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SCIENTIFIC ARTICLE

Single needle versus double needle celiac trunk neurolysis in abdominal malignancy pain management: a randomized controlled trial[☆]



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KEYWORDS

Celiac neurolysis;
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Abstract

Background: Computerized tomography-guided celiac plexus neurolysis has become almost a safe technique to alleviate abdominal malignancy pain. We compared the single needle technique with changing patients' position and the double needle technique using posterior anterocrural approach.

Methods: In Double Needles Celiac Neurolysis Group ($n=17$), we used two needles posterior anterocrural technique injecting 12.5 mL phenol 10% on each side in prone position. In Single Needle Celiac Neurolysis Group ($n=17$), we used single needle posterior anterocrural approach. 25 mL of phenol 10% was injected from left side while patients were in left lateral position then turned to right side. The monitoring parameters were failure block rate and duration of patient positioning, technique time, Visual Analog Scale, complications (hypotension, diarrhea, vomiting, hemorrhage, neurological damage and infection) and rescue analgesia.

Results: The failure block rate and duration of patient positioning significantly increased in double needles celiac neurolysis vs. single needle celiac neurolysis (30.8% vs. 0%; 13.8 ± 1.2 vs. 8.9 ± 1 ; $p=0.046$, $p \leq 0.001$ respectively). Also, the technique time increased significantly in double needles celiac neurolysis than single needle celiac neurolysis (24.5 ± 5.1 vs. 15.4 ± 1.8 ; $p \leq 0.001$). No significant differences existed as regards Visual Analog Scale: double needles celiac neurolysis = 2 (0–5), 2 (0–4), 3 (0–6), 3 (2–6) and single needle celiac neurolysis = 3 (0–5), 2 (0–5), 2 (0–4), 4 (2–6) after 1 day, 1 week, 1 and 3 months respectively. However, Visual Analog Scale in each group reduced significantly compared with basal values ($p \leq 0.001$). There were no statistically significant differences as regards rescue analgesia and complications ($p > 0.05$).

[☆] The study was conducted in Pain clinic of Oncology Center of Mansoura University.

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PALAVRAS-CHAVE

Neurólise celiaca;
Tomografia
computadorizada;
Posição do paciente;
Agulha única;
Agulha dupla

Conclusion: Single needle celiac neurolysis with changing patients' position has less failure block rate, less procedure time, shorter duration of patient positioning than double needles celiac neurolysis in abdominal malignancy.

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Neurólise do tronco celiaco com o uso de agulha única *versus* agulha dupla no manejo da dor abdominal maligna: estudo randômico controlado

Resumo

Introdução: A neurólise do plexo celiaco guiada por tomografia computadorizada tornou-se uma técnica relativamente segura para aliviar a dor abdominal maligna. Comparamos a técnica de agulha única mudando o posicionamento do paciente e a técnica de agulha dupla usando a abordagem anterocrural posterior.

Métodos: No grupo designado para neurólise celiaca com agulha dupla (n = 17), a técnica de abordagem anterocrural posterior foi utilizada com duas agulhas para injetar 12.5 mL de fenol a 10% de cada lado em decúbito ventral. No grupo designado para neurólise celiaca com agulha única (n = 17), a abordagem anterocrural posterior foi utilizada com uma única agulha para injetar 25 mL de fenol a 10% do lado esquerdo com o paciente em decúbito lateral esquerdo e posteriormente virado para o lado direito. Os parâmetros de monitorização foram a taxa de falha dos bloqueios e a duração do posicionamento dos pacientes, o tempo da técnica, os escores da escala visual analógica, as complicações (hipotensão, diarreia, vômitos, hemorragia, dano neurológico e infecção) e a analgesia de resgate.

Resultados: A taxa de falha dos bloqueios e a duração do posicionamento dos pacientes aumentaram significativamente na neurólise celiaca com o uso de agulha dupla *vs.* agulha única (30.8% *vs.* 0%; $13,8 \pm 1,2$ *vs.* $8,9 \pm 1$; $p = 0,046$, $p \leq 0,001$, respectivamente). Além disso, o tempo da técnica foi significativamente maior na neurólise celiaca com agulha dupla que na neurólise celiaca com agulha única ($24,5 \pm 5,1$ *vs.* $15,4 \pm 1,8$; $p \leq 0,001$). Não houve diferença significativa em relação aos escores da escala visual analógica: neurólise celiaca com agulha dupla = 2 (0-5), 2 (0-4), 3 (0-6), 3 (2-6) e neurólise celiaca com agulha única = 3 (0-5), 2 (0-5), 2 (0-4), 4 (2-6) após um dia, uma semana, um e três meses, respectivamente. No entanto, os escores da escala visual analógica para cada grupo foram significativamente menores comparados aos valores basais ($p \leq 0,001$). Não houve diferença estatisticamente significativa quanto à analgesia de resgate e complicações ($p > 0,05$).

