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A comparative study of transdiscal versus transaortic celiac plexus neurolytic block for upper gastrointestinal cancer patients. A prospective, randomized control study

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Abstract: *Aim:* To compare transdiscal and transaortic techniques of neurolytic celiac plexus block for upper gastrointestinal cancer patients.
Methods: In this prospective randomized study 60 patients with upper gastrointestinal malignancies were included and randomly divided into two groups, group TD and group TA, receiving neurolytic celiac plexus blocks via transdiscal and transaortic techniques, respectively. The primary outcome was quality of life (QoL) as assessed by WHOQOL BREF questionnaire and secondary outcomes were pain relief using visual analogue scale (VAS), and occurrence of complications like hypotension, loose motion, bleeding and discitis.
Result: QoL and VAS score were significantly improved in both groups post procedure. Transdiscal approach is more effective in improving VAS score than transaortic approach (1 *vs* 3) after 1 week and the relief of pain was better in TD group (3 vs 6) at the end of 2 months. Transdiscal approach was found to be more effective in improving QoL (227.00±28.85 *vs* 191.17±35.78) as compared to transaortic approach. However, post-procedural QoL improved in both groups when compared to pre-procedural QoL ($p<0.05$). Hypotension, diarrhea and bleeding from aorta were higher in TA group; however, no serious complications were seen in any of the groups.
Conclusion: Transdiscal technique is better in terms of adequate pain relief and improving QoL as compared to transaortic technique of NCPB in patients of upper GI malignancies and is associated with lesser incidences of complications.

Keywords: Celiac plexus block; transaortic approach; transdiscal approach; WHOQOL-BREF score; VAS score; upper GI malignancies.

Introduction

Neurolytic celiac plexus block (NCPB) is one of the effective modalities for relief of intractable pain due to upper gastrointestinal (GI) malignancies or chronic pancreatitis resistant to oral or parenteral opioids, as 4th step of WHO cancer pain relief ladder (1). In addition, well-known side effects may limit the acceptability and usefulness of oral or parenteral opioids therapy. Neurolysis of the sympathetic axis is a safe and cost-effective approach in visceral pain management associated with cancer. The benefits include improved analgesia, reduced opioid consumption, favorable economic implications, and superior clinical effects due to the deleterious properties of high-dose chronic opioid therapy. There are several techniques of neurolytic celiac plexus block like transcrural, retrocrural, transaortic and transdiscal approach. The conventional transcrural approach, which involves the "walking off" the vertebra technique, is associated with greater technical difficulty due to various anatomical considerations (17). The transaortic approach involves needle placement beyond the anterior aortic wall in its central axis, so the drug nearly encircles the aorta anteroposteriorly. The transdiscal is a relatively newer technique which is relatively safe and effective with rare incidences of serious complications like visceral puncture and neurologic complications, including paraplegia, leg weakness, sensory deficits, and paresthesia. However, the comparative study of transdiscal with transaortic approach is lacking in the literature. The aim of the study is to compare the efficacy of the two procedures i.e., transdiscal and transaortic celiac plexus block for the management of pain in patients presenting with upper GI cancers.

Several quality of life (QoL) assessment tools have been developed and studied in cancer patients. The WHOQOL-100 allows detailed assessment of

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each individual facet relating to quality of life (2). However, the WHOQOL-100 may be too lengthy in various circumstances. The WHOQOL-BREF Field Trial Version has therefore been developed to provide a broad and comprehensive quality of life assessment and contains a total of 26 questions. Evaluation of QoL in GI cancer patients has shown close co-relation between improved QoL score and better patient prognosis (9).

