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Lumbar medial branch cryoneurolysis under ultrasound guidance: initial report of five cases

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Abstract

Aims: To assess the feasibility and preliminary results of ultrasound guided medial branch cryoneurolysis in the management of facet joint syndrome. **Material and methods:** Between March 2017 and August 2017, a total of 20 patients underwent medial branch blocks, 12 of which were positive. Five patients chose to participate in the study and 8 medial branch cryoneurolysis were performed. The primary endpoint of the study was the feasibility of the procedure. The secondary endpoint was the efficacy on pain assessed over the following year after the procedure. **Results:** Technical feasibility of cryoneurolysis under ultrasound guidance was 100%. Accurate needle positioning at the accurate target in the angle between the posterior aspect of the transverse process and the lateral aspect of the facet joint was achieved in all cases. Needle progression could be depicted with US guidance in all cases. Mean pre-procedural Visual Analogue Scale and Oswestry disability Index scores were 6.8 (range 5-8) and 20.6 (range 12- 31), respectively. Follow up showed a decrease of Visual Analogue Scale score at one month (1.75, range 0-7), and at three months (1.75 range 0-3), Mean self-reported improvement at 6 months was 76% (60-100%) and 77% at 12 months (50-100%). We report one case of failure at one month. No complications were noted during or after the procedure. **Conclusion:** Our findings suggest that ultrasound is a valid imaging modality to perform lumbar medial branch cryoneurolysis. Initial results show that cryoneurolysis under ultrasound guidance appears as a safe and effective procedure in patients suffering for facet joint pain.

Keywords: ultrasound guidance; facet block; facet denervation; low back pain; cryoneurolysis

Introduction

Chronic low back pain is one of the most common pain syndromes and represents an enormous burden and cost generator for society. Lumbar facet joint syndrome constitutes a common source of pain and represents a misunderstood, misdiagnosed and improperly treated pathology [1] although it has been reported in up to 47% of low back pain syndromes in the USA [2]. Management of facet joint pain include conservative management, intra-articular steroid injections and medial branch neurolysis. The latter is a validated treatment performed worldwide with dedicated guidelines edited by the interventional spine society [3]. Nerve fibers can either be destroyed by heat (radiofrequency) [4] or cold (cryoneurolysis) application [5]. Literature is replete with studies reporting the use of medial branch denervation with good results in the following year after the procedure [4,6-9]. However, all of the available studies assessing medial branch neurolysis report the use of X-Ray based imaging guidance (Fluoroscopy or CT). Some authors have reported the safe and effective use of ultrasound (US) guidance to perform spinal infiltrations [10-12]. Further, the use of US guidance to perform medial branch blocks has been validated in cadaver studies [13]. The objective of this study was therefore to assess the feasibility of medial branch cryoneurolysis performed under US guidance.

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Material and methods

Setting

This pilot study was prospectively conducted in our institution between April 2017 and August 2017 and follow up was performed until August 2019. Local institutional review board approval was obtained as well as written informed consent for all included patients.

Patient inclusion and study protocol

Patients were included in the study according to the following criteria: adult patient, positive medial branch block (as defined below) and low back pain >3 months.

Patients under anticoagulant or anti-platelet therapy or presenting back pain of possibly other origin (discogenic pain, acute pain, trauma) or ruled out by a negative block were not considered for inclusion in the protocol. Between March 2017 and August 2017, a total of 20 patients underwent medial branch blocks, 12 of which were positive. Five patients who underwent 8 cryoneurolysis sessions chose to participate and were therefore included in the study.

The primary endpoint of the study was the feasibility of the procedure, described as follows: possibility of accurately placing the cryoprobe in the articulo-transverse space, under US guidance and to perform at least one cryoneurolysis cycle with the following criteria: pre-stim reproducing low back pain and tingling sensation at an intensity of less than 1mA and post-stim after freezing of at least 3 mA.

The following criteria were assessed and considered as secondary endpoints: Visual Analogue Scale (VAS), Self-reported improvement (SRI) and Oswestry disability Index (ODI) scores at 1 and 3 months and SRI at 6 and 12 months, occurrence of post procedural pain and occurrence of complications.

Procedure

All cryoneurolyses were performed under local anesthesia with a C3 Cryosystem (Inomed®, Emmendigen, Germany) and an Aplio i800 ultrasound system (Canon Medical Systems Corporation, Otawara, Japan) using a i8CX1 MHz convex probe.

