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Original Research Article

Comparative analysis of transaortic celiac plexus rhizolysis vs. bilateral splanchnic nerve radiofrequency ablation in managing intractable pain in upper gastrointestinal malignancies: A prospective randomized controlled study

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Abstract

Background and Aims: Intractable abdominal pain is common in patients with upper gastrointestinal malignancies and significantly impacts their quality of life. Despite pharmacological treatment, many patients do not experience sufficient pain relief. Coeliac plexus rhizolysis (CPR) and splanchnic nerve radiofrequency ablation (SRF) are two interventional techniques used to target pain pathways. CPR involves ablating the coeliac plexus, while SRF targets the splanchnic nerves. This study compares the efficacy and safety of these two procedures in managing pain in patients with upper GI cancers.

Materials and Methods: Randomised, prospective, comparative and single-blinded interventional study was conducted in the Pain medicine unit, department of Anaesthesiology, in a tertiary care teaching medical institute. After ethical clearance, thirty patients were included in each group and assessed for pain by Visual Analogue Scale (VAS), the dosage of oral morphine, and quality of life (QOL) up to 6 months. Pre-procedural and post-procedural VAS scores were evaluated using the Paired Student t-test and Cohen's Method for effect analysis. An Independent student t-test was used to compare QOL and morphine consumption.

Result: Both interventions resulted in significant pain relief, with splanchnic nerve radiofrequency ablation (SRF) showing greater efficacy compared to coeliac plexus rhizolysis (CPR). The pre- and post-procedure VAS scores were as follows: SRF (7.5 ± 1.04 to 2.13 ± 1.48) and CPR (7.93 ± 1.34 to 3.28 ± 1.44). The SRF group also demonstrated lower morphine consumption (13.4 ± 15.3 mg/day) compared to CPR (26.11 ± 23.5 mg/day) and improved QOL (WHO QOL score: SRF 67.75% vs. CPR 42.50%). Adverse events included more transient hypotension and diarrhea in the CPR group, while the SRF group had more transient backache.

Conclusion: Splanchnic nerve radiofrequency ablation (SRF) demonstrates superior efficacy over coeliac plexus rhizolysis (CPR) in terms of pain reduction, opioid sparing, and quality of life improvement for patients with upper gastrointestinal malignancies.

Keywords: Coeliac plexus rhizolysis, Radio-frequency ablation, Splanchnic nerve, Upper gastrointestinal malignancy.

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1. Introduction

Globally, upper gastrointestinal malignancies rank among the top causes of cancer-related deaths, with significant regional variations, such as gallbladder carcinoma predominance in northern India.[1] In northern India, where this study was done, the carcinoma gallbladder is more prevalent.[2]

According to the European Society for Medical Oncology (ESMO) clinical practice guidelines published in the Annals of Oncology,[3] pain is prevalent among 14–100% of cancer patients and occurs in 50–70% of those under active treatment. In addition, about 70-90% of patients in advanced stages of abdominal malignancies suffer from intractable abdominal pain. World Health Organization (WHO) Analgesic ladder is a guideline for using narcotic and other

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adjuvant drugs in pain management; still, 10-15% of patients are resistant to oral analgesic therapy and continue to suffer from intractable pain. For patients resistant to WHO analgesic ladder interventions, minimally invasive procedures like coeliac plexus rhizolysis (CPR) and splanchnic nerve radio-frequency ablation (SRF) have emerged as effective strategies for managing intractable pain.[4]

Thoracic splanchnic nerves supply upper abdominal viscera through (greater {T5-T9}, lesser {T10-T11} and least {T12} splanchnic nerve) which synapse through the coeliac plexus before reaching the central nervous system. The Coeliac plexus is situated anterolaterally to descending aorta at the level of the L1-L2 vertebra. Therefore, both thoracic splanchnic nerves and coeliac plexus can be targeted for managing pain due to upper abdominal malignancy.[5]

CPR can be done through various approaches and likely to have long-lasting analgesic efficacy for pancreatic and other types of intraabdominal cancer with mild and transient side-effects.[6-8]

SRF has also been found to manage pain due to upper abdominal malignancy effectively. Radiofrequency thermo-ablation is reported to be a more predictable and safe technique compared to chemical neurolysis of splanchnic nerves or coeliac plexus neurolysis for the management of abdominal pain, but the evidence is still limited.

