Cryoneurolysis in Patients with Dorsal Neuropathic Pain Secondary to Tumor Invasion

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ABSTRACT

Purpose: To evaluate the safety and efficacy of cryoneurolysis (CNL) in patients with refractory thoracic neuropathic pain related to tumor invasion.

Materials and Methods: Between January 2013 and May 2017, this single-center and retrospective study reviewed 27 computed tomography-guided CNLs performed on 26 patients for refractory thoracic neuropathic pain related to tumor invasion. Patients with cognitive impairment were excluded. Pain levels were recorded on a visual analog scale (VAS) before the procedure, on days 1, 7, 14, 28 and at each subsequent follow-up appointment. CNL was clinically successful if the postprocedural VAS decreased by 3 points or more. To determine the duration of clinical success, the end of pain relief was defined as either an increased VAS of 2 or more points, the introduction of a new analgesic treatment, a death with controlled pain, or for lost to follow-up patients, the latest follow-up appointment date with controlled pain.

Results: Technical success rate was 96.7% and clinical success rate was 100%. Mean preprocedural pain score was 6.4 ± 1.7 and decreased to 2.4 ± 2.4 at day 1; 1.8 ± 1.7 at day 7 ($P < .001$); 3.3 ± 2.5 at day 14; 3.4 ± 2.6 at day 28 ($P < .05$). The median duration of pain relief was 45 days (range 14–70). Two minor complications occurred.

Conclusions: Cryoneurolysis is a safe procedure that significantly decreased pain scores in patients with thoracic neuropathic pain related to tumor invasion, with a median duration of clinical success of 45 days.

ABBREVIATIONS

CNL = cryoneurolysis, ESMO = European Society for Medical Oncology, VAS = visual analog scale

INTRODUCTION

According to the Ripamonti et al (1), systematic literature review in the European Society for Medical Oncology (ESMO) Clinical Practice Guidelines, pain prevalence is 64% in patients with metastatic cancer, out of which 33% presented with neuropathic pain. In 43% of the cases, neuropathic pain is related to treatment, and in up to 69% of the cases to tumor invasion. The World Health Organization cancer pain relief program (2) outlines strategies for cancer pain treatment based on a sequential 3-step analgesic ladder from nonopioids to weak opioids to strong opioids. Nevertheless, 10% of patients are refractory to all conventional strategies or dose-limiting analgesic-related side effects (3) and unrelieved pain continues to be a worldwide public health issue.

To obtain long-term analgesia, neuroablation methods, such as neurolysis using alcohol or phenol, radiofrequency using heat, and cryoneurolysis (CNL) using cold, have been developed by anesthesiologists, surgeons, and interventional radiologists. Cryotherapy aimed at obtaining neuropathic pain relief was first studied in 1976 by Lloyd et al (4), who suggested that cryoanalgesia was superior to other methods

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of peripheral nerve destruction. CNL safety and efficacy has been studied in many areas, including postthoracotomy pain syndrome (5) and head facial pain (6,7), but clinical applications in cancer-related pain are scarce.

The aim of this study is to evaluate CNL safety and efficacy in patients with refractory thoracic neuropathic pain secondary to tumor invasion. The secondary aim is to identify factors that influence thoracic CNL duration of efficacy.

MATERIALS AND METHODS

Patient Selection

This monocentric and retrospective study was approved by the institutional ethics committee of the hospital. All procedures performed in studies involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study received approval by our institutional review board. Every patient received information and has given their consent for the procedure