Material and methods

The study was approved by the Ethical Committee and written informed consent was obtained from all patients. Assuming a difference of at least 40% in the primary outcome between the groups, with an alpha error of 5% and power (1-β) of 80%, 27 patients were required in each group. To make provisions for drop-outs, we included 60 patients in our study, 30 in each group. The patients suffering from pain due to upper GI malignancies were selected and were randomly allocated in two groups based on computer generated randomization numbers, Group TD for patients undergoing transdiscal neurolytic celiac plexus block (NPCB) and Group TA undergoing transaortic NPSB. Allocation concealment was ensured with sealed opaque envelopes. Demographic and clinical data, including age, gender, date of enrollment, medical or surgical condition, laboratory and radiological reports were noted down. Neurolytic celiac plexus block was performed in all patients and were followed up to 2 months. Patients of either sex of age from 20-80 years suffering from severe pain with visual analogue scale (VAS) more than 7 due to upper GI malignancies were included in the study. Patients with features of coagulopathy, local infection at area of needle insertion, with mental disorders, and refusal to undergo the procedure were excluded from the study.

All procedures were performed in the designated pain operation theatre under full aseptic precautions under fluoroscopic guidance and hemodynamic monitoring including blood pressure, electrocardiogram and pulse oximetry. Intravenous access was obtained in a peripheral vein using 18 G canula. Antibiotic prophylaxis was done with one gram of ceftriaxone intravenously 30 minutes before performing the procedure; also, one liter of a crystalloid solution was infused during the procedure. Patients were placed in prone position with the pillows beneath the iliac crests and chest. Midazolam 0.03 mg/kg and fentanyl 1 µg/kg were given intravenously for sedation to all patients.

Table 1

WHOQOL bref questionnaire table

DOMAINS	Facets incorporated within domains
Physical health	Activities of daily living Dependence on medicinal substances and medical aids Energy and fatigue Mobility Pain and discomfort Sleep and rest Work Capacity
Psychological	Bodily image and appearance Negative feelings Positive feelings Self-esteem Spirituality / Religion / Personal beliefs Thinking, learning, memory and concentration
Social relationships	Personal relationships Social support Sexual activity
Environment	Financial resources Freedom, physical safety, and security Health and social care: accessibility and quality Home environment Opportunities for acquiring new information and skills Participation in and opportunities for recreation / leisure activities Physical environment (pollution / noise / traffic / climate) Transport

The patient heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), Spo_2, VAS score and Quality of life score (QoL) was noted before the procedure. HR, SBP and DBP were measured every 30 minutes for 2 h postoperatively, then at 6 h and after 24 h postoperatively. The pain relief was noted immediately after the procedure using VAS and was followed up at 1st week, 2nd week, 4th week, 6th week and at the end of 2 months for VAS. The patients were followed up for QoL using WHOQOL BREF questionnaire at the end of 2 months. The various complications of the procedure i.e., hypotension, loose motion, discitis, visceral puncture, pain at local site, any neurological complications were assessed after the procedure. QoL was the primary outcome and VAS, and complications as the secondary outcomes.

Quality of life was assessed using the well-validated quality of life WHOQOL BREF questionnaire. The questionnaire consists of 26 questions, and it is divided into four domains (Table 1) comprising physical health, psychological, social relationships and environment, respectively. The raw data generated by the questionnaire are then compared against a scale to get the final value.

The scale ranges from 1 to 100. Higher results mean higher quality of life. Patients completed the WHOQOL BREF questionnaire 24 hours before undergoing the neurolytic celiac plexus block and at 2 months follow-up of the procedure. Before the patients were asked to complete the questionnaires, they were informed about the aim and purpose of the study.

Hypotension was termed to occur when SBP was more than 20% lower than the baseline (more than 1 episode) in 24hr follow up, which was managed with intravenous fluids and if required with small boluses of injection ephedrine. Loose motion is said to occur when there were more than 4 watery motions post procedure in 24 hours, which was managed conservatively. USG abdomen was done in all patients to rule out visceral puncture or hematoma 2 days after the procedure. MRI was advised to patients complaining of severe back pain and pain at the injection site in patients undergoing transdiscal approach to rule out discitis, which was managed with intravenous broad spectrum antibiotics. Those patients who died prior to completion of study of 2 months, and who did not turn out for follow up were dropped out from the study.