This study aimed to compare the efficacy of CPR and SRF in managing refractory upper abdominal malignancy pain, focusing on pain relief, opioid consumption, and QOL improvement.

2. Materials and Methods

After getting institutional ethical committee approval, the proposed study was enlisted under the Clinical Trial Registry of India (CTRI/2019/12/022314); this randomised, prospective, comparative and single-blinded interventional study was conducted in the Pain medicine Outpatient department (OPD) under the department of Anaesthesiology of a tertiary care, research and teaching institute over a period of eighteen months. This study followed the Good Clinical Practice (GCP) guidelines established by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health, Government of India. It also adhered to the specified standards of ethics outlined in the Declaration of Helsinki (1975, revised in 2013) and the Ethical Guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research (ICMR) in 2006, New Delhi.

Seventy-six patients who met the inclusion criteria (patients >18 years of age, suffering from intractable malignant abdominal pain, on maximum tolerable doses of oral opioids with inadequate pain relief or intolerable side effects) were assessed for eligibility to be included in the study. Patients who declined consent or have a history of drug allergy; coagulation abnormalities or local infections; uncontrolled hypertension and cardiac disorder; distorted coeliac plexus anatomy on CT-abdomen, and difficulty in lying in a prone position due to massive ascites; were excluded from the study.

A computer-generated random number table randomised the patients into two groups. The group allocation was done with sealed opaque envelopes, opened just before the intervention by a person not involved in the data collection. All interventions were done by experienced Pain Physicians (Anaesthesiologists). Patients in Group SRF received bilateral splanchnic nerve radio-frequency treatment, and Group CPR received coeliac plexus rhizolysis by the trans-aortic route. It was a 'single-blinded study', where the follow-ups and data analysis were done by a resident doctor, who was otherwise blinded for the intervention done.

All patients underwent a thorough pre-operative evaluation, including routine tests such as complete blood count, coagulation profile, and non-contrast CT abdomen (NCCT-abdomen) to exclude any anatomical distortions. Baseline assessments, including pain scores using the Visual Analog Scale (VAS), oral morphine doses, and quality of life (WHO BREF scores), were recorded prior to the intervention.

The procedures were performed in a dedicated pain medicine operating room under fluoroscopic guidance. The following drugs and instruments were prepared: Injection bupivacaine 0.5% (Neon Laboratories, India), 100% absolute alcohol (Fisher Chemicals, Belgium), SMK radiofrequency (RF) cannula (20 Gauge, 15 cm length, with a 10 mm active tip, Kimberly-Clark Inc., Germany) for splanchnic nerve radiofrequency ablation, and four-channel radiofrequency pain management generator (Kimberly-Clark Inc., Germany). Additionally, 22G 15 cm Quincke-type spinal needles (Becton Dickinson Ltd, Netherlands) for coeliac plexus rhizolysis and a small-bore IV extension set were made ready.

Patient monitoring was conducted in accordance with the Indian Society of Anaesthesiologists (ISA) guidelines, including continuous non-invasive blood pressure, peripheral oxygen saturation, and ECG monitoring. An 18-gauge wide-bore intravenous access was established, and an intravenous drip of Lactated Ringer's solution was initiated.

The patients were positioned in the prone position with a pillow under the abdomen to reduce lumbar lordosis. The entry points for the spinal needle and RF cannula were marked under fluoroscopic guidance and prepared in a standard sterile manner. 1% Injection Lignocaine Hydrochloride (Neon Laboratories, India) was used for local anaesthesia at the planned intervention sites. Both splanchnic nerve radiofrequency ablation (SRF) and coeliac plexus rhizolysis (CPR) were performed with the patient in the prone position, under fluoroscopic guidance.

