

Randomized Trial



Pulsed Radiofrequency for Chronic Inguinal Neuralgia

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Background: Chronic inguinal neuralgia has been reported after inguinal herniorrhaphy, caesarean section, appendectomy, and trauma to the lower quadrant of the abdomen or inguinal region.

Objectives: This study was designed to evaluate the efficacy of pulsed radiofrequency in management of chronic inguinal neuralgia.

Study Design: Randomized, double-blind controlled trial.

Setting: Hospital outpatient setting.

Methods: Twenty-one patients were allocated into 2 groups. Group 1 received 2 cycles of pulsed radiofrequency (PRF) for each nerve root. In Group 2, after stimulation, we spent the same time to mimic PRF. Both groups received bupivacaine 0.25% + 4 mg dexamethasone in 2 mL for each nerve root. Visual Analogue Scale (VAS) was assessed. Duration of the first block effective pain relief was reported. Repeated PRF blockade was allowed for any patient who reported a VAS > 30 mm in both groups during the one year follow-up period. The number and duration of blocks were reported and adverse effects were also reported.

Results: Significantly longer duration of pain relief was noticed in Group 1 ($P = 0.005$) after the first block, while the durations of pain relief of the second block were comparable ($P = 0.59$). In Group 1 the second PRF produced pain relief from the twenty-fourth week until the tenth month while in Group 2, pain relief was reported from the sixteenth week until the eighth month after the use of PRF. All patients in Group 2 received 3 blocks (the first was a sham PRF) during the one year follow-up period. Meanwhile, 2 PRF blocks were sufficient to achieve pain relief for patients in Group 1 except 4 patients who needed a third PRF block. No adverse events were reported.

Limitations: Small sample size.

Conclusion: For intractable chronic inguinal pain, PRF for the dorsal root ganglion represents a promising treatment modality.

Key words: Radiofrequency, chronic, inguinal neuralgia

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Chronic inguinal neuralgia is an underestimated cause of short-term and persistent postoperative pain. It has been reported after inguinal herniorrhaphy, caesarean section, appendectomy, and trauma to the lower quadrant of the abdomen or

inguinal region (1-4).

The incidence of postoperative neuropathy following major pelvic surgery has been reported to be 1.9% (5). The prevalence of nerve entrapment in patients following a Pfannenstiel incision for various sur-

gical procedures has been reported as 3.7% (6). The risk for post-hernia repair chronic pain ranges from 7.83% to 40.47% (7). Unfortunately, 2% to 4% of reported post-herniorrhaphy chronic pain is severe enough to affect patients' daily activities (8). Persistent post-herniorrhaphy pain is mainly neuropathic, resulting from nerve injury, entrapment, or compression (9,10).

Patients with chronic inguinal pain may be treated by their primary surgeon, referred to a pain clinic, or infrequently, referred to a neurosurgeon. Existing treatments modalities for inguinal neuralgia are quite limited. Oral anti-neuropathic drugs have their own limitations including side effects with high doses and efficacy (11). A few specific treatment modalities have been suggested for chronic inguinal neuralgia pain, such as neurectomy (12,13), spinal cord stimulation (SCS) (14), and transcutaneous electrical nerve stimulation (TENS) (15). A case series of 5 patients with ilioinguinal neuralgia had reported the use of pulsed radiofrequency (PRF) as a tool for management of inguinal neuralgia (16). Therefore, this randomized blind clinical trial was designed to evaluate the efficacy of PRF as a treatment modality in management of chronic inguinal neuralgia.

METHODS

After the approval of the institutional ethical committee, 53 adult patients who were suffering from chronic inguinal pain for more than 6 month duration were referred to our institutional pain clinic from May 2010 to April 2013. Patients, aged 20 – 60 years old, who had chronic inguinal neuropathic pain (chronic lower abdomen, groin pain that might radiate into the superior medial thigh and the scrotum or labia major) for more than 6 months duration and reported positive response to the local anesthesia diagnostic blockade were included in the study.