Patients were placed in prone position. A planning US was performed to detect the adequate facet joint levels and sono-morphologic targets (fig 1). Local subcutaneous anaesthesia was performed using 4 mL of Bupivacaine (0.5%). However, anaesthesia was not performed deeper than 25 mm from the skin entry point, in order to avoid a medial branch block. A 12 G coaxial needle (Inomed®) was then inserted by in-plane technique until the target (angle between the lateral aspect of the facet joint and the posterior aspect of the transverse process) was reached (Movie 1). A 2.0 mm cryoprobe was then introduced through the coaxial-needle. Stimulation and freezing steps included (fig 2): 1) a sensory stimulation at 100 Hz (pre- stim) which should create a tingling sensation described and felt by the patient, with an intensity of less than1 mA; 2) a motor stimulation at 2 Hz, with a maximum intensity of 5 mA, to exclude possible motor nerve needle contact; 3) a 2 minute freezing cycle followed these stimulations; 4) a control post freeze stimulation (post-stim) to confirm the absence of persisting tingling sensation after freezing; 5)in case of persistent facet tingling sensation, a second and even third cycle could be performed after slight needle adjustment, always under US guidance.

The patient was supervised 30 minutes at the interventional ultrasound unit and was then transferred back to the outpatient´s department of the Clinics of Neurosurgery.

The following intra procedural data were documented: procedure time (in minutes), intra-operative pain (using VAS scores), needle and ice ball depiction

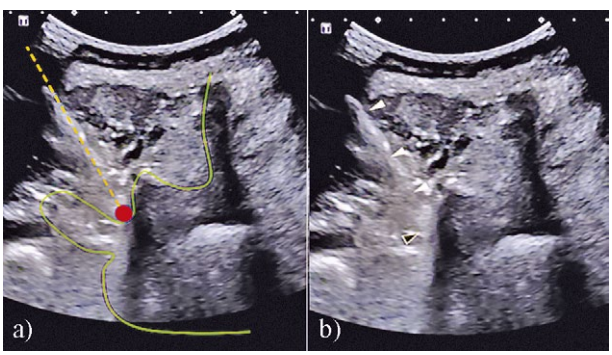

Fig 1. a) Example of an axial view at the L4-5 level showing the vertebral anatomical landmarks to be recognized and theoretical needle target located at the angle formed by the lateral aspect of the facet and the posterior aspect of the transverse process; b) axial ultrasound image showing the cryoneurolysis coaxial in place (white arrowheads) accurately located at the pre-planned target (black arrowhead)

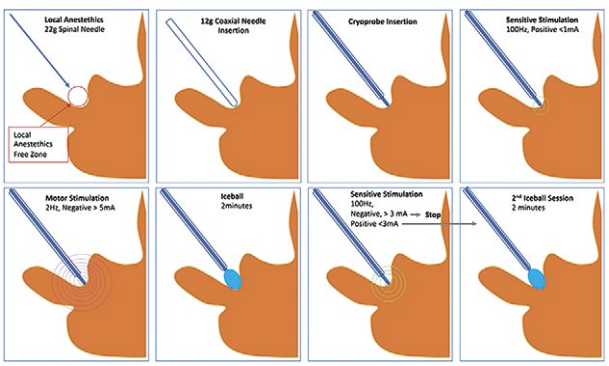

Fig 2. Schematic drawing illustrating all the steps of a cryoneurolysis

with greyscale and Duplex ultrasound (grey-scale- and Duplex-imaging)

Statistical analysis

In this observational study, descriptive statistics (means, standard deviations and extreme values) were used for cohort description, assessment of pain and procedure description.

Results

Patients

Five patients (2 males and 3 females with a mean age of 44.8 years) who underwent eight cryoneurolysis sessions were included. All patients showed a benefit from a previous positive medial branch block, defined as a decrease of pain >75% within the four hours following the procedure performed under US guidance. All of the included patients underwent unilateral L4-L5 and L5-S1 cryoneurolysis in one session. Three of the five patients suffered from bilateral pain and underwent two cryosessions. History of spine surgery was present in all but two patients. Details on pain follow-ups are described in table I.

Procedure

Technical feasibility as previously defined of cryoneurolysis under US guidance was 100%. Main procedure time was 29 minutes (range 19-43). Mean intraprocedural VAS score was 4.25/10 (range 2-7).

Imaging data

In all cases, accurate needle positioning at the correct target was achieved: the posterior aspect of the transverse process and the lateral aspect of the facet joint were clearly visible (fig 1), along with the depiction of the needle tip during needle progression (fig 1 and Movie 1, on the journal site).

