IAR Journal of Anaesthesiology and Critical Care
ISSN Print : 2709-1872 | **ISSN Online :** 2709-1880
Frequency : Bi-Monthly
Language : English
Origin : Kenya
Website : https://www.iarconsortium.org/journal/IARJACC/details/

OPEN ACCESS JOURNALS

Reserch Article

Comparison of Post Procedural Medication Requirement and Side Effects among the Patients of Chronic Pelvic Pain in Pulsed Radiofrequency Ablation versus Thermal Radiofrequency Ablation of Ganglion Impar

Article History

Received: 20.05.2022
Revision: 30.05.2022
Accepted: 10.06.2022
Published: 20.06.2022

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How to Cite the Article:
Madhav Verma, Kartik Syal, Rajesh Kumar Verma, Manoj Maitan & Akshu Bhardwaj. (2022); Comparison of Post Procedural Medication Requirement and Side Effects among the Patients of Chronic Pelvic Pain in Pulsed Radiofrequency Ablation versus Thermal Radiofrequency Ablation of Ganglion Impar. *IAR J Anaes Crtic Cre.* 3(3) 20-24

Abstract: ***Background:*** The present study was done to compare the Post Procedural medication requirement and side effects among the patients of chronic pelvic pain in pulsed radiofrequency ablation versus thermal radiofrequency ablation of Ganglion Impar. ***Material &Methods:*** The present study was prospective, randomized, single blinded study and was based on series of 30 patients presenting with chronic pelvic pain , having already failed conservative medical management, presenting in Pain clinic if IGMC Shimla. The patients were divided into 2 groups of 15 patients. Patients in Group A(n=15) were given thermal radiofrequency ablation where as patients in Group B were given pulsed radiofrequency ablation.***Results:*** Mean age (in years) in group A and B was found to be 47.60± 6.833 and 42.67±7.807 years respectively. The p value was calculated to be 0.76 which was found to be statistically non significant. In Group A, 13(86.7%) patients didn't need any Medication to be started Post Procedure and 2(13.3 %) need medication post procedural while in Group B, 6(40.0%) patients didn't need any Medication to be started Post Procedure and 9(60.0 %) need medication post procedural. The P value was 0.021 which was statistically significant. In both Group A and B None of the patients had any side effects post procedural. ***Conclusion:*** Present study showed that Post Procedural medication requirement was significantly less in group A as compared to group B and none of the patients had any side effects post procedural in both Groups.

Keywords: Comparison,Post Procedural medication requirement, side effects, Pulsed and Thermal Radiofrequency Ablation ,Ganglion Impar , Chronic Pelvic Pain.

INTRODUCTION

The management of Chronic pelvic pain (CPP) involves a multimodal approach with key goal directed towards maximal achievable functional restoration and significant reduction in severity and intensity of pain.[1,2]

Although it is imperative but trial of medical and behavioural therapy is to be given but it is seen that the interventional block technique such as Ganglion Impar block has shown superior patient's satisfaction and improves patient's quality of life. Various methods exist to block the ganglion impar ,such as local anesthetics, concomitant use of local anaesthetics and steroids, alcohol or phenol and neurolysis by radiofrequency ablation. Blocking the Ganglion Impar attenuates this sympathetically mediated recalcitrant chronic pelvic pain, leading to reduction of opioids consumption, less side effects and an improvement in the patients' quality of life.[3-5]

A radiofrequency ablation is a minimally invasive procedure that destroys the nerve fibers carrying pain signals to the brain. Radiofrequency ablation (RFA) of Ganglion Impar is a well-established, drug-free treatment that has been clinically proven to provide safe, effective, lasting relief from chronic pain. Two important advantages of radiofrequency current (over previously used low frequency AC or pulses of DC) are that it does not directly stimulate nerves or heart muscle and therefore can often be used without the need for general anaesthesia.

Both TRF(Thermal radiofrequency ablation) and PRF(Pulsed radiofrequency ablation) treatment induce distance-dependent tissue destruction under the stimulating needle. The acute effects of PRF are more reversible and less neurodestructive in nature than the TRF mode, even in normothermia conditions hence PRF is better than TRF. PRF produces a transient inhibition of evoked synaptic activity and classic thermal RF (TRF) produces a lasting inhibition.[6,7]

The purpose of this study is to present that patients with chronic pelvic pain that did not improve with medications but could be controlled after giving Ganglion Impar block using radiofrequency ablation. While viewing medical literature the studies of ganglion impar block were done using steroids, local anaesthestic, neurolytics and radiofrequency ablation , but we could find very few studies which compared the Post Procedural medication requirement and side effects among Thermal versus Pulsed radiofrequency ablation in Ganglion Impar block for treatment of chronic pelvic pain in female patients.