Exclusion criteria included patients who had infection at the site of needle entry; coagulopathy; renal, cardiac, or hepatic diseases; glaucoma; senile; enlarged prostate; diabetes mellitus; and patients who refused to participate in the study. Patients who were suffering from somatic chronic inguinal pain or reported negative response to local anesthetics diagnostic blockade were also excluded.

Patient Evaluation

In the first visit to the pain clinic, after taking a medical history and thorough clinical examination, the type of pain was evaluated. Neuropathic pain was diag-

nosed according to Douleur Neuropathique en 4 questions (DN4) (17). Seventeen patients who were found to be suffering from somatic pain were excluded.

Thirty-six patients who received specific oral anti-neuropathic therapy (pregabalin 150 mg /12 hours) as the first line treatment were assessed after 10 days. In case of failure to achieve improvement (50% reduction of pain score), tricyclic antidepressant therapy (amitryptaline) was added in a dose of 25 mg at night. After one month, patients were re-evaluated to assess improvement, 11 patients who reported reduction of their pain by more than 50% were excluded from the study (Fig. 1).

Diagnostic Blockade

The study procedures had been explained (injection and follow-up) for the patients and a written informed consent was obtained. Twenty-five patients underwent fluoroscopically guided diagnostic selective T12, L1, and L2 nerve root blocks using 2 mL bupivacaine 0.25% for each nerve root. Four patients who reported a negative response to the diagnostic blockade were excluded from the study. Twenty-one patients who had positive responses to the diagnostic blockades were included in the study.

Study Procedures

Randomization was performed using sealed envelopes, indicating the group to which patients were assigned. A blinded chief nurse, who was not involved in the study or in data collection, read the number contained in the envelope and made the group assignment.

The patient was placed in a prone position and the lower dorsal and lumbosacral area was sterilized with betadine and draped with sterile towels with a pillow under the abdomen to straighten the dorso-lumber curve. Fluoroscopically guided localization of T12, L1, and L2 under direct anteroposterior view was performed and then T12-L1 end plates were aligned. The fluoroscope was turned obliquely to the symptomatic side until the facet joints of the respective levels were defined and the "Scotty dog" appeared.

Skin was anesthetized with 1% lidocaine using a 25-gauge 1½ inch needle at the "6 o'clock," position below the pedicle. A 22-gauge blunt straight radio-frequency needle with 5 mm active tip was inserted through the entry point and advanced under fluoroscopic guidance to the targeted dorsal root ganglion (DRG). Lateral views were then obtained to confirm proper placement of the tip of the needle at the fo-



Fig. 1. Antero-posterior view showed T12, L1, and L2 transforaminal epidural. The needles were close to the DRG and epidural spread of the dye can be noticed in all levels.

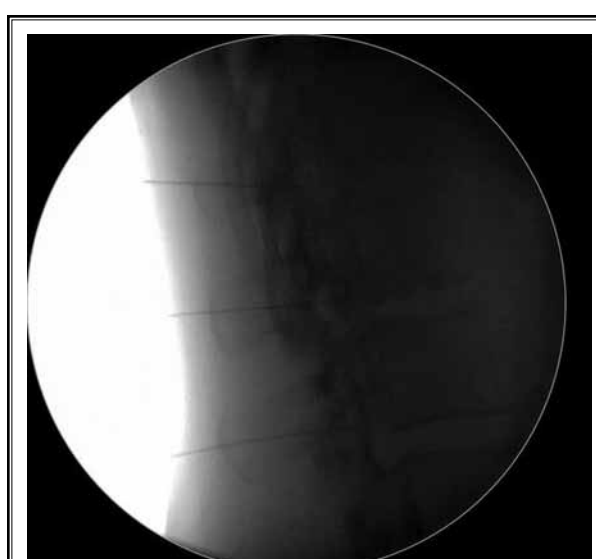


Fig. 2. Lateral view showed the needles in the foramen with anterior epidural spread of the dye.

ramen, dorsal to the epidural space. Injection of 1 mL nonionic contrast material (Omnipaque 300 mg/mL under continuous imaging) revealed epidural spread and excluded intravascular injection (Figs. 1,2).