All patients who underwent thoracic nerve CNL between January 2012 and May 2017 were identified by a search of the hospital's medical information system using three keywords ("cryoneurolysis" or "cryoneuroablation" and "thoracic"). Patients were referred for CNL by a multidisciplinary tumor board if their cases met the following criteria: thoracic neuropathic pain, pain refractory to conventional therapy (including grade III analgesics and neuropathic pain treatment), and tumor invasion related to the pain. Thoracic neuropathic pain was diagnosed by a pain physician during a dedicated consultation as being a pain with a neuropathic component, confirmed by the DN4 neuropathic pain diagnostic questionnaire (8), and metameric topography, confirmed by a painful skin area corresponding to a dermatome. If the metameric topography was atypical, the diagnosis was confirmed with a therapeutic test by anesthetic nerve infiltration with 3 mL of bupivacaine (4.5 mg/mL) performed on the suspected thoracic nerve roots. Neuropathic pain had to be assessed with a visual analog scale (VAS) $\geq$4 points (with a VAS ranging from 0 = no pain to 10 = worst possible pain). The tumor invasion of the thoracic nerve roots that was responsible for the pain was proven on computed tomography (CT) or magnetic resonance imaging. Each patient also had a consultation by an interventional radiologist to explain the procedure.

Patients with bleeding disorder (blood platelets <50,000/mm^3, prothrombin time <50%), local or systemic infection, and thoracic epidural infiltration were not considered for CNL. Patients with a cognitive impairment that could have biased the pain assessment were excluded.

A total of 31 patients who underwent 32 thoracic CNLs were identified. One patient underwent a second CNL related to the development of a distinct neuropathic pain from new pleural metastasis on CT: the mean interval between the 2 procedures was 3 months; this patient was included twice in this study. Three patients had a concomitant direct percutaneous tumor cryoablation during the CNL procedure (2 costal tumors and 1 spinous process tumor), because of other tumors causing a local nociceptive pain unrelated to the neuropathic pain. Assessing the effectiveness of these 3 cryoablations was not the goal of the study. Three patients were excluded because of cognitive impairment, and 2 patients were excluded because of the absence of tumor invasion related to the pain (1 patient had a local breast carcinoma treated by conservative surgery and radiotherapy; 1 patient had a gastric carcinoma with liver metastasis only). Consequently, 27 CNLs on 26 patients were included in this study (Fig 1). There were 19 males and 8 females. The median age was 56 (range 14–78). The general characteristics of the 26 patients are presented in Table 1.

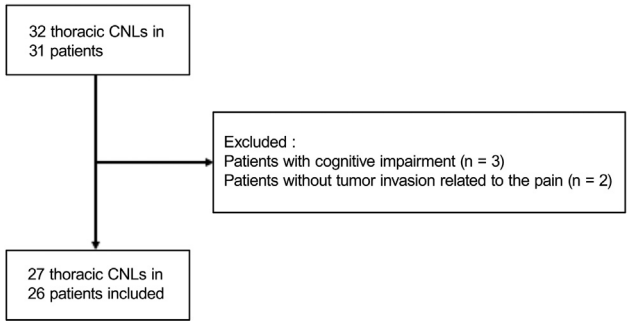

Figure 1. Patient flowchart.

CNL Technique

Thoracic CNL is a percutaneous ablation technique using cryotherapy and targeting thoracic nerves. It was performed under CT guidance with the patient under moderate sedation or general anesthesia, in a prone position, by 3 trained interventional radiologists, doctor of medicine or doctor of philosophy, with a median of 8 years of experience, in a dedicated interventional radiology room. A single cryoprobe (ice Rod or ice sphere, Galil) was placed at each level of nerve root invasion under the transverse vertebral process. The probe tip was advanced as close as possible to the intervertebral foramina where the nerve emerges, using repeated CT guidance (2.5- to 5.0-mm section thickness). A single freeze-thaw-freeze cycle was performed for each root, with a duration of 10 minutes, 8 minutes, and 10 minutes for the different phases, respectively. CT imaging was performed throughout the freezing cycle to monitor the growth of the ice ball (Fig 2). After the final freezing procedure, the cryoprobes were warmed by active helium gas heating to >20C° and then removed. The technical success was considered attained if the procedure was performed with all the steps as described previously. In some cases, carbodissection of the epidural space by injection of carbon dioxide was performed at the beginning of the procedure to protect the spinal cord. In that case, a 22-gauge needle was placed in the epidural space under CT guidance. Then, insufflation was performed with a small amount of carbon dioxide (5–10 mL) through a special antibacterial gas filter.

