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Pulsed radiofrequency applied to the suprascapular nerve before rotator cuff tear arthroscopic repair: A prospective randomized clinical trial

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A B S T R A C T

Background: clinical studies have demonstrated efficacy of pulsed radiofrequency (PRF) in treating many pain syndromes. PRF energy is delivered via a percutaneous needle under image guide to reach suprascapular nerve as it supplies more than 70% of the shoulder sensation. PRF was introduced as a non-destructive minimally invasive procedure in comparison with arthroscopic management of rotator cuff injury. However, there is a controversy regarding both measures in treating shoulder pain in rotator cuff injuries as standard method.

Objective: to evaluate the ability of PRF to produce shoulder pain relief by applying of PRF to the suprascapular nerve and measure the pain relief by VAS score at various time intervals prior to arthroscopic repair for rotator cuff injuries. The study should be in comparison with control group undergo arthroscopic repair without attacking of the suprascapular nerve by PRF.

Methods: a prospective randomised controlled trial study including 40 patients divided as PRF or (P) group and control group (C) group equally. Each patient in our study whom their history and examination were fulfilled quietly including pain assessment by Visual Assessment Score (VAS). In The (P) group, a needle inserted through a well-known point in the shoulder leading directly to the suprascapular notch (where the nerve hooked above it) under image guidance. Radiofrequency waves at 2Hz of 20 millisecond and 42 C in pattern of three cycles each one lasting for 120 seconds. VAS score was assessed postoperatively for 7 time intervals started from immediate postoperative (after arthroscopic repair) up to 3 months.

Result: Pulsed radiofrequency produced a dramatic progressive pain relief through our study time. In the 1st 48 hours the VAS score dropped about 30% in (P) group with comparison to 22% in control group. At 3 months interval the VAS score was reduced by 45% from preoperative period in comparison to 23% of the control group (P=0.000)

Conclusion:
PRF is the safest, optimally invasive method to treat shoulder joint pain in rotator cuff injuries especially in unfitted patients for surgeries

1.0 Inroduction

Pulsed radiofrequency (PRF) is a novel therapeutic modality with many potential applications in pain management. A variation of conventional continuous radiofrequency (CRF), which has been in use since the mid-1970s, PRF offers the advantage of pain control without the tissue destruction and painful sequelae associated with CRF. This theoretical benefit of PRF is especially alluring in cases of neuropathic pain in which CRF is relatively contraindicated.

History of Radiofrequency for Chronic Pain: Although Cosman and his associates built the first CRF lesion generator in the early 1950s, CRF was first used to treat pain in 1974 (Uematsu, Udvarhelyi, Benson, & Siebens, 1974). In the early years, technological constraints limited CRF therapy to cervical and lumbar facet disease. However, the introduction of the 22-gauge RF cannula in 1981 allowed clinicians to administer CRF in precise anatomical locations and to control lesion size (Ahadian, 2004).\ Since that time, CRF has been used to treat a host of painful conditions ranging from lumbar radicular pain to intercostal neuralgia and cervicogenic headaches (Geurts et al., 2003). Unfortunately, a significant hindrance to the greater acceptance of CRF has been the risk of motor deficits and deafferentation syndrome. PRF was developed, in part, as a less destructive alternative to CRF. The impetus to conduct research into PRF emerged from an Austrian conference in 1995; Ayrapetyan, a scientist from Armenia, proposed that the clinical effect of CRF might be secondary to magnetic field exposure rather than tissue destruction (Sluijter, 2005).Subsequent theoretical work by Cosman showed that the magnetic field produced by CRF was most likely too weak to have a biological effect, but that the rapidly changing electrical field was perhaps significant enough to do so (Cosman, 2005) . Later discussions by Cosman, Sluijter, and Rittman centered on the notion that PRF, in theory, was capable of delivering radiofrequency energy sufficient to modulate the electrical field, but insufficient to cause tissue thermocoagulation. Several months after the initial conference, Radionics engineered a prototype PRF generator (see fig.1). Sluijter used this machine in early 1996 to conduct preliminary clinical trials and wrote the first report of the clinical effects of PRF on dorsal root ganglia in 1998 (Sluijter ME, Cosman E, Rittman W, 1998).

