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Initial experience of CT-guided pulsed radiofrequency ablation of the pudendal nerve for chronic recalcitrant pelvic pain

M.D. Collard [a], Y. Xi [a], A.A. Patel [a], K.M. Scott [b], S. Jones [c], A. Chhabra [a,d,*]

[a] Radiology Department, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390, USA
[b] Physical Medicine and Rehabilitation Department, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390, USA
[c] Anesthesia and Pain Management Department, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390, USA
[d] Orthopedic Surgery Department, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390, USA

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AIM: To evaluate initial experience with computed tomography (CT)-guided pulsed radiofrequency ablation (pRFA) of the pudendal nerve in cases of recalcitrant neuropathic pelvic pain. Endpoints include technical feasibility, safety, and efficacy of therapy.

MATERIALS AND METHODS: Ten patients who underwent pRFA ablation for neuropathic pudendal nerve pain during the trial period were followed for response to treatment for 6 months. Each patient was treated with pRFA under CT-guidance with concurrent perineural injection of anaesthetic and/or corticosteroid. Pain scores were then measured using a numeric rating scale at fixed intervals up to 6 months.

RESULTS: All procedures were considered technically successful with no immediate complications. pRFA demonstrated improved duration of pain improvement compared to the most recent perineural injection (p=0.0195), but not compared to the initial injection (p=0.64). Reported pain scores were lower with pRFA than with both the first and most recent injection but this did not reach statistical significance (p=0.1094 and p=0.7539, respectively).

CONCLUSION: Overall, pRFA of the pudendal nerve using CT-guidance can be a safe and effective therapy. This technique provides direct visualisation of the nerve to maximise safety and efficacy while offering a novel form of therapy for patients with chronic, recalcitrant pelvic pain.

Introduction

Chronic pelvic pain has become recognised as a relatively common disorder, most frequently encountered in women, with a broad range of proven and suspected aetiologies. Although there remains some debate regarding a discrete definition, this disorder is typically described as non-

* Guarantor and correspondent: A. Chhabra, Department of Radiology, UT Southwestern Medical Center, Dallas, TX 75039, USA. Tel.: +1 (214) 648 7770.
E-mail address: avneesh.chhabra@utsouthwestern.edu (A. Chhabra).

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cyclical pain localised to the superficial or deep pelvis lasting for at least 6 months.[1] Reported prevalence in western nations has been reported from 4–15% of adult and elderly women, closely approximating the rates of asthma and back pain, while some studies have reported rates as high as 27% in females.[2,3]

These patients can present to various clinical settings and see multiple specialists, most commonly gynaecologists and urologists. A significant proportion of both men and women consult general practitioners, physiatrists, and pain medicine physicians for this problem. Although quantification has been difficult, there is undoubted significant healthcare costs associated with this disorder, primarily related to clinic visits, medications, and ambulatory procedures, with severe cases resulting in surgeries such as laparoscopy and hysterectomy.[4] Furthermore, the patient morbidity related to this disorder is significant and often severe, frequently limiting occupational function, sexual function, and overall quality of life.

Within the umbrella of chronic pelvic pain, there are specifically described urogenital and rectal pain syndromes that can be distinguished by their anatomical region of pain, such as vulvodynia and proctodynia.[5] These anatomical regions of pain are frequently related to a specific peripheral nerve distribution, made more certain by the presence of neuropathic pain symptoms, such as burning or allodynia.[6] In contrast to the typical neuropathic pain of diabetes mellitus, pelvic neuropathy is more frequently associated with prior trauma or surgery, although many cases of apparent neuropathy have no identifiable cause.

