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COMPARATIVE STUDY OF PULSED RADIOFREQUENCY AND TRANSFORAMINAL STEROID INJECTIONS VERSUS SPINEMED FOR MANAGEMENT OF RADICULAR PAIN DUE TO LUMBAR DISC HERNIATION

By

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ABSTRACT

Background: In young and middle-aged individuals, lumbar disc herniation is a prevalent disease that affects the spine.

Objective: To evaluate the efficacy of pulsed radio frequency and transforaminal steroid injection versus SpineMed system in the treatment of radicular pain caused by a herniated lumber disc at levels L4-5 and L5-S1.

Patients and Methods: This was a prospective randomized clinical trial carried out on 60 patients aged from 20 to 50 years with lumbar disc herniation at levels L4-5 and L5-S1. At AL-Agouza Rheumatology and rehabilitation center from November 2019 to January 2020. Patients were classified into two equal groups: Group 1 was treated by pulsed radio frequency and transforaminal epidural steroid injection (TFESI) (2ml triamcinolone and 2ml ropivacaine), and Group 2 underwent the SpineMed system program, which comprised of 20 to 25 sessions, each of 30-minutes over a 5-week period.

Results: According to the Oswestry disability index, there was a substantial reduction in mean in group I comparing to group II before injection, and after 2 weeks, and after 3 months. According to their complications, we discovered no statistically significant variation among groups.

Conclusions: PRF stimulation at DRG with TFESI was superior to SpineMed system in the treatment of refractory radicular pain.

Key words: Pulsed radiofrequency, transforaminal steroid injections, spineMed, radicular pain, lumbar disc herniation.

INTRODUCTION

In young and middle-aged individuals, lumbar disc herniation is a prevalent disease that affects the spine. The lumbar intervertebral disc is a complex structure made up of collagen, proteoglycans, and sparse fibrochondrocytic cells that disperse pressures on the spine. Senescence of the disc fibrochondrocytes occurs as part of the natural ageing process, and proteoglycan synthesis decreases *(Schoenfeld and Weiner, 2010)*.

Transforaminal epidural steroid injection (TFESI) is a traditional, minimally invasive treatment for radicular

pain that has a definite short-term efficacy, with pain relief or functional recovery being more robust at 2 weeks than 2 months. However, due to drug metabolism, the medium- and long-term efficacy is debatable *(Ding et al., 2018)*.

Pulsed radiofrequency (PRF) has been shown to be safe and effective in treating many kinds of chronic pain by providing an electrical field and heat bursts to specific neurons or tissues without harming these structures *(Kwak et al., 2018)*.

The SpineMed system is a distraction and positioning device for the spine that is intended to isolate and decompress lumbar discs. The pressure exerted on the discs may be significantly decreased when the person is distracted. Reduced intradiscal pressure may assist in drawing the gel-like nucleus pulposis back into the disc's core, alleviating strain on a compressed nerve root. Reduced pressures may also improve the body's natural healing powers by increasing the passage of fluids and nutrients through the end plates back into the disc *(Ma and Kim, 2010* and *Ma et al., 2011)*.

The goal of this research was to see how effective pulsed radio frequency and transforaminal steroid injection are in comparison to SpineMed in treating radicular pain caused by a herniated lumber disc at level L4-5 and L5- S1.

PATIENTS AND METHODS

This was a prospective randomized clinical study that included 60 patients with lumbar disc herniation at levels L4-5 and L5-S1, who were recruited from the outpatient clinics of Al-Hussein University Hospital, and Al-Agouza Rheumatology and Rehabilitation Center from November 2019 to January 2020. Informed and written consents have been obtained from the patients after acquiring permission of the medical and ethical committee of Al-Hussein University Hospital and Al-Agouza Rheumatology and Rehabilitation Center.

Patients with lumbar disc herniation with relevant MRI findings, patients who were rejected or intolerant of surgery and needed minimally invasive therapy, patients with severe lumbar radicular pain rather than lumbar axial pain, and patients who were refractory to treatment and physiotherapy were included in this study.

The exclusion criteria was structured of patients with failed back surgery, vertebral canal stenosis, degenerative spondylolisthesis more than grade two, osteoporosis, spinal infection, spinal tumors, pregnancy, diabetes mellitus and sever neurological deficits such as bowel and bladder dysfunction.

During the research, all 60 individuals were evenly split into two groups and treated; they were categorized into two groups. Group 1 was treated by pulsed radio frequency and transforaminal injection of steroid (2ml triamcinolone) and (2ml ropivacaine). Group 2 underwent the SpineMed program, which comprises of 20 to 25 30-minute sessions. Over a 5-week period, sessions were usually given 4-5 times each week.