Table 1. Population Characteristics

Population Characteristics	N = 27	100%
Gender		
Male	19	70.4%
Female	8	29.6%
Median age	56.0 (14–78)	
Performance status		
1	9	34.6%
2	10	38.5%
3	6	23.1%
4	1	3.8%
Tumor type		
Pulmonary	5	18.50%
Soft-tissue sarcoma	4	14.80%
ENT carcinoma	3	11.10%
Colorectal cancer	3	11.10%
Endometria carcinoma	2	7.40%
Papillary thyroid carcinoma	2	7.40%
Giant cell	1	3.70%
Pleural mesothelioma	1	3.70%
Prostate carcinoma	1	3.70%
Kidney carcinoma	1	3.70%
Breast carcinoma	1	3.70%
Esophageal carcinoma	1	3.70%
Gastric carcinoma	1	3.70%
Epithelioid Hemangioendothelioma	1	3.70%
Tumor control		
Yes	11	40.70%
No	16	59.30%
Radiotherapy before procedure		
Yes	13	48.10%
No	14	51.90%
Chemotherapy before procedure		
Yes	25	92.60%
No	2	7.40%
Metastasis topography		
Costovertebral	9	33.30%
Costal	14	51.90%
Pleuropulmonary	18	66.70%
Time before CNL of uncontrolled pain (median)	3.0 (1–10)	

CNL = cryoneurolysis; ENT = ear, nose, and throat.

Pain Assessment and Data Collection

By researching the hospital's medical information system, the following information was collected: demographic information (gender, age, performance status), type of primary tumor, duration of uncontrolled pain according to pain management team consultation, time interval since the last chemotherapy and the last radiotherapy if radiation was performed to the affected area, opioid therapy consumption, and other previous analgesic treatments used before the procedure. Tumor control or progression before the procedure was determined based on the conclusion of the last CT (scan time of 80 seconds) before the CNL. A resident radiologist specified the topography of tumor invasion underlying the pain (costovertebral, costal, or pleuropulmonary) base on the same CT. Concerning the CNL, a previous anesthetic test, the type of anesthesia, the number of levels treated, the Cryoprobe's type and number, the achievement of carbodissection, the achievement of concomitant cryoablation, and any potential complication according to the new Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee (9) were recorded.

The patient's pain levels were recorded on a VAS before the procedure, as well as on days 1, 7, 14, and 28 and at each subsequent follow-up appointment with the pain physician until the patient's death or loss to follow-up. New interventional antalgic treatment and concomitant grade III analgesics consumption were recorded. Grade III analgesics were defined as morphine and its derivatives. Consumption was calculated in sustained release morphine per day and expressed in milligram per 24 hours. Tumor control or progression at the end of clinical success was determined based on the conclusion of the CT performed after pain recurrence.

The clinical success after CNL was defined as a decrease of 3 points or more on the VAS in the first week after the procedure. After a clinical success, pain recurrence was defined either as an increased VAS of 2 or more points from the lowest postprocedural VAS, the introduction of a new analgesic treatment, a death with controlled pain, or the last follow-up appointment date with controlled pain. The duration of clinical success was the time from the CNL to the date of pain recurrence.