The same steps were repeated for the L1 and L2 roots. Then sensory stimulation of the nerve roots was tested by eliciting parasthesia response in the dermatomal distribution of the affected nerve using Neurotherm Radiofrequency machine 1100 at 50 Hz and 0.4V – 0.6V). Motor stimulation was then tested at 2 Hz and voltage double the sensory threshold but at least one volt to elicit contraction in the paraspinal muscles for T12, and the inguinal and upper thigh only for L1 and L2 nerve roots.

One mL lidocaine 2% was injected for each nerve root and we waited for one minute to reduce patient discomfort especially with simultaneous PRF of the 3 DRGs. Group 1 received 2 cycles of PRF for the DRG at 42°C for 120 seconds for each nerve root. In Group 2, after stimulation, we spent the same amount of time to mimic PRF. Both groups received bupivacaine 0.25% + 4 mg dexamethasone in a total volume of 2 mL for each nerve root to ensure patients' blindness about the intervention (Fig.3).



Fig. 3. Antero-posterior view after injection of 1 mL lidocaine 2% and application of PRF electrodes.

Evaluation Parameters

A pain physician blinded to the assignment groups was responsible for follow-up of the patients and medical prescriptions according to the predetermined protocol. Patients were evaluated for pain severity us-

ing a Visual Analogue Scale (VAS) (100 mm unmarked line in which 0 = no pain and 100 mm = worst pain imaginable) before the block (basal), and every 2 weeks for 6 months and every month for another 6 months after the block. Telephone consultations were allowed if any increase in pain occurred during follow-up. Duration of the first block effective pain relief (VAS \leq 30 mm) was reported. If pain intensity (VAS) increased to more than 30 mm for 3 days in spite of acetaminophen 4000 mg/day, the patients received the same oral anti-neuropathic therapy used before for one month. When persistent pain was noticed (VAS \geq 30 mm), PRF was applied to the suffering patients in both groups using the same above mentioned technique and patients were re-evaluated for the efficacy and duration of the second block. Repeated PRF blockade (without local anesthetic and steroid) was allowed for any patient who reported VAS > 30 mm in both groups during one year of follow-up period and the number of blocks were reported. Adverse effects included neuritis and any sensory or motor deficits were also reported.

Statistical Analysis

A statistical analysis was carried out using SPSS version 16 (SPSS Inc., Chicago, IL). The descriptions of data were done in the form of mean \pm standard deviation for quantitative data and in frequency and proportion for qualitative data. Data analysis was done to test statistically significant differences between the 2 groups. For quantitative data, Student's t-test was used to compare the 2 groups. For qualitative data, chi-square test was used. *P* value was considered significant if \leq 0.05.

RESULTS

Fifty-three adult patients were recruited to be involved in this randomized blind clinical trial. They were suffering from chronic inguinal pain and referred from different clinics in our university hospitals, including general surgery, neurosurgery, and gynecological clinics.

History, clinical examination, and Douleur Neuropathique en 4 questions (DN4) confirmed the neuropathic nature of pain in 67.9% (36/53), and 32.1% (17/53) had somatic pain and were excluded from the study.

Eleven patients (30.6%) responded to the oral anti-neuropathic therapy and were excluded from the study. Twenty-five of 36 patients (69.4%) reported intractable inguinal pain that did not respond to medical therapy.

Diagnostic blockade was negative in 4 cases and those patients were excluded from the study. Blockade was proved positive in 21/25 of patients who were randomly allocated into 2 groups (Fig. 4).

Twenty-one adult patients aged between 20 and 60 years were randomly assigned into 2 groups. The demographic data, the affected side, duration of pre procedure pain in months, and types of operations were comparable in both groups (Table 1).

