Original article

The Evaluation of Radiofrequency Ablation and Medial branch block in the pain Management of Lumber Spinal Pain. A two-year follow-up study

Shahzad Anwar[1], Muhammad Waseem Hassan[2], Gull-a-Rukh Shaukat[3], Muhammad Umer Saeed[4] Fatima Tirmzi[5]

[1]Director School of pain and Regenerative Medicine, The University of Lahore, CEO Iffat Anwar medical Complex, [2]Professor of Pain and Regenerative medicine, school of pain and regenerative medicine, The university of Lahore, [3]Research Associate & Biostatistician, Iffat Anwar Medical Complex, Lahore Pakistan, [4]Department of Payhology, Faculty of Medicine, King Abdulaziz University, Rabigh, Saudi Arabia, [5]MBBS student at, CMH Medical College, Lahore Pakistan

Corresponding Author: Dr. Shahzad Anwar, Email: shahzadtirmzi@yahoo.com

ABSTRACT

Background: Chronic back pain, which is increasingly common and has a considerable economic impact, is a significant disabling factor. For the past decade, radiofrequency ablation (RFA) is a method that is frequently used to treat many kinds of chronic pain. Therefore, the objective of the current investigation was to determine the long-term clinical outcomes of an RFA.

Patients and Methods: Randomized control trail was conducted from March 2019 to December 2021 at Iffat Anwar Medical Complex and department of pain medication Azra Naheed Medical Complex. After taking the written informed consent the patients meeting the inclusion criteria: low back pain for past 2 years, both gender, age > 30 years and failed to respond the previous treatments were enrolled in current study. After radiological assessment total 60 patients were randomized equally into two groups (Group A= Medial Branch Block, Group B= RFA) by using computer generated sequence. The primary outcome of the study was to determine the improvement in low back pain by using visual analog scale and physical impairment by using Oswestry low back disability index scale. Patients were followed till 2 years after the successful procedure. All the data was entered and analyzed by using SPSS 25.0.

Results: A sample of 60 patients were selected. The mean age of the patients was 57.6+9.6 years. 35 (58.3%) of the patients were between 56 and 75 years of age. In the current study, 41 (60.0%) were females, including 21 (51.2%) in Control and 20(48.7%) in intervention group. At 12th (week), one, 1.5, and 2 (years), 30%, 80%, 33.3%, and 90.0% of patients reported a reduction in pain with a significant difference (P-value < 0.05). Patients showed a long-term effect in terms of pain reduction and disability after RFA therapy.

Conclusion: A significant number of people with lumbar spine pain benefit from effective and long-lasting therapy while using RFA of the lumbar medial branch. Lumbar zygapophysial joints have been subjected to radiofrequency denervation this results in long-term pain relief under normal clinical conditions.

Keywords:

Lumber spinal pain, Radiofrequency, Pain management, Efficacy

INTRODUCTION

Chronic back pain, which is increasingly common and has a significant economic impact, is a major disabling factor. Back pain has a complicated etiology. Consequently, it can be quite difficult to treat effectively.[1] Acute low back pain typically resolves within a three-month timeframe, while chronic low back pain persists beyond three months. This pain can stem from various sources, including the lumbar facet joints, sacroiliac joint, and intervertebral discs.[2]

At least 15% of all adult patients and up to 90% of elderly people with low back pain are thought to have lumbar joint pathology as the cause of their condition.[3] In addition, low back pain was the most common reason for the number of years lived with disability among the top 30 diseases and injuries in the United States in 2010.[4] Despite significant innovations and improvements in overall health, prolonged disability and morbidities now account for more than half of the burden of health care facilities in the U.S.[5]

Chronic low back pain can be managed through non-invasive approaches, including medications, manual therapies (such as massage, physical therapy, and spinal manipulation), exercise regimens (such as aerobic workouts and muscle-strengthening exercises), and educational or psychological therapies.[6] In clinical practice, diagnostic local anesthetic blocks, like medial nerve blocks, are often utilized to identify the source of

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pain in cases where clinical assessments or imaging tests are insufficient for accurate diagnosis due to the complexity of painful joints.[7] In situations where less invasive methods prove ineffective, more invasive techniques such as cryoablation, radiofrequency ablation (RFA), nerve blocks, and surgical interventions can be considered as alternative options for addressing chronic low back pain.[8]