Statistical Analysis

The raw data were described in terms of mean and standard deviations, medians, minimum and maximum for quantitative variables, and in terms of frequencies and percentage for qualitative variables. To evaluate CNL clinical success and its duration, the difference between pre- and postprocedural VAS was calculated; for a paired sample analysis, with a Student *t*-test; and a survival curve without pain recurrence for global population was established. As pain recurred, patients were listed as failed, deceased patients with controlled pain and lost to follow-up patient were censured, and patients with an incomplete procedure were not assessed. To identify some factors affecting the thoracic CNL's duration of efficiency, Cox models were performed with disease stability, performance status, topography of tumor invasion, block test, and number of levels treated. Statistical analysis was conducted by using SAS software (SAS Institute, Cary, NC, version 9.4), with a P value $<.05$ considered significant.

RESULTS

General Data

The pain was uncontrolled for 3.5 ± 2.3 months (range -10) before the procedure (as listed in Table 1) and all patients

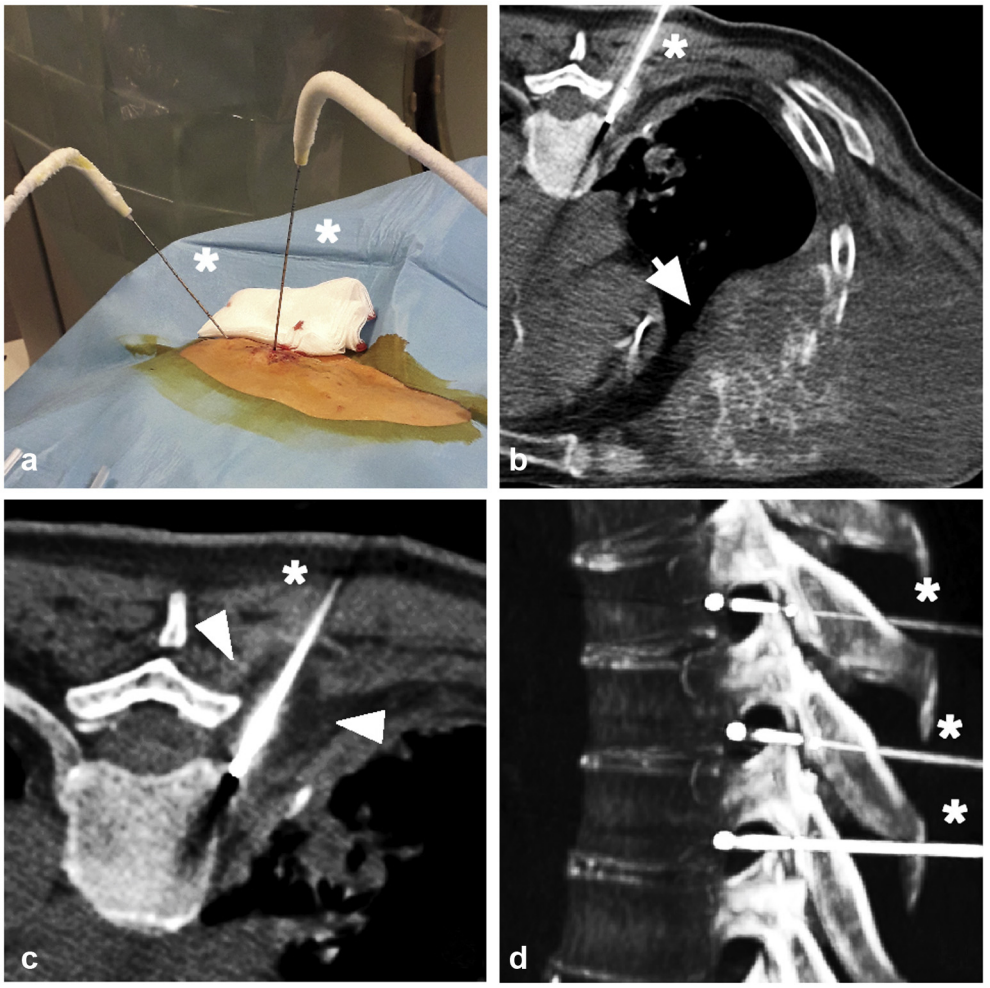

Figure 2. Cryoneurolysis procedure. A patient with a thoracic sarcoma suffering from a left thoracic neuropathic pain had a first CNL from T4 to T7 with excellent results (VAS from 10 to 1). Three months later, the pain recurred on metameric levels T8, T9, and T10, correlated to disease progression. He underwent a second CNL for these 3 levels. **(a)** Photo of the first procedure, patient in prone position with cryoablation probes (*) positioned under CT guidance. **(b)** Axial CT image showing the thoracic sarcoma (white arrow), and 1 of the cryoablation probes (*) positioned under CT guidance close to the intervertebral foramina and the chest nerve root. **(c)** Repeated CT imaging during the freezing cycle to monitor the growth of the ice ball (white arrowheads). **(d)** CT with volume rendering technique reconstructions during the second procedure, showing the cryoablation probes positioning (*), with 1 needle for each treated level.