Mechanism of Action:

CRF uses high-frequency alternating current to induce coagulative necrosis in the target tissue. Tissue destruction occurs with probe temperatures between 60° and 80° C. Because tissue heating decreases rapidly with distance from the electrode tip, CRF lesions are well circumscribed, thus offering an advantage over chemical neurolysis. With CRF, the magnitude of tissue destruction is related to the temperature of the tissue, as well as the size of the electrode and duration of the procedure. In contrast, PRF uses radiofrequency current in short (20 ms), high-voltage bursts; the "silent" phase (480 ms) of PRF allows time for heat elimination, generally keeping the target tissue below 42° C. Although conventional theory espouses the notion that PRF does not cause thermal lesions, Cosman and Cosman (Cosman, 2005) demonstrated that even PRF can produce bursts of heat within the range requisite for tissue destruction. The possibility of tissue destruction with PRF is substantiated by in vitro egg white studies using PRF electrodes at 60° C or higher (Heavner, Boswell, & Racz, 2006).

However, histopathologic work in rat dorsal root ganglia and sciatic nerves using PRF electrodes at 42° C has shown that PRF causes only transient endoneurial edema; this in contrast with the wallerian degeneration effected by CRF at 80° C (Podhajsky, Sekiguchi, Kikuchi, & Myers, 2005). Similar studies in rabbit dorsal root ganglia corroborate the notion that PRF is orders of magnitude less disruptive of cellular morphology than CRF (Erdine et al., 2005). Therefore, it appears that any thermal damage from PRF is minimal and not the manner by which PRF exerts its clinical effect. Accordingly, the mechanism by which PRF causes pain relief in the absence of significant heat-induced tissue damage is debatable. The notion that the electrical fields generated by PRF can affect neuronal membranes is supported by neurophysiologic studies that demonstrate PRF changes synaptic signaling and causes electroporation (Cosman, 2005). A popular theory is that the rapidly changing electric fields produced by PRF alter the transmission of pain signals via a pathway involving c-Fos, a so-called immediate early gene. This theory is substantiated in a study by van Zundert et al. at 2003, who demonstrated that CRF at 67° C, PRF at 42° C for 120 seconds, or PRF at 42° C for 8 minutes performed on rat dorsal root ganglia all increased c-Fos expression in the dorsal horn, a response that was sustained as long as 7 days after treatment. These results not only indicate a mechanism of c-Fos activation that is independent of temperature, but also hint at the inhibition of excitatory C fibers and long-term depression as a viable therapeutic mechanism in PRF. Unfortunately, this study somewhat contradicts a previous study conducted by Higuchi et al. 2002,

Figure (1): NeuroTherm radiofrequency lesion generator (Kane et al., 2008).

Anatomy of Suprascapular nerve: The suprascapular nerve (SSN) is a mixed nerve that provides the motor innervation of the supraspinatus and infraspinatus muscles and the sensory and proprioceptive innervation of the posterior aspect of the glenohumeral joint, as well as the acromioclavicular joint, subacromial bursa, and scapula. This nerve carries afferents from approximately 70% of the shoulder joint. The nerve arises from the upper trunk of the brachial plexus and is composed predominantly of C5-C6 level fibers. Some authors suggest that the nerve may also receive contributions from the fourth cervical nerve root in as many as 25% of people. Although the suprascapular nerve is a mixed nerve, it typically carries no cutaneous afferent fibers. The SSN is thought to carry cutaneous afferent fibers in only 15-25% of the general population (Gray's anatomy, 2008).

