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Comparative evaluation of different concentrations of alcohol in ultrasound guided coeliac plexus neurolysis for pain relief in upper abdominal malignancies

Pragya Verma¹, Sarita Singh¹, Gyan P Singh¹, Hemlata Verma¹,
Manish Kumar Singh^{1,*}¹Dept. of Anaesthesiology, King George's Medical University, Lucknow, Uttar Pradesh, India

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ABSTRACT

Introduction: Patients suffering from advanced upper abdominal malignancies have pain as predominant symptom affects their quality of life and survival. USG guided coeliac plexus neurolysis become benevolence in these patients on part of their pain management and quality of life improvement.

Objective: To compare the efficacy of USG guided coeliac plexus neurolysis for pain relief in upper abdominal malignancies by using different concentration of alcohol (50% vs 75%).

Materials and Methods: This Prospective, comparative, randomised double blinded study was conducted during Sep 2019 – Aug 2020 at our tertiary care centre. Total 60 cases were taken as per following inclusion and exclusion criteria and randomly divided into 2 groups i.e. 30 each group, we compare Visual Analogue Scale (VAS) score, quality of life (QOL) and need of rescue analgesia profile between the groups to know the efficacy of USG guided coeliac plexus block.

Observation and Result: In our study, we observed that the baseline mean VAS score in group I was 8.26 ± 0.78 while in group II was 8.03 ± 0.76 . No significant difference was found in mean VAS score at this time between the groups ($p=0.24$). The baseline mean QOL score in group-I was 77.46 ± 3.40 while for the cases of group II the mean QOL score was 77.36 ± 3.33 . No significant difference was found in mean QOL score at baseline between the groups ($p=0.90$). The baseline mean morphine consumption in group-I was 113.33 ± 39.24 mg while for the cases of group-II the mean morphine consumption was 120.33 ± 38.37 mg. No significant difference was found in mean morphine consumption at this time between the groups ($p=0.48$).

Conclusions: Both groups having 50% alcohol and 75% alcohol decreases the VAS score from baseline in patients having upper abdominal malignancies along with QOL and dosages of rescue analgesia whereas no significant difference in VAS score in patients of both groups.

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1. Introduction

Patients suffering from advanced upper abdominal malignancies undergo moderate to severe pain due to the disease process and also due to inadequate pain relief. In 90% of these patients, pain is a predominant symptom affecting their survival and quality of life, making it the

most common unsolved and unattended problem for these patients, hence these diseases create the necessity for good pain management which is an important goal in the holistic patient care.¹⁻³

The upper abdominal malignancies mostly originate from pancreas, stomach, liver, gallbladder, lymph nodes, spleen and mesentery resulting in intractable abdominal pain, which in advanced cases is often neuropathic in origin because of compression of peripheral nerves or

* Corresponding author.

E-mail address: manish.is.singh34@gmail.com (M. K. Singh).

direct metastatic invasion. Infection, oedema, soft tissues infiltration, bony metastases are some other possible causes of the pain.⁴ There are many modes of pain control in such patients like opiates, neuropathic blocks etc. Morphine is a standard opiate which is the drug of choice in beating moderate to severe pain but is effective only in dosages that induce consequential side effects, for example vomiting, constipation, delirium and addiction.

Coeliac plexus neurolysis (CPN) appeared as a widely accepted choice for symptomatic pain relief, it serves as an adjunct modality for palliative care of patients with upper abdominal tumours.⁵ CPN is associated with opioid dose reduction and is a minimally invasive procedure having < 2% incidence of major complications. To control pain and disrupt these neural impulses CPN involves the injection of neurolytic agent such as ethanol (absolute alcohol), phenol in combination with local anaesthetic agent into or around the coeliac plexus.

Ultrasound (US) as a recent advancement has proven itself an attractive technology to minimise the complications of CT and fluoroscopy. Ultrasound is a real time technique in interventional pain management. Ultrasound guidance is a simple technique allowing direct visualisation of important vascular structures and observation of the diffusion of the neurolytic agent without contrast. It allows the identification of soft tissues, vessels and nerves without imposing patients and medical personnel to radiation.⁶ Ultrasound seems to be safer, more convenient and accurate as it avoids complications associated with posterior approach, allows comfortable position and single puncture.⁷ In addition, the assessment with colour Doppler ultrasonography (USG) helps in avoiding injury of the interposing vessels.⁸

Now the USG guided anterior approach has been used by various researchers with different concentrations of absolute alcohol and phenol.^{6–10} This study was conducted for comparative evaluation of different concentrations of alcohol in USG guided CPN for pain relief in patients of upper abdominal malignancies.