Technique of Transdiscal Celiac Plexus Block

The transdiscal block was performed under image intensifier with patient in prone position. The target was the disc of T 11 and T 12, and local skin infiltration was done with 5 ml of lidocaine 2% at the needle insertion site. A 22G 15 cm needle was placed lateral to the superior articular process of T11 vertebrae using gun barrel technique under image intensifier. The needle was advanced until there was loss of resistance. The accurate placement of needle anterior to the disc was confirmed by giving 1 ml of non-ionic contrast agent which showed a smooth curvilinear contour corresponding to the anterolateral aortic space. Then, 10 ml of 2 % lidocaine followed by 20 ml of 60% ethyl alcohol was injected for neurolysis on each side after the negative aspiration test for blood, cerebrospinal fluid (CSF) or lymph.

Technique of Transaortic Celiac Plexus Block

The block was performed with the patients in the prone position. A tunnel view was used for needle insertion. Target point in the tunnel vision was just lateral to the middle of L1 vertebra only on the left side, where local anesthesia was applied with 5 ml of 2% lidocaine at the needle insertion site, which was 2.5-4.0 cm away from the midline. Then we advanced the needle (15 cm, 22G needle) gradually with intermittent aspiration till aorta was entered as evinced by appearance of blood. The needle was further advanced till cessation of blood flow and loss of resistance indicating penetration of the anterior wall of aorta, after which 1 ml of non-ionic contrast agent was injected which remained at midline on the posteroanterior view. Lateral view confirmed preaortic T12-L2 spread. Then 10 ml of 2 % lidocaine followed by 40 ml of 60% ethyl alcohol was injected for neurolysis through the needle after a negative aspiration test for blood, CSF or lymph.

All patients were kept in the post anesthesia care unit for 3 hours following the procedure for hemodynamic monitoring and management of complications if any. The patients were transferred to the ward once they were declared stable. They were discharged from the hospital 24 hours following the procedure or later until they were symptom free.

Statistical analysis

Statistical analysis was done using SPSS 16. Student's t test and Mann Whitney U test was used to compare the significant difference in mean. For paired samples Paired Student t-test was used. For categorical variables Chi square test and Fisher's-exact tests were used. P value <0.05 was considered as statistically significant.

Results

A total of 82 patients were assessed for the eligibility, out of which 60 patients were included in the study and 22 patients were excluded (17 for not fulfilling the criteria and 5 refused to participate) (Fig. 1). Both groups were comparable in terms of demographic profile, duration of pain and diagnosis of GI malignancies (p>0.05) (Table 2).

Table 2

Demographic and other variables

Variables	Group TD (N=30)	Group TA (N=30)
Ages (years)	46.93 ± 9.98	51.00 ± 11.72
Sex (M/F)	21/9	20/10
Weight (kg)	53.12 ± 5.38	52.85 ± 7.90
Duration of pain (months)	1.2 ± 1.08	1.8 ± 1.01
GI malignancies (NO.) - pancreatic - gall bladder - others	 10 15 5	 8 18 4