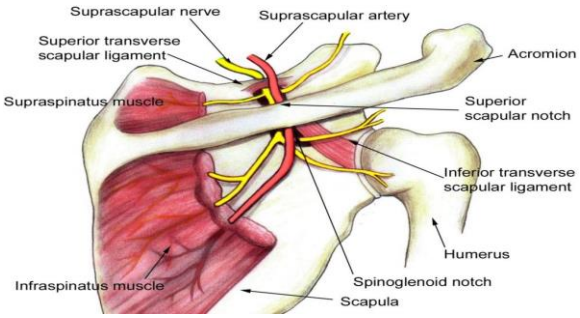

Figure (2) : Clinically relevant anatomy of the suprascapular nerve (SSN) and the structures it innervates (Thomas H Trojian, 2013).

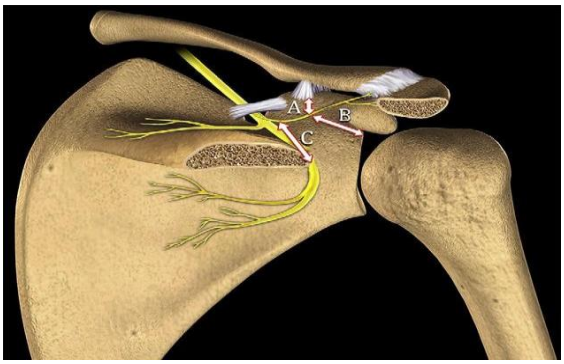

Figure (3): This posterior view of the right shoulder shows the distance between the sensory nerve near the coracoclavicular (CC) ligaments and the insertion of the CC ligament (A), the distance between the sensory nerve near the CC ligament and the superior rim of the glenoid (B), and the distance between the spinoglenoid notch and the sensory branch at the suprascapular notch (C) (Ebraheim et al., 2011).

In its initial course, the SSN courses posterior and parallel to the inferior belly of the omohyoid muscle and anterior to the trapezius muscle in the posterior triangle of the neck. The nerve then passes dorsally through the suprascapular notch (see figure 2), where it is retained by the transverse scapular ligament, into the suprascapular fossa, where 2 motor branches to the supraspinatus muscle originate (Nam et al., 2011). Just proximal to the suprascapular notch, the SSN gives off the superior articular branch, which travels with its fellow nerve through the notch before proceeding laterally to innervate the acromioclavicular joint and its associated bursa and the coracoclavicular and coracohumeral ligaments (see fig.3).

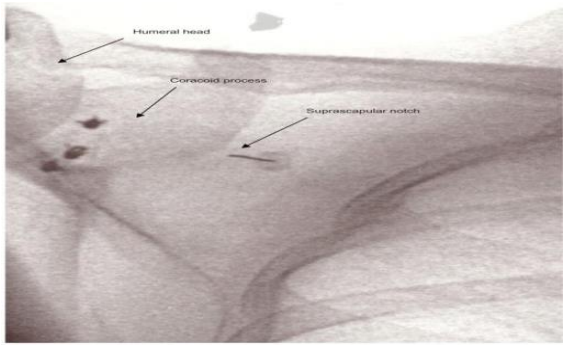

Figure (4): Radiofrequency cannula placed in the classic U-shaped notch with the patient in the prone position (R. V Shah & Racz, 2003).

In roughly 15-80% of cadavers studied, the spinoglenoid (inferior transverse scapular) ligament traverses this notch, creating a tunnel through which the nerve travels. Interestingly, the spinoglenoid ligament is reportedly more common in males than in females; this observation may provide an anatomic basis for any possible sex-related predominance in the prevalence of volleyball shoulder. The inferior articular branch, which contains afferents from the posterior glenohumeral joint capsule, joins the suprascapular nerve at the level of the spine of the scapula. After exiting the fibro-osseous tunnel at the spinoglenoid notch the nerve turns inferomedially before arborizing into 3 or 4 terminal branches that supply the infraspinatus muscle (E braheim et al., 2011).