Pulsed radio frequency and transforaminal epidural steroid injection procedure: RF needle was connected to RF generator inserted around DRG under supervision of C_ arm SpineMed procedure: The pelvic tilt portion was electrically inclined to allow for the

targeting of certain spinal segments. Using a SpineMed computer, a customized traction programme is modified to manage stress and distraction of the specific disc section. The SpineMed program was divided into 20-25 sessions over the course of 5 weeks, each lasting 30 minutes. patients were monitored for 6 hours in the recovery room before they were discharged.

Assessment was done by evaluating pain intensity by Visual Analogue Scale (VAS) used for leg radiating pain, before treatment, as well as 3 months after treatment. To assess functional impairments linked to lumbar radicular pain, the Oswestry disability index (ODI) was used.

Statistical analysis:

SPSS version 20.0, was used to analyze the data. The mean and standard deviation were used to represent quantitative data (SD). Frequency and percentage were used to represent qualitative data. The independent-samples t-test, the paired sample t-test or Mann-whitney U test, and the Chi-square were used for comparison. The confidence interval was set at 95%, while the acceptable margin of error was set at 5%.

RESULTS

According to demographic data (sex, age, and duration), diagnosis, and risk factors, we discovered no statistically significant variation among groups **(Table 1)**.

Table (1): Comparing between groups based on demographic data

Groups / Demographic Data	Group I *(n=30)*	Group II *(n=30)*	p-value
Sex			
Female	14 (46.7%)	12 (40.0%)	0.602
Male	16 (53.3%)	18 (60.0%)	
Age (years)			
Mean ± SD	42.50±8.16	41.17±6.34	0.483
Range	20-50	28-50	
Duration (years)			
Mean ± SD	1.13±1.09	0.98±0.45	0.489
Range	0.3-6	0.5-2	
Diagnosis			
L4-L5	13 (43.3%)	18 (60.0%)	0.429
L4-L5, RT L5-S1	8 (26.7%)	6 (20.0%)	
L5-S1	9 (30.0%)	6 (20.0%)	
Risk factors			
Smoker	8 (26.7%)	9 (30.0%)	0.774
Obese	6 (20.0%)	4 (13.3%)	0.488

t: Independent Sample t-test; $\chi 2$: Chi-square test

There was no statistically significant variation among groups based on their history **(Table (1)**.

Table (1): Comparing between groups based on personal history

Groups / History of Taking	Group I *(n=30)*	Group II *(n=30)*	p-value
Character of pain			
Discogenic LBP	28 (93.3%)	30 (100.0%)	0.150
Mechanical LBP	2 (6.7%)	0 (0.0%)	
Radiated to			
BOTH LL	6 (20.0%)	4 (13.3%)	0.758
LT LL	12 (40.0%)	12 (40.0%)	
RT LL	12 (40.0%)	14 (46.7%)	
What increase			
Exercise	13 (43.3%)	12 (40.0%)	0.683
Standing	9 (30.0%)	7 (23.3%)	
Walking	8 (26.7%)	11 (36.7%)	
What decrease			
Rest	29 (96.7%)	25 (83.3%)	0.085
Sleeping	1 (3.3%)	5 (16.7%)	
Numbness or Not			
No	4 (13.3%)	4 (13.3%)	1.000
Yes	26 (86.7%)	26 (86.7%)	
Numbness Frequency	**n=26**	**n=26**	
L4	2 (7.7%)	0 (0.0%)	0.387
L5	13 (50.0%)	18 (69.2%)	
L4-L5	4 (15.4%)	2 (7.7%)	
L5-S1	4 (15.4%)	5 (19.2%)	
S1	3 (11.5%)	1 (3.8%)	

t: Independent Sample t-test; $\chi 2$: Chi-square test

According to their physical and neurological examinations, there was no statistically significant variation among groups **(Table 3)**.

Table (2): Comparing between groups based on physical, neurological and radiological examination

Groups / Physical Examination	Group I *(n=30)*	Group II *(n=30)*	p-value
Abnormal **Stance**	1 (3.3%)	0 (0.0%)	1.000
Abnormal **Gait**	4 (13.3%)	0 (0.0%)	0.112
Abnormal **Posture**	2 (6.7%)	0 (0.0%)	0.492
Palpation **(Tender)**	19 (63.3%)	18 (60.0%)	0.791
Range of motion			
Limited Flexion	16 (53.3%)	14 (46.7%)	0.117
Limited Flexion, Extension	0 (0.0%)	4 (13.3%)	
Normal	14 (46.7%)	12 (40.0%)	
Straight leg raising test			
Negative	3 (10.0%)	5 (16.7%)	0.448
Positive	27 (90.0%)	25 (83.3%)	
Femoral stretch test			
Negative	26 (86.7%)	30 (100.0%)	0.112
Positive	4 (13.3%)	0 (0.0%)	
Neurological examination			
Abnormal Motor	1 (3.3%)	1 (3.3%)	1.000
Abnormal Sensory	1 (3.3%)	0 (0.0%)	1.000
Abnormal Reflexes	7 (23.3%)	5 (16.7%)	0.519
Radiological examination			
Plain X-ray lumber spine			
Abnormal	15 (50.0%)	11 (36.7%)	0.297
Normal	15 (50.0%)	19 (63.3%)	
MRI lumber spine			
L4-L5	17 (56.7%)	14 (46.7%)	0.609
L4-L5, L5-S1	10 (33.3%)	13 (43.3%)	
L5-S1	3 (10.0%)	3 (10.0%)	