Shealy utilized RFA for the first time to treat low back pain in 1975, and it can be effective for people with no known pathology such as osteoporosis, cancer, infection etc. The procedure involves passing a high-frequency electric current through an insulated needle. The electric field moves the molecules at the tip of the needle, resulting in the generation of heat energy. The heat from the tip of the RFA device is directed to a specific nerve to cause a tiny lesion that suppresses the pain signal. [9] Dreyfuss et al. conducted a study in which they employed dual comparative medial branch blocks (BBs) to determine the suitability of individuals for lumbar medial branch radiofrequency ablation (RFA), aiming for an 80% reduction in pain. The study findings revealed that close to 60% of the patients experienced a significant 90% pain relief, and a substantial 87% reported a 60% reduction in pain at the 12-month follow-up.[10]

The idea behind radiofrequency ablation for chronic pain is that transmitting radiofrequency currents close to nociceptive pathways will block pain receptors. The nerves responsible for transmitting and/or modifying pain perception are the target of tissue damage caused by the thermal energy associated with radiofrequency ablation. Intra-articular facet injections and medial branch blocks are both thought to be more effective predictors of lumbar medial branch RFA success than sham techniques.[11] RFA's potential long-term effects as a therapy option have not been thoroughly investigated. Therefore, more convincing evidence is required to support RFA's effectiveness in the Lumber spine. Therefore, the objective of the current investigation was to evaluate of radiofrequency ablation and its comparison with medial branch blocks in the pain management of facetogenic low back pain.

PATIENTS AND METHODS

After taking the ethical approval from Azra Naheed Medical college, a randomized control trail was conducted from March 2019 to December 2021 at Iffat Anwar Medical Complex. After taking the informed consent the patients meeting the inclusion criteria: low back pain from past 2 years, both gender, age > 30 years and failed to respond the previous treatments were enrolled in current study. Pregnant women, people with coagulopathies, cancer, infections, people with mental disabilities and psychiatric disorders, previous history of comorbidities (Uncontrolled diabetes mellitus, hypertension), spinal stenosis, spondylolisthesis, and people who had lost more than 75% of their disc height were excluded from current study.

After radiological assessment total 60 patients were randomized equally into two groups (Group A= Medial Branch Block, Group B= RFA) by using computer generated sequence.

PROCEDURE

Medial Branch Block

Patients were positioned in a prone (face-down) orientation on the fluoroscopy table. The lumbar spine was then uncovered, cleaned, and covered with drapes, adhering to established sterility protocols. The appropriate lumbar spine levels were found by fluoroscopy. The superficial subcutaneous tissue of the skin and the medial nerve branches was anaesthetized with 1 to 4 ml of 1% lidocaine. Following the local anesthesia of the skin and subcutaneous tissues, a standard 22-25-gauge spinal needle, ranging from 3.5 to 6 inches in length, was carefully advanced into the designated target areas under the guidance of fluoroscopy. Both lateral and anterior-posterior views were used to ensure the accurate placement of the needle, and a small quantity of contrast was introduced to confirm the location and rule out any inadvertent vascular injection. Subsequently, either 0.5 ml of 0.5% bupivacaine or 4% lidocaine was administered. Patients were provided with a pain journal and instructed to record their pain relief every 15 minutes. A successful series of blocks were determined by a 50% reduction in the patient's pain.

Radiofrequency Ablation

In the prone position, the procedure was carried out. The proper lumbar levels were determined using fluoroscopy. The skin and subcutaneous tissues close to the targeted medial branch nerves were anesthetized with 1 to 4 mL of 1% lidocaine. In the so-called "tunnel technique," 18-gauge probes with 10-mm active tips was inserted in the direction of the radiograph beam and proceeded until bone contact was formed with the lower part of the transverse process. The targeted nerve and its surrounding tissues were anesthetized by injecting 2 mL of bupivacaine (0.5%) into the cannula once it had been positioned. The cannula was then

allowed to slide upward in the groove, remaining in contact with the bone surface until the tip was at the upper edge and in the middle of the curve formed by the upper edge of the transverse process rising to the lateral edge of the articular process. The cannula was then rotated so that the bevel rested against the bone. The position was examined from three different angles: cephalad view, posterolateral view, and tunnel view. After insertion of the thermistor probe, a lesion was performed for 90 seconds at a temperature of 80°C. After retraction of the cannula by 5 mm, another lesion was created. Four additional lesions were performed immediately lateral and medial to the first two lesions to account for possible variations in the position of the target nerve.