With the first block, a significantly longer duration of effective pain relief (VAS \leq 30 mm) was noticed in Group 1 compared with Group 2 (17.7 \pm 3.9 versus 7.6 \pm 1.6 weeks, *P* = 0.005) while the duration of effective pain relief of the second block was comparable (20.7 \pm 3.9 versus 20.4 \pm 2.6 weeks, in both groups, respectively, *P* = 0.59) (Table 1).

After the resolution of the analgesic effect of the first block, all patients (21) in both groups used the same oral anti-neuropathic for one month but their symptoms again had not improved.

Regarding the efficacy of the second blocks, in Group 1 the second PRF produced effective pain relief from the twenty-fourth week until the tenth month; while in Group 2, effective pain relief was reported from the sixteenth week until the eighth month after the use of PRF (Fig. 5).

All patients in Group 2 received 3 blocks (the first was a sham PRF plus local anesthetic and steroid and the second and third were PRF) during the one year follow-up period. Meanwhile, 2 PRF blocks were sufficient to achieve pain relief for patients in Group 1 except for 4 patients who needed 3 PRF blocks. No serious adverse events were reported during or after the interventional procedures.

Comparison of VAS between both groups during the follow-up period was comparable at the basal measurement and at the second week (*P* = 0.3, 0.46, respectively). Meanwhile it decreased significantly in Group 1 versus Group 2 from the fourth week until the fourteenth week of the follow-up period (*P* values were 0.026, 0.008, < 0.0001, < 0.0001, 0.006, and < 0.0001, respectively). It increased significantly in Group 1 versus Group 2 from the sixteenth week until the twenty-fourth week (*P* < 0.0001), but it was comparable at 7 and 8 months (*P* values = 0.1, 0.26, respectively). Then it decreased significantly in Group 1 at 9 months (*P* < 0.0001), while it decreased significantly in Group 2 from 10 months and onwards (*P* values were 0.04, 0.002, and < 0.0001, respectively) (Fig. 5).

