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Observation of Long-Term Clinical Results of Knee Intra Articular Pulsed Radiofrequency Combined with Genicular Nerve Radiofrequency Ablation for Chronic Knee Pain

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Original Article

Summary

Background: *Intra-articular pulsed radiofrequency combined with genicular nerve radiofrequency ablation can cause sensory denervation results in greater pain reduction and improve functions in patients with chronic knee pain.*

Aim of study: *To assess the long-term clinical results of Intra articular pulsed radiofrequency combined with genicular nerve radiofrequency ablation for treatment of chronic knee pain.*

Methodology*: This was an observational retrospective study conducted at Zanko Private Hospital in Erbil city-Iraq during the period from January 2019 to May 2020. Eighteen patients with chronic knee pain for whom conventional treatment was failed were included and treated with intra articular pulsed radiofrequency combined with genicular nerve radiofrequency ablation (GNRFA). Final results of treatment was reported at ≥ 24 months of follow up and the successful treatment defined by a reduction in pain scores of ≥ 50%.*

Results*: The mean age of the patients was 64.6 ± 8.2 years, females contributed for 83.3% of the studied group. At ≥ 24 months a reduction in numerical rating scale (NRS) of ≥ 50 %, ≥ 80% and ≥ 95%, was reported in 83.3%, 72.2% and 11.1% , respectively. 16.7% of patients reported 6 and 55.6% reported 7 on Patient's global impression of change (PGIC), and 83.3%, of patients reported MCID (PGIC ≥ 6). None of the patients developed an adverse reaction or side effect*

Conclusion*: Knee intra articular pulsed radiofrequency combined with GNRFA was useful, effective and safe tool for treatment of chronic knee pain giving long-term improvement in pain and physical activity and functionality.*

Keywords: *Knee pain , Chronic, Osteoarthritis, Radiofrequency, Genicular Nerve, Outcome*

1. INTRODUCTION

Pain traditionally defined as a unpleasant experience of sensation associated directly to tissue damage or aggression. In this way, the sensation of pain would be proportional to the damage, However, currently, the definition of pain also takes into account the affective and emotional components. The International Association for the Study of Pain describes pain as "an unpleasant sensory and emotional experience associated with, or described in terms of, actual or potential damage.". From this perspective, pain is unique and subjective, that is, the same pain does not affect all people equally because there will always be components that make this difference possible (1,2)

The complexity of the phenomenon of pain means that it can be classified it in different ways, and there are different pain classification system that play important roles in the management of pain, these systems based on anatomical location, etiology, intensity, duration or pathophysiological classification. On the other hand there are different scales used in assessment of pain intensity such as Numeric rating scale (NRS), verbal descriptor, FACES scale, Wong-Baker, Iowa , and functional pain scales (3). However, the most used are the numerical rating scale, and visual analog scale (VAS) (4). It is worth remembering that the threshold for the perception of pain is subjective and different in each subject, so that when faced with the same stimulus, the perception may be different among individuals (5).

Chronic Pain: this is the name given to pain that persists over time, it is almost always established between three and six months, occurs at intervals of months or years or is associated with permanent pathologies. Chronic pain is usually continuous, intractable, intermittent, or recurrent. Even when mild, it can be so vicious that it becomes a condition in itself, often requiring daily management. It can also be accompanied by concomitant psychic alterations and does not fulfill, like acute pain, a defined function, but is part of the disease. It generates feelings of helplessness, despair and absurdity (6,7).

The knee joint is a ball and socket joint formed by two bones the femur and tibia and a fibrocartilage pad called the meniscus. This type of joint allows movement in three directions: flexion, extension, and rotation. Flexion refers to bending forward or backward; extension means straightening out; and rotation occurs when the leg moves from side to side. The knee joint has been classified as a modified hinge since 1892. In fact, the classification was created

because of the way the ligaments attach to the bone (8,9).

The main ligament attaching the femur to the tibia is called the anterior cruciate ligament (ACL). This ligament attaches at the top of the femur and runs down to the bottom of the tibia. When the ACL tears, the knee becomes unstable and causes pain (10).

