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RESEARCH REPORT

THE EFFECT OF CRYOABLATION ON FUNCTIONING AND GAIT IN PATIENTS WITH LOW BACK PAIN

WPŁYW KRIOABLACJI NA FUNKCJONOWANIE I CHÓD U PACJENTÓW Z BÓLEM ODCINKA LĘDŹWIOWEGO

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ABSTRACT

Introduction

Low back pain and comorbid afflictions negatively influence the quality of life, postural control and gait. Facet joint syndrome is one of the causes of low back pain. Cryoablation is a minimal invasive percutaneuous technique for zygapophysial joint syndrome.

Aim

The aim of the study was to investigate the effectiveness of the cryoablation in patients with chronic low back pain on pain, disability and spatiotemporal gait parameters in the course of facet joint syndrome.

Material and methods

The study included 19 patients (13 women, 7 men) with chronic low back and facet arthropathic changes in MRI, and with failure in conservative treatment. The evaluation was performed before and with one-month follow-up after cryoablation and included pain assessment (Numeric Rating Scale), the evaluation of functional state and disability (Revised Oswestry Low Back Pain Disability Index, Roland-Morris Disability Questionnaire) and analysis of spatiotemporal gait parameters (treadmill).

Results

A significant improvement in pain, functioning and spatiotemporal gait parameters such as distance and the number of steps were found.

Conclusions

Cryoablation is an effective method for pain reduction in facet joint syndrome, which improves functioning and gait. Cryoanalgesia is a safe procedure for the treatment of low back pain related to facet joint syndrome if earlier conservative management failed.

Keywords: cryoablation, low back pain, functional assessment, gait.

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STRESZCZENIE

Wstęp

Ból odcinka lędźwiowego kręgosłupa i dolegliwości współistniejące negatywnie wpływają na jakość życia, kontrolę posturalną i chód. Ból ze stawów międzywyrostkowych jest jedną z przyczyn dolegliwości bólowych dolnego odcinka kręgosłupa. Krioablacja jest małoinwazyjną przezskórną metodą leczenia bólu pochodzącego ze stawów międzywyrostkowych.

Cel

Celem pracy było zbadanie wpływu krioablacji na ból, niepełnosprawność i czasowo-przestrzenne parametry chodu u pacjentów z przewlekłym bólem pochodzącym ze stawów międzywyrostkowych odcinka lędźwiowego.

Materiał i metody

Do badania włączono 19 pacjentów (13 kobiet, 7 mężczyzn) z przewlekłym bólem odcinka lędźwiowego oraz zmianami zwyrodnieniowymi w stawach międzywyrostkowych widocznymi w rezonansie magnetycznym, u których leczenie zachowawcze było nieskuteczne. Ocena była wykonana przed i miesiąc po zabiegu i obejmowała ewaluację bólu (Numeric Rating Scale), stanu funkcjonalnego i niepełnosprawności (Revised Oswestry Low Back Pain Disability Index, Roland-Morris Disability Questionnaire) oraz analizę czasowo-przestrzennych parametrów chodu (badanie na bieżni).

Wyniki

Zaobserwowano znaczącą poprawę w redukcji bólu, poprawy stanu funkcjonalnego oraz czasowo-przestrzennych parametrów chodu (dystans, liczba kroków).

Wnioski

Krioablacja jest skuteczną metodą w redukcji bólu pochodzącego ze stawów międzywyrostkowych odcinka lędźwiowego oraz poprawie funkcjonowania i chodu. Jest to bezpieczny zabieg u pacjentów, u których wcześniejsze leczenie zachowawcze było nieskuteczne.

Słowa kluczowe: krioablacja, ból odcinka lędźwiowego, ocena funkcjonowania, chód.

