Original paper

Own observations in the application of peripheral cryoneuroablation in the treatment of the trigeminal neuralgia

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Abstract

Introduction: Trigeminal neuralgia (TN) is characterised by severe paroxysmal, stabbing and lancinating pain, described by patients as "unbearable". Management of the problem poses serious difficulties in medical practice.
Aim of the research: The retrospective study was designed to assess the effectiveness of cryoneuroablation applied to patients with TN in reducing the pain and achieving remission or temporary relief of the suffering.
Material and methods: Analyses took into account the medical histories of 107 patients, including 66 females and 39 males, ranging in age from 67 to 94 years. The procedure was performed in an outpatient setting, under local anaesthesia, using a cryoprobe with an operating surface of 0.5 cm diameter.
Results: In all the patients the cryoneuroablation treatment was followed by a period with no pain (remission), ranging from 4 to 48 months. A pain-free period of less than six months was observed in 10 patients, and more than 30 months in 25 patients, i.e. 1 in 5 individuals subjected to the treatment.
Conclusions: Owing to the effective regeneration of the nerve damaged by low temperatures, cryoneuroablation can be recognised among the methods recommended for widespread use in the treatment of TN.

Introduction

Trigeminal neuralgia (TN) is a type of disorder characterised by sudden episodes of severe facial pain regarding the peripheral endings of the trigeminal nerve: orbital (I), maxillary (II), and mandibular (III) branches of the trigeminal nerve, described as stabbing, lancinating, or burning, ranging in duration from a few seconds to a few minutes. In practice, the most common are TN of maxillary (V2) and mandibular (V3) branches. Early stages of the disorder are accompanied by long periods of spontaneous remission, which continue even for months. The duration of remissions, however, tends to decrease as the disorder progresses. The related pain, described by patients as unbearable, most commonly occurs only on one side of the face and may be triggered by various factors, such as irritation of specific facial areas, e.g. lip, nose wing, or gum, as well as by mechanical stimuli, e.g. touch or pressure, or by thermal stimuli, e.g. changes in temperature, heat, or cold. Afraid to provoke the pain, those affected limit their life activity. Between pain attacks, patients do not experience pain. According to the International Classification of Headache Disorders (ICHD-3), classic, secondary, and idiopathic forms are distinguished. The most common form is the classic form (75% of cases), diagnosed on the basis of interview data, with changes referred to as "neurovascular conflict" (compression of the trigeminal nerve root by vessels) confirmed by MR imaging. The secondary form affects 15% of patients and is characterized by symptoms of neuralgia related to morphological changes in the brain, i.e. arteriovenous malformation, cerebellar pontine angle tumour, and multiple sclerosis. No significant cause can be determined for the idiopathic form, which is diagnosed in approximately 10% of cases [1–4].

According to various statistics, the prevalence of TN is in the range of 6–10 cases per 100,000 people, and the condition is twice as common in females as in males. TN more often affects elderly people and rarely occurs in individuals below 50 years of age [5, 6]. We still do not fully understand the aetiology and pathogenesis of TN, either in its idiopathic or symptomatic form [7, 8].

Treatment of TN poses a lot of difficulties for therapists, and despite the fact that novel pharmacotherapies and medical technologies are being introduced, it continues to be a problem in multidisciplinary practice (neurologists, otolaryngologists, family doctors, maxillofacial surgeons, and dentists) [9–13]. Many researchers emphasised the importance of local

treatments in TN, which involve suppression of excitability in peripheral sensory branches of the fifth nerve, leading to reduced intensity or periodic blocking of pain by injecting local anaesthetics, alcohol, or glycerol, or by applying acupuncture, laser therapy, or botulismotoxin [14–16]. The effects of surgical or electrosurgical procedures applied to damaged peripheral nerves (neurotomy, exeresis, electrocoagulation) reported in most studies were unsatisfying [17, 18].

Gamma knife, microvascular decompression, rhizotomy, or thermal electrocoagulation are increasingly applied in the treatment of TN [19–24]. Cryoanalgesia is a method designed to provide pain relief, involving use of low temperatures of liquid nitrogen; the technique can be used in the treatment of TN. It was modified several times and subjected to critical assessments; however, it returned recently as an advanced technique of cryoneuroablation, also known as cryoneurolysis, cryodestruction, or cryoblockade. Its unquestionable advantage is the fact that it spares the myelin sheath of the peripheral sensory nerves. Analgesia is achieved by destroying only the nerve fibre, while the myelin sheath is unaffected. The procedure does not lead to neuritis or neuromas, unlike other methods and most importantly surgical interventions, which additionally result in the phenomenon of the so-called "anaesthesia dolorosa". By applying low temperatures, it is possible to block conduction in the peripheral nerve, similar to that achieved as an effect of local anaesthetics [25–27].