Conclusão: A neurólise celiaca com o uso de agulha única e a alteração do posicionamento do paciente apresenta uma taxa menor de falha do bloqueio, menos tempo de procedimento e menor duração do posicionamento do paciente que o uso de duas agulhas para neurólise celiaca em malignidade abdominal.

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Introduction

Patients suffering from intractable pain associated with abdominal malignancy have often dramatic affection to his quality of life and survival.¹ Management of intractable pain associated with abdominal malignancies is a complex process and challenging and often associated with chronic use of high-dose narcotic analgesics with several adverse effects.²

Celiac Plexus Neurolysis (CPN) is defined as the usage of a neurolytic agent such as ethanol or phenol, in combination with a local anesthetic agent to permanently destroy visceral afferent nociceptors that relay through the celiac plexus.³ Since 1914, different approaches and techniques

utilizing different routes to reach the celiac plexus were developed to improve the accuracy of needle placement, increase efficacy, and decrease complications of CPN.⁴

Computerized Tomography (CT) – guided CPN is a safe technique that allows excellent visualization of abdominal anatomy, accuracy in needle tip location and observation of the distribution of neurolytic agent with contrast.⁵ It has become a popular technique with low complication rate and is gaining universal acceptance.⁶

Fluoroscopic, ultrasound and endoscopic techniques are an alternative guidance for CPN. Fluoroscopy has a poor resolution of the surrounding structures on the other hand, ultrasound guidance is a simple technique allowing direct visualization of important vascular structures, and

observation of the diffusion of the neurolytic agent without contrast but it needs more hand skills and training.⁷

Double needles posterior antecrural approach with prone position is the most commonly performed approach for celiac neurolysis. Despite the prone position is stable and allows safe access to the celiac plexus; it is not comfortable in patients who have difficulty in maintaining a safe airway, obese patients and patients with severe abdominal pain. In addition, the risk of pneumothorax is possible with this position which is reduced in lateral position.⁵

Single needle is used in posterior transintervertebral disk, posterior transaortic and anterior approaches. Posterior transintervertebral disk approach is not usually used in clinical practice because of the high risk of disk trauma, disk herniation, diskitis, and spinal cord puncture. As regards the posterior transaortic approach, it has increased the risk for retroperitoneal hemorrhage, mainly in patients with coagulopathy or hypertension.⁶ Despite the advantage of the anterior approach in comfort supine positioning of the patients, the entrance of the needle may puncture some vital organs as stomach, liver, bowel, pancreas or aorta.⁸

There were no reported previous studies dealing with the efficacy of single needle posterior anterocrural approach for effective celiac neurolysis by using patients positioning to optimize the neurolytic agents spread bilaterally.

Therefore, we conducted our novel study using a CT guided posterior anterocrural approach of CPN in upper abdominal malignancy patients using a single needle injection technique with changing patients' positions. We compared this technique with the classic double needle posterior anterocrural injection technique and evaluated the difference between both techniques as regards Visual Analogue Scale (VAS), duration of patients positioning, duration of the procedure, failure rate, need for rescue analgesia and post CPN complications.

Methods

Study design and participants

Our study was a prospective randomized open blinded end-point study conducted in Anesthesia Department of Medical Faculty and Pain Clinics of Mansoura Oncology Center, Egypt during the period from June 2015 till December 2015. The study was accepted by Institutional Research Board of Mansoura University (Code n° R/15.07.07), registered in the ClinicalTrials.gov (Identifier: NCT02692456) and followed the 2008 Helsinki declaration ethical standards. Informed written consents were taken from patients.

Inclusion criteria for our study included: (1) Patients aged between 35 and 80 years of either sex who had suffered from intractable upper abdominal pain due to abdominal cancer either gastric cancer, pancreatic cancer, and hepatoma; (2) VAS \geq 4; (3) Administration of large doses of analgesics including opioids without improvement of VAS $>$ 5; (4) Uncontrollable side effects of opioids like vomiting or severe constipation; (5) Satisfactory improvement with a diagnostic celiac plexus block before going to permanent neurolysis using local anesthesia and steroids.