Introduction

Low back pain is defined as "pain, increased muscle tension and/or stiffness with or without referred lower limb pain and localised between the costal margin and the inferior gluteal folds" (Airaksinen *et al.*, 2006) (Violante, Mattioli and Bonfiglioli, 2015). Pain can be diagnosed as specific and nonspecific, as well as acute, subacute, and chronic (Violante, Mattioli, and Bonfiglioli, 2015). The specific typology differentiates in terms of low back pain source – axial (nociceptive) pain, somatic referred pain and radicular pain (Bogduk, 2009). The axial (nociceptive) pain (Bogduk, 2009) determined as dull and aching is related to noxious irritation of lumbar structures like – muscles (myofascial pain) (Allegri *et al.*, 2016; Urits *et al.*, 2019), interspinous ligaments (Panjabi, 2006), zygapophysial joints (facet-mediated pain) (Bogduk, 2009; Urits *et al.*, 2019), sacroiliac joint (Rashbaum *et al.*, 2016), the posterior surface of the intervertebral discs (discogenic pain) (Fujii *et al.*, 2019) or spinal stenosis (Urits *et al.*, 2019). Somatic referred pain results from irritation of nerve endings of lumbar spine structures and spreads to lower limbs and is perceived in regions supplied with the same innervations, without nerve roots compression and neurological signs (Bogduk, 2009). This pain is described as dull, aching, gnawing, or expanding pressure (Bogduk, 2009). The main source of radicular pain is disc herniation, inflammation of the dorsal nerve root with/without compression, and inflammation of its ganglion (Bogduk, 2009). The character of sensation is "lancinating, shocking, or electric" (Bogduk, 2009). Whereas radiculopathy is a condition in which the spinal nerve or its roots is compressed (Bogduk, 2009). The neurological signs are dermatomal numbness (due to blocked sensory fibers) and/or the myotomal weakness (resulted from blocked motor fibers) (Bogduk, 2009).

Low back pain and comorbid afflictions negatively influence the quality of life, mental health, functioning, postural control, and gait (Nolet *et al.,* 2015; Fujii *et al.,* 2018; Hartvigsen *et al.,* 2018; Uchmanowicz *et al.,* 2019; Demirel *et al.,* 2020; Mutubuki *et al.,* 2020).

The treatment depends on the diagnosis and includes pharmacotherapy, psychological approach, physiotherapy, minimally invasive percutaneous interventions (intra-articular injections, medial branch nerve blocks, radiofrequency neurotomy, or cryoablation of the medial branch nerves in facet joint syndrome and sacroiliac joint syndrome, epidural steroid injections in lumbar radicular pain and spinal stenosis) or surgery procedures (Airaksinen *et al.,* 2006; Allegri *et al.,* 2016; Rashbaum *et al.,* 2016; Perolat *et al.,* 2018; Fujii *et al.,* 2019).

One of minimally invasive percutaneous technique for facet joint syndrome is the cryoablation (cryoanalgesia, kryorhizotomy, cryodenervation, cryoneurolysis) (Lloyd, Barnard and Glynn, 1976; Bärlocher, Krauss and Seiler, 2003; Trescot, 2003; Birkenmaier *et al.,* 2007; Wolter *et al.,* 2011; Bellini and Barbieri, 2015). Cryoablation is performed by a percutaneous insertion of a cryoprobe with compressed gas (nitrous oxide or carbon dioxide), which expands (due to to the principles of the general gas law – an absorption of heat from surrounding tissues accompanies the expansion of any gas) (Lloyd R. Saberski, 2011). The cryoprobe is built of two tubes; outer and smaller inner ones; the latter one terminates in a fine nozzle (Saberski LR, 2011). High-pressure gas (about 45–55 bar) is passed between tubes and is released through a small opening into a chamber at the tip of the probe (Saberski LR, 2011). In the chamber, the gas expands, and the reduction in pressure (about 5–7 bar) results in a rapid decrease in temperature and cooling of the probe tip (Saberski LR, 2011). The cooling of the probe produces a tip surface temperature of approximately −70°C. Tissue in contact with the tip cools rapidly and forms an ice ball (Saberski LR, 2011). The technique consists of a frost and defrost cycle (Trescot, 2003). The procedure is performed with minimal sedation and followed by nerve stimulation for its precise localisation (Trescot, 2003). Cryoanalgesia provides degeneration of axons and myelin sheaths with preservation of epineurium and perineurium, which allows for further nerve regeneration (Saberski LR, 2011). A temporary anesthetic blockade lasts weeks to months (Saberski LR, 2011). The analgetic effect is explained by a block of afferent input to the central nervous system (Saberski LR, 2011). Another hypothesis includes a role of autoimmune response – cryolesions may release sequestered tissue protein or facilitate changes in protein antigenic properties (Trescot, 2003; Saberski LR, 2011).

So far there are a few studies on the effectiveness of cryoanalgesia on pain, but none has evaluated its influence on the improvement of the level of disability and gait parameters.

Aim

The aim of the study was to investigate the effectiveness of the cryoablation in patients with chronic low back pain on pain, disability and spatiotemporal gait parameters in the course of facet joint syndrome.