Visual analogue scale:

The visual analogue scale or visual analogue scale (VAS) is a psychometric response scale which can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points. This continuous (or "analogue") aspect of the scale differentiates it from discrete scales such as the Likert scale. There is evidence showing that visual analogue scales have superior metrical characteristics than discrete scales, thus a wider range of statistical methods can be applied to the measurements(Hawker, Mian, Kendzerska, & French, 2011) The VAS can be compared to other linear scales such as the Likert scale or Borg scale. The sensitivity and reproducibility of the results are broadly very similar, although the VAS may outperform the other scales in some cases. These advantages extend to measurement instruments made up from combinations of visual

analogue scales, such as semantic differentials(Aicher, Peil, Peil, & Diener, 2012) Recent advances in methodologies for Internet-based research include the development and evaluation of visual analogue scales for use in Internet-based questionnaires.

Materials and Methods

Data Collection: This prospective, randomized clinical trial was carried out in Assiut university hospital pain clinic. Written informed consent was obtained from all patients. 40 cases scheduled for arthroscopic rotator cuff surgery were included. Those study patients group were randomly assigned into two groups. Group (P) is the pulsed radiofrequency group and group (C) is the control group. Patient's age, sex, weight, height, residence and contacting with patients including phone number and address were recorded. All groups underwent VAS assessment 10 days before surgery, after R.F,and at fixed time intervals at 2h, 6h, 12h, 24h and 48h after surgery. Analgesic consumption was also recorded. Any complications or breakthrough pain were recorded.

1Inclusion and exclusion criteria:

Inclusion criteria

1. Patients scheduled for arthroscopic surgery of the shoulder.
2. ASA physical status 1-3.
3. Age group above 17y.

Exclusion criteria

1. Infection at site of injection.
2. Coagulopathy or other bleeding diathesis.
3. Pre-existing neurologic deficit in the
4. working area.
5. History of chronic Opioid use.
6. Failure to communicate with investigator or the hospital staff.

Method: Randomization was done .using computer-generated random table for the two groups as previously described. Consents were fulfilled by the patients. Visual analogue score before the procedure for all patients. Ten days before the scheduled surgery,(group P) underwent R.F to the suprascapular nerve .then VAS was reported after the intervention. 2ml lidocaine 1% injected in the site of probe insertion after good sterialization by Betadine © solution. C-arm was utilized and oblique about 16 degree to the right and angled cephalo-caudal about 18 degrees. The suprascapular notch was well visualized there (see fig.4). 20 gauge needle, 10 cm length, 5 mm active tip, straight blunt radiofrequency needle was advanced towards the notch. Sensory and motor stimulation were advanced to test suprascapular nerve. The sensory stimulation at 50Hz, 0.2 millisecond pulse width and 0.3V was performed to reproducible paraesthesia, while motor stimulation was carried out at 2 Hz millisecond at 0.4v to produce infraspinatus and supraspinatus muscle contraction. 42 C was the optimum temperature and frequency of 2 Hz and a pulse width of 20millisecond was set. Three cycles of 120 seconds were done. Group (P) cases were allowed to go home 1 hour after the procedure. VAS score were recorded as described previously. (group C) no intervention was performed. All patients was proceeded to the scheduled surgery. The postoperative medications were ketorolac 30 mg and paracetamol 1gm as IV infusion every 8h. Breakthrough pain is defined as VAS>6. In these cases, morphine 2mg was given IV. After discharge paracetamol 1gm was prescribed every 6h

Data Analysis:

Analysis of data was done by IBM computer using SPSS (statistical program for social science version 20) as follows:

- Description of quantitative variables as mean, SD and range.
- Description of qualitative variables as number and percentage.
- Chi-square test was used to compare qualitative variables between groups.
- Fisher exact test was used instead if chi-square when one expected cell or more less than 5.
- Unpaired t-test was used to compare quantitative variables, in parametric data (SD<50% mean).
- Mann Whitney test was used instead of unpaired t-test in non- parametric data (SD>50% mean).
- Paired t-test was used to compare quantitative variables in the same group before and after. P value >0.05 insignificant P<0.05 significant P<0.01 highly significant

Results

Demographics distribution

The demographic result of our study is fully illustrated in the table (1). There were no statistically significant differences among age, gender, occupation and residence.