At six months following the treatment, the same orthopedic physician evaluated all of the patients to determine whether there were any differences between the two groups in terms of pain relief and physical impairment.

The primary outcome of the study was to determine the improvement in low back pain by using visual analog scale and physical impairment by using Oswestry low back disability index scale. Patients were followed till 2 years after the successful procedure. The patients in MBB group were followed till 12th week of treatment. The majority of patients reported the reoccurrence of the pain.

Data analysis procedure

The data analysis was conducted using SPSS version 25.0. Quantitative variables were expressed as Mean±SD, while qualitative variables were represented in terms of frequency and percentages. To compare the differences in pain scores and Oswestry low back disability scores between the two groups, an independent sample t-test was employed. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Total 60 patients were enrolled in current study. The mean age of patients was 57.6+9.6. majority 35(58.3%) patients were 56-75 years old. There were 41(60.0%) females in current study among which 21(51.2%) in Control and 20(48.7%) in intervention group. Majority of patients were married [Control = 23(76.6%) Vs. Intervention = 26(86.7%)]. However, 51.7% were overweight (Control = 14(46.7%) Vs. Intervention = 17(56.7%) and 63.3% have spondylosis [Control = 21(70.0%) Vs. Intervention = 17(56.7%)]. (Table 1)

The pain score was measured by using VAS. At baseline the both groups have same pain score (P-value > 0.05). Pain at 12th week shows insignificant difference in both groups [Control = 2.37+1.21 Vs. Intervention= 2.30+1.08]. Both the treatment has same effect at 12th week (P-value > 0.05). The patients Oswestry disability index score shows in significant difference at baseline and the at 12th week after RFA the intervention group showed less disability as compared to control group [Control = 22.17+4.95 Vs. Intervention = 16.70+4.88)] (P-value < 0.05). (Table 2)

The patients in RFA group were followed till 2 years for pain reduction. At 12th 50.0% patients have less than 50% pain reduction but it gradually increased at 1 years as 80%. After 1.5 years 56.6% patients reduce pain <50% and 2 years 90% patients have pain reduction greater than 50%. Table 3, showed the pain reduction till 2 years. At 12th week, 1 year, 1.5 year and 2 years, 30%, 80%, 33.3% and 90.0% of patients reported 50% pain reductions with a significant difference (p-value<0.05).

Table 1: Baseline characteristics of patients

Variable	Control (n=30)	Intervention (n=30)	Total
Age			
35-55 years	12(48.0%)	13(52.0%)	25(41.6%)
56-75 years	18(51.4%)	17(48.5%)	35(58.3%)
Gender			
Female	21(51.2%)	20(48.7%)	41(60.0%)
Male	9(47.3%)	10(52.6%)	19(40.0%)
Marital Status			
Single	7(23.3%)	4(13.3%)	11(18.3%)
Married	23(76.6%)	26(86.7%)	49(81.7%)
BMI			
Underweight	3(10.0%)	2(6.7%)	5(8.3%)
Normal	10(33.3%)	9(30.0%)	19(31.7%)
Overweight	14(46.7%)	17(56.7%)	31(51.7%)
Obese	3(10.0%)	2(6.7%)	5(8.3%)
Spondylosis			
Yes	21(70.0%)	17(56.7%)	38(63.3%)
No	9(30.0%)	13(43.3%)	22(36.7%)

Table 2: mean difference of pain among both groups

Variables	Group	Mean	SD	P-value
Baseline Pain	Control	7.40	1.734	0.56
	Intervention	7.13	1.756	
Pain at (12th Week)	Control	2.37	1.217	0.82
	Intervention	2.30	1.088	
Baseline ODI	Control	35.80	6.975	0.61
	Intervention	36.67	6.110	
ODI at (12th Week)	Control	22.17	4.956	0.000
	Intervention	16.70	4.886	