Material and methods

The study included 19 patients (13 women, 7 men) with chronic low back and facet arthropathic changes in MRI, and with failure in conservative treatment (pharmacotherapy, physical therapy). All participants were referred for the procedure by a neurosurgeon. Cryoablations were performed for the first time at L4/L5 level in every patient.

Exclusion criteria included an occurrence of any red flags (progressive motor or sensory loss, cauda equina syndrome, a history of cancer, previous spinal procedure eg. fusion, vertebral fractures), ambulation with crutches or walkers, any surgeries in lower limbs, a time limit for walking below 6 minutes, any balance issues.

Cryoablation was performed bilaterally in 8 patients, in 4 patients on the right side and in 7 patients on the left side by the same neurosurgeon.

All subjects expressed written consent to participation in the study, which was conducted in agreement with the Declaration of Helsinki and with the approval of the Bioethics Committee of Poznan University of Medical Sciences (the reference number 711/17).

Outcome measures

The evaluation of patients was performed before and with one-month follow-up after cryoablation and included: a questionnaire with sociodemographic data, pain assessment, validated questionnaires on functional state and disability, as well as gait analysis.

The Numeric Rating Score

The numeric rating score (NRS) is a numbered version of a visual analogue scale (Chiarotto *et al.*, 2019). The NRS is a self-reported 11-point numeric scale with one-point intervals which evaluates the intensity of the pain (Chiarotto *et al.,* 2019). A patient scores her/his intensity of pain between two extremes – from 0 (no pain) to 10 (worst pain) (Chiarotto *et al.,* 2019).

The Revised Oswestry Low Back Pain Disability Index (*RODI*)

We used the validated Polish version of Revised Oswestry Low Back Pain Disability Index (Misterska, Jankowski and Glowacki, 2011), a modified version of Oswestry Low Back Pain Disability Index (Fairbank and Pynsent, 2000), (Hudson-Cook, Tomes-Nicholson, and Breen, 1989; 'Kwestionariusz Revised Oswestry Low Back Pain Disability Scale-wersja polska'/'the Questionnaire of Revised Oswestry Low Back Pain Disability Scale-the Polish version'). The RODI is one of the outcome measures officially acknowledged by the Polish Ministry of Health for the evaluation of the treatment of chronic low back pain (*Program Profilaktyki Przewlekłych Bólów Kręgosłupa | Pacjent.gov – The Chronic Back Pain Prophylaxis Programme / Pacjent.gov*). The questionnaire concerns patient's assessment of ten domains: pain intensity and its changes as well as the level of limitation of daily life activities like personal care, lifting, walking, sitting, standing, sleeping, social life and traveling (Misterska, Jankowski and Glowacki, 2011). A patient marks an answer on a 6-point scale (from 0 – no limitations on functional status to 5 – maximum restrictions) (Misterska, Jankowski and Glowacki, 2011). The maximum sum of points is 50 (Misterska, Jankowski and Glowacki, 2011). The general result may also be presented in percentage values, which corresponds to the level of disability – scores from 0% to 20% indicate/reflect minimal disability; 20% to 40% moderate disability; 40% to 60% severe disability; 60% to 80% crippled; and 80% to 100% bedbound (Davidson and Keating, 2005).

The Roland-Morris Disability Questionnaire (*RMDQ*)

The Roland-Morris Disability Questionnaire (RMDQ) is a research tool that measured the influence of low back pain on the disability level within the day of the examination (Roland and Morris, 1983). We used a validated Polish version of RMDQ (Opara, Szary and Kucharz, 2006; 'The Roland-Morris Disability Questionnaire (RMDQ), Polish version'). The questionnaire includes 24 statements with "yes" or "no" answer (Roland and Morris, 1983). The total score is a sum of "yes" answers and it describes a functional state of a patient, the result of 0–3 points reflects no disability, 4–10 low degree of disability, 11–17 moderate, 18–24 severe, respectively (Topolska *et al.,* 2011).

The gait analysis

The 6-minute walk test (6MWT) is used for an evaluation of functional performance and aerobic capacity as well as a prediction of mortality and morbidity of several chronic conditions (Laskin *et al.,* 2007). The 6 MWT can be performed on a track, a treadmill, and a walkway. We assessed spatiotemporal parameters such as (1) distance, (2) a number of steps, (3) an average walking speed, (4) an average step cycle, (5) an average step length, (6) coefficient of variation, (7) time on each foot (gait symmetry) within 6 minutes with the use of Gait Trainer 3 Biodex (Biodex Medical Systems, NY, USA) (Biodex Medical Systems, Inc.). Before the test, a participant was acquainted with a gait measurement procedure. During the pre-test an individual was to set a comfortable speed relevant to her/his normal walk (for treadmill speed). He or she was allowed to rest hands on railings for safety during the test.