Exclusion criteria were: those who refused to share, patients with bleeding tendency or coagulopathy, success of oral analgesics with no serious side effects even at higher

doses, cardiac patients, renal or hepatic failure, distant vertebral metastasis with back pain similar to that associated with abdominal cancer, evidence of local infection at the puncture site and failure of improvement with a diagnostic celiac plexus block before going to permanent neurolysis.

All patients were assessed for the intensity of pain during the last week before the procedure by VAS (If no pain the score was zero, if it is worst pain imaginable the score was 10). Complete blood count, liver, renal function tests and coagulation profile including prothrombin time, partial thromboplastin time, international normalized ratio and prothrombin activity were done.

Patients were randomly allocated into one of two groups. The first group was Double Needles Celiac Neurolysis (DNCN) Group ($n = 17$) where patients received CPN using two needles posterior anterocrural technique while patient was in prone position and injecting 12.5 mL phenol 10% on each side with both needles lateral to the aorta. The second group was Single Needle Celiac Neurolysis (SNCN) Group ($n = 17$) where patients received CPN using single needle posterior anterocrural approach and injecting 25 mL of phenol 10% from left side to be just in the front of the aorta near the origin of celiac trunk while patient was in lateral position with his left side up, then after the injection the patient turned to be his right side up for more homogenous spread of the dye.

Before the procedure, an intravenous cannula was secured. Intravenous sedation with midazolam 1-2 mg and prophylactic antibiotic (cefotaxime 1 g) was given in all patients. Standard monitors were connected to the patient included pulse oximetry for oxygen saturation and electrocardiogram for heart rate and non-invasive blood pressure for mean arterial blood pressure. Oxygen was allowed for all patients during the procedure at a rate of 3 l/min through nasal cannula. Emergency medications including atropine, adrenaline and ephedrine were available during the procedure.

Previous patients' CT scans were assessed by the interventionist before the procedure to identify the exact location of celiac and superior mesenteric arteries, adjacent veins to plan the puncture pathway. Patients were positioned according to their group either on prone or lateral position. Thin CT section was done in the axial plane for all patients to detect the site of celiac plexus and in the coronal plane for correct site for needle placement. We identified the point of skin entry with a marker pen.

The patient should be learned about the purpose and steps of the procedure. The procedures were performed on a 64 MDCT scanner (Brilliance 64-Philips). First, a level of T12-L1 disc was detected. Adequate sterilization of the skin was achieved using bovidone iodine. A guide spinal needle of 25 gauges was placed for local anesthesia using CT-fluoroscopy without IV contrast injection. Next, the fine spinal needle was removed and 20 cm long 22 gauge chiba biopsy needle was inserted. This needle is a disposable needle with chiba cannula tip that enables soft penetration and avoids the risk of vessel laceration and reaches deep points without any excessive deviation. It is equipped with a Luer Lock hub and spindle inside. The centimeter cannula has a sliding stopper for determining the insertion depth (Fig. 1). The needle was inserted approximately near the celiac artery. Then 30 mL of non-ionic contrast medium



Figure 1 Shows the chiba needle.

(loversol, Optiray 350) was administered intravenously at a flow rate of 3-4 mL.sec⁻¹.

Imaging was performed at a late arterial phase (30-40s from start of injection). The CT acquisition parameters were 200 mAs, 120 kVp, 512 × 512 matrix, 1.172 pitches, 64 × 0.625 mm section collimation, and 4 mm slice thickness. In cases with suspicious adjacent veins or varices due to portal hypertension, another imaging was performed at a portal phase (60s from start of injection). The celiac and superior mesenteric arteries were identified after contrast injection. Then chiba needle was adjusted according to related vessels to avoid intra-vascular injection and it was advanced gently toward the target.

If the lung or the pleura were within the needle pathway, saline was injected in order to push the lung or the pleura away from the field. When the needle tip was near the aorta, fine adjustments was performed in DNCN Group where the two needles tips were placed lateral to the aorta from each side. While in SNCN Group, the single needle tip was just in the front of the aorta near the origin of celiac trunk (1 cm below the celiac artery and above the superior mesenteric artery).

When an ideal needle tip position was confirmed, the stylet was removed and aspiration was performed to ensure absence of blood. A volume of 3 mL of lidocaine 2% mixed with contrast was injected to confirm the position. After injection, another CT (a cross-sectional view) was taken to show the spread of contrast freely in the retroperitoneal space around the celiac plexus and the aorta.

