Med. J. Cairo Univ., Vol. 90, No. 8, December: 2557-2563, 2022
www.medicaljournalofcairouniversity.net

Outcome of Combined Radiofrequency Medial Branch Rhizotomy and Steroid Nerve Block in Lumbar Facet Arthropathy: A Randomized Controlled Clinical Trial

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Abstract

Background: The facet joints are synovial joints that may be pain generators in patients with chronic low back pain. This is now well known as facet syndrome. The aim of this study is to provideour experience about efficacy, safety and technique of combined treatment with medial branch radiofrequency rhizotomy and steroid block for lumbar facet syndrome. Although radiofrequency ablation is frequently used, there is no high quality evidence for its efficacy.

Aim of Study: The aim of this study is to present our experience using combined treatment with medial branch radiofrequency neurotomy and steroid block in the management of chronic low back pain due to facet arthropathy. Technique, safety, and efficacy will be reported.

Patients and Methods: Thirty-eight patientswere managed by combined treatment with medial branch radiofrequency rhizotomy and steroid block (the intervention group). The VAS (Visual analog scale) before the intervention (pre-VAS), one week after the intervention (immediate post VAS), at one month (post VAS 1), at three months (post VAS 2) and at six months after the intervention (post VAS 3) were compared at each time point with the control group (38 patients). The control group received the best medical treatment and a regular exercise program for six months. Diagnostic block was done for all cases.

Results: There were significant differences between both groups concerning immediate post VAS, post VAS 1, post VAS 2 and post VAS 3 as the p-values were <0.01 in all relationships. No adverse events of infection, neurologic injury, or any other complication were reported.

Conclusion: Participants with lumbar facet syndrome who received combined treatment with medial branch radiofrequency rhizotomy and steroid block experienced significant clinical improvement compared to those who received conservative treatment.

Key Words: *Facet –VAS – Block – Radiofrequency – Rhizotomy.*

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Introduction

The facet joints are synovial joints allowing somegliding movements. The support of the lax capsule of these joints is partially by the ligamentum flavum anteriorly and by the supraspinous ligament posteriorly. The limitation of movements in the facet joints is mainly due to the outermost fibers of the annulus fibrosus [1]. When degenerative changesoccur in these fibres, excessive movement in the joint is allowed. This is the explanation why discdegenerative changes lead to facet joints degeneration [2].

The capsule of the facet jointand its synovial membrane are supplied by sensory innervations including unmyelinated C fibers [3]. In the lumbar spine, the medial branch runs from the neural foramen to the facet joint over the medial part of the transverse process at its junction with the superior articular process. Two medial branches supply every joint, one from above and one from the same level of that joint [4].

Radiofrequency (RF) facet joint neurotomy is applying a RF procedure to the facet joint to destroy the medial branches supplying it [5]. The rationale for this procedure depends on the concept that destroying the facet joint nerve supply will decrease the pain. It is indicated if there is complaint of persistent facet syndrome and if there is good response to diagnostic block [6]. The procedure includes running a high-frequency current via an insulated needle. The electric field leads to movement of molecules that causes thermal energy. The heat is directed to make a small lesion into the nerve that deactivates the pain signal [7].

Facet joint injections may be performed for both diagnostic and therapeutic indications. Diagnostic injection may be performed to confirm the

diagnosis of a facet syndrome [8]. Intra-articular steroid injectionmay be used for its antiinflammatory effect as a therapeutic procedure and long-term pain control may be achieved in some cases [9].

The aim of this study is to present our experience using combined treatment with medial branch radiofrequency neurotomy and steroid block in the management of chronic low back pain due to facet arthropathy. Technique, safety, and efficacy would be reported.

Patients and Methods

Study design:

This was a prospective randomized controlled clinicaltrial of participants with chronic lumbar paramedian pain (facet joint mediated pain) treated with medial branch radiofrequency neurotomy and steroid block. The control group received a regular exercise program in addition to medical treatment for six months. The patients provided informed consent. The study aim and design was approved by the medical and Ethical Committee of the Neurosurgery Department at our University.

