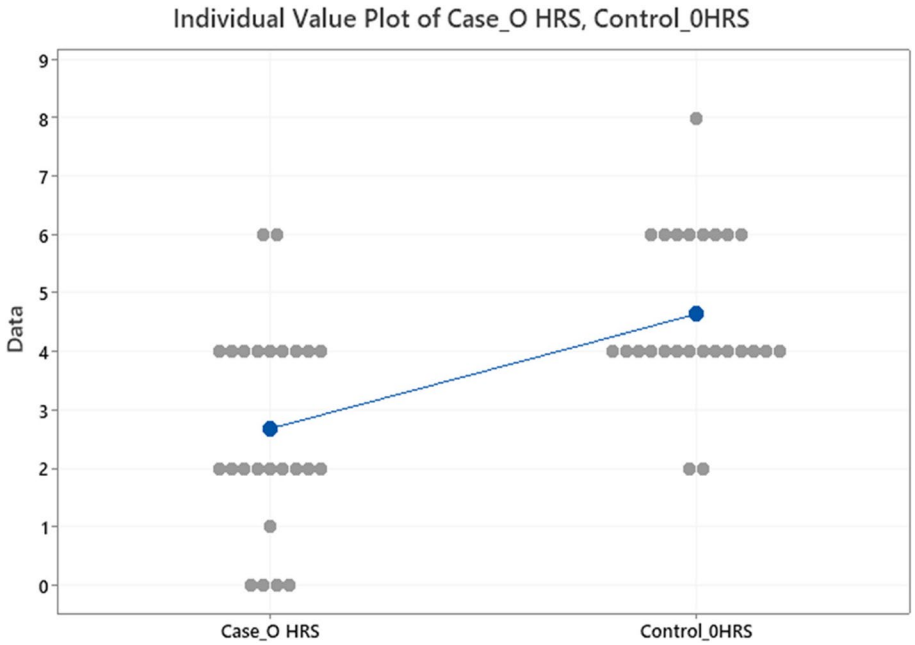

Fig. 1 Scattergram showing number of subjects in both groups at 0 h after surgery

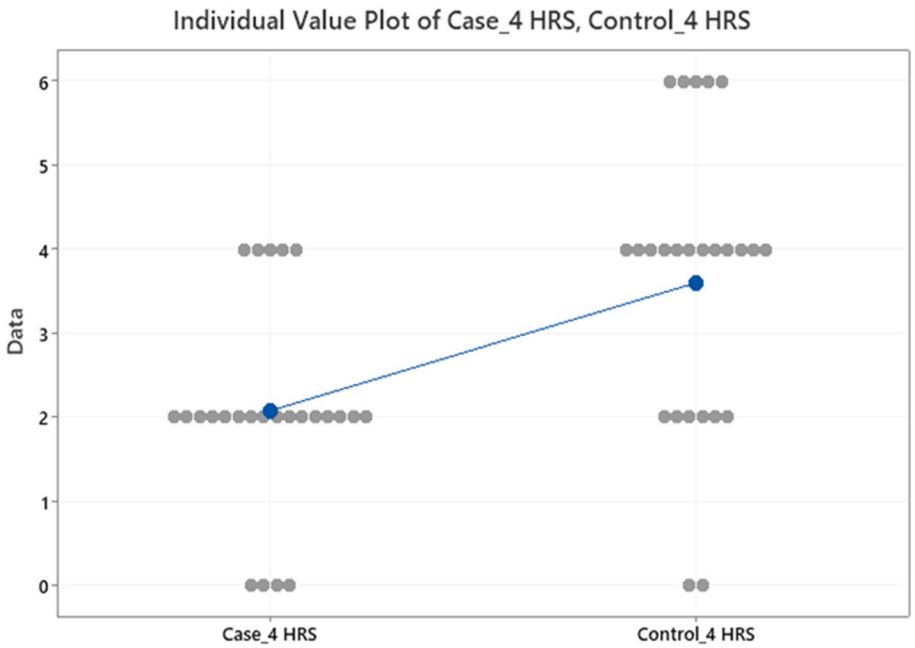

Fig. 2 Scattergram showing number of subjects in both groups at 4 h after surgery

Discussion

In ENT practice, endoscopic sinus surgery is a routine surgical procedure. Due to the rich neurovascular supply of the sinonasal region, any trauma results in excruciating pain and hemorrhage. A successful surgical procedure necessitates a good hemostasis since it considerably lowers the risk of complications. There is severe pain for serval hours after endoscopic sinus surgery [11].