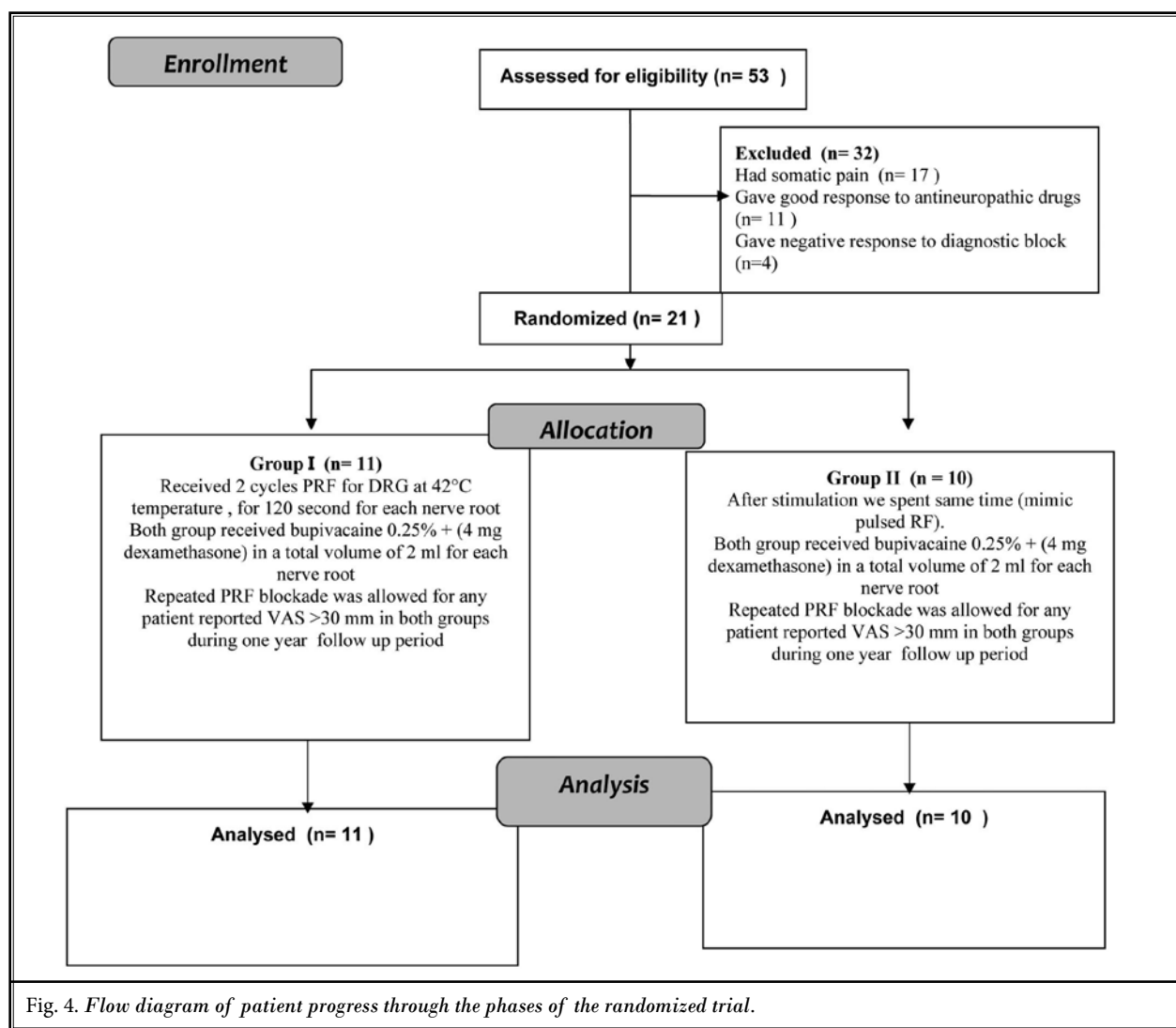


Fig. 4. Flow diagram of patient progress through the phases of the randomized trial.

Table 1. Patients’ demographic data, causative operations, duration of pre-procedure pain, and duration of pain relief after blocks in both groups.

	Group I (N = 11)	Group II (N = 10)	P values
Age (years)	38.1 ± 9.2	36.6 ± 9.4	0.89
Male/Female	7/4	5/5	0.85
Side (right/left)	6/5	6/4	0.8
Duration of pre-procedure pain (months)	23.1 ± 4.3	22.3 ± 5.1	0.52
Duration of effective pain relief of first block (weeks)	17.7 ± 3.9	7.6 ± 1.6	0.005 a
Duration of effective pain relief of second block (weeks)	20.7 ± 3.9	20.4 ± 2.6	0.59
Operation Types			
Inguinal herniorrhaphy	6	6	0.1
Cesarean section	3	4	
Appendectomy	1	0	
Hysterectomy	1	0	

a Significant difference between both groups.

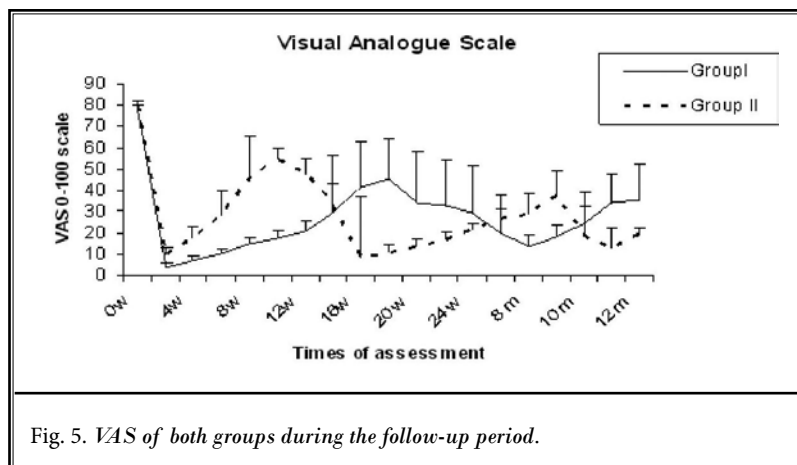


Fig. 5. VAS of both groups during the follow-up period.