had high doses of grade III analgesics ranging between 90 and 540 mg sustained release morphine per day. One patient was not medicated with morphine because of side effects. Seven patients (25.9 %) complained of side effects with opioid therapy (constipation, nausea, drowsiness, and falls). Three patients (11.1%) had local treatments before thoracic CNL (1 radiotherapy, 1 intrathecal pump, 1 percutaneous radiofrequency) without pain relief, or with a short-term relief and a contraindication to renew the treatment.

Cryoneurolysis

The technical success rate was 96.7%: 1 procedure had to be terminated prematurely because of high level of dorsal pain during the needle positioning despite moderate sedation. One to 5 thoracic nerves per patient were treated by CNL, with a median of 2 levels (range 1–5). Technical characteristics are reported in (Table 2). According to the Society of International Radiology classification, no major complications occurred (8). Two grade I or II minor complications occurred: 1 transient hypotension and 1 unexplained knee pain. There was no report of neuritis or neuroma after CNL.

Pain Assessment

The clinical success rate was 100%. Preprocedural mean VAS score was 6.4 ± 1.7 and decreased significantly ($P <$ .05) at 2.4 ± 2.4 at day 1, 1.8 ± 1.7 at day 7, 3.3 ± 2.5 at day 14, and 3.4 ± 2.6 at day 28, as summarized in Table 3 and Figure 3. Daily opioid therapy consumption decrease in the same time with a median from 240 mg/24 h (range 20–540) before the procedure, to 220 mg/24 h (range 20–540) at day 1, 180 mg/24 h (range 0–540) at day 7, 190 m g/24 h (range 0–540) at day 14, and 190 mg/24 h (range 0–480) at day 28.

Table 2. Characteristics of the CNL Procedure

Nerve block test	N = 27	100%
Yes	14	51.90%
No	13	48.1%
Anesthesia		
General anesthesia	17	63.0%
Moderate sedation	10	37.0%
Number of levels treated		
Median (range)		2.0 (1–5)
Mean (SD)		2.7 (1.3)
1	5	18.5%
2	9	33.3%
3	8	29.6%
4	2	7.4%
5	3	11.1%
Cryoprobe type		
Ice rode	9	33.3%
Ice sphere	18	66.7%
Carbodissection		
No	21	77.8%
Yes	6	22.2%
Complications		
No	24	88.9%
Yes (minor)	3	11.1%

CNL = cryoneurolysis; SD = standard deviation.

Table 3. VAS Evolution, and Difference between Pre- and Post-CNL VAS

Statistical Criteria	VAS Pre-CNL	VAS Day 1	VAS Day 7	VAS Day 14	VAS Day 28
N	27	16	18	15	14
Mean (SEM)	6.4 (1.7)	2.4 (2.4)	1.8 (1.7)	3.3 (2.5)	3.4 (2.6)
Median (SD)	6.0 (4–10)	2.0 (0–10)	1.5 (0–6)	2.0 (0–8)	3.0 (0–8)
P value		<.0001	<.0001	.0051	.0036

CNL = cryoneurolysis; SD = standard deviation; SEM = standard error of the mean; VAS = visual analog scale.