Primary hypothesis:

Combined treatment with medial branch radiofrequency neurotomy and steroid block into symptomatic facet joint will improve participant-reported pain and function.

Study population:

Two hundred out of 3919 patients with chronic low back pain (LBP) were assessed for eligibility at our spine outpatient clinicbetween October 2018 and October 2020 based on the general inclusion and exclusion criteria set (Table 1). Seventy six patients met the inclusion criteria and were included into the study. Thirty eight patients were treated with medial branch radiofrequency neurotomy and steroid block. The other half was the control group. Randomization was done using random number table preferred by the statistician to determine to which group the patient was assigned.

General demographic information, including age and sex, as well as baseline outcome scores, were obtained from participant questionnaires and charts. Baseline information was obtained from each participant using visual analog scale. One week before the procedure, the patient provided informed consent, a baseline assessment, and blood samples to assess platelet count, white blood cell count, prothrombin time (PT), and International Normalized Ratio (INR) to make sure that all values were within normal.

Table (1): General inclusion and exclusion criteria set.

Inclusion criteria	Exclusion criteria
• Low back pain and tenderness (paramedian) >6 months	• Bleeding disorders
• Absent contraindications	• Undergoing anticoagulation therapy
• Positive diagnostic facet block	• Pregnancy
	• Presence of infection
	• Any psychiatric condition
	• Pediatric population
	• Previous lumbar procedure

Methods:

Patients were diagnosed with facet pain by clinical means, imaging, diagnostic injection, and by exclusion of other causes of LBP. Diagnostic block of the lumbar facet joints was done with local anesthetic and the patients that reported reduction of more than 50% on the visual analog scale after 30 minutes of the diagnostic block were included in the study.

Diagnostic block:

Using 22 gauge needles, the facet joints were injected under fluoroscopic guidance. The needles were directed intra-articular and 0.5ml lidocaine 2% were injected per joint. The needle intra-articular position was confirmed with injection of 0.25ml radiopaque contrast prior to the block. The facet joints with the most paravertebral tenderness with palpation were the joints to be blocked. Three groups of lumbar facet joints were made and the block was made for one group each time. The groups were Th12-L2, L2-L4 and L4-S1. Double level intra-articular injection was done to enhance the patient response. Bilateral block of both sides was done in patients with LBP on both sides.

The intervention group underwent a combined treatment of medial branch radiofrequency neurotomy and steroid block.

Radiofrequency facet ablation:

The procedure was done with the patients in the prone position on a radiolucent operating table with an abdominal cushion to decrease lumbar lordosis. Preparing the patient's back in a sterile fashion was done and the target point was identified using the C-arm fluoroscopic device. Local anesthetic was applied to the skin and subcutaneous tissues. The radiofrequency treatment was done with a RF generator using a thermocouple with 10cm electrodes (22G, 5mm active tip). Three or six RF cannulas were used according to the pathology was unilateral or bilateral. The RF cannulas were directed to the site of the medial branch of the dorsal ramus at the angle between the transverse

process and the superior articular facet. The radiofrequency cannulas should be parallel to the nerve to be lesioned (Figs. 1,2). Checking the impedance and stimulation was the next step.Sensory and motor stimulation were performed in all patients at 50 and 2Hz respectively. Injection of 1ml of lidocaine 2% before lesioning was done. Lesioning should be done by application of heat at 80 °C for 90 seconds. Injection of 20mg of methylprednisolone acetate into every ablated nerve was done.

The control group received medical treatment in the form of non steroidal anti inflammatory drugs, topical analgesics and nerve tonics. They received also regular exercise program performed by well trained specialists in physical therapy in our institute.

Follow-up questionnaires were then administered postoperatively.