The statistical analysis

The statistical analysis was performed with Statistica version 13.1. The descriptive statistic was reported as mean value with standard deviation, median, minimum and maximum. The Shapiro-Wilk test was used to assess the normality of distributions in the test score. Nonparametric analyses were used when the data did not meet the assumptions for parametric analysis. The dependent Student's t-test or Wilcoxon signed-rank tests were conducted to compare the differences between the results obtained before and after cryoablation. A p-value of less than 0.05 was considered statistically significant.

Table 1. Characteristics of participants.

Variables	mean ±SD	median	min-max
Age (years)	53.0 ± 7.9	53.0	36.0–64.0
Weight (kg)	70.4 ± 14.0	67.0	50.0–104.0
Height (m)	1.6 ± 0.1	1.6	1.5–1.9
BMI	25.9 ± 4.3	25.3	17.5–32.0
Duration of low back pain (months)	62.3 ± 52.9	42.0	6.0–180.0

Results

The characteristics of participants are presented in Table 1. Thirteen individuals suffered from pain with radiation to lower limbs and six presented local pain. Ten participants were smokers. All participants completed secondary education, thirteen were professionally active, four were retired due to health conditions, two retired due to age.

We found significant differences in NRS ($p = 0.003$), RMDQ ($p < 0.001$) and RODI ($p = 0.004$) between evaluations before and after cryoablation (Table 2). Three patients reported no improvement. The difference of 2 points between the mean value of NRS before and after the evaluation is also clinically significant (Suzuki *et al.,* 2020). Mean value of RMDQ reveals that individuals showed moderate disability on average (from low to severe) before cryoanalgesia, and low degree of disability after (from no disability to moderate). The mean value of RODI indicates that before cryoablation participants presented severe disability on average (from moderate to crippled), but in follow-up, the level of this disability was moderate on average (from minimal to crippled). The differences in mean values of RMDQ and RODI are also clinically meaningful (Ostelo and de Vet, 2005).

The results of gait analysis after cryoblation indicate the improvement in every parameter, but significant differences were found in distance ($p = 0.038$) and the number of steps ($p = 0.019$) (Table 2).

Table 2. Pain, functional performance, gait analyses rating before and one month after cryoablation.

	Before			**After**		
Variables	mean ± SD	median	min–max	mean ± SD	median	min–max
NRS	6.1 ± 1.9	6.0	2.0–9.0	4.1# ± 2.0	5.0	0.0–8.0
RMDQ	13.7 ± 4.2	13.0	4.0–19.0	7.7# ± 5.1	8.0	0.0–15.0
RODI (%)	52.0 ± 11.8	52.0	22.0–72.0	35.8# ± 19.9	38.0	6.0–72.0
Distance (m)	118.4 ± 39.5	107.0	65–202	155.8# ± 64.7	140.0	79–292
Number of steps	401.2 ± 82.3	395.0	271.0–573.0	447.4# ± 87.1	453.0	295.0–604.0
Treadmill speed (m/s)	1.2 ± 0.4	1.3	0.6–2.0	1.5 ± 0.7	1.3	0.4–2.9
Average walking speed (m/s)	0.33 ± 0.11	0.36	0.18–0.56	0.43# ± 0.18	0.39	0.22–0.81
Average step cycle (cycle/s)	0.57 ± 0.11	0.57	0.38–0.81	0.62 ± 0.12	0.63	0.41–0.84
Average step length LLL* (cm)	28.6 ± 9.1	27.0	10–45	33.9 ± 12.0	30.0	20–58
Average step lenght RLL** (cm)	31.6 ± 8.7	36.0	14–45	35.9 ± 10.4	32.0	21–57
Coefficient of variation LLL (%)	13.6 ± 7.2	11.0	6–32	9.9 ± 4.3	10.0	3–20
Coefficient of RLL (%)	12.5 ± 5.4	12.0	4–23	10.9 ± 4.8	11.0	3–22
Time on LLL feet (%)	48.7 ± 2.6	49.0	42–53	46.7 ± 10.7	49.0	47–51
Time on RLL feet (%)	51.3 ± 2.6	51.0	47–58	50.9 ± 1.4	51.0	49–55

Discussion

Cryoablation is the minimally invasive method used in the treatment of chronic low back pain caused by facet joints arthropathy (Cunha E Sa and Behari, 2011). It has been estimated that 15–54% of low back pain originates from zygapophyseal joints.