t: Independent Sample t-test; $\chi 2$: Chi-square test

According to the ODI, after 2 weeks and 3 months, group I had a statistically significant reduction in mean in contrast with group I **(Table (3)**.

Table (3): Comparing between groups based on Oswestry Disability Index.

Groups / Oswestry disability index	Group I *(n=30)*	Group II *(n=30)*	p-value
Before Injection			
Mean ± SD	23.50±8.33	22.10±8.30	0.517
Range	9-38	7-39	
After 2wks			
Mean ± SD	12.73±7.34	16.03±8.76	0.019
Range	4-31	3-33	
After 3months			
Mean ± SD	11.37±6.68	16.33±8.27	<0.001*
Range	3-31	4-31	

Using: t-Independent Sample t-test

There was a statistically significant decrease in mean after 2 weeks and 3 months compared to before injection according to ODI (Disability)% in both groups I and II. (**Error! Reference source not found.**).

Table (4): The extent of the difference over the periods through Oswestry Disability Index

Groups / Oswestry Disability Index (Disability)%	Group I *(n=30)*	Group II *(n=30)*
Before Injection		
Mean ± SD	46.63±16.58	43.73±16.81
After 2 weeks		
Mean ± SD	24.97±14.75	31.63±17.44
p-value	<0.001	0.008
After 3 months		
Mean ± SD	22.33±13.20	32.00±16.43
p-value	<0.001	0.011

Using: Paired Sample t-test

According to their complications, there was no statistically significant variation among groups **(Table 6)**.

Table (5): Comparing among groups based on complications

Groups / Complications	Group I (n=30)	Group II (n=30)	p-value
No	27 (90%)	29 (96.7%)	0.602
Yes	3 (10%)	1 (3.3%)	
Numbness	1 (3.3%)	0 (0.0%)	
Pain	2 (3.3%)	1 (3.3%)	

DISCUSSION

According to the ODI after 2 weeks and 3 months, there was a statistically significant reduction in mean in group I compared to group II, and we found no statistically significant variation among groups based on their problems. Since we didn't include FBSS patients in our research, our outcome was much better.

Kim et al. (2012) evaluated and compared the effectiveness of TFESI in patients with far lateral herniation of the lumbar disc (FHLD) and intraspinal herniation of the lumbar disc (iHLD). The VAS and ODI scores in the FHLD group improved significantly 12 weeks after injection, according to the researchers. Furthermore, they discovered no statistically significant variation among both groups in terms of VAS and ODI. However, since we utilized PRF with TFESI, there was a greater improvement.

Tak et al. (2015) assessed TFESI of corticosteroid to study functional improvement and pain reduction after TFESI, concur with our findings. Gadolinium-enhanced MRI was used to divide patients into improving and non-improving groups. At one week and four weeks following TFESI, the enhanced group showed higher improvement in NRS and ODI than the non-enhanced. However, after one week and four weeks after TFESI, they discovered no significant variation in NRS and ODI improvement between the pre-DRG alone enhanced group and the pre-DRG and post-DRG enhanced group. But our result was more significant improvement as we used PRF with TFESI.

Manson et al. (2013) found similar findings. They observed no significant variations in wait times comparing TFESI patients and those who needed surgery, and no complication in TFESIs.

Taskaynatan et al. (2015) examined the therapeutic efficacy of TFESI in patients with persistent low back pain and radicular leg discomfort owing to lumbar disc herniation, which agreed with our findings. They showed that TFESI may be utilized as a therapeutic option for persistent radicular low back pain.

Kennedy et al. (2018) determined outcomes for patients with acute unilateral lumbar radicular pain owing to single level herniated nucleus post lumbar epidural steroid injection at 5 years, based on our findings. They showed that lumbar disc herniation is a condition that can be successfully treated with TFESI in the short term.

Vuka et al. (2020) investigated the effectiveness and safety of dorsal root ganglion (DRG) targeted pulsed radiofrequency (PRF) against any comparator for non-neuropathic pain therapy, concur with our findings. They showed that the PRF typically started after other therapies had failed in these trials.