For SRF, the greater, lesser, and least splanchnic nerves, which run antero-caudally bilaterally along the thoracic (T11 and T12) vertebrae, converge in front of the lumbar (L1) vertebra to form the celiac plexus. The entry points were marked 3-4 cm lateral to the midline at the level of the T11 and T12 vertebrae, at the costovertebral angle on both sides. After local anaesthesia, four RF cannulas were inserted in "tunnel view" towards the lateral side of the vertebral body. The final position of the cannulas was confirmed in lateral fluoroscopic views, with the tip positioned at the junction of the anterior 1/3 and middle 1/3 of the vertebral body. After confirming proper placement, a non-ionic, water-soluble contrast dye (Omnipaque-300, GE Healthcare Inc., U.S.) was injected. It was confirmed by fluoroscopy as it spread along the lateral border of the T11-T12 vertebrae in the anterior-posterior (A.P.) view. Sensory and motor stimulation (50 Hz for sensory, 2 Hz for motor) was performed to ensure proper nerve targeting. Sensory stimulation at ≤ 0.5 Volt produced epigastric tingling, and no motor nerve stimulation was noted. After injecting 2 ml of 2% lidocaine for local pain control, two monopolar RF lesions were created at 80°C for 90 seconds (**Figure 1**, Upper Panel).

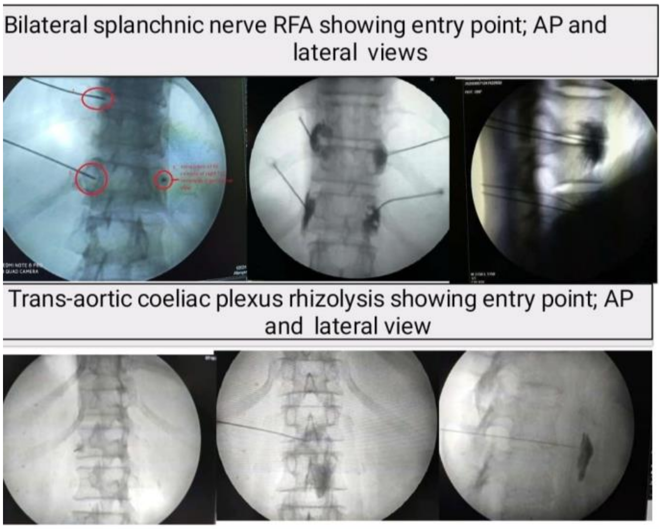

Figure 1: Fluoroscopic images of splanchnic nerve radio-frequency ablation SRF (Upper Panel) and Coeliac Plexus Rhizolysis CPR (Lower Panel)

For CPR, the first lumbar (L1) vertebra was visualized in the A.P. view, followed by a left-sided oblique tilt until the transverse process (T.P.) of L1 merged with the vertebral body (V.B.). The entry point was marked at the junction of the L1 T.P. and L1 V.B. After administering local anaesthesia with 1% lignocaine, a 22G 15 cm Quincke's spinal needle was inserted from the entry point in a "gun-barrel view." The needle was advanced until it penetrated the posterior wall of the descending aorta, confirmed by the movement of the needle due to aortic pulsation and the appearance of pulsatile blood in the needle hub. A 5 ml syringe filled with water-soluble contrast dye was attached to the needle, and under live lateral fluoroscopy, the needle was advanced while dye was injected. The dye spread across the aortic wall and attained a static state when it crossed the anterior wall of the aorta. The needle placement and dye spread were confirmed in the A.P. view, where the dye spread should be in front of the L1 vertebral body. After negative aspiration, 5 ml of 2% lignocaine was injected, followed by incremental doses of 100% alcohol (total volume of 15 ml). The final concentration was 75% alcohol (5 ml lignocaine + 15 ml alcohol). To ensure safety, negative aspiration was performed repeatedly to avoid inadvertent intravascular injection, and intermittent fluoroscopy was used to monitor for unwanted spread of the dye. Continuous communication with the patient helped to monitor for any increase in pain or neurological symptoms, such as tingling or weakness in the lower limbs. After the alcohol injection, the needle was removed following a saline flush to prevent spillage. Patients were kept prone for 30 minutes to avoid backflow and were monitored in the recovery room for 2 hours for vital signs (**Figure 1**).