The highest concentration of neurons in the head and neck is found in the sphenopalatine ganglion, also known

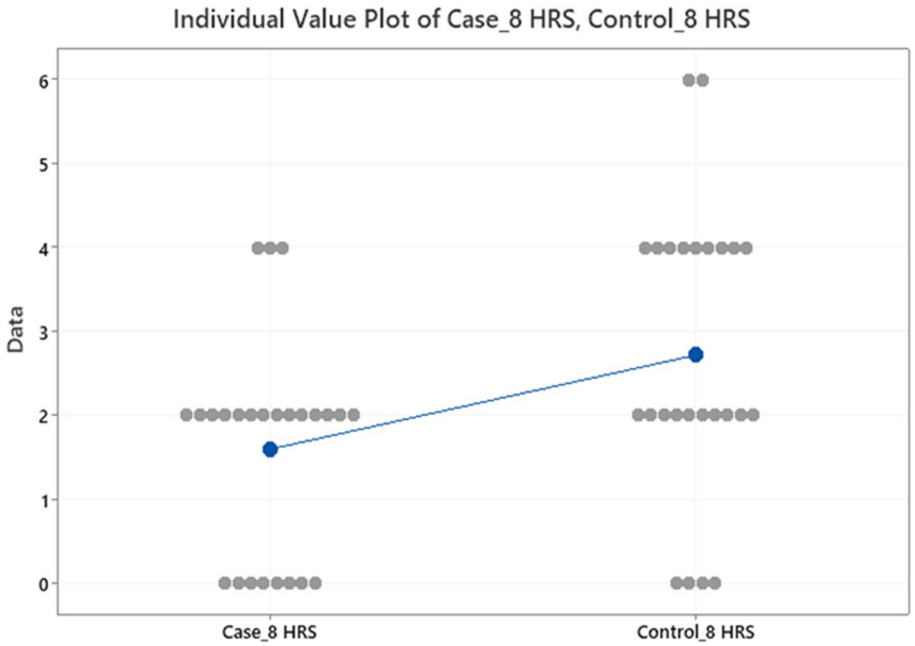

Fig. 3 Scattergram showing number of subjects in both groups at 8 h after surgery

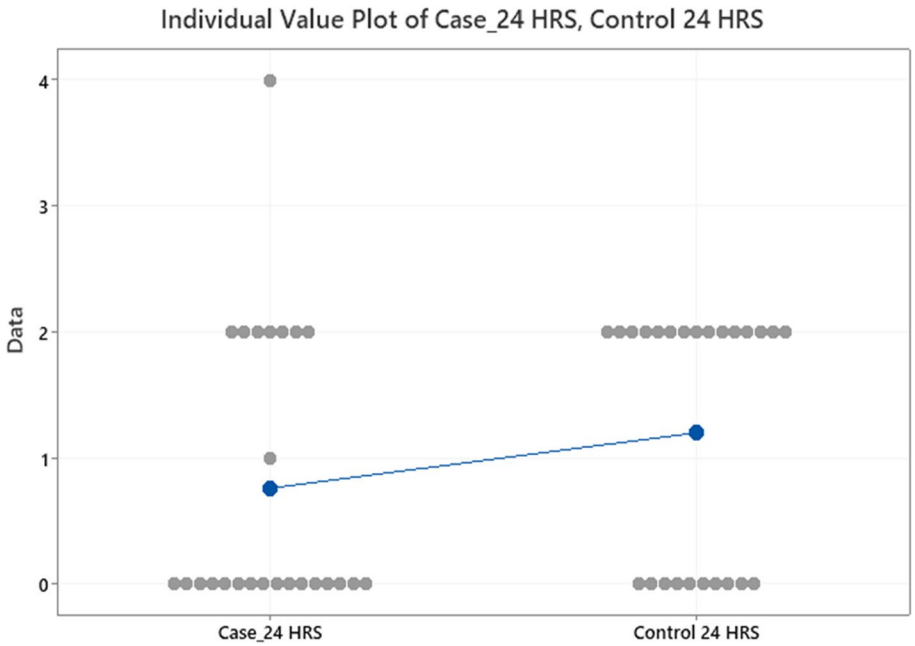

Fig. 4 Scattergram showing number of subjects in both groups at 24 h after surgery

as the pterygopalatine or Meckel's ganglion. The orbit, nose, palate, and buccal mucosa are all supplied by the trigeminal and facial nerves, while the superficial and deep petrosal nerves, respectively, carry sympathetic and parasympathetic fibers. Due to the ganglion's thin layer of connective tissue and mucous membrane, local anesthetic medication diffusion is sped up, resulting in efficient ganglion blockade. Additionally, autonomic neural block results in less blood flow to the affected location, which improves the working field [1].

Compared to lignocaine, bupivacaine is a more effective and long-lasting local anesthetic agent [1]. It is utilized for local infiltration or epidural anesthesia for the treatment of postoperative pain. As a result of its lipophilic nature, it is quite effective at low concentrations. With high doses, it can sometimes result in cardiac arrest and more vasodilation than lignocaine [2–8].

Sphenopalatine ganglion stimulation is an emerging field of research for refractory cluster headaches [9]. The patient's sphenopalatine ganglion, which is stimulated during a headache, is covered with a remote-controlled microelectrode. Although this technique has been proved to be effective, it is linked to serious adverse effects that can last for up to 30 days, including headache, face pain and swelling, and toothaches.