After confirmation that the contrast was surrounding the artery and there was no dorsal spread to avoid injury to somatic nerves or no spread to the renal pelvis, injection of 12.5 mL of phenol 10% mixed with 2.5 mL of contrast was done through each needle in DNCN (Fig. 2).

In single needle approach, a volume of 25 mL of phenol 10% mixed with 5 mL of contrast was injected slowly in increments after careful aspiration (Figs. 3 and 4). After the injection, the patient turned to be his right side up for more homogenous spread of the dye. Patients were kept still in their position for 20 min to stabilize agent positioning and another CT was done to show the spread of phenol (Fig. 5).

Before the needle was removed, a volume of 3 mL of normal saline was injected through each needle to ensure that there was no backward spread of phenol during withdrawal of the needle, and then the site of entry was covered with sterile gauze and plaster tape.

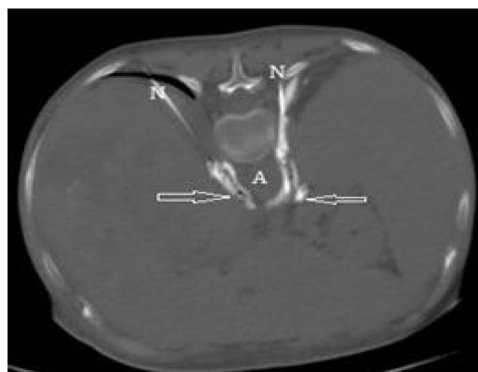


Figure 2 The arrows show the spread of phenol 10% with contrast around the aorta (A), N (needles).

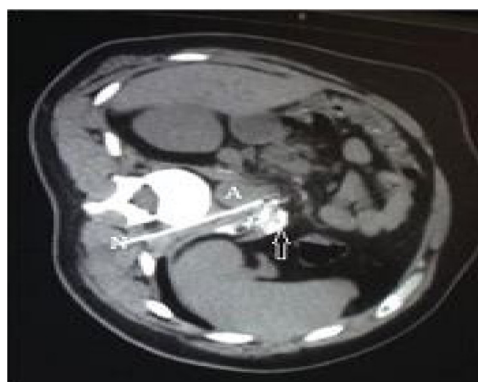


Figure 3 The arrow show the spread of the contrast at the left side of the aorta (A), the single needle (N) introduced in the patient left side at the level of celiac trunk.



Figure 4 The arrow shows the phenol 10% with the contrast after injection, aorta (A).

The following parameters were monitored in every patient: (1) Failure rate of prone and lateral position as primary outcome; (2) Duration of patients positioning (DNCN Group to prone position and SNCN Group to left lateral position); (3) Total time of the technique starting from positioning till needle withdrawal; (4) Pain intensity was assessed 1 day, 1 week, 1 month and 3 months post procedure by VAS; (5) Post blocks complication as postural hypotension, diarrhea, vomiting, hemorrhage, neurological

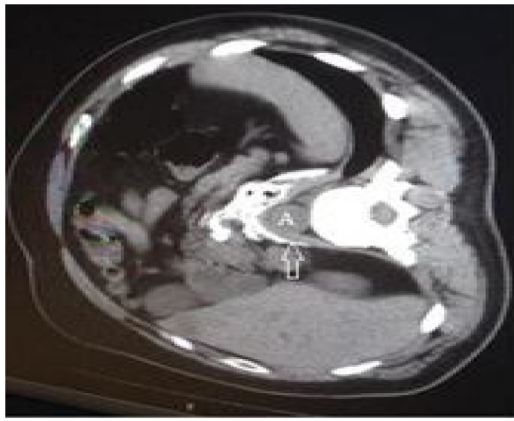


Figure 5 The arrow shows the spread of phenol 10% with contrast to the right side of the aorta after 20 min positioning of the patient on his right side.

Table 1 Demographic data (age, sex, weight and height), types of abdominal malignancy and duration of analgesia.

	SNCN group (n = 17)	DNCN group (n = 13)	p-Value
Age (years)	62.7 ± 1.7	61.8 ± 16.3	0.59
Sex (F/M)	6/11	3/10	0.32
Weight (kg)	77.8 ± 8.9	75.8 ± 9.2	0.49
Height (cm)	170.8 ± 6.8	168.7 ± 8.3	0.36
<i>Types of malignancy</i>			>0.05
Cancer pancreas	7 (41.2)	5 (38.5)	
Hepatoma	7 (41.2)	6 (46.1)	
Cancer stomach	3 (17.6)	2 (15.4)	

DNCN, Double Needles Celiac Neurolysis Group; SNCN, Single Needle Celiac Neurolysis Group. Data were presented as mean ± SD and numbers (%).

damage and infection; (6) Percentage of patients who required rescue analgesia if VAS increased more than four.