One of the most frequently cited nerves to be associated with pelvic neuropathy is the pudendal nerve. This nerve is known to primarily provide sensory innervation to the perineum and external genitalia, with some innervation to the external urethral and anal sphincters.[7] Although commonly associated with prior surgery or trauma, pudendal neuropathy is also proposed to have associated entrapment syndromes, most likely related to its proximity to the sacrospinal and sacrotuberous ligaments.[7,8]

The treatment of neuropathic pain, and pelvic neuropathy specifically, is frequently a multimodal approach, both due to the various forms of treatment available and the inconsistent therapeutic responses within and between these patients. Medical therapy is typically the first line, with medications directed at neuropathic pain such as gabapentin and tricyclic anti-depressants. Although opioid analgesics can be useful during acute pain flares, there is very little evidence to support their use in chronic pain syndromes. Pelvic physical therapy is variably reported to be of some benefit.[9,10] Beyond these options, the traditional subsequent treatments offered to patients include injections and surgery. Surgical neurolysis to resolve a suspected entrapment has demonstrated mixed results and is associated with relatively significant morbidity.[11,12]

Knowledge of the typical anatomical location of the pudendal nerve and its injury/entrapment site allows for the ability to localise directed percutaneous treatments. One commonly utilised approach is fluoroscopic guidance via a transgluteal approach using the ischial spine as a bony landmark, which has demonstrated some efficacy despite the inability to visualise the nerve itself.[13] Although there are reported uses of nerve monitoring to guide treatment, there are now greater studies reporting the use of ultrasound or computed tomography (CT) guidance for direct nerve visualisation.[7,14] Studies have shown that direct perineural injection of short-acting anaesthetic, sometimes combined with corticosteroids, can provide both diagnostic information and therapeutic relief of peripheral neuropathy.[15] Experience with steroid injections have demonstrated limited temporal relief of symptoms, particularly with repeat injection, leading to the exploration of additional forms of treatment.[16] One recent study demonstrated no incremental benefit to steroids over local anaesthetic alone, further clouding the picture.[17]

Nerve ablation has demonstrated the potential for significant, prolonged benefits without the risks of surgery. Studies have shown improvement with both cryoablation and radiofrequency ablation (RFA). For example, there are multiple studies from South Korea demonstrating treatment of peripheral neuropathy with pulsed RFA (pRFA), such as by treating the superficial peroneal nerve for complex regional pain syndrome, the occipital nerve for occipital neuralgia, and the genicular nerve for osteoarthritis of the knee.[18–20] Cryoablation has been used with promising results in chronic inguinal pain related to genitofemoral neuropathy.[21] The mechanism of action obviously differs between these types of ablation. Nerve ablation using cryoablation and continuous RFA (cRFA) are intended to completely disable the nerve and result in total denervation in hopes of providing permanent relief. Although this may be ideal for sensory nerves such as the genitofemoral nerve, ablative treatment of nerves with motor function could result in unwanted adverse effects. A potential alternative is pRFA. Peripheral neuropathy is believed to be at least partially due to inappropriate pain impulses being activated within the pathological nerve.[22] pRFA induces a neuromodulation effect, in essence recalibrating the nerve's ion channels and halting the inappropriate pain signals without causing complete denervation or affecting its motor functionality.[23] This has been shown to be effective with peripheral nerves as described above, with additional studies showing benefit for inguinal pain following herniorrhaphy, hip osteoarthritis, and phantom limb pain.[24–26]

Accessing these nerves for therapy has been demonstrated in various ways, from neural feedback guidance, to ultrasound, to direct visualisation via laparoscopy. Ultrasound guidance is perhaps the most documented in the literature, likely due to its relative availability, lower cost, and benefit of real time guidance.[27,28] Ultrasound, however, is limited by depth of access and field of view, making deeper ablations potentially more dangerous to surrounding structures. As such, CT-guidance can be of most use in these cases, with magnetic resonance imaging (MRI) offering a potential alternative although associated with significantly greater time and financial costs.[15,29]

CT-guided treatment of pudendal neuropathy has had limited description in the literature. CT-guided perineural injection has been shown to be successful temporarily, with

CT shown to offer superior visualisation of the pudendal nerve along its course.[14] To the authors' knowledge, there has been limited evaluation of the use of CT guidance for pudendal nerve pRFA, with preliminary results showing relative promise compared to other minimally invasive treatment methods.[30–32] This study seeks to broaden that experience and describe the authors' experience with this relatively novel treatment approach for patients that have failed less aggressive therapies yet sought to avoid surgical options.