DISCUSSION

The current study showed that PRF for DRG of T12, L1, and L2 nerve roots provided significantly longer lasting pain relief compared to local anesthetic and steroid selective nerve root blockade. It seems to be a safe and effective treatment modality for chronic inguinal neuropathic pain.

The pathogenesis of chronic inguinal pain following surgery is not completely understood. It may be somatic, visceral, and neuropathic. Injuries to the ilioinguinal, iliohypogastric, and genitofemoral nerves are well recognized causes of chronic postoperative neuropathic inguinal pain (18,19).

The choice of T12, L1, or L2 based on ilioinguinal and iliohypogastric nerves arises from the anterior rami of L1 with contributing filaments from the T12 while the genitofemoral nerve arises from L1 and L2 nerve roots (20). Klaassen and his coworkers (21) studied the anatomical variations of the ilioinguinal nerve in cadavers and reported that the ilioinguinal nerve originated from L1 in 65%, from T12 and L1 in 14%, from L1 and L2 in 11%, and from L2 and L3 in 10% so, the ilioinguinal nerve originated from T12, L1, and L2 in 90% of the specimens.

It is often difficult to identify the specific nerve injury that is giving rise to a patient's symptoms because these nerves are derived from overlapping nerve roots and distal communications may exist between the ilioinguinal and iliohypogastric nerves (22). Additionally, significant anatomical variability of the skin supply exists between the ilioinguinal and genitofemoral nerve, further obscuring the cause of a patient's pain (22). So, differentiation between the 3 nerves may prove difficult, and isolated nerve blockade or section may fail to eliminate the pain generator adequately and the only sure way to eliminate all causes of neuropathic inguinal pain is to block or section all the nerves (12,16).

Ectopic impulses responsible for neuropathic pain reach the central nervous system by propagating proximally from the site of the nerve injury (23). It is desirable that the nerve would be blocked proximal to the point of nerve injury. Therefore, our rationale was to perform proximal T12, L1, and L2 nerve root blockades using either local anesthetic and

steroid or PRF.

The role of selective nerve root blocks in providing accurate diagnosis prior to surgical intervention is limited (24). Diagnostic selective nerve root blocks have often been used to confirm the pain-generating nerve root. The aim of the diagnostic blockade in the current study was to confirm the diagnosis of chronic inguinal neuropathic pain rather than to determine which nerve was involved as we performed 3 nerve root injections simultaneously. Therefore, the overflow of the injectate from the injected levels into the epidural space would affect the specificity of the diagnostic blockade which made no difference to our predetermined protocol to perform PRF for the DRG of T12, L1, and L2 nerves which are the most commonly affected nerve roots whenever positive diagnostic blockade has been confirmed.

The mechanism by which PRF causes pain relief is debatable. A popular theory is that the rapidly changing electric fields produced by PRF alter the transmission of pain signals via a pathway involving c-Fos, a so-called immediate early gene (25). Higuchi et al (26) reported that the DRG exposed to PRF but not continuous RF at 38° had markedly increased c-fos expression in dorsal horn laminae I and II. Therefore, C-fos expression is not temperature dependent, but rather induced by pulsed electrical fields. On the other hand, van Zundert and his colleagues (27) demonstrated that continuous radio-frequency at 67° C, PRF at 42° C for 120 seconds, or PRF at 42° C for 8 minutes performed on rat DRG all increased c-Fos expression in the dorsal horn. These results are seemingly consistent with prior evidence that c-fos expression is temperature independent.