Knee pain is a pain in or around the knee. It is one of the ailments that affects the majority of patients who come to health service consultations. Almost 25% of people at age of 55 years or over, usually suffer knee pain (11). However, this pain not only has a place in the physical cause, but also psychological and social factors. Pain is a universal experience, everyone has experienced pain at some point in their lives. Chronic knee pain is the most common pain within chronic musculoskeletal diseases, and represent a common cause of disability and compromised quality of life for patients., it is multifactorial in its pathophysiology, but it is usually related to knee osteoarthritis, post-surgical and post-traumatic pain (12,13)

There are many causes of knee pain, the most frequent causes of chronic knee pain are osteoarthritis which is associated with greater difficulty in analgesic management (14). There are different other causes contribute to knee pain; some common injuries like ligament sprains in medial, lateral collateral ligaments, ACL, PCL, meniscal injuries and tears, muscle strains and fractures. Some diseases also contribute to knee pain, osteoarthritis is the most frequent one. Rheumatoid arthritis, chondromalacia, ankylosing spondylitis, osteomyelitis, tumors , gout and other diseases also responsible (15). Inflammations like bursitis of the knee, tendinitis and synovitis, are not uncommon causes. Deformities play important etiological relation with knee pain; knee flexion deformity, genu varum, valgum and genu recurvatum. Some syndromes like Patellofemoral pain syndrome, plica syndrome and joint hypermobility syndrome are among the causes of knee pain. Dislocations of knee joints often cause knee pain(16) .

Other causes of pain include cold temperature where the knee pain commonly affect people exposed to cold temperature, the pain associated with cold temperatures, could be due to tenosynovitis of the tendons around the knee or chondrocyte injury in frostbite (17–19). Lower physical activity and other modifiable risk factors also contribute to the development of knee pain (20). Sometime, knee pain is referred one due to sharing the same innervation of the spinal segment. Referred pain from hip joint pathology like in slipped capital femoral epiphysis

may cause knee pain (21)..

Diagnosis:

Timely diagnosis of the causes of knee pain allows to make the treatment of knee pain the most effective. For diagnosis, the localization of pain, its degree, nature, factors that increase or alleviate, as well as the time of occurrence - newly arisen or recurring, are important. The time of maximum pain is important - before the first movements in the joint or after a period of physical activity, whether the pain appears in the morning, after waking up or during the day. The location and severity of pain may vary depending on the cause. Signs that sometimes accompany knee pain include: Swelling and stiffness of the joint on the affected side, redness and warmth to the touch, feeling of weakness or instability in the knee, popping or crackling noises, inability to fully straighten the knee. (21–23)

Usually, an examination by a doctor is enough to make a diagnosis, but sometimes an additional examination is justified and includes: Blood tests, for example: rheumatoid factor, uric acid concentration, antinuclear antibodies, etc. Visualization methods: Standard radiography is the primary method of investigation, but it is less sensitive than computed tomography (CT), magnetic resonance imaging (MRI) or ultrasound (ultrasound). Ultrasound is a convenient and widely available method for detecting joint effusion and soft tissue damage around the knee. MRI is the most sensitive method for detecting lesions that are not visualized on a conventional x-ray, as well as changes in the soft tissues and intra-articular structures of the knee. CT is applicable in cases where MRI is contraindicated , not available to the patient. MRI has to be avoided unless there other diagnostic methods failed or inconclusive, on the other hand, in some cases, MRI could not prove the diagnosis (24–26) Arthrocentesis and examination of the joint fluid is the most accurate method for excluding infection and identifying crystalline arthritis. Arthrocentesis and examination of synovial fluid is also important for other causes of knee pain and is most accurate method to exclude infection and identify unexplained arthritis (27,28).