Materials and methods

A retrospective analysis was performed of all patients having undergone pRFA of the pudendal nerve with approval from the institutional review board. The informed consent was waived. Ablation procedures were performed from November 2016 through February 2017. All patients were referred from a physical medicine and rehabilitation physician that specialises in chronic pelvic pain. These patients were all clinically diagnosed as having neuropathic pain in the pudendal nerve distribution, with diagnosis based on multiple factors including symptoms and medical therapy response. Patient reported onset of their pelvic pain and duration of pain prior to intervention was recorded. In addition, all patients had previously undergone magnetic resonance neurography (MRN) of the lumbosacral plexus and had been previously treated with at least one CT-guided perineural steroid and/or local anaesthetic injection with documented pain relief of >50% on a visual analogue scale. For the purposes of accurate analysis, one patient who underwent pudendal nerve ablation without signs or symptoms of neuropathy was excluded from analysis. All patients who underwent pudendal nerve ablation during this period were otherwise included.

Data regarding clinical history, imaging, medical, and surgical therapy was collected, as well as basic demographic information. Response to therapy was assessed using retrospective chart reviews of the medical records as well as with prospective telephone questionnaires. The pain symptoms were assessed qualitatively as well as quantitatively using the pain numeric rating scale (NRS) from 0–10 with 0 representing no pain whatsoever and 10 representing the patient's worst pain imaginable. Data regarding the patient's pain levels at regular follow-up intervals of 24 hours, 48 hours, 6 weeks, 3 months, and 6 months post-ablation were recorded from the pain response sheet that had been provided to the patients at the time of ablation as well as phone questionnaire. In addition, change in perceived quality of life was documented at the 6 weeks, 3 months, and 6 months intervals.

All ablation procedures were performed with CT guidance, with variable use of CT fluoroscopy based on operator preference. Procedures were performed with the assistance of radiology trainees with a single faculty attending who oversaw all ablations for consistent procedure performance. All procedures consisted of pRFA using the Neurotherm 2000iX Radiofrequency Generator (St Jude Medical, Saint Paul, MN, USA). Data related to the procedure including sedative medications and duration were collected.

All ablation procedures followed the same process: patients were brought to CT with a procedural nurse, positioned prone, and placed on cardiac and oxygen monitors, followed by performance of a pre-procedure timeout. Initial CT with radiopaque markers was used to plan needle placement, with superficial anaesthesia then achieved using 1% lidocaine along this track. A 22 G coaxial needle was then placed under intermittent CT guidance with tip terminating adjacent to the pudendal nerve in Alcock's canal, identified as the posterior-most structure within the pudendal neurovascular bundle. Confirmation of needle tip placement was achieved by injecting 1 ml of a 1:5 dilution of Isovue 200 iodinated contrast medium and verifying adequate localisation on CT. Once positioning was confirmed, ablation probes were placed into the coaxial needles and sensory neural stimulation testing was performed at 2.5 V and motor stimulation testing at 3 V. pRFA was then performed at 42°C for 120 seconds, at the completion of which 5 ml of a mixture containing 2 ml 1% lidocaine, 2 ml 0.5% bupivacaine, and 1 ml dexamethasone 4 mg/ml was injected in the perineural space.

Statistical analysis was performed by a faculty statistician. Descriptive statistics are listed as mean ± SD and counts for continuous and categorical data, respectively. Comparisons were done using the Wilcoxon signed rank test and Spearman's rank correlation. A p-value of 0.05 was considered statistically significant. SAS 9.4 (SAS Institute, Cary, NC) was used for all analysis.

Results

During the study period, 10 patients with neuropathic pudendal nerve pain underwent pulsed radiofrequency of a total of 14 individual pudendal nerves, with four patients undergoing bilateral treatments. Two patients were treated bilaterally twice for a total of 12 separate ablation procedures and 18 individual nerve ablations. Of the 10 patients included in the study, eight were female and two were male with average age 59.5±13.9 years (Table 1). The average BMI was 24.6±3. The median duration of time from initial symptoms onset was 54.5 months with range from 12–432 months. Four patients reported bilateral pain and thus had bilateral pudendal nerve pRFA performed, with three procedures performed only on the left and three only on the right (Table 2). MRN demonstrated abnormalities of the

Table 1
Demographics.