During cryoneurolysis, detection of the ice ball formation was not possible in grey scale mode. However, Duplex US (Power Mode) allowed indirect visualization of the "ice ball-forming" in each of the cases (fig 3, Movie 2, on the journal site) due to freezing induced focal tissue motion at the cryo-tip.

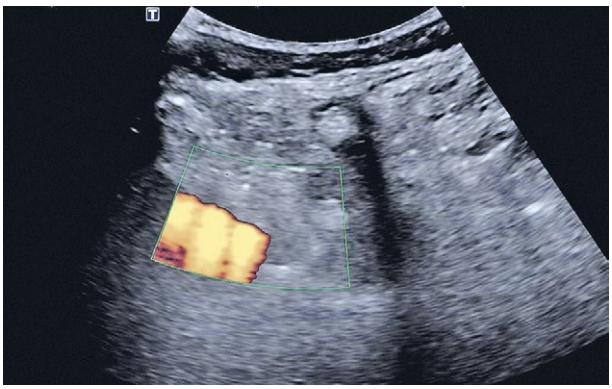

Fig 3. Image showing Power Doppler depiction of the ice ball formation during cryoneurolysis

Cryoneurolysis data

The mean sensitive pre-stim threshold obtained was 0.62 mA. In all cases and prior to freezing cycles, pre-freezing motor stimulation greater than 5 mA was obtained. In one case, motor simulation of the L5 root appeared at 2.5 mA which led to a needle repositioning. Mean number of freezing cycles was 1.8 per level. In all cases, a sensitive stimulation threshold greater than 3 mA was obtained after 1, 2 or 3 freezing cycles and determined the end of the procedure.

Pain

Mean pre-procedural VAS and ODI scores were 6.8 (range 5-8) and 20.6 (range 12- 31), respectively. Immediate post-interventional mean VAS score was 1/10 (range 0-3). At one month post procedure, mean VAS was score was 1.75 (range 0-7), mean ODI was 14.4 (range 8-22) and mean SRI was 75% (range 20-100). At three months post procedure, mean VAS score was 1.75

Table I. Information on pain for each patient

Patient	Pre procedure		Day 0	1 Month			3 Months			6 Months	12 Months
	VAS	ODI	VAS	VAS	SRI	ODI	VAS	SRI	ODI	SRI	SRI
1	7	12	0	0	100%	8	0	100%	8	80	100
2	7	12	0	0	100%	8	0	100%	8	80	100
3	5	24	1	1	70%	16	0	80%	12	80	80
4	5	24	1	0	70%	16	0	80%	12	80	80
5	7	13	2	2	80%	9	2	70%	10	70	60
6	8	31	2	0	100%	22	3	70%	19	70	70
7	8	31	2	7	20%	22	NA	NA	NA	NA	NA
8	8	18	3	4	60%	14	2	70%	13	60	50
Mean	**6.8**	**20.625**	**1**	**1.75**	**75%**	**14.4**	**1.75**	**82%**	**12.1**	**76%**	**77%**

VAS, Visual Analogue Scale; SRI Self-reported improvement; ODI, Oswestry disability Index

Table II. Procedure details for each patient

Patient	Session	Side	Level	Number of cycles	Stim data (mA)	Procedure time (min)	Intra procedural pain (VAS)	Ice ball depiction	
								Grey Scale	Power Doppler
1	1	left	L4/5	2	1	43	6	No	Yes
			L5/S1	1	0.4			No	Yes
	2	right	L4/5	2	0.6	28	4	No	Yes
			L5/S1	2	0.45			No	Yes
2	3	right	L4/5	2	0.7	38	7	No	Yes
			L5/S1	2	0.6			No	Yes
	4	left	L4/5	2	0.7	31	2	No	Yes
			L5/S1	2	0.5			No	Yes
3	5	right	L4/5	1	0.6	25	3	No	Yes
			L5/S1	2	0.8			No	Yes
4	6	left	L4/5	2	0.9	27	5	No	Yes
			L5/S1	2	0.5			No	Yes
	7	right	L4/5	1	0.4	19	2	No	Yes
			L5/S1	2	0.7			No	Yes
5	8	left	L4/5	2	0.5	21	5	No	Yes
			L5/S1	2	0.6			No	Yes
				1.81	0.62	**29**	**4.5**		

VAS, Visual Analogue Scale

(range 0-3), mean ODI was 12.6 (range 8-19) and mean SRI was 82% (50-100). Mean SRI at 6 months was 76% (60-100%) and 77% at 12 months (50-100%) (table II). We report one case of failure at one month, who benefited from a second facet denervation procedure, and was therefore excluded from long term analysis.