Sample size determination was based on the expected minimum reduction in pain after intervention with two procedures from a previous study by Shwita et al.[9] where it was found that the overall prevalence of intractable pain was 80%, using this study, sample size (N) was calculated by using the following formula.

$$N = \frac{Z^2 PQ}{e^2}$$

P = Anticipated population proportion= 80%; Confidence interval = 95%

Relative precession. = 5%; Q = Free of disease (100-P) = 20%

Z = Point of normal distribution (as per the table of area under the normal curve for the given confidence level of 95%) =1.96; e = Allowable error in the estimation = 0.05. Assuming 80% power, a 5% significance level with a 95% confidence interval, an assumed standard deviation being 0.9, as well as an absolute error being 0.5, the total sample size calculated per group came to 25 in each group.

Considering a potential 20% loss to follow-up due to patient dropouts, the study aimed to include 30 patients in each group. Thus, 60 patients were randomized into two groups during the 18-month study period. During the follow-up, 3 patients did not participate, leaving 29 patients in the SRF Group I and 28 patients in the CPR Group II, who were included in the final statistical analysis for the 6-month follow-up period or until their demise.

The data collected was compiled using a Microsoft Excel spreadsheet. Statistical Analysis was done using the statistical analysis software "Statistical Package for the Social Sciences" SPSS version 21.0, Chicago, Illinois, USA. Demographic data were analysed with the difference in mean values, and the Chi-square test was used for categorical variables. Un-paired student t-test was used to compare pre-procedural and post-procedural VAS. $P < 0.05$ was considered significant. An Independent student t-test was applied to compare the pre-procedural and post-procedural data on Quality of Life (QOL) and morphine consumption.

3. Result

Seventy-six patients were assessed for inclusion criteria; among them, 16 patients were excluded (Four due to massive ascites and inability to lie prone, twelve due to distorted coeliac plexus anatomy on non-contrast computerised tomography (NCCT-abdomen); finally, sixty patients were included in the study. Three patients did not participate in the follow-up, so data from twenty-nine patients in the SRF group and twenty-eight patients in the CPR group was analysed finally (**Figure 2**).