2. Materials and Methods

After getting approval from the Ethical Committee of our University (Reg. No. ECR/262/Inst/UP/2013/ RR-19) and (CTRI Reg. No.-CTRI /2020 /01 / 023008) the study was conducted on patients visiting Pain clinic OPD in Department of Anaesthesiology in collaboration with General surgery, Oncosurgery and Gastrosurgery departments of King George Medical University, Lucknow, UP, India.

2.1. Duration of study

One year (September 2019 to Aug 2020).

2.2. Study design

Prospective, comparative, randomised double blinded study.

2.3. Sample size

Total 60 cases were taken in the study and randomly divided into 2 groups i.e. 30 each group.

2.4. Study groups

Group A- comprises patients in which 30-40ml of 50% alcohol was used for ultrasound guided CPN.

Group B- comprises patients in which 30-40ml of 75% alcohol was used for ultrasound guided CPN.

2.5. Sample size

Sample size is calculated based on maximum and minimum variation in VAS score among one of the study groups and assuming null hypothesis of equality in two groups using the formula:

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 (\sigma_1^2 + \sigma_2^2)}{d^2}$$

Where s_1 = standard deviation of VAS in Group I ($s_1 = 2.22$),

s_2 = standard deviation of VAS in Group II ($s_2 = 0.71$)

$\sigma_1 = 0.28$ The min and max SD's of VAS score (according to the reference paper "Anju Ghai et. al.")

d = mean (s_1, s_2), the difference considered to be clinically significant

Type I error $\alpha = 5\%$ corresponding to 95% confidence level

Type II error $\beta = 20\%$ for detecting results with 80% power of study

z_{α} & z_{β} are constant values that depend on desired level of significance

after calculation-

$n = 27$ each group

To account for data loss/ patient attrition of 10%, we included 30 patients per group.

Thus, the required sample size $n = 30$ in each group.

2.6. Inclusion criteria

1. All patients who presented with upper abdominal malignancy of either sex having age between 40 and 75 years.
2. Patients of upper abdominal malignancy having pain which was not relieved by nonsteroidal anti-inflammatory drugs (NSAIDs) or strong opioids like morphine (according to WHO ladder III).
3. Patients of upper abdominal malignancy developing complications on low dosages of morphine.

2.7. Exclusion criteria

1. Patients who were not willing to participate in the study.
2. Patient on anticoagulation therapy with deranged coagulation profile.
3. Local or intra-abdominal infection.
4. Sepsis and huge ascites.
5. Patients with bowel obstruction.
6. With physical opioid dependence and drug seeking behaviors.

2.8. Pre-procedure assessment

1. Written and informed consent was taken.
2. Baseline VAS score was measured.
3. Baseline quality of life was measured by filling McGill Quality of Life questionnaire.
4. Baseline morphine consumption by the patient was noted.

2.9. Methodology

A detailed patient check-up was done, and the procedure was explained to the patient. Gut was prepared with four tablets of bisacodyl 15mg and six charcoal tablets the night before procedure. Anti-hypertensive medications were continued to prevent the risk of rebound hypertension. Patients were kept nil per oral as per American Society of Anaesthesiologists preoperative fasting guidelines.

The Ultrasound guided CPN was performed in both groups of patients and evaluation of degree of pain relief was done on the basis of VAS score.

Group A: (30-40ml of 50% ethyl alcohol)

Group B: (30-40 ml of 75% ethyl alcohol)

The CPN was performed in the supine position. Ultrasonography was done by colour Doppler ultrasound system with high frequency curvilinear probe (3-5 MHz). After cleaning, draping and transducer preparation, the transducer was positioned just caudal to xiphoid process over the epigastrium. Abdominal aorta and coeliac trunk were localised following the descending aorta from the distal oesophagus. For correct identification of coeliac trunk and the SMA we obtained both short axis and long axis views. Lidocaine 1% was infiltrated at this point of entry. A 23G long spinal needle was introduced trans-gastrically under direct vision and advanced to reach the preaortic zone at the coeliac trunk level, identified by coloured dopler imaging. USG revealed the exact position of the needle during its progression and its location in relation to the coeliac trunk. Once the tip of the needle was in the antero-cephalad position to the coeliac artery take-off, suction was applied to rule out that needle tip insertion in blood vessels. After confirmation, 3ml of sterile normal saline was injected to flush the needle, which was followed by 10-15ml of 1% local anaesthetic. The spread of solution

was localized around the aorta at the level of the coeliac trunk, predominantly in the preaortic zone. If the injection successfully relieved pain on the table, neurolysis with 30 to 40 ml of 50% alcohol was carried out and the same procedure was performed in group B with 30 to 40 ml of 75% alcohol. After alcohol injection, an echogenic cloud was seen on USG at the target site that confirmed its location. Maximum filling of the retro-pancreatic space with ethanol indicated sufficient neurolysis and the needle track was cleared with normal saline during withdrawal of the needle to diminish irritation by neurolytic solution (ethanol) along the needle path. During the procedure both patient and assessor were unaware of the concentration of alcohol used.