Independent Sample t test P-value <0.05**

Table 3: Comparison of pain reduction in Intervention group at different time points

Variable	At 12th week	At 1 year	At 1.5 Year	At 2 Year
Less than 50%	15(50.0%)	2 (6.7%)	17(56.7%)	3(10.0%)
Greater than 50%	9(30.0%)	24(80.0%)	10(33.3%)	27(90.0%)
80%	6(20.0%)	4(13.3%)	3(10.0%)	0(0.0%)
P-value	0.000	0.000	0.000	0.000

One sample t-test, test value = 0 P-value < 0.05**

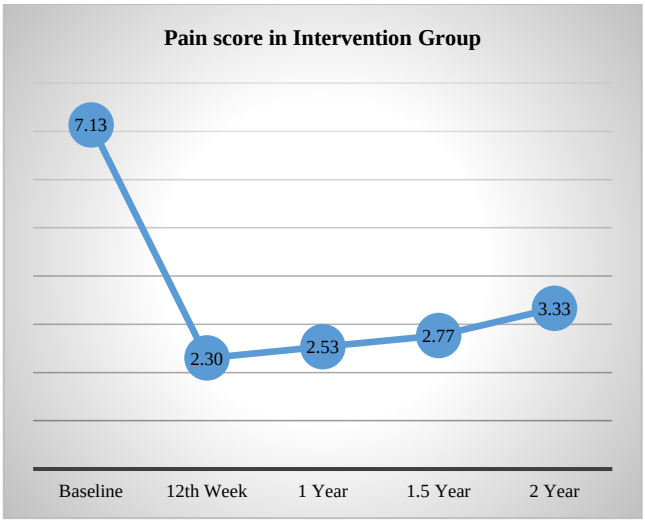

Figure 1: Comparison of Pain score in intervention group till 2 years

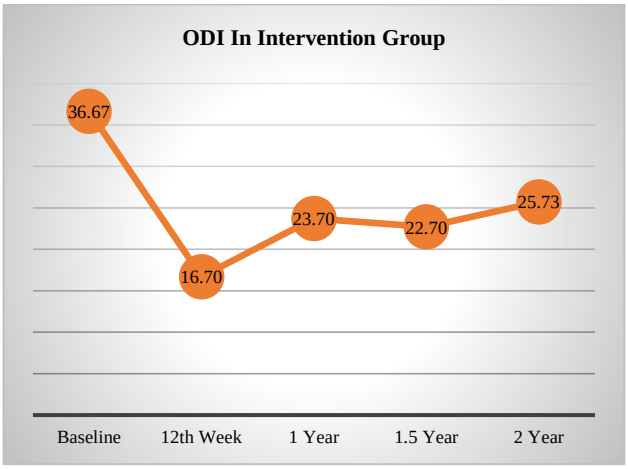

Figure 2: Comparison of Oswestry Disability Index score in intervention group till 2 years

The difference of pain score from baseline to 2 years were shown in figure 1. The patients show long term effect of pain reduction after receiving RFA therapy. At baseline patients have severe low back pain but after treatment it gradually decreases. At 2 years follow up the mean pain score among participants were 3.33. (Figure 1).

The difference of Oswestry disability index from baseline to 2 years were shown in Figure 2. The patients show long term effect of disability reduction after receiving RFA therapy. At baseline patients have severe disability but after treatment it gradually decreases. At 2 years follow up the mean ODI score among participants were 25.73. (Figure 2).

DISCUSSION

RFA use has steadily increased, with a notable increase between 2007 and 2016. During this decade, there was a significant overall increase of 130.6%, representing an average annual growth rate of approximately 9.7%.[12] The individuals who participated in this study suffered from long-lasting, severe, debilitating pain that had resisted all previous treatments. For these individuals, no single medication is likely to completely relieve their symptoms. However, each of these patients was able to identify a specific area of pain that was a candidate for RFA treatment and could be relieved by medial branch blocks under controlled conditions.