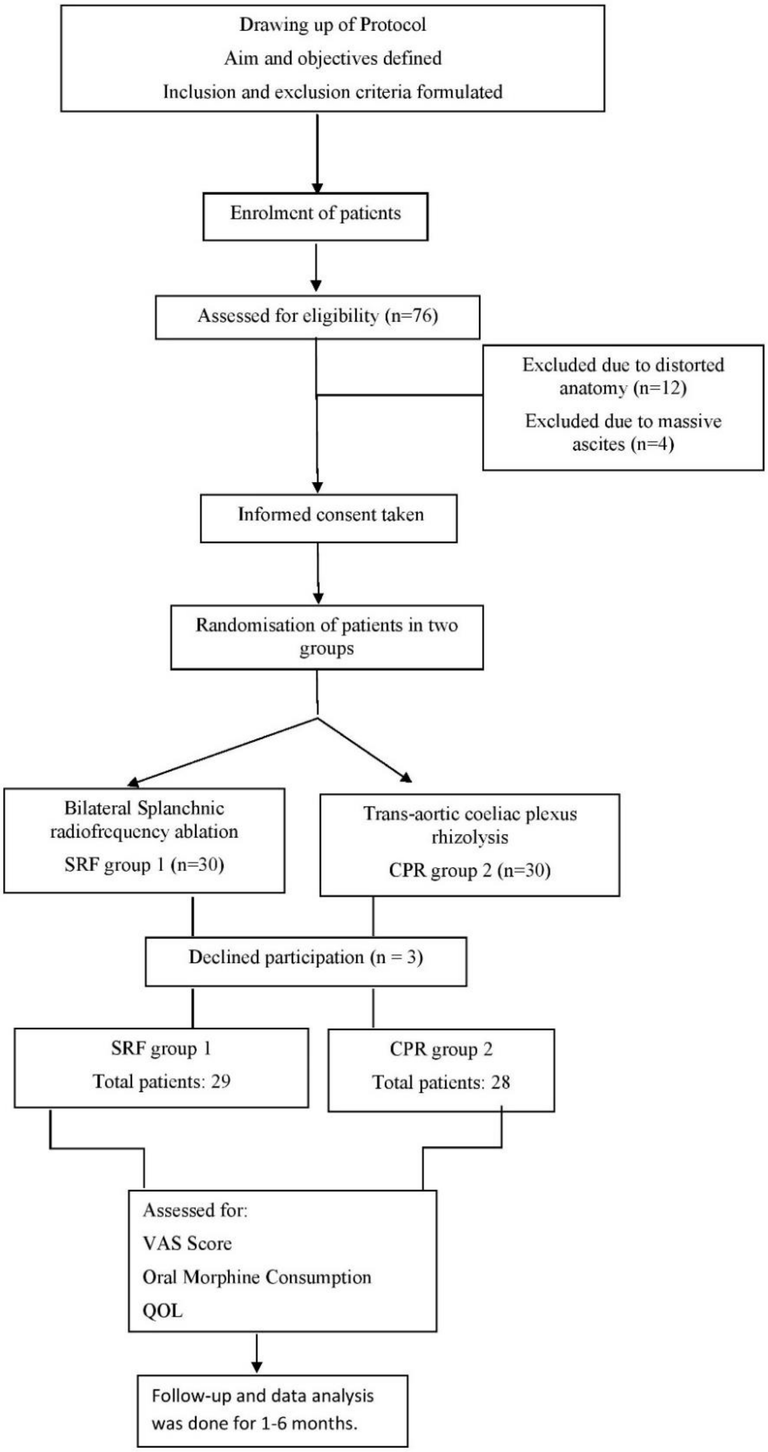

Figure 2: Consort flow diagram

Both groups were demographically homogeneous with statistically non-significant (p value 0.873) in terms of age and sex.

The study population comprised 63.15% (36) patients with Carcinoma gall bladder, 29.8% (17) carcinoma pancreas, two metastatic deposits in the abdomen with unknown primary and 1 case each of carcinoma liver and stomach.

Both SRF and CPR groups showed VAS reduction from baseline values (7.5 ±1.04 SRF group and; 7.93±1.34 CPR group) at each follow-up up to 6 months, i.e. (1.5±1.44 and 1.7± 1.23, P-value = 0.034 at one month; 1.88±1.58 and 2.3±1.7, P-value = 0.014 at three months; 2.13±1.48 And 3.28±1.4, P-value = 0.002 at six months.; in SRF and CPR group respectively). However, on comparison between the groups, VAS Score reduced significantly more in the SRF group than CPR group at six months; (7.5 ±1.04 (cm)pre-procedural to 2.13±1.48 (cm) in the SRF group; from 7.93±1.34 (cm) to 3.28±1.44 (cm) in CPR group); showing superiority of SRF over CPR in terms of pain reduction. Comparing effect size using Cohens'D method pre-procedure to 1 month shows a small effect size (0.33 to 0.14), which increased from the third month post-procedure and reached to highest at six months (0.25 and 0.79; at 3 and 6 months, respectively),showing better VAS score in terms of effect size in SRF group than CPR group (**Table 1** & **Figure 3**).

Table 1: Comparison of SRF and CPR group according to vas scores (expressed as cm on a scale) (unpaired student t test)

Type	N	Mean± SD	SEM	T	Df	Cohen's d	Effect size	p value
Pre-pro SRF	30	7.5±1.04	0.190	39.41	29	0.33	0.16	0.041 (S)
Pre-proCPR	30	7.9±1.34	0.24	32.97	29			
Post-pro1month SRF	29	1.5± 1.44	0.28	6.38	28	0.14	0.074	0.034(S)
Post-pro 1 month CPR	28	1.7±1.23	0.237	7.17	27			
Post-pro 3 months SRF	25	1.88±1.58	0.317	5.91	24	0.25	0.12	0.014(S)
Post-pro 3 months CPR	26	2.3±1.7	0.33	7	25			
Post-pro 6 months SRF	19	2.13±1.48	0.33	6.33	19	0.79	0.37	0.002(S)
Post-pro 6 months CPR	18	3.28±1.4	0.34	3.14	17			