p>0.05

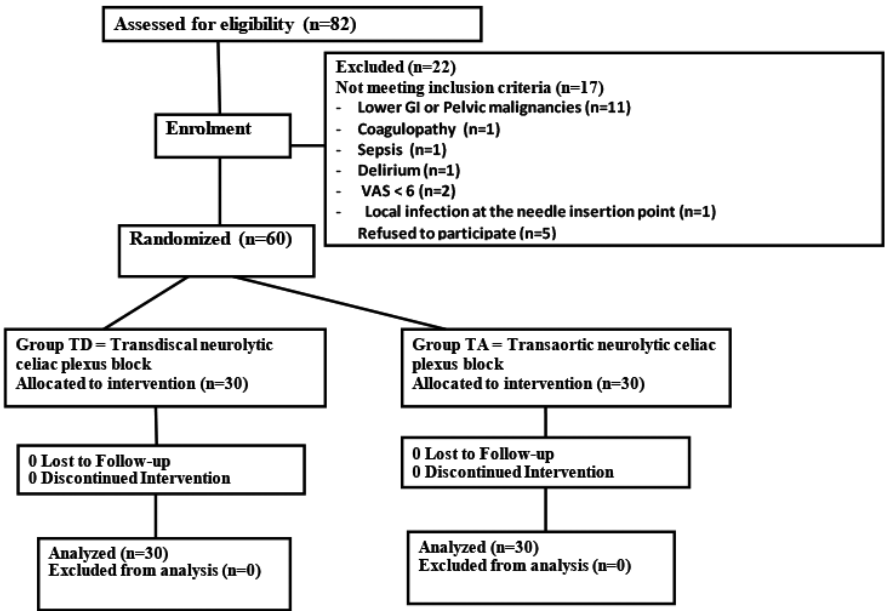

Fig. 1. — Study Design.

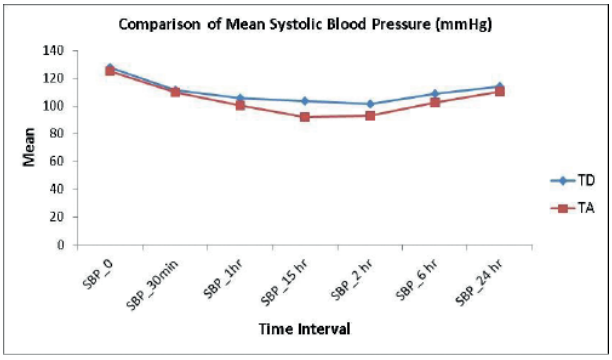

Fig. 2. — Comparison of mean SBP.

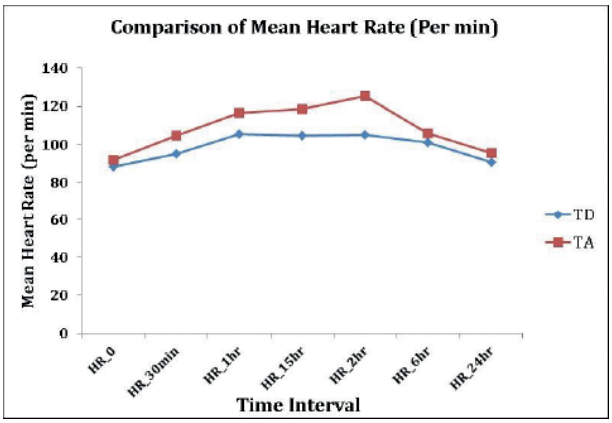

Fig. 3. — Comparison of mean HR.

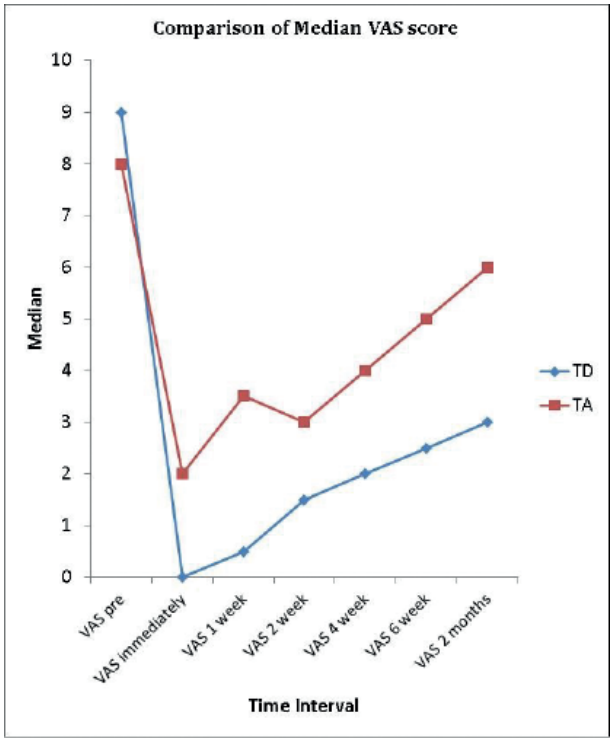

Fig. 4. — Comparison of median VAS.