All the parameters including VAS scores were recorded by an assessor who was unaware of the group allocation and did not participate in performing the procedure.

The following parameters were recorded:

1. Degree of pain relief – This was assessed by using VAS score (0-10) at weekly interval up to 12 weeks. Based on 10cm line, the left extremity represents no pain at all (score 0) and right extremity represent unbearable pain (score 10) the procedure was considered successful if there was satisfactory pain relief with VAS score ≤ 3 with or without morphine or reduction in the dose of morphine.
2. Requirement of oral analgesics –This was assessed at baseline (pre-procedural) and post-procedural at first 24 hours in post procedure room, then weekly upto 12 weeks after the procedure and their dosing were changed according to VAS score.
3. QOL of the patients – Improvement in quality of life was assessed by McGill Quality of Life Questionnaire assessed by using 100point scale.
4. Incidence of side effects/complications i.e., pain at injection site, transient hypotension, inadequate effect of block, vascular penetration, bradycardia, diarrhoea, were recorded and compared between the groups.

2.10. Follow up

After performing the blocks, the patients were taken to the post procedure room for 24 hours and were then followed up at 1 week, 1 month, 2 months and 3 months. A failed block was defined as failure to lower the VAS by 50% of the pre procedural measured VAS within 24 hours of blockade. The patients who required repeat block were not included in the study.

Follow up was done at the patient's next OPD visit at 1 week, monthly visits from 1 to 3 months and regular mobile communications were carried out to ask regarding pain relief with respect to VAS score; requirement of rescue analgesia i.e. total dose of morphine used and improvement in quality of life.

3. Observation and Results

The present study was undertaken to compare the efficacy of pain relief of ultrasound guided CPN with 50% concentration of alcohol Vs ultrasound guided CPN with 75% concentration alcohol in patients of upper abdominal malignancies. For this purpose, a prospective, double blinded randomised trial was carried out in which a total of 60 patients were enrolled. Out of these 60 patients, 30 patients were randomly allocated in Group I in which 50% alcohol given and remaining 30 patients allocated to group II in which 75% alcohol given.

After loss to follow up, the total no. of patients who were followed up till the end of 3 months were:

Group I - 27 subjects

Group II - 28 subjects

(Statistical analysis has been applied on all the data that has 'been collected in all the cases, including the cases which could not be followed up after a certain time period.

The primary outcome measure of the study was pain relief assessed by visual analogue scale (VAS) score. The secondary outcome measures of the study were quality of life as assessed by McGill Quality of life questionnaire, requirement of rescue analgesia, and incidence of any side effect of neurolysis in the patients.

3.1. Demographic characteristics

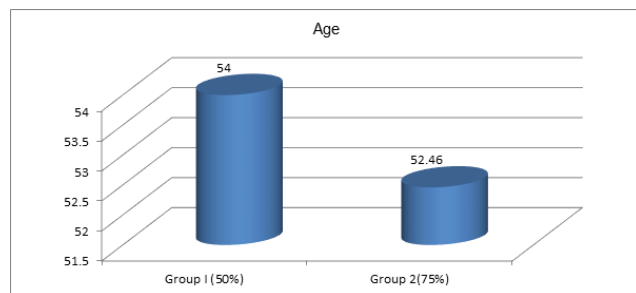


Fig. 1: Distribution of cases according to age

In our study age of patients ranged from 40 to 75 years. The mean age of the included patients for group I was 54 ± 9.38 years that was slightly more than the patients of group II having a mean of 52.46 ± 7.93 years. But no significant difference was found in mean ages of the two groups ($p=0.49$).

In both of our groups majority of patients were females. In group I, males were 26.66% while females were 73.33%. In the group II, males were 43.33% while females were 56.66%. However, no significant difference was found in proportion of males & females between the two groups ($p=0.40$).

