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Diagnostic Methods

Evaluation of the efficacy of Superior Cluneal Nerve Block in low back pain: A prospective observational study☆

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ABSTRACT

Introduction: Superior cluneal nerve (SCN) entrapment giving rise to low back pain (LBP) remains undiagnosed many times; in this clinical study authors have evaluated therapeutic role of lidocaine injection of SCN for low back pain relief in patients with SCN entrapment.
Methods: The present study was a prospective, observational study; 25 patients with unilateral LBP over the iliac crest and buttock for more than six months not responding to conservative measures were included in this clinical trial. SCN lidocaine injection was done under fluoroscopy guidance; patients having more than 50% reduction in numeric rating scale (NRS) score, for at least 2 h following SCN injection, were enrolled in the study and followed for 6 months. The primary outcome measure was severity of LBP, measured by NRS score. Secondary outcome measures were percentage pain relief; Oswestry Disability Index (ODI) score, reduction of analgesic usage, DSM-IV score for psychological assessment. All these assessments were done prior to the procedure and at 2 weeks, 1, 3 and 6 months after the procedure.
Results: A significant reduction in the NRS scores was observed at 2 weeks, 1, 3 and 6 months after SCN lidocaine injection as compared to the baseline (P value < 0.05); authors also observed a significant pain relief and significantly reduced ODI scores, analgesic consumption and DSM scores compared to the baseline values (P value < 0.05).
Conclusion: A single SCN lidocaine injection provided significant pain relief in LBP patients with SCN entrapment for a period of 6 months.

1. Introduction

Low back pain is commonly attributed to facet joints, intervertebral disc, sacroiliac joint, muscles, and ligaments. The exact cause of non-radicular low back pain can be delineated only in 15% cases following detailed history taking, physical examination, and appropriate investigations; however, use of diagnostic interventions increases the possibility of identifying a cause in 85% cases (Sittitavornwong et al., 2013). Superior cluneal nerve (SCN) entrapment may be a source of low back pain in 10% of patients (Manchikanti et al., 2013). Many times, SCN entrapment remains undiagnosed on account of non-inclusion of SCN entrapment in the commonly available algorithms for low back pain management.

SCN entrapment gives rise to unilateral low back pain over the iliac crest and upper buttock; it may be associated with pain in the posterior thigh. This clinical presentation resembles other causes of low back pain like sacroiliac joint pain, facet joint pain, lumbar disc prolapse and myofascial pain. A simple method to identify SCN entrapment in this kind of clinical presentation is local anesthetic blockade of SCN at the posterior superior iliac crest; besides serving as a diagnostic block, local anesthetic blockade of SCN also provides long-term therapeutic pain relief. There is lack of clinical trials demonstrating the efficacy of local anesthetic blockade of SCN and its follow up; authors could find only few case reports and case

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series (Talu et al., 2000; Akbas et al., 2005; Aly et al., 2002; Maigne; Doursounian, 1997; Chiba et al., 2016) mentioning the role of SCN local anesthetic block.

In this observational study, authors have evaluated the efficacy of lidocaine injection of superior cluneal nerve for providing low back pain relief over a follow up period of six months.

2. Materials and methods

2.1. Study Design

The present study was a prospective, observational study; the study was conducted after approval from the Institute's ethical committee (IEC code: 2017-55-IP-96) and obtaining written informed consent from the patients; this clinical trial has been registered in the clinical trials registry, India (Registration number: CTRI/2017/05/008670).

2.2. Inclusion criteria

Patients in the age group of 18–60 years with the complaint of unilateral low back pain over the iliac crest and buttock for more than six months not responding to conservative measures were included in this clinical trial.

3. Exclusion criteria

Patients who had undergone spine surgery, vertebral fracture, infectious diseases of the spine, patients with radicular symptoms, uncontrolled psychiatric ailments, uncontrolled medical diseases, spine malignancy, coagulopathy, infection at the local site and patient's refusal.