Table (1): Comparison between the studied groups as regard general data**.**

Variables	Cases n=20	Control n=20
Age	49±9	47.8±11.5
Gender		
Male	12(60%)	7(35%)
Female	8(40%)	13(65%)
Occupation		
House wife	7(35%)	13(65%)
Manual	8(40%)	5(25%)
Clark	4(20%)	2(10%)
Professional	1(5%)	

Male and female difference was of no statistical significance in total over all study among our cases. The only exception was in 6-12 hour intervals, the males had lower VAS than females see table (2).

Table (2): Comparison between males and females as regard pre and postoperative results among cases.

Variable	Males n=12	Females n=8
VAS preoperative	7.5±1.5	7.1±1.4
After intervention	3.2+0.8	2.9+2
After 2hours from surgery	3.5+1.4	3.8+1.6
After 6hours from surgery	2.1±2.6	3.1±2
After 12 hours from surgery	2.2±1.7	3.5±1.6
After 24hours from surgery	2.7±1.7	2.9±1.3
After 48 hours from surgery	2.5±2	2.7±1.6
After 3 months from surgery	2.1±1.6	2.3±1.6

Anthropometric relationship:

Regarding height, weight and BMI, the data collected and analysed in both groups show no statistical significance by using unpaired t-test (p=0.39, 0.21 and 0.30) respectively.

Table (3): Comparison between the studied groups as regard anthropometric data**.**

Variables	**Cases** n=20	**Controls** n=20
Weight (kg)	74.2±9	72.5±11.7
Weight (kg)	165±33.6	155±28.5
BMI	27.6±7	30±8.7

VAS score in both groups:

When their VAS score was assessed and compared between the two groups by using unpaired t-test, the (P) group had lower scores in comparison to controls in all intervals after intervention. (p= 0.04 at 2 hours, p=0.005 at 6 hours, p=0.000 at 12h through 3 months).

Table (4): Comparison between the studied groups as regard VAS before and after treatment.

Variable	Males n=12	Control n=8
VAS preoperative	7.5±2	7.3±3
After intervention	3	6.1±1.3
After 2hours from surgery	3.7±1.2	4.6±1.7
After 6hours from surgery	2.7±0.9	4.8±2
After 12 hours from surgery	3.1±1.02	5±1.4
After 24hours from surgery	2.8±1.6	4.1±0.7
After 48 hours from surgery	2.6±1.4	5.1±1.1
After 3 months from surgery	2.2±0.6	3.7±0.8

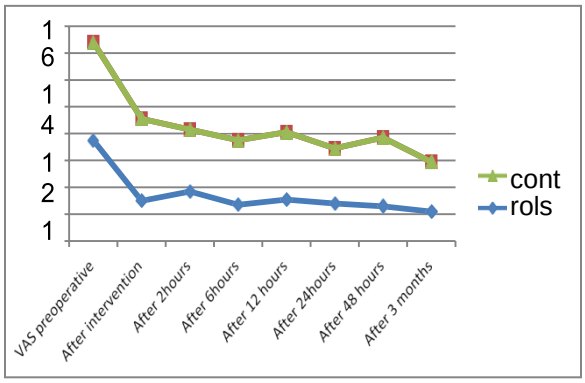

Figure (5): The summation of VAS score at each interval in both groups.