Aims and Objectives

To compare the Post Procedural medication requirement and side effects among pulsed radiofrequency ablation versus thermal radiofrequency ablation of Ganglion Impar in patients of chronic pelvic pain.

MATERIAL AND METHODOLOGY

After obtaining approval from the Institutional ethics committee , CTRI registration number CRTI/2020/10/028306 and written informed consent of the patients, the proposed study was carried out in adult female patients of age groups 18-60 years , visiting the pain clinic for chronic pelvic pain, who had already taken medications for 2 weeks but inadequate benefit was reported by medications and physiotherapy trial.

Source of data:-

This study was conducted on patients with chronic pelvic pain at IGMC and associated hospital KNSH for M & Ch Shimla with the approval of research and Ethics Committee.

Study design:-

This study was randomized, single blinded prospective and controlled study.

Inclusion Criteria:-

- Patient giving consent to participate in the study.
- Female patients with chronic pelvic pain after ruling out any obstetrics and gyanecological cause through specialist opinion and USG or negative diagnostic laproscopy.
- Patients above the age of 18 years and below 60 years
- Patients who have had atleast two weeks trial of medications without significant effect.
- Patient with normal anatomy for ganglion impar block.

Exclusion Criteria:-

- Patient refusal.
- Patients with uncontrolled systemic diseases.
- Patients with infection or injury at the injection site.
- Patients with coccygectomy.
- Allergy to iodine contrast medium
- Hypersensitivity
- Patient with bleeding disorders and the patients on anticoagulants

A total of 30 patients from pain clinic who were suffering from chronic pelvic pain were included after obtaining written consent.

Sample Size Calculation:-

The sample size was calculated to be of 15 subjects for each group; this was calculated on the basis of a similar study in chronic pelvic pain patients where the minimum number of patients required were found to be 31, with a power of at least 80% and α of 0.05 Anticipating loss of subjects during the study, we enrolled 30 patients in our study, 15 in each group [37].

The patients were divided into 2 groups of 15 patients each using computer generated random numbers.

- Group A [Group –Thermal RFA] patients were treated with thermal radiofrequency ablation.
- Group B [Group – Pulsed RFA] patients were treated with pulsed radiofrequency ablation.

The study was randomized, single blinded prospective and controlled study with follow up done weekly for three weeks either by routine checkup in the pain clinic or through a phone call.They underwent radiofrequency ablation of Ganglion Impar by trans-sacro-coccygeal technique using C-arm guidance.

The ganglion impar block was administered in all these patients under all aseptic precautions using C-arm guidance to mark and identify bony landmarks.

METHODOLOGY

All patients underwent a routine preanaesthetic checkup. During this, thorough history, general examination, routine investigations of the patients i.e. FBS/RBS, bleeding time (BT), clotting time (CT) of the patient was carried out.

After confirmation of inclusion criteria of the patient by the anesthesiologist the procedure was undertaken. Written informed consent was taken from the patient prior to the procedure explaining the various risks and

benefits of the procedure. A 20-gauge venous access was secured and basic monitors such as noninvasive blood pressure, and saturation (SpO_2) probe will be connected.

The procedure was carried out with the patient in prone position with pillow under the abdomen to allow flexion of the lumbosacral spine and the lower extrimities rotated internally.

The procedure was performed using C-arm to identify and mark the essential bony landmarks. Under strict aseptic precautions the saccrococcygeal and gluteal regions were cleaned with savlon and painted with povidone iodine 10%. The area was drapped with sterile towels, and the access region was left open. A skin wheal was raised with 1% lidocaine using 25 gauge needle after the identification of the disc in lateral projection. A true lateral image was obtained by superimposing the two greater sciatic notches.

22G, 5 cm long with 5mm active tip radiofrequency needle was then introduced from the marked site to pierce the saccrococcygeal joint and position was confirmed after injecting non-ionic dye and needle placement was confirmed by induction of reverse comma sign/"crescent" sign in lateral fluroscopic views. A diagnostic block was performed using 1% lidocaine 10ml.