The survival curve without pain recurrence was plotted using pain scores collected between days 1 and 1,189. Four patients were censured (1 lost to follow-up and 3 dead with controlled pain) and 1 was not assessed (patient with an incomplete procedure). The curve showed a clinical success duration of 45 days (range 14–70) (**Fig 4**). At the point of pain recurrence, 85% of patients had tumor progression. The median survival after the procedure was 4.9 months (CI 2.9–7.2).

Cox models did not show any factor affecting the thoracic CNL duration of efficiency (**Table 4**). Time to treatment's failure was 70 days for controlled tumor and 37 days for uncontrolled tumor, without statistical significance ($P = .06$).

DISCUSSION

The present study shows thoracic CNL feasibility with a technical success rate of 96.7%. Only 1 patient, suffering from high dorsal pain during the needle positioning, could not undergo a complete procedure. The study also assesses CNL clinical efficiency for thoracic neuropathic pain resulting from tumor invasion with a clinical success rate of 100%. Despite a long history of pain, with a median of 3 months of uncontrolled pain before the CNL, and neuropathic pains refractory to a variety of therapeutic approaches including oral treatment and sometimes interventional treatments, all patients had a decreased VAS after the procedure. The median duration of clinical success was 45 days, which is short-term relief, but a substantial duration for patients with metastatic cancer and a limited life expectancy, with a median survival after the procedure of 4.9 months. One hypothesis to improve pain relief duration is to offer an earlier procedure in the care pathway, and patients with stable tumor even if the study failed to prove it statistically ($P = .06$).

In conjunction with other studies (4,10,11), CNL appears to be safe with no major complications, and only 2 minor complications in this study. This procedure could be performed even in frail patients; in this study, 26.9% of the population had a performance status score of 3 or 4. The procedure is undertaken under general anesthesia or moderate sedation, with the latter option being a less cumbersome procedure in fragile patients and allowing oral communication during the CNL to assess the pain. One of the CNL's main advantages is to allow for a moderate sedation with minimal discomfort. In comparison, radiofrequency appears to be more painful in the few data from the literature, with studies mainly comparing the 2 techniques for renal carcinoma ablation (12,13). Thacker et al (14) found that the use of cryotherapy compared with radiofrequency was associated with a greater reduction in postoperative analgesic dose and shorter hospital stays for the treatment of painful bone metastasis, but with both procedures performed under general anesthesia.

CT guidance allows the radiologist to control the needle positioning avoiding major complications (pneumothorax and spinal cord injury) and to monitor the ice cube's growth during the procedure and the ablated zone (15). CNL is an inherently safe technique because the treatment temperature cannot grow colder than the boiling point of either gas (nitrous oxide: -88°C; carbon dioxide: -79°C) (16). The application of cold temperatures leads to varying degrees of injury to the nerve, depending on the temperature. Studies in animal models show that Wallerian degeneration occurs with temperatures between -20°C and -100°C (17) and that beyond -140°C the nerve fibers showed necrosis (18). In animal models, the reliability of axonal regeneration relies on the integrity of the endoneurium, with a regeneration rate of 1–1.5 mm/week (4). By contrast, injuries occurring at temperatures lower than -100°C, transection-like surgery, or thermal heat tumors like radiofrequency cause irreversible nerve injury with a risk of neuroma and aberrant axonal