The comparison of VAS scores at baseline and different follow up intervals between two groups are shown in Table 1. In our study, we observed that the baseline mean

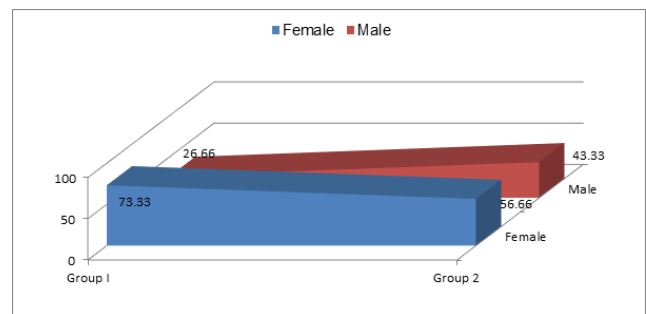


Fig. 2: Gender distribution of cases

VAS score in group I was 8.26 ± 0.78 while in group II was 8.03 ± 0.76 . No significant difference was found in mean VAS score at this time between the groups ($p=0.24$).

After 24 hrs, the mean VAS score in group I was 2.63 ± 1.84 while in group II, the mean VAS score was 2.36 ± 1.47 but the difference was not found to be statistically significant ($p=0.53$).

At all the follow up intervals beginning from 1 week and monthly intervals from 1 to 3 months mean VAS scores were lower as compared to baseline. But the difference between both the groups were not statistically significant at all the follow up time intervals upto 2 months. At 1 week mean VAS score in group I was 1.51 ± 0.50 while in group II, the mean VAS score was 1.60 ± 0.49 ($P=0.51$). After 1 month the mean VAS score in group I was 1.70 ± 0.46 while for the cases of group II, the mean VAS score was 1.53 ± 0.63 ($P=0.26$). After 2 months, the mean VAS score in group I was 1.85 ± 0.36 while for the cases of group II, the mean VAS score was 1.60 ± 0.62 ($p=0.08$).

After 3 months, the mean VAS score in group I was 2.33 ± 0.48 while for the cases of group II, the mean VAS score was 2.00 ± 0.60 . Significant difference was found in mean VAS score at this time between the groups ($p<0.05$).

As shown in Table 2, the baseline mean QOL score in group-I was 77.46 ± 3.40 while for the cases of group II the mean QOL score was 77.36 ± 3.33 . No significant difference was found in mean QOL score at baseline between the groups ($p=0.90$).

During the course of study, at all the subsequent follow up intervals, from 24 hours to 3 months, mean QOL scores showed a steady decline in both the groups except at 2 months but the difference between both the groups was not statistically significant at all the follow up time intervals. ($p>0.05$).

As shown in Table 3, the baseline mean morphine consumption in group-I was 113.33 ± 39.24 mg while for the cases of group-II the mean morphine consumption was 120.33 ± 38.37 mg. No significant difference was found in mean morphine consumption at this time between the groups ($p=0.48$).