Adıgüzel et al. (2017) examined the effectiveness of TFESI on low back pain alleviation. They found that the median initial ODI score was 25.0, with 17.0 and 12.5 points assessed at the second and 12th weeks post-injection, respectively. At the second and 12th weeks after the injection, we found statistically significant increase in the outcome measures.

Facchini et al. (2017) assessed the effectiveness of pulsed radiofrequency (PRF) therapy of pain associated with various spine disorders, disagree with our findings. They discovered that using PRF to treat lumbar facet pain was less successful than using traditional RF methods. More research is needed to determine the efficacy of PRF in various types of spinal disorders.

Quraishi (2012) found that the ‘treatment' and ‘control' groups both improved in pain but not in disability However, these variations were not significant. Furthermore, the one research that followed patients for a year found no significant differences in VAS or ODI between the therapy and control groups.

Ma and Kim (2010) determined the impact of a 4-week course of motorized spinal decompression given through SpineMed coupled with physical therapy modalities on patients' treatment with lumbar radiculopathy.

Soual and Gaudy (2017) investigated the impact of non-surgical SpineMed decompression device on patients of low back pain and neck discomfort in order to evaluate its efficacy. More than 80% of our subjects showed a substantial improvement as a result of their treatment. This improvement in patients' capacity to carry out daily activities, substantially improved pain ratings, and a considerable reduction in disability status and an increase in functional status. We have shown the clinical efficacy of non-surgical disc decompression in this retrospective research.

Sample size was relatively small and may need further studies with increasing sample size. More randomized trials we needed to be conducted to verify the findings of our study. The main result of PRF and TFESI need longer duration to show modulation in the pain pathway.

CONCLUSION

PRF stimulation at DRG with TFESI was superior to SpineMed in the treatment of refractory radicular pain.

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دراسة مقارنة بين علاج آلام جذور الأعصاب بسبب الفتق الغضروفي القطني بواسطة التردد الحراري وحقن الغضروف حول النهايات العصبية بواسطة الكورتيزون وبين علاج الفتق الغضروفي القطني بواسطة جهاز شد الفقرات

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خلفية البحث: تعتبر حالة فتق القرص القطني من الحالات الشائعة المتكررة التي تؤثر على العمود الفقري في المرضى الصغار ومتوسطي العمر.

الهدف من البحث: مقارنة فعالية التردد الحراري وحقن الغضروف حول النهايات العصبية بواسطة الكورتيزون وبين علاج الفتق الغضروفي القطني بواسطة جهاز شد الفقرات في علاج آلام جذور الأعصاب بسبب الفتق الغضروفي القطني عند القرص بين الفقرة القطنية الرابعة والخامسة والفقرة القطنية الخامسة والعجزية الأولى.

المرضى وطرق البحث: أجريت هذه الدراسة العشوائية المستقبلية على 60 مريضًا تتراوح أعمارهم بين 20 و50 عامًا يعانون من فتق القرص القطني عند القرص بين الفقرة القطنية الرابعة والخامسة والفقرة القطنية الخامسة والعجزية الأولى بمركز العجوزه للروماتيزم والطب الطبيعي من نوفمبر 2019 إلى نوفمبر 2020 وقد تم تقسيمهم إلى مجموعتين متساويتين: المجموعة 1: تم علاجهم عن طريق التردد الحراري وحقن الغضروف حول النهايات العصبية بواسطة الكورتيزون (2 مل تريامسينولون) والتخدير الموضعي (2 مل روبيفاكين). المجموعة 2: تم علاجهم عن طريق جهاز شد الفقرات بعدد 20-25 جلسة بواقع 4 – 5 جلسات في الأسبوع مدة كل منها 30 دقيقة على مدى 5 أسابيع.

نتـــائج البحـــث: وجـــد فـــروق ذات دلالـــة إحصـــائية بـــين المجمـــوعتين فيمـــا يتعلـــق بمؤشـــر أوسويســـتري للإعاقـــة قبـــل الحقـــن وبعـــد أســـبوعين وبعـــد ثلاثـــة أشـــهر حيـــث وجـــد انخفـــاض فـــي المجموعـــة الأولـــى مقارنـــة بالمجموعـــة الثانيـــة. ولـــم توجـــد فـــروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بالمضاعفات.

الاســـتنتاج: التـــردد الحـــراري فـــي تحفيـــز العقـــد الجذريـــة الظهريـــة بعـــد حقـــن الكـــورتيزون أفضـــل مـــن جهـــاز شـــد الفقـــرات فيمـــا يتعلـــق بعـــلاج آلام جـــذور الأعصـــاب في الغضروف.

الكلمـــات الدالـــة: الفتـــق الغضـــروفي القطنـــي، الكـــورتيزون، جهـــاز شـــد الفقـــرات، آلام جذور الأعصاب، التردد الحراري.