Management:

At present, there is no specific ideal treatment for the management of chronic knee pain and the severity of symptoms varies for little known reasons between individuals, even with comparable degrees of involvement. For this reason, general management is based on a

combination of pharmacological and non-pharmacological treatment modalities. Among the main treatments are management focused on rehabilitation such as supervised physical therapy (29), weight reduction (30). Drugs such as acetaminophen, non-steroidal anti-inflammatory drugs, neuromodulators, opioids (31), interventional management such as regional blocks, intra-articular injections of local anesthetic, steroids and hyaluronic acid (32,33).

Genicular nerve block has shown as a beneficial interventional treatment in chronic knee pain of knee OA (34). The variability in the sensory nerves of the knee and the location of the genicular nerves take a considerable attention in chronic pain management. There are three main nerves that supply sensory innervations to the knee joint; the superior lateral (SLGN), superior medial (SMGN), and the inferior medial genicular nerves (IMGN). Before entering the anterior capsule, the course of these nerves, in general, is adjacent to the periosteum except the nerves of vastus lateralis and vastus medialis. Due to their locations and variability of these genicular nerves, a debate has been raised about the ideal location to be targeted with genicular radiofrequency ablation (RFA) (35).

Radiofrequency ablation (RFA):

This method also called Radiofrequency denervation (RFD), Facet rhizolysis, or radiofrequency neurotomy. Is a minimally invasive method that allows to safely deal with pain in the knee joint. RFA of the sensory nerves of the knee is indicated when pain medications do not provide sufficient pain relief, even when powerful drugs or combinations are prescribed. In cases for whom surgery postponed for any reason, or surgery is necessary but the patient has contraindications to its implementation, for example, severe concomitant diseases or when the pain remains despite knee replacement. This technology uses radiofrequency waves for heating parts of the pain transmitting nerves that create heat lesions which lead to preventing the nerves to send the pain signals to the brain. Radiofrequency ablation creates heat to the nerves of 90°C to break down nerves (radiofrequency denervation) (36–38) . This treatment can provide lasting relief from 6 months to 2 years. Pain relief after RFA is long-last in comparison to other therapeutic methods like injections. There are three methods of RFA these are; conventional continuous radiofrequency (CRF) ablation in which a continuous high voltage current is used to produce heat lesion (39–41)..

The second procedure is the Pulsed radiofrequency (PRF) ablation in which short bursts of

high voltage current is used with silent phases in between. Pulsed radiofrequency (neuromodulation) transfers heat to the nerves at a lower temperature of 40-45°C. It is can provide long-lasting pain relief by disrupting the myelin sheath and pain fibers (39–41).

The third method is the Water-cooled radiofrequency (WCRF) ablation, in this method a special needle is used which is heated and also cooled using continuous flow of water. This cooling system is to prevent overheating (42). Radiofrequency ablation is performed by an algologist after examining the patient and decision is made about the procedure according to patient's preferences. The procedure is performed on an outpatient basis, hospitalization is not required; After the necessary preparation, under sterile conditions, The procedures are performed under CT or Ultrasound guided with the majority only requiring local anesthetic injection, determines the location of the sensitive branches of the nerves of the knee joint, after which the injection site is anesthetized with a local anesthetic (43–45).

Further, needles are passed under continuous ultrasound control, through which electrodes are then installed, heated by a radiofrequency generator to the required temperature; The whole procedure is performed under local anesthesia and does not cause significant discomfort for the patient. In some cases, the first stage before RFA is a therapeutic and diagnostic blockade - the introduction of an anesthetic into the points where RFA is planned to be performed. This is necessary in order to accurately assess the potential effectiveness of the procedure (43–47)

2. PATIENTS and METHODS

This was an observational retrospective study conducted during the period from January 2019 to May 2020. After approval of the study by the Scientific Council of the Arab Board of Health Specialization , Iraqi Council of Regional Anesthesia and Interventional Pain Management a total of 18 consecutive patients with chronic knee pain for more than 6 months for whom conventional treatment was failed and they were treated with intra articular pulsed radiofrequency combined with genicular nerve radiofrequency ablation (GNRFA) targeting the superomedial, superolateral and infero medial genicular nerves during the study period at Zanko Private Hospital in Erbil city in northern of Iraq

Inclusion criteria:

1. Adult patients aged older than 18 years
2. Had knee pain for longer than 6 months.
3. Patients who showed no or insufficient response to other conventional treatment modalities
4. Patient with knee pain score of more than 3 on numeric rating scale (NRS).
5. Patient with OA grading score of 2 or more (KL≥ 2).