Age (years)	59.5±13.9
Body mass index	24.6±3
No. of ablations per patient	
One ablation	8
Two ablations	2
Laterality	
Left	3
Right	3
Bilateral	4

Table 2
Number of pudendal nerve perineural injections per patient prior to pulsed radiofrequency ablation.

No. of injections	No. of patients	No. of nerves
1	3	4
2	4	5
3	1	1
4	1	1
5	1	1
6	0	0
7	0	0
8	1	2
Total	10	14

pudendal nerve (hyperintensity and/or thickening) in 9/14 (64%) of nerves treated (Figs 1 and 2). The most recent pain exacerbation prior to pRFA was present for an average of 7±0.95 months.

All nerves were previously treated with at least one prior CT-guided perineural injection consisting of local anaesthetic and corticosteroid, with an average of 3±2 prior injections per nerve (range 1–8). Differences between first and last injection were analysed, with no significant difference in best pain score between the first and most recent perineural injections (p=0.2813), but with the most recent injection demonstrating significantly decreased duration of symptomatic improvement compared to the initial injection (p=0.0273; Table 3).

Procedure duration averaged 96±41 minutes from patient arrival at CT to patient departure to the recovery area, which included setting up sedation, time out, etc. The time from needle insertion for pudendal ablation and injection to removal ranged from 5–15 minutes. Sensory and motor testing was performed with each procedure, with patient sensation in the pudendal nerve distribution used as an additional indicator of proper probe placement. Where documented, sensory and motor testing was noted to have been perceived by all patients, except patient 5 who did not feel the sensory testing, and patient 10 who did not feel either sensory or motor testing but still underwent the ablation due to confirmed appropriate introducer needle placement on CT imaging.

All procedures consisted of concurrent lidocaine and bupivacaine administration, with concurrent corticosteroid administration performed at all ablation sites except three based on referring provider recommendation. Two pRFA procedures were performed with concurrent sciatic nerve perineural injection, with one of these patients also receiving a contemporaneous piriformis muscle injection of onobotulinumtoxin A (Botox).

Of the 14 total procedures, 12 were performed with moderate sedation using fentanyl and midazolam titrated for patient comfort with continuous monitoring by a procedural nurse. One patient elected to forego sedation based on personal preference and another with an allergy to opiate medications received only midazolam, with both

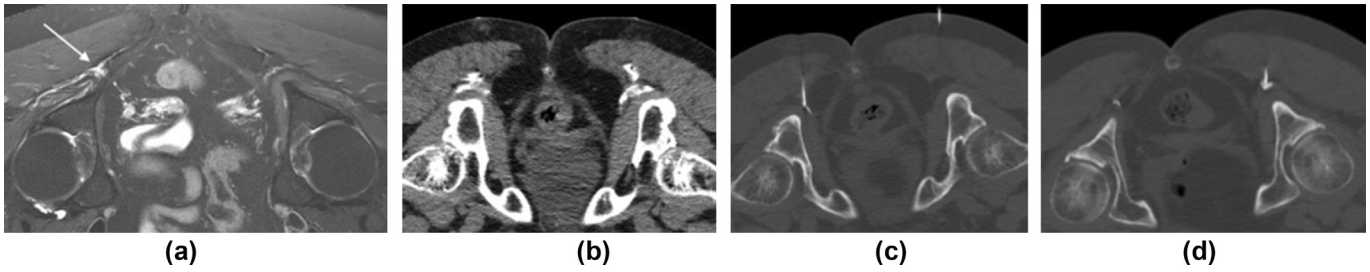

Figure 1 A 65-year-old woman with suspected bilateral pudendal neuralgia. (a) Axial T2 spectral attenuated inversion recovery (SPAIR) image shows a mildly hyperintense right pudendal nerve in the pudendal neurovascular bundle. (b) Initial perineural injection demonstrating injectate containing a mixture of iodinated contrast, anaesthetic, and corticosteroids spreading within Alcock's canal along the course of the pudendal nerve. (c) Bilateral pudendal nerve ablation with introducer needle in place on the right. (d) Post-ablation changes seen on the right with ablation probe in place on the left.