VAS score changes per interval:

The VAS score recording before and after treatment among cases shows not only decline in VAS among cases in comparison to controls at per each interval, but also obvious decline in pain score "progressively". Its ranged from 15.3%-60%. The majority of our cases were 45% improved after 3 months interval. In control group, decline of VAS score was also achieved per interval by using unpaired t-test. But actual pain satisfaction wasnot achieved as good as PRF group. The 3 months interval pain score reduction was 23%. In either group, the pain score was not changed after 6-12 h interval, and had no changes comparing to preoperative results by using Mann-Whitney test. The most important change noted was 3 months intervals (30% in cases vs. 23% in control).

T**able (5):** Change of pain score before and after treatment among cases**.**

Variable	Males n=12	**% of change**
VAS preoperative	7.5±2	
After intervention	3	15%
After 2hours from surgery	3.7±1.2	6 %
After 6hours from surgery	2.7±0.9	16 %
After 12 hours from surgery	3.1±1.02	1 %
After 24hours from surgery	2.8±1.6	24.5 %
After 48 hours from surgery	2.601.4	30.3 %
After 3 months from surgery	2.2±0.6	45.6%

Table (6): Comparison between pain score before and after treatment among controls.

Variable	Males n=12	**% of change**
VAS preoperative	4.9±2	
After intervention	-	**-**
After 2hours from surgery	3.7±1.2	24%
After 6hours from surgery	4.7±0.9	3.9 %
After 12 hours from surgery	4.9±1.02	0.7 %
After 24hours from surgery	5.5±1.6	12.5 %
After 48 hours from surgery	5.6±1.4	22 %
After 3 months from surgery	5.9±0.6	23 %

Analgesic requirement:

Highly significant relationship between our cases and analgesia consumption in control group had been discovered. No case in (P) group require additional analgesics postoperatively while 7 patient in control group (n=20) requires additional heavy analgesia.

Table (7): Comparison between both groups as regard analgesic requirement

Variables	**(P) group n=2**	**Controls** n=20	**P**
No	20(100%)	13(65%)	0.000 HS
Yes	0	7(35%)	

Regression analysis:

Logistic regression was used to see which variables predicted a good or excellent outcome. Variables included age, a known injury, occupation, previous surgery, cervical spine disease, presence of tear, male or female gender, and significant pain relief more than 50%. None of the variables were significant

Discussion

Patient of the (P) group in our study showed great reduction in their pain scores after the intervention and in the 1st 48 hours after surgery. On the other hand, when these patients were followed up after 3 months from the interventions their pain scores remained lower than those in the control group.

Arthroscopic surgery in the shoulder causes slow improvement in the patients VAS over time at 3 months interval.Postoperatively patients had their VAS low because they performed surgery to repair their tear in the rotator cuff. This causes VAS to be low in the control group too. However, the (P) group patients still had significant lower VAS at 3 months interval. This could be due to the effect of pulsed radiofrequency on pain transmission at this time. During our follow up, we observed a very good cooperation with physiotherapy during their therapeutic sessions since the time of surgery cannot be overlooked (Holzer et al., 2013). Moreover, cutting the chronic pain circuit at the time of intervention 3 months before might, at least, had ameliorated the controls sensitization and is amplifying component in pain perception and this can also explain lower pain score in the (P) group after 3 months (Ross et al., 2014).

Pulsed radiofrequency versus continuous radiofrequency

The mechanism by which PRF causes pain relief in the absence of significant heat- induced tissue damage is debatable. Alternating current is delivered to a target nerve without producing significant heating. Typically, a 50 kHz current is delivered in 20 ms pulses at a frequency of 2 Hz, for a period of 120 s. The relatively long pause between pulses allows for heat dissipation, principally through conduction and convection. Heating is further minimized by limiting electrode-tip temperature to ≤42°C. This results in a temperature in surrounding tissue insufficient to produce neural coagulation. In contrast to CRF, the greatest current density with PRF is delivered distal to the active tip of the electrode. This allows the electrode to be placed perpendicular to the nerve, potentially resulting in shorter procedure times. But heat production in CRF is the major disadvantage that makes it limited to be used in pain management centres. As an exception, mild discomfort at the site of injection which was resolved after 3 weeks maximum (Shabat, 2006) no side effects related to the pulsed radiofrequency technique were reported to date (Cahana, 2005). Thermal injury of the CRF has been well studied in the past decade by Cosman, Edine and Heavner. Cosman et al (2005) concluded that CRF lesioning causes heat destruction of neurons. Pulsed RF lesioning (PRFL) produces heat bursts with temperatures in the range associated with destructive heat lesions. PRFL also produces very high electric fields that may be capable of disrupting neuronal membranes and function. Erdine et al., (2005) disagreed with the previous conclusion as his experiment on dorsal root ganglion of rats showed that that PRF application is less destructive of cellular morphology than CRF at clinically used "doses". The controversy of this side effect was explained by two