Exclusion criteria:

1. Patient's refusal.
2. Unstable vital condition.
3. Patients who showed no response during the first months after the intervention.

Procedure

Bipolar radiofrequency ablation of genicular nerves; the procedure performed under sterile preparation after appropriate positioning of the patients. Subcutaneous anesthesia was applied, A bipolar RFA cannula of gauge 18 with 5 mm active tip was used; it has a 100 mm length. Under fluoroscopic and ultrasound guidance, the cannula was introduced to the specified locations of SMGN, SLGN and IMGN. RF at 80 °C was conducted for four minutes. Combined with this procedure, pulsed radiofrequency was performed for all patients. All procedures were performed under aseptic technique where the region wiped with iodine-based antiseptic before intervention and the sterility rules were strictly followed. After palpation of the anterolateral knee part, local anesthesia with lidocaine 1% was applied to anesthetize the access point. A needle of 22 gauge, 10 mm active tip and 100 mm length used as an introducer and intra-articularly placed through the specified area. When satisfied placement obtained, the introducer stylet was removed and radiofrequency probe was placed in via the introducer needle. Pulsed radiofrequency then initiated with a temperature of 42 °C and a pulse width of 20-millisecond at two Hertz for six minutes. Patients was transferred to the recovery room when the procedure is completed. Patients at recovery room were monitored for up to 60 minutes to assess for any complication or discomfort then discharged home. All patients were instructed to have rest for 24 hours.

Data collection and analysis:

Data were collected using a pre-constructed data collection sheet (questionnaire), including the demographic characteristics of the patients; age, sex, medical history, surgical history, duration of pain and the pain intensity according to NRS. The questionnaire also included data about the procedure performed, post intervention information and follow up findings and outcomes. Patients instructed to evaluate their symptoms after 12 and 24 months post intervention, follow up and assessment made by telephone or direct contact with the patient. Post intervention pain relief was compared to that before intervention. The long term clinical outcome of the patients was assessed using the PGIC which is a scale of 1-7 points. The score of one indicates no change while a score of 7 indicates much better improvement. The self-report measure PGIC reflects a patient's belief about the efficacy of treatment. Although widely used in chronic pain clinical trials, PGIC's validity has not been formally assessed. PGIC is a 7-point scale depicting a patient's rating of overall improvement. Patients rate their change as "very much improved," "much improved," "minimally improved," "no change," "minimally worse," "much worse," or "very much worse.

All patients asked for using other treatment modalities and co-intervention after the RFA such as physiotherapy, message, analgesic agents or surgery.

Study outcomes:

The primary results of intervention was the reduction in the knee pain based on NRS after intervention by 50% or more after a period of 24 months or more. As a secondary outcome, the proportion of patients who had 75% or more or 90% reduction in knee pain with MCID for the PGIC of 6 or more at ≥ 24 months after procedure.

Statistical analysis:

Data were entered, managed and analyzed using the statistical package for social sciences version 26. Appropriate statistical tests were applied according to the type of variables. Scale variables compared using Mann-Whitney and mean ranks comparison while chi-square and Fisher's exact tests as applicable, used to compare categorical variables. Level of significance (P. value) of 0.05 or less considered significant.