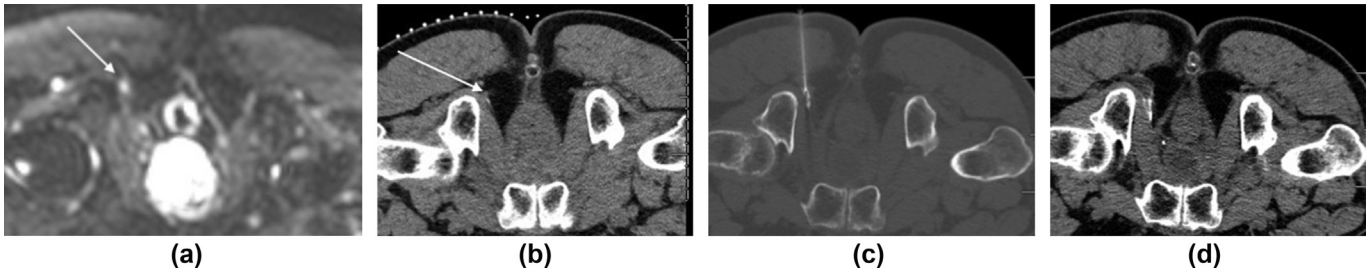

Figure 2 A 73-year-old man status post-prostatectomy for prostate cancer with chronic right pelvic pain since surgery. (a) Axial diffusion tensor imaging (DTI; b=600) image selectively shows the moderately hyperintense right pudendal nerve in the pudendal canal. (b) Planning CT acquisition demonstrating the isodense nerve just posterior to the adjacent denser blood vessel. (c) Pre-ablation CT image demonstrating contrast within Alcock's canal injected through the introducer needle. (d) Post-ablation CT image with expected ablation changes and injectate within Alcock's canal.

Table 3
Post-treatment pain scores and duration of pain relief.

Patient	Lowest pain score			Longest duration of relief (weeks)			Improved quality of life and decreased analgesic use after pRFA		
	First injection	Last injection	pRFA	First injection	Last injection	pRFA	At 6 weeks	At 3 months	At 6 months
1	0	0	0	12	4	12	Yes	No	No
2	2	1	5	1	1	2	No	No	No
3	4	N/A	0	0	N/A	3	Yes	Yes	Yes
4	4	4	0	0.1	0.2	12	Yes	No	No
5	0	0	0	3	1	3	Yes	No	No
6	1	N/A	0	3.5	N/A	37	Yes	Yes	Yes
7	7	N/A	3	0	N/A	3	No	No	No
8	5	4	0	6	4	8	Yes	Yes	No
9	6	0	8	4	0.1	2	No	No	No
10	6	4	6	0.1	0.1	0.1	No	No	No
Overall	3.1±2.8	2.4±2.6	2.1±2.3	3.4±4.1	1.5±1.7	6.8±10.4	6	3	2

patients reporting adequate comfort throughout the procedure. An average of 88±53 μg fentanyl and 1.3±0.6 mg midazolam was administered per procedure.

All procedures were considered technically successful, with technical success defined as confirmation that the introducer needle was placed in Alcock's canal based on pre-ablation injection of dilute water-soluble iodinated contrast (Figs 1 and 2), and the peak ablation temperature measured 42–43°C with total ablation duration measuring 2 minutes. No immediate complications were reported. One patient reported subsequently having a flare of her previously diagnosed interstitial cystitis, which was debated to possibly relate to the small injection of iodinated contrast medium during the procedure.

Lowest pain score following the first ablation was compared to lowest score following the patient's first and most recent perineural injections (Fig 3). Average lowest pain score following pRFA was found to be slightly lower than first and most recent therapeutic injections, with post-pRFA pain score average of 2.14±2.28 compared to 3.07±2.78 after the first injection and 2.36±2.59 after the most recent injection. These differences, however, did not reach statistical significance, with Wilcoxon signed rank test p=0.1094 of pRFA compared to the first injection and p=0.7539 of pRFA compared to the most recent injection (Table 3).