Aim of the research

This retrospective study was designed to assess the use of cryoneuroablation in patients with TN, and to evaluate its advantages and effectiveness in reducing pain and achieving remission or temporary relief of the suffering.

Material and methods

Retrospective analyses took into account the medical histories of 107 patients, including 66 (61.7%) females and 41 (38.3%) males, ranging in age from 67 to 94 years; all of the patients in the previous 5 years had been subjected to cryoneuroablation treatment in a private practice and in the Department Maxillofacial Surgery of the Frederic Chopin Clinical Voivodeship Hospital in Rzeszow. Cryoneuroablation treatments were performed with Kriostat apparatus with the use of a cryoprobe with an operating surface of 0.5 cm diameter. The cross-surgery device and cryoprobe with different sizes of working surface are shown in Figures 1 and 2.

The procedure was performed under local anaesthesia induced by 2% lignocaine hydrochloride with noradrenaline, after exposing peripheral branches of the trigeminal nerve, i.e. infraorbital branch II in the region of the infraorbital foramen, as well as branch III in the region of the mental foramen, or the mental nerve. After the nerve was exposed, 2 cryoneuroablation treatments were performed for a duration of 60–90 s. One cycle involved freezing the nerve until an ice ball formed, followed by defrosting until the ice disappeared from the cryoprobe and the surrounding tissues. The treatment was carried out in an outpatient setting, in accordance with the generally approved technical procedure described in the literature [28–30].

Figure 1. Cryosurgery device

Figure 2. Set of cryoapplicators with different sizes of working surface

Table 1. Number of the patients, relative to sex and location of TN

Branch of nerve V	Sex				Side				Total	
	Females		Males		Right		Left			
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
II	32	48.5	20	48.8	31	54.4	21	42.0	52	48.6
III	28	42.4	18	43.9	17	29.8	29	58.0	46	43.0
II and III	6	9.1	3	7.3	9	15.8	0	0.0	9	8.4
Total	66	100.0	39	100.0	57	100.0	50	100.0	107	100.0
P-value	$\chi^2(2) = 0.11$, $p = 0.947$				$\chi^2(2) = 13.65$, $p = 0.001$, Cramér's V = 0,36					

χ^2 – result of Pearson's chi-square test, p – significance level for the differences, n – number of patients.