After 5 min , patient was ressessed and if the patient consider pain relief of atleast 2 point reduction in VAS scores, the patients were considered candidates for radiofrequency ablation of Ganglion Impar.

Before radiofrequency ablation was performed, tissue impedence check and motor and sensory tests were done. These comprised tissue impedence<600 Ohm, sensory response <50 Hz and motor response < 2 Hz at stimulation intensity between 0.4 – 0.8 volts. Patients with no significant decrease in VAS score were excluded from this study.

Thereafter radiofrequency ablation was done depending upon the group:-

- Group A:- Thermal radiofrequency ablation, was done using radiofrequency thermocouple electrode (Cosman Medical Co Inc.) connected to Cosman radiofrequency generator using following parameters: tissue impedance <600 Ohm, sensory response <50 Hz, and a motor response <2 Hz at a stimulation intensity between 0.4–0.8 volts (V) with 3 cycles each 90 seconds apart and temperature ranging from 60 -80°C.
- Group B:- Pulsed radiofrequency ablation, was done using radiofrequency thermocouple electrode using the following parameters: voltage output 45 V; 2 Hz frequency; 20 ms pulses in a one-second cycle, 120 second duration per cycle; impedance range between 150 and 500 Ohms with 3 cycles and a 42°C plateau temperature

Inj bupivacaine 5ml and inj dexamethasone 2 mg was injected the end of procedure to overcome ablation induced pain and neuritis.

Patients were kept in the recovery room for 2 hours and then sent home with the attendents on the day of the procedure with routine single dose antibiotic prophylaxis, NSAIDS in the form of Tablet Diclofenac 100mg SR for 3 days .Patients were advised to abstain from heavy workload after the procedure.Patient who complained of increase in VAS in between the follow up period were given tablet Pregablin 75 mg H.S. at night as rescue drug. Complains / side effects like parasthesias and numbness were noted.Follow-up after 24 hours,1 week, 2 weeks and 3 weeks was done either in OPD or telephonically.

Failure cases: Patients who did not achieve a successful block, that is patients in whom there is no decrease in VAS by 2 points after 24 hours of block were dropped from further study; but the number was noted as failure cases and other form of treatment was given.

Data Analysis

All the data collected from the patient's records was transferred into MS Excel sheet for further processing and analysis. Data was further analyzed using standard statistical software. In order to compare results between two study groups, appropriate parametric or non parametric test of statistical significance was used. Probability value (p-value) less than 0.05 was considered statistically significant.

RESULTS

The present study was conducted in prospective , single blind , randomized controlled manner in the Pain Clinic in the Department o Anesthesiology at Indira Gandhi Medical College and Hospital. It comprised of total 30 female patients between age group 30- 60 years. Patients were randomly divided into two groups. Patients in Group A (n=15) were given thermal radiofrequency ablation where as patients in Group B were given pulsed radiofrequency ablation. No patients experienced any interventional failure (inability to obtain proper fluoroscopic view of dye). So in each group 15 patients were studied.

Demographic Analysis

According to age distribution, in group A , 3(20%) were≤ 40 years, 6(40%) were between 41-50 years and 6(40%) were between 51-60 years of age while in group B , 8(53.3%) were≤ 40 years, 4(26.7%) were between 41-50 years and 3(20%) were between 51-60 years of age .The p value was calculated to be 0.159 which was found to statistically non significant.(Table-1)

Mean age (in years) in group A and B was found to be 47.60± 6.833 and 42.67±7.807 years respectively. The p value was calculated to be 0.76 which was found to be statistically non significant.

Table-1: Age wise Distribution of the patients

			Group		Total	P value
			A	B		
Age group	≤ 40	No. of Patients	3	8	11	0.159
		%	20.0%	53.3%	36.7%	
	41-50	No. of Patients	6	4	10	
		%	40.0%	26.7%	33.3%	
	51-60	No. of Patients	6	3	9	
		%	40.0%	20.0%	30.0%	
Total		No. of Patients	15	15	30	
		%	100.0%	100.0%	100.0%	
Mean age (years)			47.60± 6.833	42.67±7.807	45.13± 7.633	0.76

Need for Medication to be started Post Procedure

In Group A, 13(86.7%) patients didn't need any Medication to be started Post Procedure and 2(13.3 %) need medication post procedural while in Group B, 6(40.0%) patients didn't need any Medication to be started Post Procedure and 9(60.0 %) need medication post procedural. The P value was 0.021 which was statistically significant. The difference in Need for Medication to be started Post Procedure among patients is shown in Table-2.