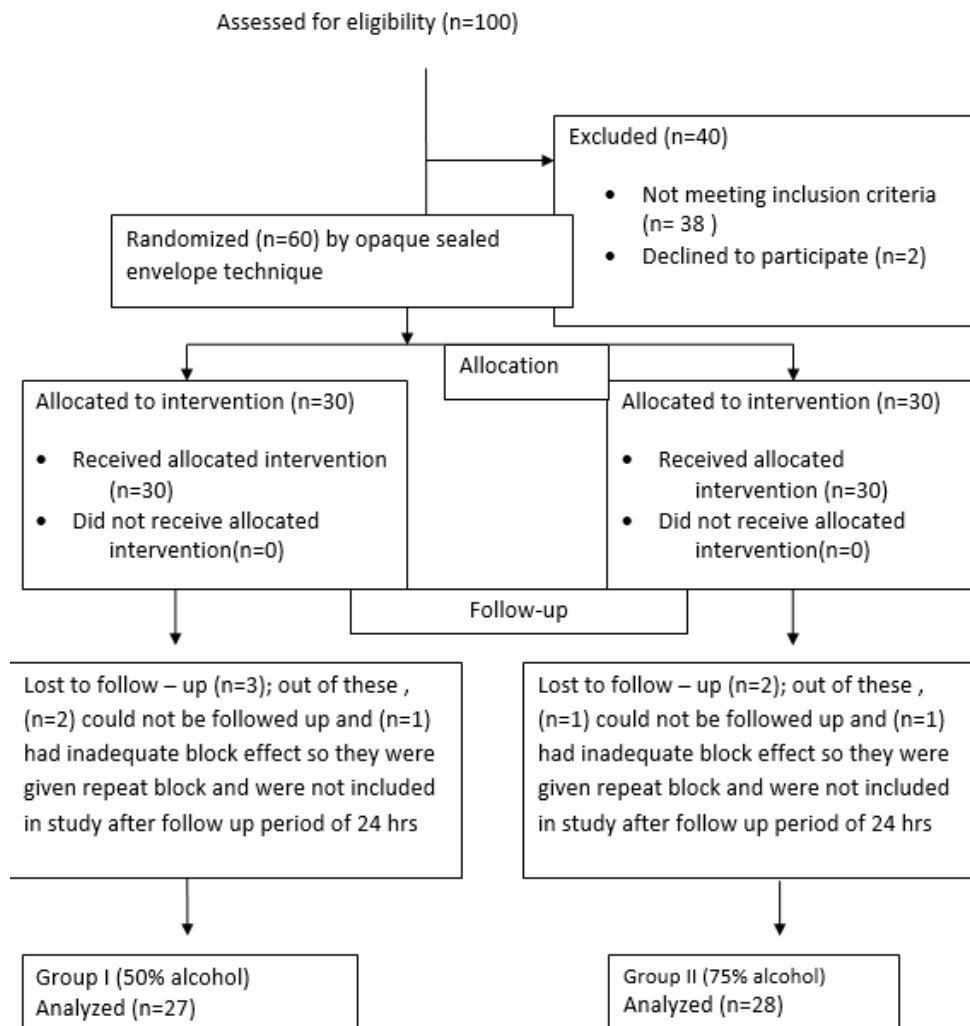


Diagram 1:

Table 1: Intergroup comparison of VAS between the groups

VAS	Group I(n=30)		Group II(n=30)		t-value	p-value
	Mean	SD	Mean	SD		
BL	8.26	0.78	8.03	0.76	1.16	0.24
24 h	2.63	1.84	2.36	1.47	0.61	0.53
1 week	1.51	0.50	1.60	0.49	-0.65	0.51
1 month	1.70	0.46	1.53	0.63	1.11	0.26
2 months	1.85	0.36	1.60	0.62	1.76	0.08
3 months	2.33	0.48	2.00	0.60	2.24	0.02

Table 2: Comparison of QOL scores between the two groups

QOL	Group I (n=30)		Group II (n=30)		t-value	p-value
	Mean	SD	Mean	SD		
BL	77.46	3.40	77.36	3.33	0.11	0.90
24 h	57.4	4.57	56.2	2.38	1.27	0.20
1 wk	46.51	3.43	45.28	3.36	1.34	0.18
1 m	43.55	2.57	42.85	2.90	0.94	0.35
2 m	39.81	2.61	38.67	2.10	1.77	0.08
3 m	48.96	5.00	47.14	6.36	1.17	0.24

Table 3: Comparison of morphine consumption between the groups

Morphine consumptions mg/day	Group I(n=30)		Group II (n=30)		t-value	p-value
	Mean	SD	Mean	SD		
BL	113.33	39.24	120.33	38.37	-0.69	0.48
24 h	84.33	25.55	69.66	29.18	2.07	0.04
1 wk	7.77	19.67	3.21	9.44	1.10	0.27
1 m	10.00	22.01	7.50	17.55	0.46	0.64
2 m	18.88	31.29	10.71	26.09	1.05	0.29
3 m	26.66	41.04	16.07	39.56	0.97	0.33
					-0.69	0.48

After 24 hours, the mean Morphine consumption in group-I reduced to 84.33 ± 25.55 mg while for the cases of group-II the mean morphine consumption reduced even more to 69.66 ± 29.18 mg. This difference in mean morphine consumption was statistically significant ($p=0.04$).

After 1 week, the mean morphine consumption in group-I reduced further to 7.77 ± 19.67 mg while for the cases of group-II the mean morphine consumption also reduced to 3.21 ± 9.44 ($p=0.27$).

After 1 month, the mean morphine consumption in group-I was 10 ± 22.01 mg while for the cases of group-II the mean morphine consumption was 7.50 ± 17.55 mg ($p=0.64$).

After 2 months, the mean morphine consumption in group-I was 18.88 ± 31.29 mg while for the cases of group-II the mean morphine consumption was 10.71 ± 26.09 mg ($p=0.29$).

After 3 months, the mean morphine consumption in group-I was 26.66 ± 41.04 mg while for the cases of group-II the mean morphine consumption was 16.07 ± 39.56 mg. ($p=0.33$). This shows that the difference between both the groups were statistically insignificant for morphine consumption at all the follow up time intervals from 1 week to 3 months.

significant difference in the side effect profile of the two groups.