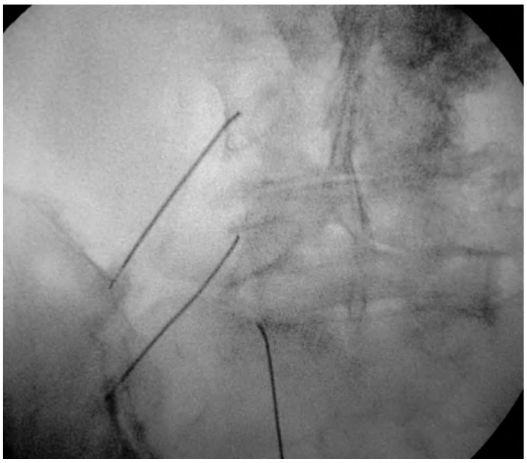

Fig. (1): Antero posterior fluoroscopic view of the latest position of the radiofrequency needles.

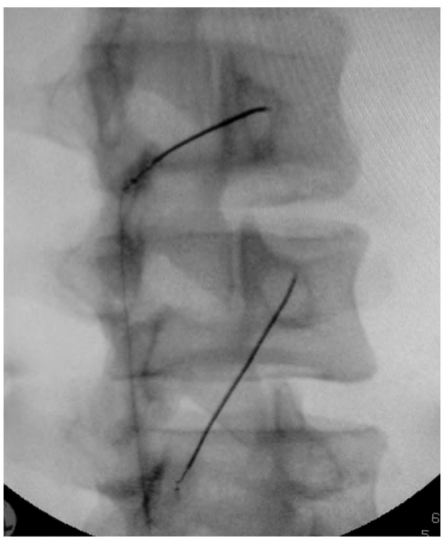

Fig. (2): Oblique fluoroscopic view of the final position of the radiofrequency needles.

Statistical analysis:

Data were statistically described in terms of mean ± standard deviation (± SD), and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student *t*-test for independent samples in comparing 2 groups of normally distributed data and Mann Whitney U test for independent samples for comparing not-normal data. Comparison of VAS over time was done using Freidman's test with Wilcoxon signed rank test for paired (matched) samples as posthoc multiple 2-group comparisons after applying Bonferroni adjustment for multiple comparisons. For comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. Correlation between various variables was done using Spearman rank correlation equation. p-values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

Power analysis:

Power analysis was done on comparing VAS between cases and controls as well as comparing VAS over time points within each group. For comparing VAS between cases and controls, Student's *t*-test for independent samples was chosen to perform the analysis, the α-error level was fixed at 0.05 and the sample size was entered to be 38 participants for each group. The intragroup SD was set at the highest recorded one (1.5 units). Power analysis showed that the intergroup difference that achieves 80% power is 0.7 units (actual calculated power = 81.5%). The power calculated by comparison of VAS between cases and controls was (pre VAS 53.1%, immediate post VAS >99.99%, post VAS 1 >99.99%, post VAS 2 >99.99% and post VAS 3 >99.99%). Regarding comparison of VAS over time points, we used paired *t*-test after setting the same α-error level and sample size. Power analysis showed that the intergroup difference that achieves 80% power is also 0.7 units. The power of the found differences is calculated. The power calculated by comparison of VAS over time points in the intervention group was (pre VASto immediate post VAS >99.99%, pre VAS to post VAS 1 >99.99%, pre VAS to post VAS 2 >99.99% and pre VAS to post VAS 3 >99.99%). The power calculated by comparison of VAS over time points in the control group was (pre VASto immediate post VAS >99.99%, pre

VAS to post VAS 1 >99.99%, pre VAS to post VAS 2 >99.99% and pre VAS to post VAS 3 = 99.99%). Calculations were done using PS Power and Sample Size Calculations Software, version 3.0.11 for MS Windows (William D. Dupont and Walton D. Vanderbilt, USA).

Outcome measures:

Patients were considered a categorical success if they achieved improvement in the VASone week after the procedure or after the conservative treatment (immediate post VAS) and at 1 (post VAS 1), 3 (post VAS 2), and 6 (post VAS 3) months post-treatment.