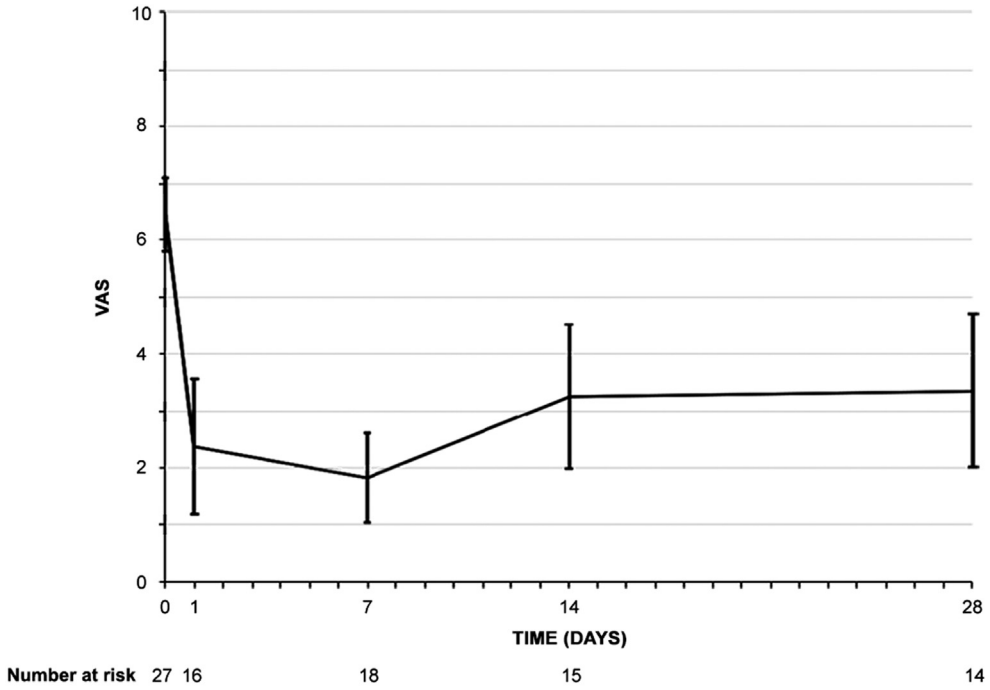

Figure 3. Evolution of mean average pain during the first month after thoracic cryoneurolysis. VAS (0–10) scores collected at each follow-up appointment (days 1, 7, 14, and 28) are shown over time for 27 patients treated. Number at risk is the number of patients completing VAS at each date. Error bars represent the 95% confidence intervals (CIs).