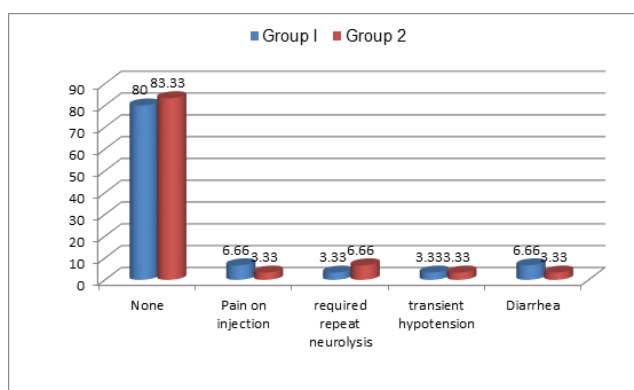
4. Discussion

Pain has always been one of the most troublesome symptoms associated with upper abdominal malignancies like CA gallbladder, CA pancreas and CA stomach. CPN is an interventional technique that has been extensively used by pain physicians for the past five decades for the treatment of abdomino-visceral pain from upper abdominal cancer.

In this study two different concentrations of alcohol i.e. 50% and 75% were chosen for CPN as Titton et al. had stated in their study that a concentration range of 50-100% alcohol is effective for CPN.¹¹ It is also supported by the study conducted by Kambadakone et al. for the varied concentrations of alcohol.⁴

We preferred to use US-guided technique over other available techniques as multiple studies have shown that US-guided technique has multi-fold benefits. Bhatnagar et al. performed CPN under US guidance and found several advantages over the other proposed procedures, as the entire procedure can be observed on a video monitor in real time.⁶ The US-guided procedures consume less time and protect the patient and the physician from exposure to unnecessary radiation. Gofeld et al. performed CPN under US guidance and reported the similar results.¹² Siddaiah and Sardesai mentioned that US guided CPN is simple, cost-effective in comparison to the EUS-guided CPN and does not require special equipment or formal training in gastroenterology.⁹ Marcy et al. found that ultrasound guidance is safe and effective and recommended its application for CPB whenever possible as it almost completely eliminates the risk of inadvertent injection of ethanol into vascular or intradural structures.⁸ Dhamija et al. also performed US guided CPN and arrived at similar inferences.¹³

The technical success rate of US-guided CPN in present study was found to be 95.2%. It failed in only two patients which could be due to technical error or due to distorted anatomy Bhatnagar et al. performed US-guided CPN for 22 patients with technical success rate of 91%.⁶

**Fig. 3:** Distribution of cases according to side effects

As shown in Figure 3, the total incidence of side effects was 20% in group I and 17% in group II. Significance was calculated for cumulative sum of side effects (none vs any complication) ($p=0.60$). There was no statistically

Regarding the anterior approach we found it more comfortable with patient in the supine position. It is supported by Bhatnagar et al. who performed CPN through anterior approach and concluded that the patient is reasonably more comfortable because the goal of interventional palliation is a simple technique with minimal discomfort in case of terminally ill patients.⁶ Marcy et al. performed anterior CPB and reported that the anterior approach to percutaneous coeliac ganglia is an easy, less invasive and safely performed procedure with a high success rate.⁸ Akhan et al. also mentioned the advantages of the anterior approach in their study and stated that major advantage is it reduced risk of neurologic complications because the tip of the needle is anterior to the spinal arteries and spinal canal.¹⁴ Narouze and Gruber concluded that the most important advantageous aspect of the anterior approach is reducing or even eliminating the potential risk of paraplegia with CPN.⁷

4.1. Degree of pain relief

CPN is effective in relieving pain as well as improving the quality of life of the patients. In our study, in group I where we used 30-40 ml of 50% alcohol, mean VAS score was 8.26 at baseline which decreased to 2.63 at 24 hrs, 1.51 at 1 week, 1.70 at 1 month, increased slightly to 1.85 at 2 months and 2.33 at 3 months. There was good pain relief for 3 months for all patients. Our study is supported by Bhatnagar et al. who performed US-guided CPN on 20 patients with the use of 15–20 mL of 50% ethanol and observed significant pain relief in all patients for 2 months. The pre block VAS score was 9.10 ± 0.85 which markedly decreased to 1.2 ± 1.02 after one day. 2 months after CPN, pain scores had decreased to 2.10 ± 0.79 ($P < 0.001$).⁶