The baseline mean SBP and HR were comparable in both groups (p>0.05). After 1.5 hr there was a significant decrease in mean SBP in the TA group as compared to the TD group which remained up to 6 h post procedure (p<0.05). Post that the mean SBP in both the groups were again comparable (Fig. 2). The heart rate was significantly higher in TA group at 30 mins, 1 h, 1.5 h and 2 h which may be due to reflex tachycardia as a result of hypotension. However, it reached nearly baseline values at 24 h (Fig. 3). The mean baseline DBP were comparable in both groups (p>0.05). From 1h post procedure there was a decrease in mean DBP in the TA group for the remaining duration of the study period which was statistically significant (p<0.05).

Pre procedural Quality of life scores were comparable in both the groups (p>0.05). Post-

Table 3

Comparison of QOL (both inter group and intra group) pre- and post-procedure

	TD (Mean ± SD)		TA (Mean ± SD)		t-value	p-value
Total Score pre-	141.90 ± 18.10		138.70 ± 14.39		0.758	0.452
Total Score post-	227.00 ± 28.85		191.17 ± 35.78		4.270	<0.001
	t-value	p-value	t-value	p-value		
	-14.063	<0.001	-7.507	<0.001		

Table 4

Complications

Complications	Group TD	Group TA	p-value
Hypotension	25	30	0.052
Loose motion	21	25	0.222
Bleeding	0	5	0.052

p>0.05

procedural assessment of QoL score showed TD group had significantly better score than TA group (p = <0.001). However, even intra-group comparison of pre-procedural and post procedural QoL scores in either group obtained a 'p' value of <0.001, which was statistically significant. The result showed a definitive improvement in quality of life in both the groups; however, TD group had significantly better QoL score than TA group (Table 3).

It was found that the median VAS scores in both the groups were comparable before the procedure. VAS scores immediately after the procedure and at follow up at 1, 2, 4 and 6 weeks and at the end of 2 months were significantly lesser in TD group than the TA group (p<0.05) (Fig. 4).

Out of 30 patients in TD group, 25 patients developed one or more episodes of hypotension while in TA group all patients developed hypotension during the procedure. All of them were adequately managed with intravascular fluid administration, abdominal binder, leg raising position. Rarely small boluses of ephedrine were needed. Similar results were obtained with the incidences of loose motion (21 *vs* 25 respectively), which was self-limiting in 1-2 days and managed with supportive therapy. 5 patients in TA group had bleeding from aorta which was identified as asymptomatic hematoma in USG and was self-limiting in all (Table 4). Local pain at injection site was complained by all patients of both groups, which was self-limiting in nature. The difference in complications was not statistically significant (p>0.05). Visceral puncture, discitis or any serious neurological complications were not seen in any of the groups.

Discussion

Percutaneous celiac plexus block is used widely to alleviate pain in upper intra-abdominal cancers. Other beneficial effects are marked reduction in the need of opioids, improved food intake and better bowel motility. Ischia et al. (3) advocated that the transaortic approach guaranteed the spread of neurolytic agent only in the area anterior to the crus of diaphragm. In patients with advanced abdominal malignancies, anatomical relationships of the retroperitoneal organs is distorted by cancer growth or due to previously performed operations, so much so that transaortic approach fails to deposit neurolytics sufficiently to celiac plexus. Transdiscal approach avoids these limitations of transaortic approach and has been associated with reduced instances of visceral injury. The trans-intervertebral disc approach for neurolytic superior hypogastric plexus block has also been used and reported with great results (4, 5).