The present study was carried out on Indian patients for the first time. Twenty-five patients received the sphenopalatine block, while the other 25 subjects in control group did not receive the block as the authors hypothesized that placebo in control group could have caused ganglion irritation, discomfort, and bleeding during surgery. The present investigation discovered a statistically significant difference in surgical field vision and pain level between the case and control groups. A study was conducted by Kesimci et al. [8] to evaluate the effects of bupivacaine, levobupivacaine, and saline in 15 patients each having endoscopic sinus surgery. In all participants, they discovered substantial variations in pain VAS up to 24 h. Additionally, they found that bupivacaine and levobupivacaine reduced blood loss in sphenopalatine block patients, but there was no statistically significant difference between these drugs and the saline group. Rezaeian et al. [6] conducted a study in 40 subjects undergoing endoscopic sinus surgery. They used 1.5 ml bupivacaine 0.5% for SPGB in the case group while control group received 1.5 ml of saline in sphenopalatine ganglion. They found significant difference in pain visual analogue score at 0, 4, 8 and 24 h after surgery. However; the case group required significantly lowered rescue analgesia as compared to control group. Similarly, Al-Qudah et al. [7] did double blind, placebo-controlled randomized trial in 60 subjects undergoing endoscopic sinus in under general anesthesia. They used 2 ml of 2% lignocaine with epinephrine or 2 ml of saline for SPGB at the end of surgery. They found statistically significant decreased pain visual analogue scores in patients with sphenopalatine ganglion block with lignocaine. Kim et al. [3] published a meta-analysis of eight published studies comparing sphenopalatine ganglion block with local anesthetic agents and placebo in 2019. They found statistically significant differences in intraoperative hemorrhage, postoperative pain, nausea and vomiting, and recovery. No adverse effects were found in the analysis. The trans-nasal route showed better control of intra-operative hemorrhage and postoperative pain. They recommended trans-nasal sphenopalatine ganglion block in endoscopic sinus surgery for a better clinical outcome.

According to a subsequent meta-analysis of six randomized controlled studies, published in 2021 by P. Wang, sphenopalatine ganglion block was found significantly advantageous at 6 and 24 h after surgery, [12]. Although, there was no significant difference during first two hours following surgery. Sphenopalatine ganglion block was also discovered to lessen postoperative nausea and vomiting.

The sphenopalatine ganglion block is risk-free, with only a small number of side effects, such as bleeding, nauseousness, headaches, visual abnormalities, and infrequently lateral rectus palsy [8, 12, 13]. However, it has been demonstrated that sphenopalatine ganglion block is helpful in reducing nausea and vomiting after endoscopic sinus surgery and septal surgery [14, 15]. Abubaker et al. [14] did a double blind, placebo-controlled randomized trial in 100 subjects undergoing endoscopic sinus surgery. They infiltrated sphenopalatine ganglion with 2 ml of 2% lignocaine with epinephrine in case group and 2 ml of normal saline in control group. They observed the subjects for 24 h and found significant decrease in the postoperative nausea vomiting in case group as compared to control group. They did not report any adverse effect in the study. Ekici et al. [15] did a randomized study in 60 subjects undergoing septoplasty. They did SPGB with bupivacaine in 30 patients while 30 did not had SPGB. They found significant lower pain score up to 24 h after surgery in SPGB group as compared to control.

There were some limitations of the present study. Sphenopalatine ganglion block has been discovered to work better under general anesthetic than under regional anesthesia [16]. Further studies are necessary since we lacked a comparator group in the current study for local, regional, and general anesthetic groups. Further, the outcomes were attained during operations without the use of hypotensive anesthesia; hence, sphenopalatine ganglion block with bupivacaine may be useful in settings with insufficient resources for hypotensive anesthesia. For a deeper comprehension of sphenopalatine ganglion block with bupivacaine, additional studies using hypotensive anesthesia are also necessary. Unequal distribution of subjects with polyp in both groups is another drawback that could have influenced the surgical field and hence a large sample size study is recommended. Further; we were not able to eliminate the confounding effect of intraoperative hemodynamic parameters on the various surgical grades in both groups individually due to a small sample size study.

Conclusion

The present study investigated the effect of sphenopalatine block with bupivacaine in endoscopic sinus surgery. It found statistically significant difference in the surgical field and visual pain score in the subjects receiving bupivacaine block. Although, the study had few limitations but sphenopalatine ganglion block is advisable in endoscopic sinus surgery to improve outcomes, according to the review of the literature and the current study.

Abbreviation

ESS	Endoscopic sinus surgery
mg	Milligram
kg	Kilogram
ml	Milliliter
ENT	Ear nose throat
VAS	Visual analogue score
mmHg	Millimeters of mercury
SD	Standard deviation

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None

Authors' contributions

SRJ and JST: conception, data collection, analysis, draft and final approval. RKA, MD, GC, and AT: conception, data analysis, critical review and final approval. All authors read and approved the final manuscript.

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Availability of data and materials

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

Declarations

Ethics approval and consent to participate

The study was carried out after Institutional Ethics Committee approval [IEC, IGMC Shimla approval number: HFW (MCII) B (12) Ethics/2020–675 dated January 11, 2021] and informed written consent from the enrolled subjects.

Consent for publication

All subjects have given informed written (Signed) consent for publication.

Competing interests

The authors declare that they have no competing interests.

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