S: Statistically significant; HS: Highly significant; NS: Statistically non-significant

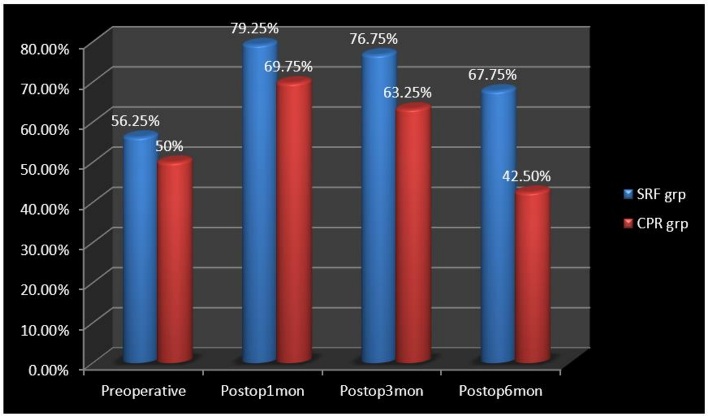

Figure 3: Comparison of overall QOL between SRF group and CPR group (expressed in percentage)

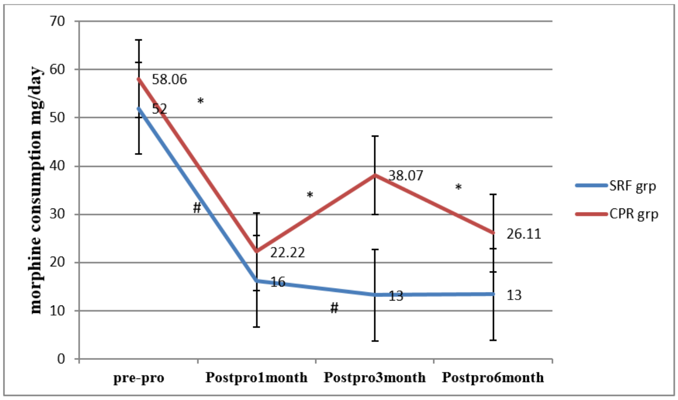

Figure 4: Morphine consumption in the various groups. Data are presented as a mean ± standard deviation. *P < 0.05 during within the group comparison. #P < 0.05 during between group comparisons

Oral morphine consumption also decreased more significantly in the SRF group in comparison to CPR groups; at the end of the six months(Mean ± S.D.; 13.4±15.3 mg/day)in the SRF group; Mean±SD; 26.11±23.5 mg/day in CPR group), showing more narcotic sparing in SRF group. (**Figure 4**)

The mean values of Quality of Life (QOL) scores across different domains showed more significant improvements in the SRF group compared to the CPR group at 1-, 3-, and 6-months post-intervention.

In terms of physical health (D1**)**, the SRF group exhibited notable improvements at each time point. At 1 month, the mean QOL score in the SRF group was 16.67 ± 4.73, compared to 14.96 ± 2.42 in the CPR group. By 6 months, the SRF group maintained a higher score of 14.84 ± 3.28, while the CPR group had decreased to 11.39 ± 1.75. These differences were statistically significant throughout the follow-up period.

For psychological health (D2)**,** the SRF group also showed more significant improvements. At 1 month, the SRF group had a mean score of 14.15 ± 3.85, which was higher than the CPR group at 11.11 ± 1.78. This difference persisted at 6 months, with the SRF group showing a score of 11.79 ± 2.50, while the CPR group's score was 8.94 ± 1.62. These improvements were statistically significant at all time points.