Existing medical treatments for inguinal neuralgia are quite limited and have fair results at best. The current study displayed that the majority of

our patients showed intractable chronic inguinal pain (69.4%) that did not respond to one month medical treatment using oral anti-neuropathic therapy (pregabalin 150 mg/12 hours and amitriptyline 25 mg at night) and 100% of those with intractable chronic inguinal pain did not respond to the same oral anti-neuropathic therapy started after resolution of the analgesic effect of the first block. This is supported with the results of previous studies which reported that chronic inguinal pain is almost resistant to anti-neuropathic therapy (28,29).

In comparison with local anesthetic and steroid injection, PRF produced a significantly longer duration of effective pain relief (17.7 ± 3.9 vs 7.6 ± 1.6 weeks) after the first block. PRF produced an average duration of effective pain relief of 19.7 ± 3.5 weeks for the overall 32 PRF blocks performed in both groups. In accordance with the results of the current study, Cohen and his colleagues (30) reported approximately comparable mean duration of pain relief (4.74 months) after DRG PRF performed for chronic postsurgical thoracic pain.

Rozen and Parvez (16), in a case series of 5 patients, reported a duration of effective pain relief of 6 to 9 months. The relatively shorter period of effective pain relief reported in our study may be attributed to the difference in RF needle criteria in both studies. In our study we used 22 G 5 mm active tip needles while in the other study 20 G 10 mm active tip needles were used, which may be associated with a more extensive blockade increasing proportionally with the width of the needle (31,32). Peripheral nerve radiofrequency for ilioinguinal neuropathy had been used for treatment of chronic inguinal pain. A case report describing the use of PRF for management of ilioinguinal neuralgia near the anterior superior iliac spine showed satisfactory pain relief after 3 months of follow-up (33). The evidence of PRF in post-inguinal herniotomy pain is fairly limited as revealed by the systemic review of Werner et al (34).

Another study that had compared ilioinguinal and iliohypogastric nerve radiofrequency neurolysis versus local injection under computed tomography (CT) guidance at the anterior superior iliac spine revealed that the duration of pain relief was statistically significantly prolonged in the RF group (12.5 months) compared to the infiltration group (1.6 months) (35). However,

the retrospective nature of the study and difficulty in localization of peripheral nerves with the need for CT usage which is time and money consuming were the main limitations. Compared with thermal conventional RF, PRF avoids the possible complications of post-procedure neuritis, motor dysfunction, and deafferentation pain especially in non-cancer patients. Pain physicians should consider temporary but possibly long-lasting alternatives such as PRF especially if these techniques are reproducible and have reported durable pain relief with less risk of complications (16). No serious adverse effects were reported in the current study apart from local pain at the site of injection which spontaneously improved within 2 or 3 days.

In the present study, pain recurrence after PRF occurred in all patients and repeated PRF was performed in both groups. Even after surgical neurectomy, Zacest and his coworkers (36) reported recurrent pain in 68% of their patients presumably due to regrowth of nerve fibers, which may again become mechanosensitive.

Whereas adverse events in the present study were self-limited, the potential exists for more serious complications such as paraplegia following procedures at nerve roots in the lower dorsal and upper lumbar area from injury of the artery of Adamkiewicz which arises in 85% of people between T9 and L2, mostly on the left side (37). The authors avoided usage of particulate steroids and used a nonparticulate one (dexamethasone) and injected the contrast under continuous fluoroscopic imaging through the study. Catastrophic events have also been attributed to vascular injury from needle placement (38). Thus, besides the risks associated with transforaminal and/or RF procedures such as bleeding, infection, and nerve injury, caution must be exercised to avoid damaging the blood supply to the spinal cord.

The limitations of this study include the small number of cases and the study was not powered.

CONCLUSION

In conclusion, for intractable chronic inguinal pain, PRF for the DRG represents a promising treatment modality. It is superior to local anesthetic and steroid injection. It provides effective pain relief for about 20 weeks and can be repeated.

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