Table-2: Need for Medication to be started Post Procedure

			Group		Total	P value
			A	B		
Need for Medication to be started Post Procedure	No	No. of Patients	13	6	19	.021
		%	86.7%	40.0%	63.3%	
	Yes	No. of Patients	2	9	11	
		%	13.3%	60.0%	36.7%	
Total		No. of Patients	15	15	30	
		%	100.0%	100.0%	100.0%	

Side effects

In both Group A and B None of the patients had any side effects post procedural. The difference inpost procedural side effects among patients is shown in Table-3.

Table-3: Post Procedure Side effects

			Group		Total	P value
			A	B		
Post procedural side effects	No	No. of Patients	15	15	30	NA
		%	100.0%	100.0%	100.0%	
	Yes	No. of Patients	0	0	0	
		%	0%	0%	0%	
Total		No. of Patients	15	15	30	
		%	100.0%	100.0%	100.0%	

DISCUSSION

Chronic pelvic pain (CPP) is an idiopathic multifactorial disorder which results due to intricate interaction between neurological and musculoskeletal systems which is mediated by sympathetic nerves. Chronic pelvic pain is a common problem with higher

incidence in female and has high degree of functional and emotional impairment. This sympathetically mediated pelvic pain pain is poorly localized type of pain with a burning quality and a sense of urgency in the perineal region. The initiating factor in neuropathic pain is mainly damage to the tissue caused by either inflammation or nerve damage .[5,6]

We conducted a prospective single blinded randomized control study with a calculated sample size of 30 with history of pelvic pain where we compared thermal radiofrequency ablation versus pulsed

radiofrequency ablation. No literature is available with similar study design using the above mentioned techniques. Thermal radiofrequency ablation was found to be better as compared to pulsed radiofrequency ablation in management of immediate and chronic pelvic pain. The patients were followed for a period of 3 weeks.[7]

In our study, post procedural analgesics were stopped. They were started only when patient started feeling discomfort while performing heavy work and after careful consultation with the investigator. In our study, analgesic requirement was observed in 13.3% of patients in thermal RFA group (2 patients) while in pulsed RFA group , 60.0 % of the patients (9 patients) required medication post procedural during their 1 month follow up period. The P value was 0.021 which was statistically significant. Hence it was observed that analgesic supplementation in patients of thermal RFA group was significantly lower than the patients in the pulsed RFA group. Further with decrease in analgesic requirement of the patient side effects associated with supplemental analgesics can be avoided.

In the literature we could not find any study which described the need of supplemental analgesics post procedure. However as the patients had significant reduction in VAS score as compared to their baseline values, we consider cessation of supplemental analgesia post procedure and resuming it only when patient required supplementation.

Hence we can conclude that post procedural VAS score and functional abilities of the patient tend to improve drastically due to which the need for supplemental analgesia diminishes and the medications that were previously being consumed on daily basis can be omitted or titrated downwards to suit the analgesic requirements of the patients.

In our study no side effects were observed immediately after performing the procedure and during the follow up period. The patients were discharged from the post anesthesia care unit only after stable hemodynamics. Usmani et al[8] conducted a similar study and found that ganglion impar block by conventional radiofrequency ablation provided a significantly better quality of pain with no major side effects as compared with pulsed radiofrequency ablation.

Limitations

Our study was limited by the limited amount of research that has been conducted in this field. Very few studies have been conducted which described Ganglion Impar using radiofrequency ablation for chronic pelvic pain. We found no study which compared thermal radiofrequency versus pulsed radiofrequency ablation of Ganglion Impar in patients with chronic pelvic pain. The sample size was low in our study due to the Covid pandemic which affected many patients. Above all our study was dependent on referral of patients from other departments who did not respond to conservative management. Lack of general awareness of pain clinic and procedures and under treatment of the symptoms also contribute to poor patient compliance.

Conclusion

Present study showed that Post Procedural medication requirement was significantly less in group A as compared to group B and none of the patients had any side effects post procedural in both Groups **.**Under the light of the above mentioned results, we can conclude that thermal radiofrequency ablation of ganglion impar for chronic pelvic pain produces prolonged pain free period and better functional capacity in the patients as compared to patients who were treated with pulsed radio frequency ablation.

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