3.1. Study intervention

The diagnostic criteria proposed for SCN entrapment is pain over the iliac crest and buttock accompanied by a trigger point over the posterior iliac crest 7–8 cm from the midline; the trigger point compression gives rise to radiating pain in buttock (Maigne, Doursounian 1997). The diagnosis of SCN entrapment was confirmed by lidocaine injection of SCN (Maigne, Doursounian 1997). This procedure was done in operation theatre under fluoroscopic guidance and full aseptic precautions. The patient was positioned prone and iliac crest identified in antero-posterior fluoroscopy view; a metallic marker was placed over the needle entry point at the posterior superior iliac crest 7 cm from the midline. Under fluoroscopy guidance, a 25G 10 cm spinal needle was inserted at the needle entry point; the needle was advanced in an end on fashion towards the iliac crest and 2 ml 1% lidocaine was injected after hitting the iliac crest (Fig. 1). A positive response was defined as $\geq$ 50% reduction in numerical rating scale (NRS) scores for at least 2 h following lidocaine injection; positive response confirmed the diagnosis of SCN entrapment and patients having a positive response were followed for a period of 6 months.

Post-procedure patients were kept under observation for 2 h and discharged after that. A fixed-dose analgesic combination containing, acetaminophen (325 mg) and tramadol (37.5 mg) was prescribed three times a day for one week in the post-procedure period; this analgesic dose was decreased to half if the NRS score of pain was less than 3 in the second week. The analgesic was discontinued in the third week if the NRS score was found to be less than 2; the patient was advised to take the same analgesic if NRS score was more than 3 on an as-needed basis during the study follow up period. A repeat injection of SCN with lidocaine was performed whenever the severity of pain increased to NRS score of $\geq$5 or pain relief decreased to less than 50%.

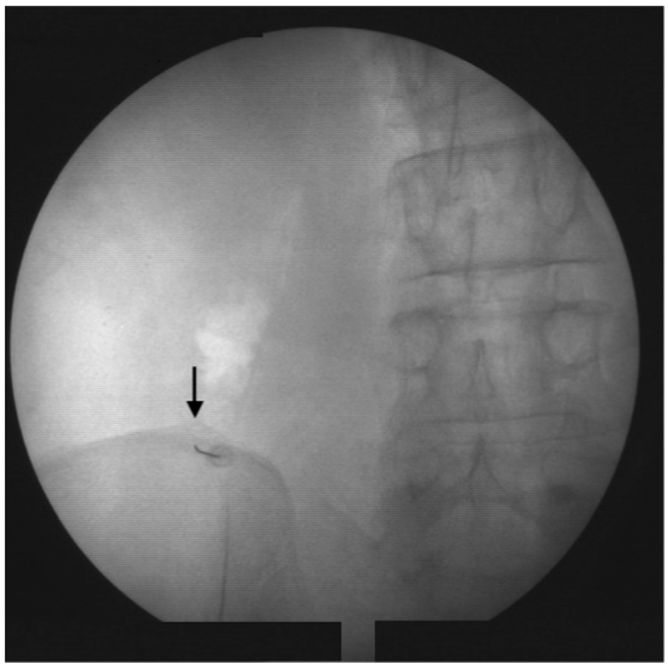

Fig. 1. Fluoroscopic image demonstrating needle position (arrow) for superior cluneal nerve block.

3.2. Outcome measures and assessment

The primary outcome measure was the severity of low back pain ($\geq$50% reduction in pain was considered significant); this was measured by NRS score (NRS: 11-point scale from 0 to 10, with 0 being no pain and 10 being the worst imaginable pain).

Secondary outcome measures were percentage pain relief ($\geq$50% pain relief was taken as significant pain relief); patient's functional status assessment by using Oswestry Disability Index (ODI) (Kroenke et al., 2001), reduction of analgesic usage, psychological assessment of patient by using DSM-IV scale (Diagnostic and Statistical Manual of Mental Disorders, 4th edition, 1994) (Fairbank et al., 1980); reduction of 50% or more of the analgesic dose was considered to be a reduction of analgesic dose; daily analgesic requirement of a patient was documented before the procedure. All these assessments were done before the procedure (baseline) and at 2 weeks, 1, 3- and 6-months post-procedure; the patient assessment between 2 weeks and 6 months of follow up was done by telephonic communication; these assessments were done by a research coordinator not involved in this study.