The improvement in social relationships (D3) was more prominent in the SRF group. At 1 month, the SRF group had a mean score of 7.0 ± 1.625, compared to the CPR group's 6.63 ± 1.04. The SRF group continued to show superior improvement at 3 and 6 months, with scores of 6.96 ± 1.71 and 6.89 ± 1.76, respectively, compared to 6.73 ± 1.04 and 6.67 ± 1.28 in the CPR group.

In terms of environmental health (D4), the SRF group demonstrated significantly better improvements. At 1 month, the SRF group had a mean score of 17.23 ± 3.57, which was higher than the CPR group's 15.26 ± 2.37. By 6 months, the SRF group's score remained higher at 13.84 ± 3.48, while the CPR group showed a marked decrease to 4.25 ± 7.18. These differences were statistically significant at all follow-up periods.

The overall QOL score, as measured by the WHOQOL-BREF, showed more significant improvements in the SRF group. At 1 month, the SRF group had an overall QOL score of 79.25%, compared to 69.75% in the CPR group. This gap remained significant at 3 and 6 months, with the SRF group achieving 76.75% and 67.75% compared to 63.25% and 42.50% in the CPR group. The difference in overall QOL between the groups was statistically significant throughout the study (**Figure 5**).

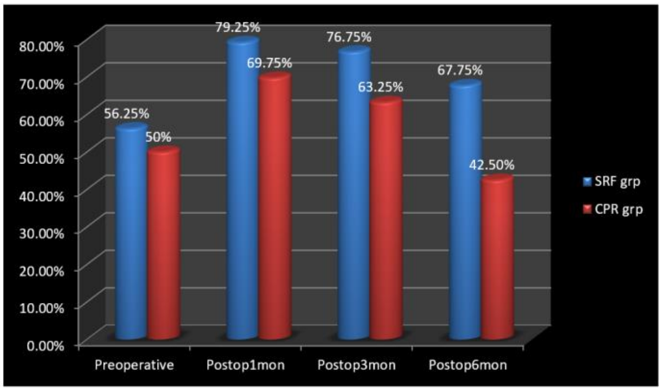

Figure 5: Comparison of overall QOL in percentage between SRF group and CPR group
(QOL- quality of life in percentage; Coeliac Plexus Rhizolysis (CPR) and Splanchnic Nerve Radio-frequency ablation (SRF)

Transient hypotension immediately after the procedure was seen in two patients in the CPR group, whereas no hypotension was seen in the SRF group. Transient Diarrhoea was seen in seven patients of CPR, which lasted for 2-3 days, whereas only one patient reported transient Diarrhoea in the SRF group. Transient backache was seen more frequently in the SRF group than the CPR group (seven patients vs two patients in SRF and CPR group, respectively) in two patients with the CPR group. In contrast, seven patients reported transient backache that lasted 2-3 days in the SRF group. Opioid-induced constipation improved in both CPR and SRF groups but more so in the SRF group due to a more narcotic-sparing effect.

4. Discussion

The coeliac plexus and splanchnic nerves are the best target sites for pain relief in patients with upper abdominal malignancies.[10] However, out of the total of sixty patients in our study, the majority were of carcinoma gallbladder (36 out of 57 patients), which shows a predominance of carcinoma gallbladder in northern India.[11]

In our study, the mean duration for performing bilateral splanchnic nerve RFA was 30±10 minutes and 15±5 minutes for coeliac plexus rhizolysis, which is almost similar to another study published in 2018.[12] The longer duration of splanchnic RFA ought to be due to the placement of four R.F. cannulae compared to single needle placement during trans-aortic celiac rhizolysis. However, this shortcoming of splanchnic RFA can be ignored due to the benefits of better pain relief and QOL as well as more opioid sparing in comparison to celiac rhizolysis.

Both groups in our study demonstrated effective pain reduction when comparing pre-procedural and post-procedural VAS scores at follow-up visits. However, the SRF group showed significantly better pain relief compared to the CPR group. There is a scarcity of prospective comparative studies on splanchnic RFA and celiac neurolysis. One study compared celiac plexus neurolysis with the more invasive splanchnicectomy using a video-thoracoscopic approach in patients with pancreatic cancer, suggesting celiac neurolysis as the preferred method due to its less invasive nature.[13] In contrast, our study utilized a much less invasive percutaneous method to target the splanchnic nerves, which we found to be more effective than CPR.