Complications

No complications were noted intra or post procedure.

No increase in pain following procedure was reported by the patients at follow-up.

Discussion

This study indicates that cryoneurolysis of the medial branch at the lumbar spine is a simple and safe procedure when performed under US guidance. Indeed, we report a 100% technical feasibility rate as cryoneurolysis was performed in all included patients with good stimulation thresholds and without complications. US therefore presents as an effective and safe guiding tool for performing medial branch cryodenervation.

Furthermore it has been reported that accurate needle placement is one of the major factors which will influence the outcome of a denervation techniques [4]. The appropriate technique was described in the International Spine Intervention Societyguidelines [3]. Emphasis was made on electrode placement which should lie parallel to the target nerve in order to achieve denervation along a substantial length of the nerve [14]. However, cryoneurolysis seems to generate a larger ablating zone at the needle tip [15] compared with radiofrequency [16]. This is particularly true with the 2.0 mm electrode used in this study, as the theoretical ice ball size at the needle tip is reported to be 5.5 mm x 8 mm. Therefore, fewer denervation cycles are needed to obtain effective neurolysis, as shown by our results with a mean number of cycles of less than two cycles.

X-ray based imaging modalities (CT and Fluoroscopy) have extensively been reported for denervation techniques [7,17,18] as osseous structures are depicted best. Nonetheless, imaging modalities allowing for "extraaxial" needle-insertions (i.e. Fluoroscopy or US) appear useful opposed to strictly axial slicing imaging modalities (i.e. computed tomography): thus fluoroscopy appears as the best tool for those procedures and is therefore the by far most frequently reported imaging modality and also one of the most available. Unfortunately, fluoroscopy remains an ionizing modality, both for the operator and the patient. These are major advantages of US: US is non-ionizing, widely available (which complies with the ALARA principle "as low as reasonably achievable" -and provides 2D-scans in any wished orientation (which is advantageous for any clear needle guidance)

Moreover, our results suggest that ultrasound is an imaging tool proving to be sufficient in depicting mandatory anatomical bony landmarks to perform medial branch

denervation, as the posterior aspect of the transverse processes and the lateral aspect of the facets were clearly defined in all reported cases by US (as hyperechoic, linear reflexes). To know and to detect US-spine anatomy is clearly mandatory to obtain an effective procedure: this has been reported previously in studies assessing US for spinal procedures [10-12,19,20] in which the authors described the mandatory spinal osseous landmarks for a safe and effective procedure. The same applies for cryoneurolysis, which requires precise needle placement at a predefined bony target. The needle tip was clearly visualized in all cases and therefore accurate needle placement could be ascertained. However, the ice ball at the needle tip was not depicted directly: some authors reported the visibility of the ice ball during cryoneurolysis under ultrasound, when performed superficially with a high frequency transducer [21]. However, a recently published study for assessing real time ex vivo ice ball detection reported that the ice ball cannot be detected using a convex low frequency transducer and suggested that "Power Duplex Mode" (amplitude Duplex) should be used to monitor the ice ball [22]. Our findings are concordant, as the ice ball was never depicted by greyscale ultrasound in our cohort, irrespective of the parameters used.

However, Power Duplex Imaging did on the other hand show the ring-down artifact as previously described but the extent of this artifact does not allow the usage of it as a marker of specific ice size and position. This finding suggests that the procedure should be done according to very strict protocol including both sensitive and motor stimulations. This allows multimodal validation of accurate needle positioning: the sensory stimulation threshold should be as low as possible (<1 mA) to confirm needle tip contact with the medial branch, and the motor stimulation should be as high as possible (>4 mA) in order to verify lack of needle tip contact with a surrounding motor nerve after US shows the morphologic correct needle position. In our series of patients, we report in this context one case of L5 stimulation with a threshold of 2.5 mA, requiring a needle re-positioning before freezing.

The limitations of our study include the small number of included patients and the short period of follow up which impact the strength of the results concerning pain evaluation. However, the aim of this study was to assess the feasibility of such a procedure.

Conclusion

Our findings suggest that US is a valid imaging modality to perform lumbar medial branch cryoneurolysis. Initial results show that cryoneurolysis under US guidance appears as a simple, safe and effective procedure in patients suffering of facet joint syndrome. Careful attention should be paid to patient selection. These findings must be confirmed in a larger series of patients.

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