3.3. Sample size and statistical analysis

Twenty-five patients were included in this study. Paired *t*-test was used to compare pre and post-treatment results of NRS scores; Fisher's exact test was used to compare pre and post-treatment results of percentage pain relief and reduction of analgesic dose; Wilcoxon signed rank test was used for the comparison of ODI and DSM-IV; P value < 0.05 was considered as significant.

4. Results

The study was conducted from May 2017 to January 2018; 58 low back pain patients were interviewed for this study (Fig. 2); twenty-five patients were enrolled for this study (17 patients did

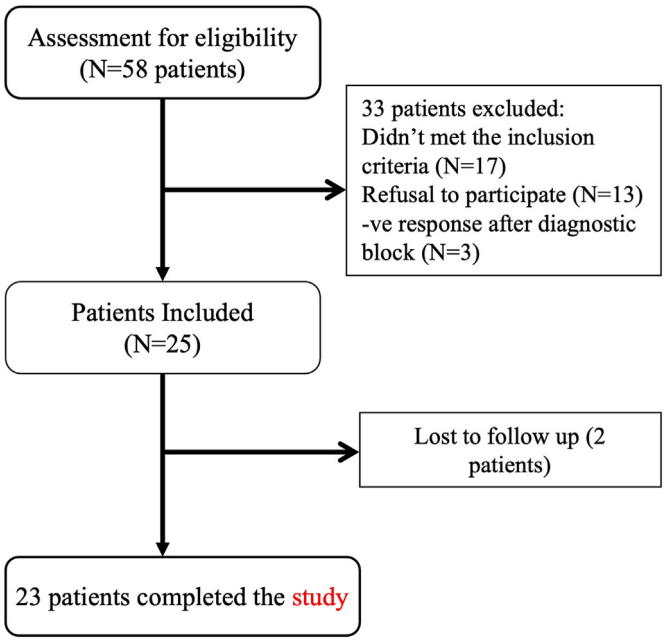

Fig. 2. Study design.

not meet the inclusion criteria; thirteen patients were not interested in participating in the study; positive response was not achieved following diagnostic block in 3 patients). Twenty-three patients completed the trial; two patients were lost to follow up after 1 month and 3 months of follow up; the outcome measure values at 1 month and 3 months follow up period for these patients were taken for subsequent follow up assessments to fulfil the intention to treat analysis. The demographic data of the patients is mentioned in Table 1.

All the patients included in the study had gluteal pain; seven patients (28%) had thigh pain, and 3 patients (12%) complained of leg pain below the knee. Change in postures and activity aggravated the patient's symptoms including standing posture (21 cases), sitting position (19 cases), forward bending (15 cases) and walking (12 cases).

The SCN lidocaine injection caused a significant reduction in the pain NRS scores after 2 weeks, 1, 3 and 6 months as compared to the baseline values (Table 2; P value < 0.05). A repeat SCN injection was required in 2 patients following an NRS score of more than 5 at 1 month and 3 months of follow up. ODI and DSM scores were also significantly decreased in all the patients at all times of follow up (Table 3; P value < 0.05); the majority of patients had reduced analgesic consumption and significant pain relief during the follow-up period of 6 months (Tables 2 and 3).

5. Discussion

The present study has demonstrated that lidocaine injection of the superior cluneal nerve is useful in reducing pain, analgesic requirements and disability from low back pain secondary to superior cluneal nerve entrapment. Lidocaine injection of SCN has served both the diagnostic and therapeutic role for the patients suffering from SCN entrapment.

Table 1
Patient demographics.

Demographic Variable	Demographic Data (N = 25)
Age (Years)	46.6 ± 13.7
Sex (Male: Female)	12:13
Weight (Kg)	59.7 ± 8.2
Height (cm)	157.5 ± 9.1
Duration of Pain (Years)	3.0 ± 2.7

Data are presented as either mean values ± SD or by absolute numbers.