Romanelli et al. injected 15-40 ml of 50% Alcohol in 14 patients of abdominal malignancies and reported that pain was relieved in 92% (completely in 61%, partially in 31%) of patients, and there was no relief from pain in 8% of the patients.¹⁵

Ghai et al. conducted a study on fifteen patients with upper abdominal malignancy with $VAS \geq 3$ using 50% alcohol and found statistically significant decrease in mean VAS score at 1st hour, after 24 hour, at 1st week, 1st month, 2nd and 3rd month ($p < 0.05$). The mean pre block VAS was 8.1 ± 1 cm (Range 7-10 cm) which was decreased to 0.53 ± 0.99 cm and 1 ± 2.22 cm at first week and first month respectively. It decreased further to 0.70 ± 1.64 cm and 0.33 ± 0.71 cm at 2nd month and 3rd month respectively.¹⁶

Kanthen P et al. managed successfully by CPN using 50% alcohol under fluoroscopy and reported that significant relief in pain was felt by the patient immediately after the procedure. The effect was sustained during follow-up with improved quality of life.¹⁷

Gimenez et al. performed neurolysis of the coeliac plexus on 38 patients, under sonographic guidance and injected 30-

40 ml of 50% alcohol. After one week and six months of treatment, it was observed that pain was completely relieved in 61% of patients, partially relieved in 31%, and unchanged in 8%. After one year of treatment, pain was completely relieved in 39% of the patients, partially relieved in 52%, and unchanged in 9% of the patients.¹⁰

Tadros et al. observed noticeable decrease in the severity of pain in all the patients and noted a sharp fall of the VAS score in the 1st day after CPN (with 50% alcohol) with relatively stationary course for three months. Baseline VAS score was 9.1 ± 0.85 , one day after CPN, acuteness of pain decreased significantly to 1.4 ± 0.71 , one week after CPN the decrease in pain severity sustained at the same level 1.6 ± 0.89 , one month after CPN the decrease in the severeness of pain remained at the same level 2 ± 0.79 and three months after CPN pain severity still decreased noticeably to 2.3 ± 1.02 . The decrease in seriousness of pain at its average before and at different intervals after CPN recorded highly significant statistical difference (P value < 0.001).¹⁸

Similarly, in group II in which we used 75% alcohol, the baseline VAS score was 8.03 which decreased to 2.36 at 24 hours, 1.60 after 1 week and was recorded as 1.53 at 1 month, 1.60 at 2 months and 2.00 at 3 months intervals.

Mercadante et al. used 25 ml of 75% alcohol and noticed that VAS scores went down after the block ($P < 0.01$) until the 4th week. There was a significant difference at intervals of 1 ($P < 0.01$), 2, 3, 4 weeks after the block and the day before death ($P = 0.05$).¹⁹

Kawamata et al. also used 15-20 ml of 80% alcohol and observed significant decrease in VAS score.²⁰

Akhan et al. used 40 ml of 70% alcohol and observed complete pain relief in seven patients (28%), considerable relief of pain in eight patients (32%) and mild to moderate relief of pain in six patients (24%), and there was no change in pain of four patients (16%). Twenty-one (84%) of the 25 patients had some (+1 or greater) relief of pain and 15 of these patients had appreciable or complete (+2 or +3) relief of pain.¹⁴ Similar results were also observed by Marcy et al. who executed CPB (30 ml ethanol 99%) and obtained pain relief in 79% of the patients. They performed US-guided CPN with the pre block VAS score 9.4 ± 0.7 . They stated that the VAS score decreased sharply to 1.3 ± 0.8 at the 1st day after neurolysis. 3 months later, VAS score was 3.9 ± 1.2 .⁸

Although there was a significant decrease in VAS within both the groups, there was no statistically significant intergroup difference in VAS in our study.

4.2. Assessment of quality of life

In our study, we compared the improvement in QOL in terms of a score depending on the answers given to McGill Quality of life questionnaire.

Finding of our study is supported by Amr and Makharitha. They found that QLQC30 assessment revealed a significant