3. RESULTS

A total of 18 patients with chronic knee pain were enrolled in this study. The mean age of the patients was 64.6 ± 8.2 (Range: 32-74) years. Females were dominant among the studied group and contributed for 83.3% with a female to male ratio of 5 to one symptomatic right knee was found in 38.9% of cases and the left side symptomatic knee was present in 27.8% while 6 cases (33.3%) had bilateral symptomatic knee. Duration of symptoms ranged from 22 to 114 months with a mean of 64.8 ± 26.2 months. Additionally, None of the patients had history of total knee arthroplasty, these findings are shown in (**Table 1 and Figure 1**). At ≥ 24 months after intervention, the proportion of patients who reported a reduction in NRS of ≥ 50 % was 83.3% (15/18). The proportion of patients with a reduction in NRS of ≥ 80% at ≥ 24 months after intervention was 72.2% (13/18) while those with a reduction in NRS of ≥ 95% was 11.1% (2/18), (**Table 2**). Regarding the proportion of patients reporting 6 on PGIC it was 16.7% (3/18), the proportion of patients reporting 7 on PGIC it was 55.6% (10/18), and the proportion of patients reporting MCID (PGIC ≥ 6) it was 83.3% (15/18). It is worth mentioned that no co-interventions like physiotherapy or other mode of intervention used by patients during the follow up. From other point of view, None of the patients developed an adverse reaction , side effect or progression to surgery during the intervention or at follow up period

Table 1. Baseline characteristics of the studied group*

Age (Year)	Mean (SD)	64.6 (8.2)
	Range	32 - 74
Gender n (%)	Male	3 (16.7)
	Female	15 (83.3)
Symptomatic knee n (%)	Right	7 (38.9)
	Left	5 (27.8)
	Bilateral	6 (33.3)
Duration of symptoms (months)	Mean (SD)	64.8 (26.2)
	Range	22 - 114

SD: standard deviation of mean, * none of patients had history of total knee arthroplasty

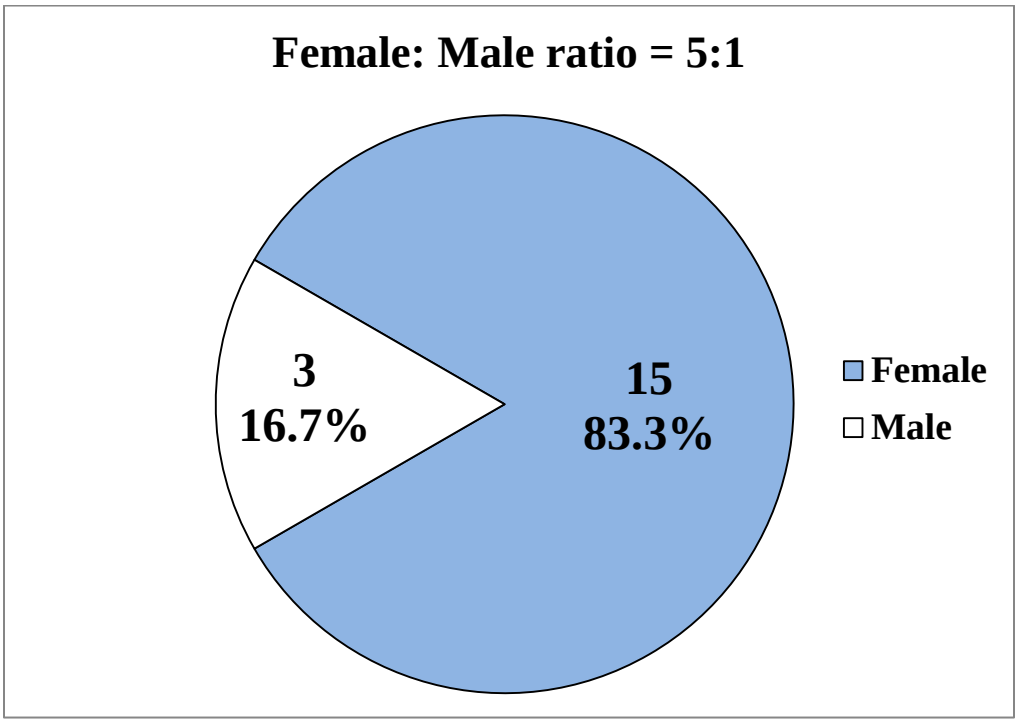

Figure 1. Pie-Chart showing the gender distribution and female to male ratio of patients