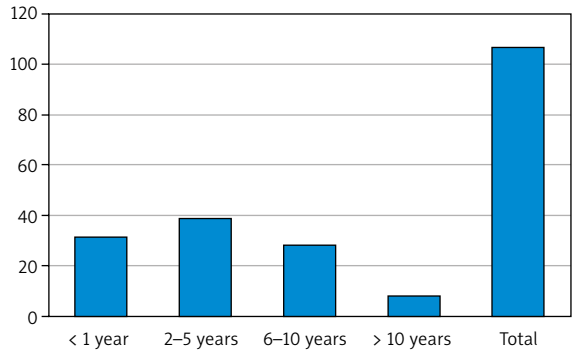

Figure 3. Duration of the disorder

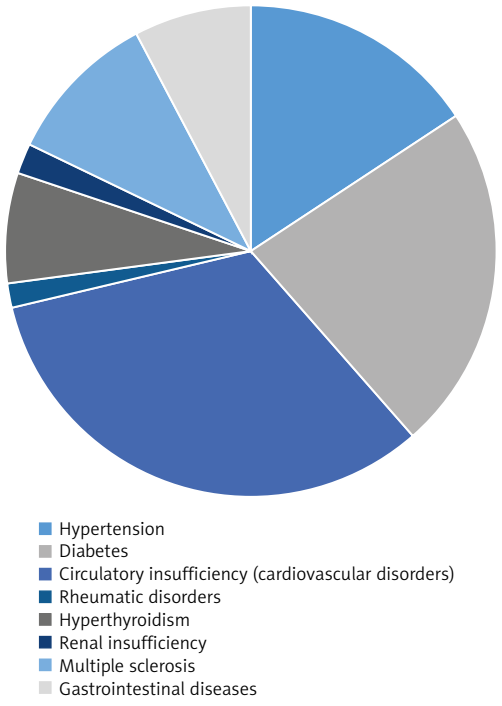

Figure 4. Comorbidities

Statistical analysis

Data analysis (Statistica 13.1. by StatSoft) was carried out using Pearson's χ^2 test. It was applied to evaluate whether the relationships observed in the sample resulted from a more general regularity occurring in the entire population or whether they reflected a random effect. The strength of correlations between the variables in the crosstabs was examined using Cramér's V test (tabs 2 × 3, 4 × 5, etc.). All the measures of correlation strength are normalised to numbers in the range of 0–1, where a value of 0–0.29 reflects a weak correlation; 0.30–0.49 represents a moderate correlation; and 0.5–1 represents a strong correlation.

Results

The findings of the current study are shown in tables and presented in related descriptions. Table 1 presents the number of patients (107 subjects) receiving the treatment, with division according to sex and location of TN. A statistically significant relationship was found between the location of neuralgia and the side of the face ($p = 0.001$). Trigeminal neuralgia in the region of branch II and the joint region of branch II and III was more frequently located on the right side, while in the case of branch III it was more commonly located on the left side. The significance of this relationship was of moderate strength (V Cr = 0.36).

The largest number, i.e. 39 (36.4%) subjects, were in the group of patients affected by the disorder for 2–5 years. There were no statistically significant differences in the number of patients affected by the condition for a varied duration of time ($p > 0.05$). The above data are shown in Figure 3.

Circulatory insufficiency was the most common comorbidity in the group of subjects, and it was statistically more frequent than any other condition, including diabetes and hypertension ($p < 0.05$). There was no statistically significant difference in the prevalence of diabetes and hypertension in the group of patients with TN, determined in the test for differences between structure indicators ($p > 0.05$) (Figure 4).

The analysis shows that prior to the treatment, 62 patients, i.e. 57.9%, reported severe pain (8–10 points in VAS); for 34 subjects, accounting for 31.8% of the group, the pain experienced was moderate (5–7 points in VAS), while mild pain (1–4 points in VAS) was observed in 11 (10.3%) subjects. The statistical analysis shows that severe pain was most commonly reported by the patients (Figure 5).

Following cryoneuroablation treatment, duration of time with no pain was in the range from 1 to 48 months. A pain-free period exceeding 30 months following the treatment was found in a total of 25 subjects, i.e. nearly 1 in 5 patients subjected to cryoneuroablation. The number of subjects representing the specific periods of remission of pain was not significantly varied in the test for differences between structure indicators ($p > 0.05$) (Table 2).

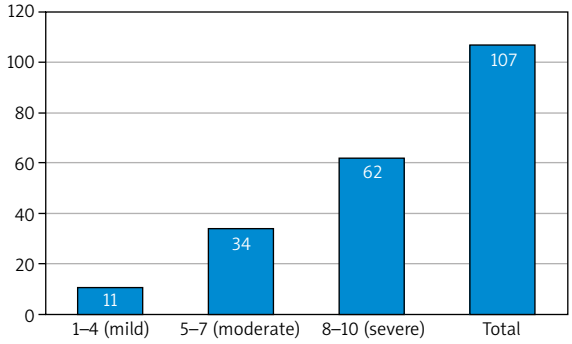

Figure 5. Pain intensity based on VAS

A statistically significant relationship was found between the duration of the disorder and the duration of remission of pain following the treatment

Table 2. Duration of time with no pain (remissions)

Variable	Duration of time without pain [months]									
	1–6	7–12	13–1 8	19–24	25–30	31–36	37–42	43–48	Total	Mean time
n	10	9	21	22	21	9	7	8	107	26
%	9.3	8.4	19.6	20.6	19.6	8.4	6.5	7.5	100.0	–

n – number of patients.