The duration of subjectively improved pain symptoms was then compared, evaluating the duration of time before pain scores either increased by two points or doubled, whichever occurred first (Fig 4). Following pRFA, pain scores remained improved for 6.75±10.44 weeks, compared to 3.42±4.07 weeks for the first perineural injection and 1.53±1.65 weeks for the most recent injection. Maximum reported length of time for pain improvement with pRFA was significantly longer than that for the most recent injection with p=0.0195, but not compared to the initial injection with p=0.64, using Wilcoxon signed rank test (Table 3). On an individual basis, three patients (2, 9, and 10) did not experience any significant therapeutic benefit, whereas patient 6 went on to develop complete indefinite pain resolution before being lost to follow-up after 6 months.

There was a variable time gap between when patients reported first experiencing their current symptoms as well as their duration of pain until their first perineural injection and first pRFA (Table 4). The duration of time during which

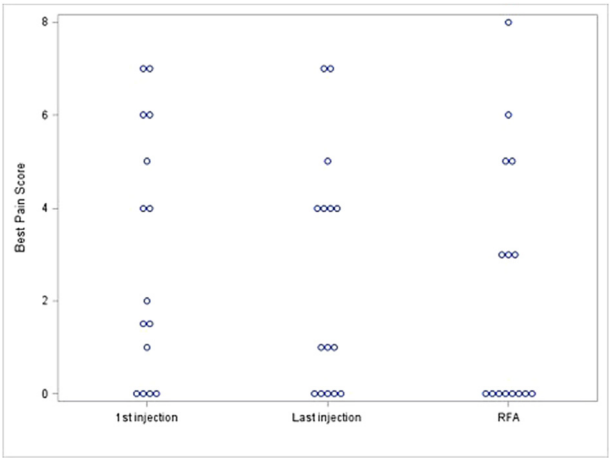

Figure 3 Pain score comparing first injection, most recent injection, and pRFA.

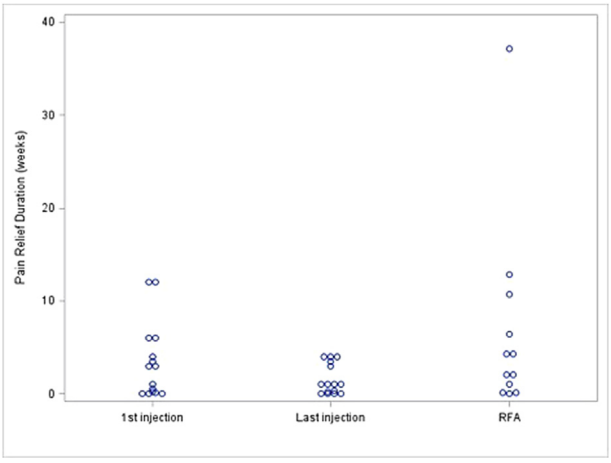

Figure 4 Pain relief duration comparing first injection, last injection, and pRFA.

Table 4
Time from pain onset to the first perineural injection, the first pulsed radiofrequency ablation (pRFA), and the gap between these two therapies (all times are given in weeks).

	Mean	SD	Median	Lower Quartile	Upper Quartile	Minimum	Maximum
Pain onset to first injection	330.4	457	270.4	108.7	306	44.3	1913
Pain onset to first pRFA	381.1	460.3	307.3	136	411.1	66.7	1934.3
Gap between injection and pRFA	21.6	18.6	11.3	7.1	37	4	60

the patient experienced their current symptoms leading up to their treatments was compared to the quantity and duration of pain relief (Table 5). There was no significant correlation between the time from the beginning of pain symptoms to the time of pRFA with regard to pain score, $\rho=-0.16$ ($p=0.58$), or the duration of pain relief, $\rho=-0.09$ ($p=0.79$). Furthermore, no significant correlation was found for the time between the last perineural injection and the first pRFA with regard to pain score, $\rho=-0.11$ ($p=0.68$), or the duration of pain relief, $\rho=$-0.14 ($p=0.67$).