The finding of current study reported that at 12th week, 1 year, 1.5 year and 2 years, 30%, 80%, 33.3% and 90.0% of patients reported pain reductions with a significant difference (p-value<0.05). At baseline patients have severe low back pain but after treatment it gradually decreases. At 2 years follow up the mean pain score among participants were 3.33. (Figure 1). These results were compared with a study conducted by Dreyfuss et al, who used two comparative MBBs to determine if patients were eligible for lumbar medial branch RFA, targeting 80% pain reduction. Their study found that nearly 60% of patients achieved 90% pain relief and 87% achieved 60% pain relief at 12 months.[10]. In another study by Macvicar et al, they published audit data reflecting treatment outcomes. Using a selection criterion of 100% pain relief with two comparable MBBs to select patients for lumbar medial branch RFA, their data showed that 53-58% of patients had complete pain relief up to 15 months after the procedure. These results provide insight into the performance of treatments when a strict selection threshold is applied.[13] Despite the fact that individuals in the current trial experienced more modest pain reduction than that observed in benchmark studies, this is not unexpected given that past studies frequently used restrictive study selection criteria that excluded people with concurrent spinal diseases. Longer-term consequences have not been extensively studied. According to Park et al[14]. and North et al[15]. approximately 55% and 45% of participants reported a reduction in pain of more than 50% after two years. This reduction was observed in patients selected on the basis of a single MBB criterion (> 50% pain reduction).

RFA is a commonly used method to treat various types of chronic pain. It stands out as one of the few interventional treatments for chronic pain that has demonstrated long-term efficacy. Studies have shown that patients who have undergone this treatment have experienced significant improvement in quality of life, overall well-being, and relief of their pain symptoms after a 6-month period.[16]

The results of the current study were also demonstrated that the patients show long term effect of disability reduction after receiving RFA therapy. At baseline patients have severe disability but after treatment it gradually decreases. These findings were contrasted with additional studies, which unveiled that after the treatment, 60% of patients achieved pain relief of 80% or more, which persisted for a minimum of 12 months. Moreover, 80% of patients maintained a pain reduction of at least 60%. These improvements in pain relief were accompanied by substantial enhancements in disability, both clinically and statistically significant.[17] In a randomized, double-blind, controlled study involving 120 patients experiencing chronic low back pain originating from facet joints, therapeutic lumbar facet joint nerve blocks were administered. At the conclusion of the two-year research period, 85% of patients in Group I (the non-steroid group) and 90% of patients in Group II (the steroid group) experienced noticeable pain relief. Additionally, functional assessment using the ODI revealed significant improvement, with at least a 40% reduction in disability ratings observed in 87% of patients in Group I and 88% of patients in Group II.[18] Another descriptive investigation confirmed the same findings. Patients were selected over a 10-year period based on their ability to experience controlled medial branch blocks that reduced their pain by at least 70%. A total of 209 patients underwent lumbar medial branch neurotomy as a component of their treatment, and 174 of these patients underwent assessment. Six to twenty-four months later, 68% of the assessed patients, which amounts to 56% of the original group, still reported a minimum of 50% pain reduction. This pain relief was linked to improvements in daily activities and a reduced reliance on analgesic medications.[19] In another research, individuals were chosen for inclusion if they reported a minimum of 50% pain reduction after both an intra-articular and a medial branch block. It demonstrated that medial branch neurotomy significantly decreased pain, improved disability, and decreased the need for analgesics. At 3 and 6 months, these benefits peaked, then they started to fade. High levels of patient satisfaction with the procedure were found in the study.[20] However, it was noted in another study that active treatment was superior than placebo treatment. In comparison to 3/16 patients treated with placebo, 7/15 patients who received active neurotomy experienced improvement. Additionally, the study found that this pain reduction was associated with significant reductions in painkiller use and improvements in impairment.[21]

CONCLUSION

A significant number of people with lumbar spine pain benefit from the effective and long-lasting therapy of RFA of the lumbar medial branch. The lumbar zygapophysial joints have been subjected to radiofrequency denervation. This results in long-term pain relief under normal clinical conditions. However, in a selected patient population, RF lumbar facet joint denervation appears to be more effective than placebo therapy. Future studies should focus on improving the RF technique and assessing the psychological profile as part of the RF treatment selection process.

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