Hiroaki Ina et al. (5) found complete pain relief in 100% of patients immediately after bilateral transdiscal block. E. Polati et al. (6) reported that 19 out of 25 patients after trans-aortic NCPB with alcohol achieved complete pain relief within 48 hours from execution of block whereas 6 patients reported partial pain relief with persistence of residual pain. In our study, immediate pain relief was better in the transdiscal group as compared to transaortic group as evident from their median VAS scores of 0 and 2, respectively. This is mainly because our transdiscal approach made it possible to place the tip of the needle in the area close to the antero-lateral or lateral wall of aorta, despite the abnormal retroperitoneal anatomy in some cases, leading to satisfactory spread of alcohol. Ischia et al. (3) reported that needle tip lay in the fatty connective tissue and in the middle of the dense connective tissue in celiac plexus in front of aorta in trans-aortic approach which was technically difficult to locate in advanced malignancy. Follow-up results of our study too show better pain relief in transdiscal approach, i.e. VAS of 1 at 1 week and 3

at the end of 2 months whereas VAS was 3 at one week and 6 at 2 months with transaortic approach which is statistically significant with a $p<0.05$.

Advances in early detection and improved treatment outcomes have steadily increased the number of cancer survivors. The quality of life (QoL) of cancer survivors has become the center of cancer survivorship (9). The WHOQOL-BREF (2, 8) is a well-established generic QoL instrument intended for use in a wide range of chronic diseases and cancer (8). It comprises 24 items divided over four domains plus two items of the General Facet describing overall QoL and general health. The domains represent Physical Health (seven items), Psychological Health (six items), Social Relationships (three items), and Environment (eight items) and are scored on a 4-20 scale with higher scores indicating a better QoL (2). The General Facet is scored on a 2-10 scale. Previous studies have demonstrated good psychometric properties of the WHOQOL-BREF in patients with lung cancer (10) and in patients with chronic diseases or different forms of cancer (8). However, very few studies have evaluated the effect of NCPB on QoL in upper GI malignancies (11-15). E. Polati et al. (6) revealed that the quality-of-life score was significantly better in patients with NCPB using alcohol than in patients with conventional drug therapy. But not much literature is available for comparing transdiscal and trans-aortic approaches using quality of life score in upper GI malignancies. In our study we found that both procedures were statistically significant in improving quality of life scores than pre-procedure scores. However, in patients undergoing transdiscal approach, quality of life score was statistically better than trans-aortic approach.

The baseline heart rate was comparable in both groups whereas heart rate was increased more in transaortic approach than transdiscal approach at 30 min, 1 h, and 2 h and was statistically significant till 6 h, after which it became statistically insignificant. The reason may be the exaggerated hypotension in transaortic approach than transdiscal approach leading to reflex tachycardia. Adverse effects related to NCPB were common sequele to sympathetic denervation and by complications due to chemical or traumatic injury to surrounding structures. Sympathetic denervation causes hypotension prevalently postural and hyper peristalsis with occurrence of diarrhea. Ricardo Plancarte et al. (20) suggested that out of 109 patients, 43% patients developed hypotension with transdiscal approach. Hiroaki Ina et al. (5) also found hypotension in 36.2% in patients undergoing transdiscal approach. Whereas in our study hypotension was present in 83.3% patients with transdiscal approach and 100% in patients with transaortic approach. The possible reason may be the high amount of alcohol, we used in our study (40 ml total) over 5-25 ml used in prior studies. However, it lasted not more than 24 hours and was easily managed with administration of crystalloid solutions, abdominal binder, leg raised position, requiring ephedrine only in few cases.