The possibility of identifying a source of low back pain increases with the utilization of a diagnostic intervention; yet in many cases, a source of low back pain cannot be identified after using diagnostic tests for facet joint pain, sacroiliac joint pain, myofascial pain or discogenic pain. SCN lidocaine injection is not a well-known intervention presently; very few clinical studies have evaluated its role for low back pain relief. Results from well-designed clinical trials may suggest the inclusion of SCN local anesthetic injection in the future algorithms for low back pain management. Authors have conducted this clinical trial to evaluate the role of SCN lidocaine injection as a diagnostic and therapeutic intervention for low back pain management.

The present study demonstrated that SCN local anesthetic injection reduced the severity of pain (mean NRS pain scores were decreased by 81% compared to baseline after 2 weeks of injection; the mean NRS pain scores remained 76% decreased from the baseline after 6 months of injection at the end of study). During the study period, only two patients required a repeat SCN block. Kuniya et al. have reported a 34% decrease in the mean VAS scores 1 week after the injection (Kuniya et al., 2014), but the injection technique and details regarding the amount or concentration of local anesthetic used were not mentioned in this study. Different concentration and volumes of local anesthetic with or without steroid have been used for diagnostic and therapeutic purposes in the past; local anesthetics have been used in the range of 2–20 ml in different case reports or case series (Talu et al., 2000; Akbas et al., 2005; Aly et al., 2002; Maigne, Doursounian 1997; Chiba et al., 2016). Authors used 2 ml 1% lidocaine for SCN local anesthetic injection in the present study based on the clinical study from Chiba et al., (2016); the basic idea of our trial was to evaluate the efficacy of a defined protocol of SCN local anesthetic injection.

Many clinical studies, case reports or case series have used 2–3 ml 0.5–1% lidocaine for performing a diagnostic SCN injection (Maigne, Doursounian 1997; Chiba et al., 2016; Morimoto et al., 2013; Mahli et al., 2002); the SCN local anesthetic injection was repeated three to four times with or without steroid in many of these case series, following a positive response after a diagnostic SCN injection. In case of recurrence of pain following repeat SCN injections, alcohol neurolysis (Morimoto D et al., 2013) or surgical decompression (Maigne, Doursounian 1997; Chiba et al., 2016; Kuniya et al., 2014; Mahli et al., 2002) of SCN has been done for long-term pain relief; both these interventions have been claimed to provide long-term pain relief in cases of SCN entrapment. An interesting fact authors observed in few of these studies was that some patients achieved significant pain relief with SCN local anesthetic injection alone (Chiba et al., 2016; Kuniya et al., 2014); these patients didn't require any further intervention for pain relief.

SCN arises from the T11-L4 dorsal rami; it provides sensory supply to the upper half of the gluteal region and the iliac crest (Lu et al., 1998; Maigne et al., 1989). It has three branches; the medial, intermediate and lateral branches. The medial branch passes through an osteofibrous tunnel formed by the iliac crest and thoracolumbar fascia (Lu et al., 1998); it is in this osteofibrous tunnel that the medial branch entrapment usually occurs. The other two branches pierce the thoracolumbar fascia above the level of iliac crest (Lu et al., 1998). However, there is a controversy in the anatomical course of SCN branches; several variations were observed in the course of these branches (Kuniya et al., 2013).

The fibrous component of the osteofibrous tunnel is formed by the posterior layer of thoracolumbar fascia and latissimius dorsi muscle fibers (Lu et al., 1998). The contraction of the latissimus

Table 2
Outcome measures.

Follow up period	NRS Score (N = 25)	Patients with significant pain relief (N = 25)	95% Confidence Interval
Baseline	6.8 ± 1.3	0	–
2 weeks	1.3 ± 1.7 * (P = 0.001)	25 * (100%) (P = 0.001)	86.3%–100%
1 month	1.6 ± 1.8 * (P = 0.001)	24 * (96%) (P = 0.001)	79.6%–99.9%
3 months	2.1 ± 2.1 * (P = 0.001)	24 * (96%) (P = 0.001)	79.6%–99.9%
6 months	1.9 ± 2.1 * (P = 0.001)	20 * (80%) (P = 0.001)	59.3%–93.2%

Data are presented as either mean values ± SD or by absolute numbers. *P < 0.05 during comparison of baseline values with other follow up periods.

Table 3
Outcome measures.