Table 3. Relationship between the duration of the disorder and the resulting duration of remission

Remission [months]	Duration of the disorder [years]					Total
		< 1 year	2–5	6–10	> 10	
1–6	n	0	5	3	2	10
	%	0.0	12.8	10.7	25.0	9.4
7–12	n	1	2	0	6	9
	%	3.1	5.1	0.0	75.0	8.4
13–18	n	11	1	0	0	12
	%	34.4	2.6	0.0	0.0	11.2
19–24	n	5	21	5	0	31
	%	15.6	53.9	17.9	0.0	29.0
25–30	n	8	1	12	0	21
	%	25.0	2.6	42.9	0.0	19.6
31–36	n	7	0	2	0	9
	%	21.9	0.0	7.1	0.0	8.4
37–42	n	0	6	1	0	7
	%	0.0	15.4	3.6	0.0	6.5
43-48	n	0	3	5	0	8
	%	0.0	7.7	17.9	0.0	7.5
Total	n	32	39	28	8	107
	%	100.0	100.0	100.0	100.0	100.0
P-value	$\chi^2(21) = 128.60$, $p < 0.001$, Cramér's V = 0.63					

χ^2 – result of Pearson's chi-square test; p – significance level for the differences; n – number of patients.

Table 4. Pain intensity level before treatment versus remission of pain following the treatment

Remission [months]	Pain intensity based on VAS, before treatment						Total	
	1–4		5–7		8–10			
1–6	0	0.0%	0	0.0%	10	16.1%	10	9.4%
7–12	2	18.2%	0	0.0%	7	11.3%	9	8.4%
13–18	0	0.0%	3	8.8%	9	14.5%	12	11.2%
19–24	5	45.5%	10	29.4%	16	25.8%	31	29.0%
25–30	0	0.0%	7	20.6%	14	22.6%	21	19.6%
31–36	4	36.4%	0	0.0%	5	8.1%	9	8.4%
37–42	0	0.0%	6	17.7%	1	1.6%	7	6.5%
43–48	0	0.0%	8	23.5%	0	0.0%	8	7.5%
Total	11	100.0%	34	100.0%	62	100.0%	107	100.0%
P-value	$\chi^2(14) = 57.38$, $p < 0.001$, Cramér's V = 0.52							

χ^2 – result of Pearson's chi-square test, p – significance level for the differences, n – number of patients.

($p < 0.001$). The correlation was strong (V Cr = 0.63). Analysis of Table 3 shows that the correlations were statistically significant for $p < 0.001$. The cryoneuroablation method was effective in the subjects suffering from TN for a shorter period of time.

As shown in Table 4, there was a statistically significant correlation between the duration of remission and pain intensity prior to the treatment ($p < 0.001$). The correlation was strong (V Cr = 0.52). In the group of 62 patients reporting severe pain (8–10 points in VAS) prior to the treatment, the duration of remission following the treatment was most commonly in the range from 3 to 30 months.

Statistically significant correlation was identified between the early therapy method, preceding cryoneuroablation, and the duration of remission of pain following the treatment ($p < 0.001$). On average, longer remission was achieved in the patients previously subjected exclusively to pharmacotherapy (from 30 to 42 months), and slightly shorter remissions (19–30 months) were observed in patients previously subjected to lignocaine blocks (Table 5).

Discussion

Despite the advancements in therapy methods and medical technologies, treatment of TN continues to pose difficulties in medical practice. Due to the chronic and recurring nature of the disorder experienced by patients for years, those affected seek help from professionals of various medical specialisations [1, 4, 9, 10, 16, 19, 25, 29]. According to the recommendations of experts from the European Academy of Neurology, the treatment of TN in the first phase should include symptomatic non-invasive treatment, i.e. pharmacotherapy: carbmazepine, phenothiazine, gabapentin, and botulinum toxin A, and in difficult cases, gradually invasive surgical interventions (vascular microdecompression, ablative treatment – neurolysis, glycolysis of Gasser's ganglion, percutaneous thermocoagulation, and stereotactic radiosurgery. Among a wide range of treatment methods, cryoablation was chosen as a minimally invasive method with a wide range of applications regardless of the patient's age [31].

In the current study, women were treated twice as often as male patients. Both the sex-related rate and the patients' age (mean age: 65.2 years) were consistent with data reported in the literature [7, 15, 18, 20, 23]. Those affected by the disorder for 2 to 5 years were represented in the study by the largest number of subjects, while more than 1 in 3 patients suffered from the condition for more than 5 years. The majority of the subjects presented with additional systemic comorbidities. The most common problems identified included circulatory insufficiency in the form of various cardiovascular disorders, as well as hypertension and diabetes. Many authors emphasise the chronic nature of TN and its association with age and systemic disorders, which makes the choice of treatment method even more problematic [2, 8, 11, 13, 17, 21, 27–29].