E. Polati et al. (6) found diarrhea occurring in 40% patient. Its incidence was higher when a pre-crural technique was employed. Ricardo Plancarte et al. (20) found diarrhea was there in 58% of patients with transdiscal approach and was not associated with any fluid and electrolyte disturbances, was limited to 48 hours and responded to symptomatic treatment. In our study, 70% of patients with trans-discal approach and 83.3% of patients undergoing trans-aortic approach had diarrhea with no major electrolyte abnormality and was managed with supportive therapy. Patients were discharged after 24 hours or later until they were symptom free.

Transdiscal approach has been believed to be more suitable for NCPB, where significant metastases have occurred resulting in distortion of normal anatomy limiting access to celiac plexus. It is also associated with less organ injury compared to conventional approaches. However, it may also be associated with a possible risk of discitis or disc degeneration, as feared from procedures like discography (19). Serdar Erdine et al. (7) reported no case of discitis in a study of 20 patients undergoing transdiscal NCPB. Similar reports were suggested by Ricardo Plancarte et al. (20) and Gyeong-Jo Byeon et al. (16). Some investigators recommend the use of suitable broad-spectrum antibiotics in single prophylactic dose whenever the intervertebral disc is entered (19). In our study too due to strict aseptic precautions and antibiotic prophylaxis, no incident of discitis or infectious complications was seen (17).

The transaortic approach has the main dis-advantage of increased risk of retroperitoneal hemorrhage, which may occur in up to 0.5% of patients particularly in those with hypertension or coagulopathy (21-22). However, we found 5 out of 30 patients in transaortic group had bleeding from aorta manifesting as asymptomatic self-limiting hematoma in USG; the incidence of which was significantly higher in our study than previous studies. This may be because of technical difficulty encountered in placing the needle tip and lack of CT guidance. But there was no visceral puncture in our study. No cases of definite paraplegia, pneumo-

thorax, osseous puncture, or diaphragmatic paralysis were seen in our study. Local pain was present in most of the patients which is similar to various other studies.

Our study has many strong points: first it was a prospective study as compared to several other similar studies which were retrospective in design. Second, it is now being recognized that QoL can provide distinctive prognostic information as a predictor of survival duration in cancer patients (18); we included QoL as the primary outcome using a well validated WHOQOL-BREF assessment tool, which in our knowledge has not been employed previously in assessing QoL in upper GI cancer patients receiving NCPB. However, our study has certain limitations too: first, the risk of observer bias exists in this study due to differences in techniques (one injection of 40 ml in transaortic group *vs* 2 injections of 20 ml each in transdiscal approach), which could have been minimized by either giving sham second injection in the transaortic group or using single injection in transdiscal approach. However, we found similar studies where 1 injection vs 2 injections techniques were used (15). Second, it may appear that the difference in results would have been influenced by the different levels of injections in the two techniques (L1 in TA group vs T11-T12 intervertebral disc in TD group). However, anatomically celiac plexus includes celiac ganglion, pre and post ganglionic sympathetic efferents (T5-T12 and L1-L2 respectively) and para sympathetic and visceral sensory afferent fibres (23). So, it is unlikely that a significant difference would have been caused by different levels of injections when we aim to block the entire celiac plexus. Third, this was a single-centre study, so multi-centre prospective studies are needed. Fourth, we did not do intra or inter group comparison between pre and post procedure analgesics consumption because previous studies had shown inconsistent results. Lastly, we kept the follow up only for 2 months, though longer duration follow up has been done by some studies (12, 18). The reason behind this was advanced stages of cancers at which most of the patients came for palliative management in the form of NCPB.

Conclusion

Neurolytic celiac plexus block has promising results in improving both the quality of life as well as immediate as well as delayed pain relief in patients with upper gastrointestinal malignancy presenting with severe pain often refractory to medical treatment. Among the different approaches of NCPB, transdiscal approach is superior to transaortic approach in improving the pain as well as quality of life, though both the approaches are independently good in improving the same.

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