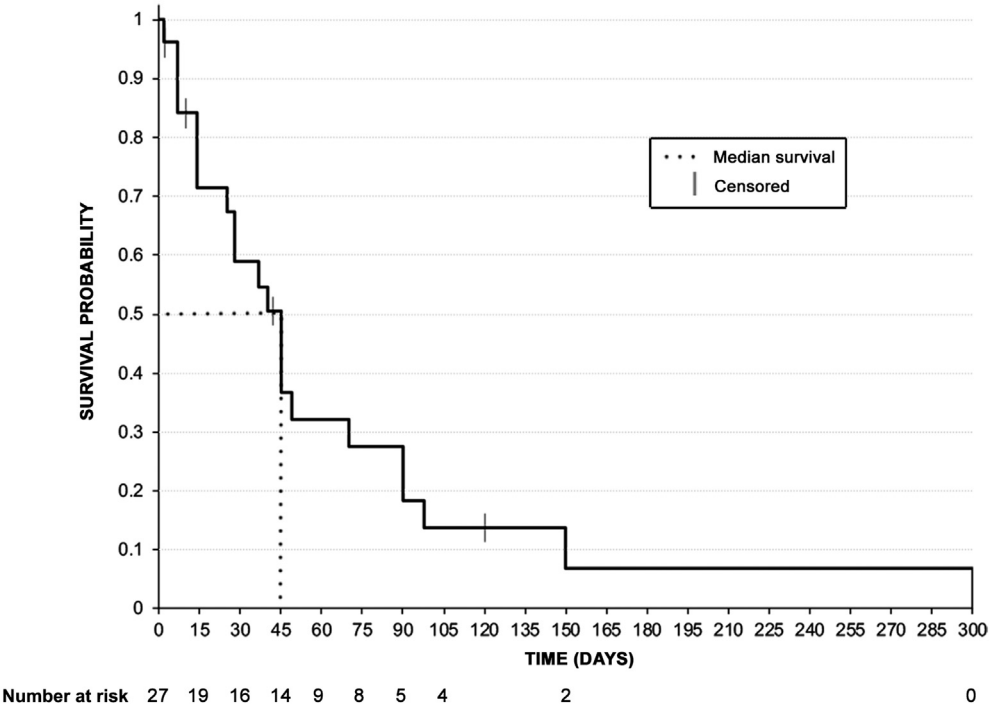

Figure 4. Survival curve without pain recurrence. Survival curve without pain recurrence over time for 27 patients treated by thoracic cryoneurolysis, showing a median duration of pain relief of 45 days (range 14–70).

regeneration (16,19). In addition, surrounding structures such as blood vessels and bone have been found to resist freeze injury (20). CNL could lead to Wallerian degeneration without damaging surrounding tissues. In more than 50 years of use, there have been no published cases of permanent nerve damage (16). Although neurolysis with alcohol and phenol is known to be effective in the literature notably for celiac plexus block in pancreatic cancer (21,22), occurrences of neuroma formation are also reported, in most cases with phenol (21,23,24). One case of paraplegia

Table 4. Multivariate Analysis

Evaluated Criteria	N	Survival (Days)	CI	Hazard Ratio	CI	*P* Value
Tumor control				0.400	0.15–1.05	.0625
No	15	37	14–45			
Yes	11	70	7–120			
Performance status				2.127	0.82–5.53	.1217
1–2	18	42	14–90			
2–3	7	28	2–45			
Duration of uncontrolled pain before CNL (month)				1.181	0.52–2.7	.6919
<3	15	42	10–49			
≥3	11	40	7–90			
Tumor invasion topography Costovertebral angle				0.520	0.22–1.24	.1412
No	17	37	10–45			
Yes	9	45	7–120			
Costal				0.680	0.29–1.59	.3725
No	13	40	14–45			
Yes	13	49	7–98			
Pleuropulmonary				1.594	0.65–3.92	.3098
No	9	45	2–150			
Yes	17	38.5	14–49			
Bloc nerve test				1.786	0.79–4.02	.1616
No	13	45	14–98			
Yes	13	25	7–45			
N levels treated				1.270	0.54–2.98	.5829
1–2	13	28	7–90			
≥3	13	45	10–70			

Note–Cox models done to determine any possible factor affecting the treatment's duration of efficiency.
CI = confidence interval; CNL = cryoneurolysis.

complicating a block of the celiac plexus has been reported, with a hypothesis of spinal cord vascular ischemia (25). Proximity of the spinal cord in this procedure with a risk of intrathecal spread of chemoneurolytics appear too risky to use alcohol. However, 1 weakness of CNL is its limited accessibility, with only a few radiology centers having the required equipment.

The study has several limitations. First, the population is heterogeneous, potentially limiting generalizability. Second, because of the retrospective study protocol, there are some missing VAS on exact dates (days 1, 7, 14, and 28). However, except for 1 patient lost to follow-up, they are no missing VAS to perform the survival curve without pain recurrence, which is the statistical analysis to determine the primary endpoint, namely, duration of clinical success. Small sample size (27 patients) is a study limitation. It could perhaps explain why there is no statistical difference in time to treatment's failure depending on the controlled or uncontrolled tumor ($P = .06$).

Additional studies are required for a greater impact in oncology pain management and to specify factors affecting significantly the treatment's durable efficiency to define the best indications. Prospectively, it would also be interesting to evaluate, more than VAS, the impact of CNL on quality of life.

In conclusion, CNL under CT guidance appears to lead to safe and significant decreased pain scores in patients with thoracic neuropathic pain related to tumor invasion, with a median duration of clinical success of 45 days.

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