The findings of the assessment of cryoneuroablation method, which has been used for more than a decade at the Maxillofacial Surgery Centre and in the private medical facility, is consistent with reports of many researchers and shows that the therapy may effectively be applied in most cases and produces beneficial effects at various phases of the disorder and at various stages.

It has been emphasised in the literature that the success of the method is directly linked to correctly conducted qualification of patients for the therapy. From the practical viewpoint, the duration of the disorder and previously applied therapies are the most important factors. The present findings show that longer remission following cryoneuroablation treatment was achieved in the patients subjected to the treat-

Table 5. Relationship between therapy methods prior to cryoneuroablation and the remissions resulting from the treatment

Remission [months]		Type of therapy prior to cryoneuroablation			Total
		Pharmacotherapy	Local nerve block		
			Lignocaine	Alcoholisation	
1–6	*n*	0	6	4	10
	%	0.0	6.5	80.0	9.4
7–12	*n*	0	8	1	9
	%	0.0	8.8	20.0	8.4
13–18	*n*	0	12	0	12
	%	0.0	13.2	0.0	11.2
19–24	*n*	0	31	0	31
	%	0.0	34.1	0.0	29.0
25–30	*n*	0	21	0	21
	%	0.0	23.1	0.0	19.6
31–36	*n*	9	0	0	9
	%	81.8	00.0	0.0	8.4
37–42	*n*	2	5	0	7
	%	18.2	5.5	0.0	6.5
43–48	*n*	0	8	0	8
	%	0.0	8.8	0.0	7.5
Total	*n*	11	91	5	107
	%	100.0	100.0	100.0	100.0
P-value		$\chi^2(14) = 96.30$, $p < 0.001$			

χ^2 – result of Pearson's chi-square test, p – significance level for the differences, n – number of patients.

ment for the first time. The achieved remission was related to the duration of the disorder in various ways. More beneficial effects, reflected by longer lasting remission, were identified in the patients previously receiving conservative treatments, i.e. pharmacotherapy and physical therapy. If cryoneuroablation treatment was performed two or more times, the duration of remission was decreased. The present findings regarding the effects of the treatment do not differ significantly from the evidence reported in the literature, and they confirm that treatment of TN is a challenging matter that may be solved by using an interdisciplinary approach [6, 17].

Local treatment in the group of patients with TN taken into account in this study, involved, in the first place, injections applied to peripheral branches of the trigeminal nerve, the so-called blocks, with local anaesthetics. In 91 cases (85.1%) lignocaine hydrochloride blocks were applied, and in 5 (4.7%) patients alcohol blocks were administered. The patients receiving cryoneuroablation therapy at various stages of the disorder were earlier subjected to no surgical interventions, such as exeresis, neurotomy, thrombolysis, or acupuncture. In the literature cryoneuroablation treatments applying low temperatures mostly from liquid nitrogen were investigated by numerous authors [6, 9, 10, 12, 13, 26–29].

The patients tolerated the procedures well, and the stitches were removed on the 7th day. Postoperative healing in most patients was normal, without pain or inflammation. Hypoesthesia in the area of nerve endings subjected to cryoablation was transient. Approximately 1/3 of patients experienced postoperative swelling of facial soft tissues, subcutaneous haemorrhages, and haematomas, which were related to vascular fragility, atherosclerosis, anticoagulant therapy, and tissue traumatisation during surgery. Administration of low temperatures in the group of 107 patients among all the cases resulted in pain-free periods, with the mean duration of remission amounting to 26 months. The current findings may be compared to those observed by Rahmana *et al.*, Pradel *et al.*, as well as Ferrer-Mileo *et al.*, who reported the longest duration of remission from 24 to 32 months [27–30].

Conclusions

Administered locally, cryoneuroablation applied to peripheral branches of the trigeminal nerve does not lead to permanent recovery from TN, but it allows those affected to achieve remission ranging from

a few months to a few years; therefore, the method can be recommended as a TN treatment for use in outpatient settings. Owing to the effective regeneration of the nerve damaged by low temperatures, cryoneuroablation can be recognised among the methods recommended for widespread use in treatment of TN.

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Ethical approval

The study was approved by the Ethics Committee of the University of Rzeszow (ref. no. 22/10/2020).

Conflict of interest

The authors declare no conflict of interest.

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