Results

Comparison between the radiofrequency and the control groups concerning the age, duration of symptoms and the VAS before and after the procedure (Table 2).

In the intervention group,the average age was 42.61 years old. The average duration of symptoms was 8.47 months. The average pre VAS was 7.89. The average immediate post VAS was 2.26. The average post VAS 1 was 3.58. The average post VAS 2 was 3.95. The average post VAS 3 was 4.87. There were significant differences between both groups concerning post VAS at each time point after the interventionas the p-values were <0.01 in all relationships. There were no significant differences between both groups concerning the age, duration of symptoms and pre VAS as the p-values were 0.880, 0.202 and 0.291 respectively.

Comparison between the radiofrequency and the control groups concerning the percent change (improvement) of pre VAS after the procedure (Table 3).

In the intervention group, the percent change of pre VAS immediately after the procedure was 71% (improvement). The percent change at post VAS 1 was 54.95%. The percent change at post VAS 2 was 50.14%. The percent change at post VAS 3 was 38.41%. There were significant differences between both groups concerning the percent change (improvement) of pre VAS after the procedure as the p-values at each time pointwere <0.01.

The relationship between the patient age, sex, duration of symptoms and the outcome in the intervention group (Table 4).

There were no significant differences between the patient age, sex, duration of symptoms and the outcome in the intervention group.

The relationship between pre-VAS and the post-VAS at each time point in the intervention group (Table 5).

There is a significant difference between pre-VAS and post-VAS at each time point after the intervention as p-value was <0.01 (p-values less than 0.05) in all relationships (Fig. 3).

In both intervention and control groups, all patients had chronic paramedian LBP. Diagnostic block was done in all cases. There were no complications in the study. In the intervention group, the number of males was 23, and the number of females was 15.

Table (2): Comparison between the radiofrequency and the control groups concerning the age, duration of symptoms and the VAS before and after the procedure.

Group	Age (years)	Duration of symptoms (months)	Pre VAS	Post VAS (immediate)	Post VAS 1	Post VAS 2	Post VAS 3
Controls:							
Mean	43.11	6.55	7.74	5.95	5.68	5.84	6.47
N	38	38	38	38	38	38	38
SD	14.877	3.073	0.554	1.184	1.544	1.480	1.447
Minimum	14	3	7	4	3	3	3
Maximum	74	13	9	8	9	9	9
Median	45.50	5.50	8.00	6.00	6.00	6.00	7.00
Cases:							
Mean	42.61	8.47	7.89	2.26	3.58	3.95	4.87
N	38	38	38	38	38	38	38
SD	13.758	8.664	0.727	1.131	1.926	1.859	1.647
Minimum	17	3	7	1	1	1	2
Maximum	70	48	9	5	9	9	9
Median	43.50	5.50	8.00	2.00	3.00	3.50	5.00

Values are expressed as mean ± SD.
VAS: Visual analog scale. N: Number. SD: Standard deviation.

Table (3): Comparison between the radiofrequency and the control groups concerning the percent change (improvement) of pre VAS after the procedure.

Group	Immediate post VAS % change	Post VAS 1 % change	Post VAS 2 % change	Post VAS 3 % change
Controls:				
Mean	–23.13	–26.37	–24.26	–15.92
N	38	38	38	38
SD	14.783	20.535	19.820	19.693
Minimum	–50	-63	–63	–63
Maximum	0	29	29	29
Median	–25.00	–25.00	–25.00	–13.00
Cases:				
Mean	–71.28	–54.95	–50.14	–38.41
N	38	38	38	38
SD	13.647	22.159	21.635	18.881
Minimum	–89	–88	–88	–75
Maximum	–44	0	0	13
Median	–73.21	–59.82	–56.35	–42.86

Values are expressed as mean ± SD.
VAS: Visual analog scale. N: Number. SD: Standard deviation.