methods. First, emphasizing the "no thermal effect" due to (pulsed) intermittent behaviour of the radiofrequency waves. Second, due to level of temperature of the tip of needle applied to the nerve. However, PRF produced barely detectable thermocoagulation at 60 C. above 60 C; the pattern of coagulation produced by PRF resembled that observed with CRF. However, the density and size of the coagulation appeared somewhat greater with CRF(Heavneetal.,2006).

PRF versus nerve decompression and pharmacotherapy:

Arthroscopic decompression of suprascapular nerve is an old era in the literatures. Mild invasiveness of its nature did not prevent its complications and recurrence rates in either rotator cuff injury patients or in absence of rotator cuff injury (A. A. Shah et al., 2011). PRF is minimal invasive maneuver in comparison to arthroscopic repair or decompression. The post op shoulder joint pain is as same as preoperative and slow decline of VAS score is well known events in arthroscopy group. In our study, major decline in VAS score was achieved very rapid and if recur later on it will take 3-8months for another setting. Other surgical options include arthroscopic subacromial decompression, tuberoplasty, and release of the long head of the biceps. Such procedures, however, should be used with caution in some patients with massive rotator cuff tears, as the humeral head may further subluxate antero-superiorly, causing increased pain. Arthroplasty is another option but, in this group of patients, is accompanied frequently by disappointing long-term results. More recently, the use of reverse-geometry shoulder prostheses appears promising, but long-term results for these implants are awaited. Regardless of surgical advances, the fact remains that many of these patients are elderly with multiple medical comorbidities. Some are poor surgical candidates, and many are unfit for anaesthesia. Approaches that do not involve medication or anaesthesia therefore lend themselves well to this group of patients (Kane et al, 2008). Cohen and coworkers (2006) studied 49 patients retrospectively to compare PRF to dorsal root ganglion with pharmacotherapy. Despite the different aspect of study area (DRG versus suprascapular nerve) he found that Pulsed RF of the DRG was a superior treatment to pharmacotherapy. Chua & Sluijter (2011) reported no statistical difference between PRF to suprascapular nerve and intra-articular corticosteroid injection in their review.

Structural Changes in targeted nerve:

During microscopic examination of sciatic nerve exposed to PRF, there were no gross macroscopic and microscopic changes observed (Erdine et al., 2005). Electron microscope revealed different changes in the intracellular composition. These changes were enlarged endoplasmic reticulum cisterns and increased number of cytoplasmic vacuoles (Erdine et al., 2005). In the same study, the CRF was also applied and the same results in light microscope were retrieved but the electron microscope changes were aggressive. In addition the Wallerian degeneration was detected in CRF group. Other studies concluded that subclinical changes included endoneurial edema caused by alterations in the function of the blood-nerve barrier, fibroblast activation, and collagen deposition on light microscope. Tissue returned to normal conditions by 7 days in nerve and 21 days in the DRG (Podhajsky et al, 2005). Therefore, a concept of intracellular alteration due to genetic alteration has been raised over the past years as mechanism of action. Several experiment were took place to delineate the mechanism of action. (Wu et al., 2012) found that Met-enkephalin levels were higher in rats treated with PRF due to experimental nerve injury. The notion that the electrical fields generated by PRF can affect neuronal membranes is supported by neurophysiologic studies that demonstrate PRF changes synaptic signaling and causes electroporation (Cosman and Cosman, 2005). A popular theory is that the rapidly changing electric fields produced by PRF alter the transmission of pain signals via a pathway involving c-Fos, a so-called immediate early gene. This theory is substantiated in a study by Van Zundert, (2005) who demonstrated that CRF at 67° C, PRF at 42° C for 120 seconds, or PRF at 42° C for 8 minutes performed on rat dorsal root ganglia all increased c-Fos expression in the dorsal horn, a response that was sustained as long as 7 days after treatment. These results not only indicate a mechanism of c-Fos activation that is independent of temperature, but also hint at the inhibition of excitatory C fibers and long- term depression as a viable therapeutic mechanism in PRF. Unfortunately, this study somewhat contradicts a previous study conducted by Higuchi et al. (2002) who found increased c-Fos immunoreactivity in laminae I and II of the rat dorsal horn only in rats treated with PRF at 38° C and not in those treated with CRF at 38° C or sham. Therefore, Richebe et al. (2005) rightfully caution against embracing the theory of a c-Fos– mediated pathway due to the paucity of consistent molecular evidence as well as the lack of controlled studies demonstrating the efficacy of PRF overall. It is also important to note that changes in c-Fos are associated with a number of cellular processes and that the upregulation of c-Fos observed with PRF may be unrelated to the mechanism by which PRF produces its therapeutic effect. In addition to c-Fos, activating transcription factor 3 (ATF3), an indicator of "cellular stress," is also increased with PRF; interestingly, this effect is seen only in small-diameter C and Ad fibers. However, as is the case with c-Fos, the actual role of ATF3 remains unclear (Byrd & Mackey, 2004). Hamann and coworkers (2006) during his experiment on PRF at sciatic nerve and DRG of rat model noted upregulation of the ATF3. Hence, the biological changes in targeted nerve are due to electro-mechanical effect and not due to heat effect. Another point that should be registered well, the main changes were detected in sensory fibers only and motor fibers were spared at electron microscope level.

Pain free interval:

The short term pain relief is clinically meaningful and well appreciated by patient. In our study the 1st 24 hour interval shows around 20% change in VAS score. The long term pain relief is similar in many observed trials. Most of clinical trials recorded 3 months period as the maximum time of pain

reduction. Pain (measured by VAS score) emerged again afterward (Byrd & Mackey, 2008). Others like Simopoulos et al (2010) perform randomized trial between CRF and PRF, he found that more than 50% of cases were pain free at 3 months interval, The vast majority of patients had lost any beneficial effects by 8 months.

Pain and restricted shoulder movement, the role of PRF:

PRF is targeting the sensory fibers only in the suprascapular nerve and no motor fibers affection either theoretically or practically. Physiologically the pain signals limit movements of the injured limb to avoid exacerbation of the inflamed tissues. ROM of the shoulder was not included in our study but as comparison to previous trials, ROM was markedly improved and correlated with VAS score changes (Simopoulos et al., 2012). There are two theories to emphasizing this phenomenon. *First*, lesioning of motor nerve fibers to half of the rotator muscles does not consistently result in functional deterioration; rather, it results in improvement, because complimentary muscles are employed in the setting of pain reduction (Simopoulos et al, 2012). *Second*, reduction of pain signaling associated with movement abduction and flexion, but on the other hand the degenerative process of rotator cuff continues thereafter (A. A. Shah et al., 2011).

Limitation of the study:

Our study was limited due to small studied group, duration of symptoms was not included, lacking of long term follow up, using of single pain score system and motor examination was not included in either group.

Further clinical studies:

PRF is a recent advance in pain management field. The controlled randomized blinded trials are still inefficient worldwide. Comparison of PRF and other modalities in big case series are mandatory to classify the suprascapular pain management among other modalities.

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