Follow up period	Patients with reduced analgesic consumption (N = 25)	ODI (N = 25)	DSM-IV (N = 25)
Baseline	0	36.6 ± 14.5	9.6 ± 5.8
2 weeks	23 * (P = 0.001)	14.6 ± 12.4 * (P = 0.001)	2.5 ± 2.4 * (P = 0.001)
1 month	23 * (P = 0.001)	12.6 ± 9.8 * (P = 0.001)	2.4 ± 2.3 * (P = 0.001)
3 months	21 * (P = 0.001)	16.5 ± 11.4 * (P = 0.001)	2.6 ± 2.6 * (P = 0.001)
6 months	16 * (P = 0.001)	18.7 ± 13.5 * (P = 0.001)	2.7 ± 2.4 * (P = 0.001)

Data are presented as either absolute numbers or by mean values ± SD; ODI: Oswestry Disability Index; DSM-IV: Depression severity measure. *P < 0.05 during comparison of baseline values with other follow up periods.

dorsi muscle fibers during extension of lumbar spine or flexion and extension of the hip joint may increase the tension of the fibers of thoracolumbar fascia (Trescot 2003); this might contribute to the entrapment of SCN branches passing through the tunnel (Lu et al., 1998; Trescot 2003). Bone graft harvesting from the iliac crest for the spine surgeries might also contribute to the SCN fiber injuries (Banwart et al., 1995; Fernyhough et al., 1992) giving rise to low back pain. However, it is proposed that cluneal neuralgia secondary to SCN entrapment in the osteofibrous tunnel is more common than the SCN injury during bone graft harvesting (Trescot AM 2003).

Authors have found that the symptoms of the patients were maximally increased by prolonged standing (84% cases) and sitting positions (76% cases); other aggravating factors were forward bending (60% cases) and walking (48% cases). The aggravating factors mentioned in the literature include prolonged standing, sitting, or walking (9 patients in the present study); lateral bending and rotation (7–8 patients in the present study); and by sitting, rising and rolling over (8 patients in the present study).

The clinical features and aggravating factors of SCN entrapment resemble other causes of low back pain including lumbar disc prolapse, facet joint arthropathy, sacro-iliac joint pain and myofascial pain. A simple diagnostic test can confirm the diagnosis of SCN entrapment; in the present study, authors observed that SCN local anesthetic injection not only helped in diagnosing SCN entrapment, but it also provided therapeutic pain relief in 23 patients during the six months period of study follow up. Hence, authors recommend considering SCN entrapment as a probable diagnosis in the low back pain algorithms and using SCN lidocaine injection for diagnostic and therapeutic purposes.

5.1. Study limitations

Firstly, the sample size is small to comment upon the outcome measures including percentage pain relief, ODI, DSM-IV and reduction in analgesic consumption. A clinical trial with a control group and larger sample size is required to make a strong statement in favour of SCN block with respect to these outcome measures; a larger sample size would also help the investigators to comment upon the inclusion of additional clinical features like thigh pain and leg pain as possible symptoms of SCN entrapment. Secondly, follow up period of 6 months is small to comment upon the above outcome measures. Thirdly, the technique used for SCN lidocaine injection in the present study has been described in the literature (Maigne, Doursounian 1997), but there is a possibility that trigger point injection over the iliac crest might have produced pain relief.

6. Conclusion

Superior cluneal nerve lidocaine injection has provided significant pain relief to 80% study participants suffering from superior cluneal nerve entrapment in the present study over a period of six months follow up; hence, superior cluneal nerve lidocaine injection has served a useful diagnostic and therapeutic role in cases of superior cluneal nerve entrapment giving rise to low back pain.

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Presentation at a meeting

Nil.

CRediT authorship contribution statement

Sujeet Gautam: study concept and design; drafting/ revising; final approval. **Navneet Gupta:** Data acquisition; drafting/ revising; final approval. **Sandeep Khuba:** Data acquisition, drafting, revising; final approval. **Anil Agarwal:** Data Interpretation, drafting, revising; final approval. **Sanjay Kumar:** Data acquisition, drafting, revising; final approval. **Pravin Kumar Das:** Study Concept; drafting/ revising; final approval.

Declaration of competing interest

None.

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