Table (4): The relationship between the patient age, sex, duration of symptoms and the outcome in the intervention group.

			Age (years)	Sex (Male)	Duration of symptoms (months)
Spearman's rho	Pre VAS	Correlation Coefficient	–0.093	0.181	–0.058
		p-value	0.581	0.278	0.730
	Post VAS (immediate)	Correlation Coefficient	0.056	–0.013	–0.021
		p-value	0.737	0.939	0.899
	Post VAS 1	Correlation Coefficient	0.018	–0.021	–0.019
		p-value	0.914	0.901	0.910
	Post VAS 2	Correlation Coefficient	0.040	–0.054	0.070
		p-value	0.811	0.749	0.675
	Post VAS 3	Correlation Coefficient	0.048	0.041	–0.001
		p-value	0.775	0.807	0.995
	Immediate post VAS % change	Correlation Coefficient	0.090	–0.025	–0.071
		p-value	0.593	0.883	0.670
	Post VAS 1% change	Correlation Coefficient	0.053	–0.030	–0.027
		p-value	0.752	0.859	0.872
	Post VAS 2% change	Correlation Coefficient	0.060	–0.111	0.048
		p-value	0.718	0.506	0.773
	Post VAS 3% change	Correlation Coefficient	0.117	–0.020	0.001
		p-value	0.484	0.906	0.994

Table (5): The relationship between pre-VAS and the post-VAS at each time point in the intervention group.

	Post VAS (immediate) Pre VAS	Post VAS 1 Pre VAS	Post VAS 2 Pre VAS	Post VAS 3 Pre VAS
p-value	0.000	0.000	0.000	0.000

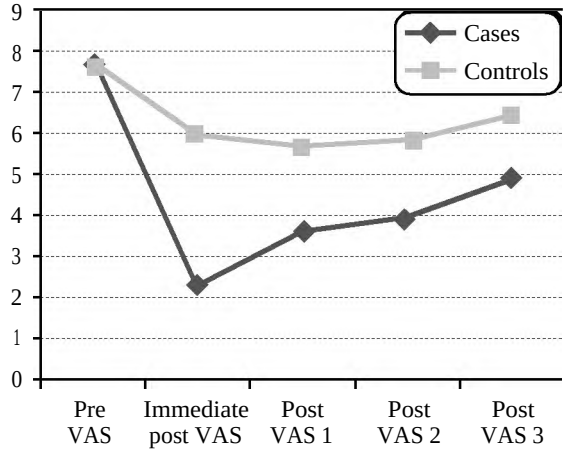

Fig. (3): The changes in the Visual Analog Scale in both groups.

Discussion

Radiofrequency interventions involve applying current flow from an active electrode to a ground plate. The body's tissue completes the circuit, making an electrical field. This electrical field leads to the creation of frictional heat dissipation, causing local tissue heating **[10]**. The rationale for the use of RF interventionsin low back pain is that these procedures can alleviate pain by ablating the nerves supplying the structures causing the pain **[11]**.

The facet joint is a synovial joint and may be affected by any of the inflammatory processes that involve joints, including rheumatoid arthritis and osteoarthritis. The fibrous and bony components of the joint may also be injured by trauma. The inflammation may cause localized hyperemia affecting other local tissues **[12]**. The exact mechanisms of facet pain areincompletely understood although demonstration of pain fibers in the joint provides some explanation for what a relatively accepted pain syndrome (facet syndrome) is **[13]**.

Facet joint injections may be done as a minimally invasive diagnostic and therapeutic procedure. History and clinical examination have been shown unable to diagnosewhether or not pain is caused by the facet joints **[14,15]**. Imaging studies have not been useful in proving that facet joints are the cause of pain although pain relief has been reported to be correlated with joint injection with corticosteroids **[16,17,18]**.