improvement in daily life activity and QOL after the coeliac block was performed.²¹ Rykowski and Hilgier also observed improved alertness and QOL in patients who had good pain relief after neurolysis.²² Matamala et al. also concluded improvement in QOL by decreasing consumption of opioids and its sedative effects and enhancement of the immune system as it was shown that at cellular level opioids had a negative effect on immunity.²³ Similarly, Zhang et al. performed CPN with 98% alcohol and used outcomes of appetite, sleep, and communication at day 7, 14, 30, 60, and 90 for the assessment of QOL. Significant improvement was found at every point in patients who were treated with a percutaneous CPN.²⁴ Wong et al. had done CPN with 90% alcohol and used the Functional Assessment of Cancer Therapy-Pancreatic Cancer (FACT-Pa) questionnaire. Evaluations were done up to 24 weeks. An improvement in the QOL after 1 week was observed in the CPN group ($P < 0.01$ for each). A progressive decline afterward was seen.²⁵ Jain et al. used 50% alcohol and measured the QOL with Karnofsky scores (0–100%): an overall QOL scale (0: very poor—10: normal life and performance level). The Karnofsky and performance scores were significantly better in CPN group ($P < 0.001$).²⁶ Polati et al. also found significant lower values on the Symptoms Distress Scale in patients who were treated with percutaneous CPN.²⁷ Özyalçın et al. had used 96% alcohol in CPN and evaluated QOL using patient's performance scale and patient satisfaction scale, until 14–18 weeks after procedure and found significant improvement.²⁸ Molnar et al. who used 70% alcohol also observed improvement in QOL using the SF-36 questionnaire.²⁹

4.3. Requirement of rescue analgesia (morphine)

Jain et al. also noticed significant decrease in morphine consumption in NCPB group. Mean consumption of morphine dropped by nearly 50% in NCPB group ($P = 0.00$) as 31% (15/48) patients experienced good pain relief without morphine.²⁶

Nagels et al. had carried out meta-analysis with sixty-six publications on CPN and concluded that there was significant decrease in usage of morphine.³⁰

Zhang et al. also presented data about morphine usage at 3 months. The consumption of oral slow release morphine tablets was significantly lower in the percutaneous CPN group (105 ± 65 mg vs 169 ± 71 mg; $P < 0.01$).²⁴

Molnar et al. observed patients five days before starting the study and noticed that subjects were at step 3 of the analgesic ladder. Each patient used a continuous and high dose of major opioid and adjuvant analgesics. An increase in the dose of analgesics was not possible because of intolerable side effects. After NCPB, patients still had to continue taking oral analgesics because opioids cannot be stopped because of metastatic pain but their doses were reduced compared to pre-treatment dose.²⁹

The above mentioned studies are in support of our study, as the mean morphine consumption was found to reduce drastically in both the groups post neurolysis.

4.4. Side effects

As far as the incidence of side effects are concerned, it was almost similar in both the groups. 20% cases of Group I and 16.6% cases of Group II experienced side effects. Out of those 20% cases (6 patients) in Group I, 2 had pain on injection, 1 required repeat neurolysis, 1 had transient hypotension and 1 had diarrhoea. Whereas out of the 16.6% cases (5 patients) of group II, 1 patient had pain on injection, 2 patients required repeat neurolysis, 1 patient had transient hypotension and 1 had diarrhoea. There was no significant difference between the two groups with respect to side effects. Eisenberg et al. concluded that common adverse effects were transient and included local pain (96%), diarrhoea (44%), and hypotension (38%).³¹ As compared to Matamala et al. (66%) and Gimenez et al. (13%) incidence of diarrhoea was lower (10.66%) in our study.^{10,23} Transient hypotension occurred in two patients (6.67%).

5. Conclusion

The study was concluded as follows-

1. Both the groups were comparable and identical to each other with respect to demographic profile & baseline VAS score and quality of life scores.
2. There was a decrease in mean VAS score from baseline in both the groups at all intervals up to 3 months. However, the difference in the VAS score between both the groups was statistically insignificant ($p > .05$) at all the follow up time intervals except at 3 months.
3. There was also an improvement in quality of life of patients in both the groups as is evident from decrease in mean QOL scores from baseline at all the subsequent intervals. At all the time intervals, mean QOL scores were lower in both groups. Here also difference between both the groups were statistically insignificant ($p > 0.05$) at all the follow up time intervals.
4. Overall requirement of rescue analgesic consumed was also decreased in both groups but there was no significant difference in intergroup comparison.

6. Limitations

1. One of the limitations of our study was sample size which was not large enough to reveal significant between-group differences.
2. Ongoing chemotherapy and radiotherapy were not considered, which may have a major effect on the quality of life of cancer patients.

3. Another limitation was the use of visual analogue scale (VAS) score for assessing pain as it is a subjective test for evaluating outcomes & is subject to bias.
4. A limited time frame for the study was also a limiting factor.

7. Source of Support

Nil.

8. Conflict of Interest

None.

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Author biography

Pragya Verma, Junior Resident

Sarita Singh, Professor

Gyan P Singh, Professor

Hemlata Verma, Associate Professor

Manish Kumar Singh, Associate Professor

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