The splanchnic nerves have a predictable anatomical location around the T11 and T12 vertebrae, which are not affected by tumours. This makes radio-frequency ablation (RFA) a more precise method. In contrast, the celiac plexus may be affected by tumour involvement in surrounding structures, which can result in inadequate and unpredictable coverage by the neurolytic agent, potentially leading to less effective pain relief compared to SRF.

In a randomized controlled trial (RCT), Polati E et al. compared neurolytic celiac plexus block (NCPB) with pharmacological therapy for treating pain from pancreatic cancer and found that NCPB was significantly more effective in reducing pain.[14] Another study by Garcea G reported an effective reduction in VAS scores from a pre-procedural score of 8.35 ± 1.05 to 3.0 ± 1.0 at three months post-procedure after bilateral splanchnic RFA for chronic abdominal pain.[15] Repeat splanchnic radiofrequency also provided consistent efficacy in patients with chronic pancreatitis and recurrent pain.[16]

Studies like those by Garcia et al., which used SRF for chronic pancreatitis abdominal pain, and a meta-analysis on NCPB by Eisenberg et al., have recognized the benefits of both SRF and CPR in managing chronic abdominal pain.[8,15] However, none of these studies have directly compared the two interventions. These studies suggested the need for additional comparative randomized trials to evaluate and contrast the effectiveness of SRF and CPR in the management of chronic abdominal pain.

In our study, both study groups have shown significant opioid sparing, which was significantly more in the SRF group. Several other studies[12,17] have also reported a notable morphine-sparing effect following splanchnic RFA in patients with abdominal cancer pain, accompanied by improvements in quality of life (QOL).

The WHOQOL-BREF is a 26-item instrument with four domains: physical health (D1-7 items), psychological health (D2-6 items), social relationships (D3-3 items), and environmental health (D4-8 items).[18] In terms of effectiveness, both study groups in our research demonstrated significant improvements in quality of life (QOL) post-intervention. However, the SRF group showed significantly better results compared to the CPR group. These findings align with those from another RCT conducted in 2015, which compared retro-crural coeliac plexus neurolysis to splanchnic nerve block and found that the splanchnic group experienced significantly better QOL starting from the second week post-procedure.[9]

Another study investigating single-needle transaortic coeliac plexus alcohol neurolysis in patients with advanced upper abdominal cancer also reported significant improvements in mean VAS scores, reduced morphine consumption, and enhanced QOL following the procedure.[19] Our results are consistent with a researcher who assessed the efficacy of bilateral radiofrequency thermo-coagulation of splanchnic nerves in pancreatic malignancy patients in a retrospective observational study. This study found significant improvements in pain scores, QOL, and opioid consumption, though slight deterioration was noted from the fifth month onward, likely due to disease progression.[20] As early as 2005, RFA of splanchnic nerves was recognized as an effective method for managing pain in patients with chronic pancreatitis, resulting in reduced opioid consumption and improvements in mood and QOL.[15]

Splanchnic nerve radiofrequency ablation (SRF) provides better pain relief, and significant narcotic sparing. However, SRF requires specialized equipment and expertise, which may limit its application in resource-constrained settings.

The limitations of our study include the short duration of follow-up and its single-centre design. Future multi-centre studies with earlier patient enrolment during their cancer treatment may provide more comprehensive insights into the potential efficacy of these pain-relieving interventions and their impact on patient survival.

5. Conclusion

Both Splanchnic Nerve Radiofrequency Ablation (SRF) and Celiac Plexus Rhizolysis (CPR) provide effective relief for intractable pain in patients with upper gastrointestinal malignancies. However, SRF demonstrates superior outcomes in terms of pain management, opioid sparing, and improvement in quality of life (QOL). Given its enhanced efficacy, SRF may be the preferred choice in advanced care settings, especially for patients with significant pain and a need for long-term relief.

6. Source of Funding

None.

7. Conflict of Interest

None.

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