Nath et al., showed that radiofrequency ablation of the facet joint is important in the treatment of chronic low back pain. Forty patients were included in their study. The half of them was active treatment group and the other half was control. Significant improvement was present inthe active group concerning back, leg pain and hip movement. No complications were present in their study except transient pain after the procedure that was managed easily **[19]**.

John et al., conducted a study including 106 patientsto show the efficacy of lumbar medial branch radiofrequency neurotomy. Patients with pain relief less than six months were considered to have failed treatment. In both practices, successful outcome was achieved in 58% and 53% of the patients. The duration of pain relief was 15 months for the first intervention and 13 months for repeat interventions. They concluded that lumbar medial branch ablation is very effective in the management of chronic low back pain if it is due to facet syndrome **[20]**.

Sara et al., conducted a study to compare between medial branch block (MBB) and medial branch radiofrequency ablation in the management of facet mediated pain. They found no correlation between the magnitude of pain relief or its duration after MBB and after radiofrequency rhizotomy. They concluded that radiofrequency ablation is a better line of treatment than medial branch block **[21]**.

Conclusion:

Our study showed that combined treatment with radiofrequency medial branch neurotomy and steroid nerve block is very effective and safe in the management of chronic LBP due to lumbar facet arthropathy.

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نتيجة علاج الجذور للفرع الانسى بالترددات الحرارية والحقن بالكورتيزون فى اعتلال المفصل الجانبى القطنى : تجربة سريرية ذات شواهد

الخلفية : المفاصل السفلية هى مفاصل زليلية قد تكون مسببة للألم فى المرضى الذين يعانون من آلام أسفل الظهر المزمنة. هذا معروف الآن باسم متلازمة الوجه. الهدف من هذه الدراسة هو تقديم خبرتنا حول الفعالية والسلامة وتقنية العلاج المشترك مع شق الجذور بالترددات الراديوية للفرع الإنسى والستيرويد لمتلازمة الوجه القطنى. على الرغم من استخدام الاجتثاث بالترددات الراديوية بشكل متكرر، لا يوجد دليل عالى الجودة على فعاليته.

الهدف من الدراسة : الهدف من هذه الدراسة هو تقديم خبرتنا باستخدام العلاج المشترك مع بضع العصب بالترددات الراديوية للفرع الإنسى وإحصار الستيرويد فى إدارة آلام أسفل الظهر المزمنة الناتجة عن الاعتلال المفصلى الوجهى. سيتم تقييم نجاح التقنية والسلامة الفعالية.

المرضى والطرق : تم علاج ٣٨ مريضاً من خلال العلاج المشترك مع بضع الجذر بالترددات الراديوية للفرع الإنسى بعد أسبوع، (VAS المقياس التناظرى البصرى) قبل التدخل (قبل) VAS. (وكتلة الستيرويد مجموعة التدخل وبعد ستة (VAS 2) فى ثلاثة أشهر بعد، (VAS 1) فى شهر واحد بعد، (VAS) واحد من التدخل مباشرة بعد فى كل نقطة زمنية مع المجموعة الضابطة (٣٨ مريضاً). تلقت (VAS 3) أشهر بعد تمت مقارنة التدخل بعد المجموعة الضابطة أفضل علاج طبى وبرنامج تمارين منتظم لمدة ستة أشهر. تم عمل كتلة تشخيصية لجميع الحالات.

وبعد VAS 1 مباشرة وبعد VAS النتائج : كانت هناك فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بعد فى جميع العلاقات. لم يتم الإبلاغ عن أى أحداث سلبية للعدوى $p<0.01$ حيث كانت قيم VAS 3 وبعد VAS 2 أو الإصابة العصبية أو أى مضاعفات أخرى.

الخلاصة : شهد المشاركون المصابون بمتلازمة الوجه القطنى والذين تلقوا علاجاً مشتركاً مع بضع الجذور بالترددات الراديوية للفرع الإنسى والستيرويد تحسناً سريرياً ملحوظاً مقارنة بأولئك الذين تلقوا علاجاً تحفظياً.