Statistical analysis

Sample size was calculated using G *power 3.1 program⁹ based on a pilot study of (5 patients of each group). Frequency of failure technique due to failure of patients positioning in prone position in DNCN Group was 40%. We estimated that 34 patients would provide a power of 87% to obtain statistically significant difference at p-value <0.05 in comparison to failure technique in SNCN Group which was zero.

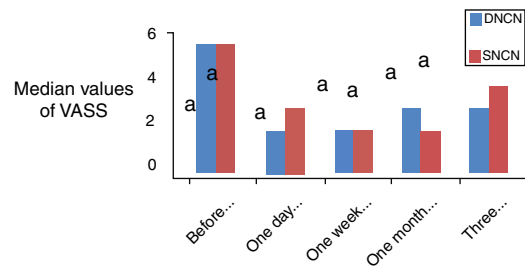


Figure 6 Median values of visual analog score. DNCN, Double Needles Celiac Neurolysis Group; SNCN, Single Needle Celiac Neurolysis Group. Data were presented as median; ^asignificant with p ≤ 0.001 within each group when compared with basal (before block).

Statistical analysis was carried out using the Statistical Package for Social Science version 16 (SPSS Inc., Chicago, IL, USA). Qualitative data were described using numbers and percentages. Continuous variables were presented as median for non-parametric data and mean and standard deviation for parametric data. Comparison between numerical variables of both groups was done by unpaired Student’s t-test for parametric data and Mann–Whitney test for non-parametric data. Chi-square test was used for comparison between categorical variables. The threshold of significance for the previously mentioned tests was fixed at 5% level (p-value).

Results

Four patients were failed to achieve the desired prone position in DNCN Group. So, they were excluded from the study.

Demographic data was compared and there was no statistically significant difference between both groups. Moreover, there were no significant differences between the both groups according to types of abdominal malignancy (Table 1).

As regard failure rate of block, it was significantly higher in DNCN Group (4 patients; 30.8%) when compared with SNCN Group (0) patients with p-value = 0.046 due to failure of positioning during the procedure. Also there was statistically significant increase in the duration of patient position and total time of technique in DNCN Group than SNCN Group (p ≤ 0.001) (Table 2).

Fig. 6 shows that there were no significant differences between the studied groups in VAS (SNCN Group = 3 (0–5), 2 (0–5), 2 (0–4), 4 (2–6) and DNCN Group = 2 (0–5), 2 (0–4), 3 (0–6), 3 (2–6) after 1 day, 1 week, 1 month and 3 months from the procedure respectively represented in

Table 2 Failure rate of block (number, %), duration of patient positioning (min) and total duration of block technique (min).

	SNCN (n = 17)	DNCN (n = 13)	p-Value
Failure rate of block (number, %)	0	4 (30.8)	0.046
Duration of patient positioning (min)	8.9 ± 1.03	13.8 ± 1.2	0.001
Total duration of block technique (min)	15.4 ± 1.8	24.5 ± 5.1	0.001

DNCN, Double Needles Celiac Neurolysis Group; SNCN, Single Needle Celiac Neurolysis Group. Data were presented as mean ± SD and numbers (%); significant with p-value < 0.05.

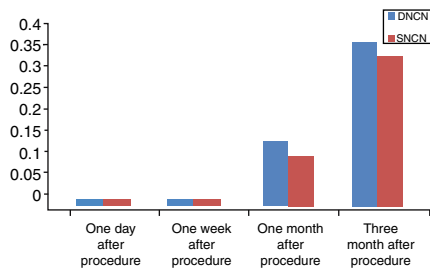


Figure 7 Percentage of patients need rescue analgesia. DNCN, Double Needles Celiac Neurolysis Group; SNCN, Single Needle Celiac Neurolysis Group. Data were presented as percent.

Table 3 Post celiac neurolysis complications in the studied groups.