Table 2. Proportions of patients with rates of reduction in NRS reported at ≥ 24 months after intervention

Variable	Number of patients	Proportion	95% CI
Reduction in NRS ≥ 50 %	15	83.3%	72% - 98%
Reduction in NRS ≥ 80 %	13	72.2%	41% - 95%
Reduction in NRS of 95%	2	11.1%	0.0% - 31%

CI: confidence interval, NRS: numerical rating scale

Table 3. Proportional distribution of patients according to patient's global impression of change at ≥ 24 months

Variable	Number of patients	Proportion	95% CI
Reporting 6 on PGIC	3	16.7%	1.0% - 46%
Reporting 7 on PGIC	10	55.6%	35% - 92%
Reporting MCID (PGIC ≥ 6)	15	83.3%	62% - 100%

PGIC: Patient's global impression of change, MCID: Minimum clinically important difference, PGIC of 6 indicates much improved, PGIC of 7 indicates very much improved

4. DISCUSSION

It is worth mentioned that no co-interventions like physiotherapy or other mode of intervention used by patients during the follow up. From other point of view, none of the patients developed an adverse reaction or outcome. Chronic knee pain is one of the most frequent reasons for consultation in health services, it is multifactorial in its pathophysiology. It affects the quality of life of patients and had an important burden on the well-being, psychological status and functionality of patients (7,11).

Radiofrequency neurotomy mainly used and applied in cases with chronic knee pain that resistant to conventional conservative treatment or surgery. In some cases chronic knee pain continue despite increasing the dose of pain killer (36–40,48,49). After the good results of radiofrequency neurotomy for trigeminal neuralgia, it began to be used for chronic pain in the sacroiliac and facet joints (50,51). This technique was later used to treat discogenic pain, cervical facet, and cancer pain (37,52). Ablation of CRF in the treatment of knee pain in OA was first used by Choi et al. (53). Intrarticular pulsed radiofrequency combined with genicular nerve radiofrequency ablation for chronic knee pain Radiofrequency appears as an interventional technique for the relief of chronic pain, reporting improvement of over 50% in several situations and can maintained for long time, however, there is still not enough medical knowledge about its usefulness in chronic knee pain, and its possible impact on pain and functionality in this group of patients (53). Therefore, the present study aimed to assess the long-term clinical results of Intraarticular pulsed radiofrequency and genicular nerve

radiofrequency ablation as a treatment for chronic knee pain among group of Iraqi patients, hence a total of 18 consecutive patients with chronic knee joint pain. The present study documented a mean age of patients of 64.6 ± 8.2 and most of the patients were older than 60 years. Females were the dominant with a female to male ratio of 5 to one. These findings are not unexpected and consistent with the clinical and epidemiological pictures of chronic knee pain taking into account that knee OA is the most common cause of chronic knee pain which is more frequent with advancing age and females particularly postmenopausal (54–57). We conducted this study to observe the long-term effect of intra articular pulsed radiofrequency and GNRFA on patients with chronic knee pain and to estimate the level of pain reduction and the degree of improvement on patient movement and physical activity. We found a significant reduction in knee pain in addition to improvement in PGIC after treatment with combined intra articular PRF and GNRFA however, at ≥ 24 months the response and improvement reported were varied from one patient to another, nonetheless, in term of treatment success, all patients had ≥ 50% reduction in NRS combined with improved movement and physical activity. On the other hand we found high proportion of patients had a reduction in NRS of ≥ 80% where the proportion was 72.2% additionally, 11.1% of patients had a reduction of ≥ 95%, so that, collectively, the proportion of patients with a reduction in NRS of ≥ 80% to 95% was up to 83.3%. Furthermore, all patients at ≥ 24 months reported PGIC of ≥ 6 and higher proportion of patients, (83.3%), with PGIC of ≥ 7 and MCID. These higher proportions reported in our study considered very good compared to other treatment modalities, in term of long term improvement.In this regard, our findings consistent with that reported in previous studies; Koshi et al. (58) assessed the long-term outcomes of GNRFA technique among 11 consecutive patients with ≥ 6 months chronic knee pain and followed them for ≥ 18 months. Koshi et al. found that at a mean time of 24 months, 91% of patients had ≥ 50% reduction in NRS, 73% had a reduction of ≥ 80% and 9% had a reduction in NRS of 100%, also they found that the proportion of patients who were much improved (PGIC ≥ 6) and very much improved (PGIC≥7) were 27% and 64%, respectively. Also they found that 91% of patients reported MCID for PGIC ≥ 6, these findings close to our results.