Subjectively, improved quality of life was reported at the 6-week follow-up mark for five of the 10 patients, as well as in two of the 10 patients at the 3 months mark, and in two of the 10 patients at the 6 months mark. In each of the cases where quality of life was felt to have been improved, there was also reported use of decreased analgesic medications.

For purposes of completeness, the excluded patient with non-neuropathic pain in the pudendal distribution did not report any benefit from ablation, but later reported partially improved pain control with altered pharmacotherapy and physical therapy regimens.

Discussion

This study evaluates the authors' initial experience using pRFA for treatment of refractory chronic pudendal neuropathy. The patients included in this study are individuals who have had limited or waning benefits with medical or less invasive therapies and were eager to find additional therapeutic options.

The primary positive finding is that patients reported a significant increase in duration in pain relief symptoms following pRFA compared to their most recent perineural injection. No significant correlation was identified with regard to therapeutic effect and the duration of pain prior to treatment or the period of time between the perineural injection and the pRFA, although this may be due to the small sample size.

Table 5
Correlation of times between therapies and times from pain onset to therapy.

	Spearman correlation (ρ)	p-Value
Time from pain onset to pRFA vs best pain score	−0.16	0.58
Time from pain onset to pRFA vs pain relief duration	−0.09	0.79
Time from last injection to pRFA vs best pain score	−0.11	0.68
Time from last injection to pRFA vs pain relief duration	−0.14	0.67

Perineural injections remain a good initial option for patients with this type of pain; however, some reports demonstrate a propensity toward disease progression and decreased pain relief and duration with successive perineural injections.[16] The ability to offer an additional therapy that can provide added benefit over typical nerve injections makes pRFA an excellent option for patients who no longer benefit from perineural injection. This is further strengthened by the minimal additional risk, as seen in this sample that had no immediate or directly related complications after 12 separate ablation procedures.

Although these procedures were found to be safe and variably effective, the incumbent costs and radiation exposure should be weighed, as well as the relatively long duration of the procedures, likely due to a variety of factors such as timeout, sedation, and establishing an aseptic environment.[27] This can be contrasted with MRI-guided interventions, which have been shown to be cost intensive, but offer significantly better visual localisation of nerves and other lesions.[33] This creates a trade-off that warrants further debate. There is distinct benefit to being able to perform CT imaging and localisation of RFA probe placement prior to an ablation or injection, and it may be that focusing on improved efficiency with CT-guided forms of this procedure can provide the optimal balance of efficiency, efficacy, and safety. The ability to combine this level of visualisation with intra-operative nerve monitoring can add an additional layer of safety to this procedure without significant additional cost or complexity.[34]

This study has limitations that warrant discussion. The sample size is considerably small, although it is a case series as compared to the case reports in the literature. Despite this fact, the initial feasibility results suggest this can be a safe procedure for patients without additional treatment options, with potential for significantly improved symptoms. This at least warrants further investigative trials with this therapy. Another limitation is the reliance on primarily subjective patient symptoms and lack of a control group. Based on the information available, the possibility of a placebo effect confounding the results cannot be refuted. Lastly, the patients in this study, although relatively small in number, feature varying disease patterns and aetiologies for their pain as well as concurrent treatment regimens, possibly confounding results.

Peripheral nerve RFA continues to demonstrate the potential for wide application for neurologically controlled processes. Recent trials have shown the ability to expand this therapy to the treatment of refractory hypertension

with renal nerve ablation, lumbar facet osteoarthritic pain with lumbar ablation neurotomy, and the treatment of hemicrania continua via ablation of the supraorbital nerve.[35–37] The data presented here demonstrate that pRFA can be a safe and effective option for patients with neuropathic pudendal nerve pain when combined with CT imaging, which can guarantee accurate therapeutic effect and minimised risk to the patient.

Conflicts of interest

The authors declare no conflict of interest.

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A.C. receives royalties from Jaypee and Wolters and also serves as a consultant for ICON Medical.

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