	SNCN (n = 17)	DNCN (n = 13)	p-Value
Hypotension	1 (5.9)	3 (23.1)	0.17
Diarrhea	3 (17.6)	5 (38.5)	0.20
Vomiting	0	1 (7.7)	0.25
Hemorrhage	0	1 (7.7)	0.25
Infection	2 (11.7)	1 (7.7)	0.71
Neurological complication	0	0	-

DNCN, Double Needles Celiac Neurolysis Group; SNCN, Single Needle Celiac Neurolysis Group. Data were presented as numbers (%).

median and range. However, VAS in each group was reduced with highly significant during the studied period when compared with basal values (SNCN Group = 6 (3–7) and DNCN Group = 6 (3–7), $p \leq 0.001$). There were no statistically significant differences between the studied groups as regarded the rescue analgesia at 1 day and 1 week (zero in both groups), 1 month SNCN Group = 2 (11.7%) and DNCN Group = 2 (15.4%) ($p = 0.77$) and 3 months SNCN Group = 6 (35.3%) and DNCN Group = 5 (38.5%) ($p = 0.86$) after procedure (Fig. 7). Also there were no significant differences in complications including hypotension ($p = 0.17$), diarrhea ($p = 0.2$), vomiting ($p = 0.25$), hemorrhage ($p = 0.25$), and infection ($p = 0.71$) (Table 3).

Discussion

Computerized tomography is the most popular technique used in celiac neurolysis. The advantages of using CT guided are: firstly, CT is a cross-section imaging system which avoids overlapping anatomic structures either anteroposteriorly or transversely. Secondly, CT is able to clearly display the retroperitoneal anatomic structures including the pancreas, the abdominal aorta as well as the number, size and location of retroperitoneal lymph nodes which are important information for a successful celiac block. Thirdly, an optimal puncture site and needle course can be selected. Fourthly, CT is able to display the exact location of the needle tip relative to the surrounding structures. Finally,

CT is also able to accurately display the range of the neurolytic agent diffusion and allow the operator to decide whether the amount of injected agent is sufficient as well as to detect whether there is any leakage into the peritoneal cavity.⁶

CT-guided CPN for abdominal visceral pain achieve moderate or major short-term pain relief in a majority of cases and the procedure is safe with minimal complications¹⁰ and this is in agreement with our study and also with Krämer et al.¹¹ who concluded that CT-guided procedure for neurolysis of the celiac plexus is safe and effective in diminishing pain especially in patients suffering from tumors of the upper abdomen.

The current study found that there were no significant differences between DNCN and SNCN as regards rescue analgesic requirements, VAS and post procedures complications. This copes with the previous studies that found CT guidance decreased pain, improved functions, and reduced opiate dependence.^{6,12} Also, the incidence and severity of complications were low.¹³ Moreover, the injection of phenol near the celiac trunk promote high success rate of celiac neurolysis.^{14,15}

There were no neurologic complications in this study owing to the anterocrural approach and the use of CT. Hypotension occurred more frequently in DNCN which may be explained by more splanchnic vasodilatation.⁶

In both groups, little percentage of patients developed transient diarrhea due to loss of sympathetic tone and loss of opioid effects¹⁶ which improved two weeks after the procedure.¹⁷ Additionally, the neurolytic agent phenol 10% was chosen due to several factors, firstly it is miscibility with contrast, secondly its local anesthetic action, finally, it is less incidence of deafferentation pain, hypotension and diarrhea than that with alcohol.¹⁸ Also, there was significant reduction of the pain score in comparison to the basal values in both groups and for three months after procedure. This finding can be attributed to two factors, the first one is the application of diagnostic blockade before permanent blockade, that was carried out in order to successfully select our candidates and the 2nd one is the deposition of the neurolytic substance near the origin of celiac trunk which is the most consistent landmark for celiac plexus.¹⁹

The shorter duration of the patient positioning and total time of procedure in the single needle group were associated with less patient discomfort and less radiation exposure.²⁰

The failure rate in DNCN group was attributed to the prone position which is not suitable for terminally ill patients who are unable to tolerate the prone position and require meticulous monitoring and adequate ventilation.²⁰

The limitations of our study that we did not follow up our patients for longer time post procedure to see exactly for how long the pain decreased in those patients, so a longer prospective study is needed for further evaluation. We did not use different volumes and concentrations of neurolytic agent (phenol) to detect the optimal volume and concentration for those patients, so we need different volumes and concentrations of neurolytic agent (phenol) to be evaluated in further studies.

Conclusion

CT guided SNCN with changing patients' position has less failure rate of block, less procedure time, shorter duration of patient positioning compared to DNCN in pain management of abdominal malignancy patients.

Conflicts of interest

The authors declare no conflicts of interest.

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