The reduction in pain reported in our study is better than many GNRFA studies that focus only on SMGN, SLGN, and IMGN without intra-articular PRF and it can be attributed to more

comprehensive denervations. However, in our study, overestimation of the effect of RFA could not be excluded due to our low number of included patients. Hence, larger studies are highly suggested to include larger sample size and obtain more precise results and conclusions about the response rates and improvement.

In the current study, our patients experienced a significant reduction in pain and improved knee function, particularly at the first 12 months after intervention, therefore, regular and scheduled follow up and evaluation is necessary and recommended particularly in OA patients for timely re-intervention if the procedure is required to be repeated.

Multiple previous studies widely investigated the effect of RFA of the genicular nerves targeting SMGN, SLGN, and IMGN, but bipolar RF current flow between two probe electrodes using a large-diameter cannula of 10-mm active tips without presence of a ground pad produces the largest circular brick-shaped lesion, but to date little studied in the field of GNRFA (59).

Pulsed radiofrequency treatment is used in this study along with conventional radiofrequency ablation. The temperature of the target tissue during PRF treatment is often set at around 42°C, so nerve damage, neuropathic pain or joints were not be a problem. In addition, PRF is less dangerous than conventional radiofrequency ablation in terms of loss of motor function, neuritis like responses, and preservation of motor and autonomic nerve fibers (48).

According to the hypothesis of Sluijter et al. that PRF can have a dual effect when administered intra-articularly. PRF has two effects on the nervous system: one is suppression of the C-fiber excitatory response, and the other is suppression of synaptic transmission (49). Furthermore, Chen et al. suggested that PRP has clear advantages in the conservative treatment of knee OA. PRP therapy can reduce long-term pain and improve knee function without additional risks (60). This method was performed under guidance with ultrasound and fluoroscopy. Ultrasound can visualize soft tissue structures such as nerve bundles and blood vessels. Ultrasound also has the advantage of not being exposed to ionizing radiation like fluorography (44,45). The use of ultrasonography in GN RF is easier and safer than fluoroscopy, so that ultrasound is easier and safer to be used compared to fluoroscopy (61). A previous study conducted by Sari et al. compared the fluoroscopy and ultrasound as imaging techniques in CRF of genicular nerves, They found no significant differences in the WOMAC

and VNRS scores after three months but a shorter time with ultrasound compared to fluoroscopy (62). In the present study we ,fortunately, did not report significant adverse reactions , side effect complication, or progression to surgery among the patients neither during the intervention nor at different time of follow up period which reflect the safety and efficacy of our procedure

5. CONCLUSIONS

Knee intra articular pulsed radiofrequency combined with GNRFA is useful, effective and safe tool for treatment of chronic knee pain resulted in significant long-term improvement in pain and physical activity and functionality. We recommended the use of pulsed radiofrequency combined with GNRFA in treatment of chronic knee pain when conservative treatment are failed despite the maximum allowed doses are administered . Further studies with larger sample size are highly suggested for more precise evaluation of the outcomes.

Ethical Clearance:

Ethical issues were taken from the research ethics committee. Informed consent was obtained from each participant. Data collection was in accordance with the World Medical Association (WMA) declaration of Helsinki for the Ethical Principles for Medical Research Involving Human Subjects, 2013 and all information and privacy of participants were kept confidentially.

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