Though the application of cold in pain treatment has been known from antiquity, the cryosurgery was proceeded in the 1960s due to the development of devices to insert cold probe for refrigeration of tissues (Trescot, 2003). The efficacy of cryoanalgesia in low back pain was described for the first time by Lloyd *et al.* in 1976 (Lloyd, Barnard and Glynn, 1976). The authors performed the procedure in 17 patients with the sciatic distribution of pain and noted that median painless period was 10 days (up to 49 days) (Lloyd, Barnard and Glynn, 1976).

Further studies investigated the influence of cryoablation on pain relief (Bärlocher, Krauss and Seiler, 2003; Staender *et al.*, 2005; Wolter *et al.*, 2011; Bellini and Barbieri, 2015), a capacity of work (Bärlocher, Krauss and Seiler, 2003; Staender *et al.*, 2005), daily activities, as well as anxiety and depression (Wolter *et al.*, 2011). The novelty of our study involves gait analysis in functional assessment of patients referred for this procedure and using validated questionnaires dedicated for patients in the low back pain as outcome measures. The NRS, ODI and RMSQ are recommended for evaluation of the treatment in low back pain (Staender *et al.*, 2005).

The results of our research concerning the reduction of pain and the decrease in disability are convergent with previous studies, although their time points of follow-up varied (Bärlocher, Krauss and Seiler, 2003; Staender *et al.*, 2005; Birkenmaier *et al.*, 2007; Wolter *et al.*, 2011).

In the study by Bärlocher, the significant improvement was found in mean VAS at all follow-up examinations (at one day, at 6 weeks, at 6 months, and 1 year) (Bärlocher, Krauss and Seiler, 2003). However, 14 patients (from the group of 50) needed repetition of the procedure due to non-sufficient pain relief within 6 weeks (Bärlocher, Krauss and Seiler, 2003). Staender *et al.* performed the follow-ups after 3 days, 3 and 6 months – the differences in mean VAS were significant at every examination and all patients reported reduction of pain more than 50% after 3 days (Staender *et al.*, 2005). Nevertheless, 16 patients (of 76 subjects) experienced "therapy failure" – pain relief lasted less than 1 month (Staender *et al.*, 2005). Additionally, the reduction of medication intake due to the WHO pain scale and a return to work in a few participants were noted. Birkenmaier *et al.* found that in 72% of patients (from the cohort of 50 participants) after 6 weeks were pain-free or experienced meaningful improvement, but the others (n = 13) reported no substantial pain relief (Birkenmaier *et al.,* 2007). In the group with responders to the treatment, the significant mean pain decrease maintained up to one year (Birkenmaier *et al.,* 2007). Moreover, the authors observed that the improvement in daily life activities was related to pain reduction (Birkenmaier *et al.,* 2007). Similar results were obtained by Wolter *et al.* – in addition to reduced pain, a significant improvement was found in the pain disability index (in domains like daily duties, recreation, professional, social and other life activities) (Wolter *et al.,* 2011). The other important, but earlier not analysed aspect of their study was the measurement of the level of anxiety and depression (Wolter *et al.,* 2011). In patients who benefited from the cryoablation, the depression declined (Wolter *et al.,* 2011).

The numerous studies indicate a deterioration of gait in low back pain (including facet joint syndrome) in temporal and spatial variables as well as biomechanics of trunk and limbs (Lamoth *et al.,* 2006; Huang *et al.,* 2011; Barzilay *et al.,* 2016; Hicks *et al.,* 2017; Bonab *et al.,* 2020). The spatiotemporal parameters in gait are characterized by slower velocity, longer gait cycle duration, shorter step length, lower cadence (steps/min) (Barzilay *et al.,* 2016; Hicks *et al.,* 2017; Bonab *et al.,* 2020). Thus gait examination is suggested to be an objective outcome measure of the efficacy of conservative and surgical treatment (Khodadadeh and Eisenstein, 1993; Toosizadeh *et al.,* 2015; Barzilay *et al.,* 2016). We observed a significant improvement in distance and a number of steps in 6 MWT. To the best of our knowledge, there is only one previous study on the influence of minimally invasive percutaneous techniques with denervation of medial branches on walking (Stegemöller *et al.,* 2015). Stoegemuller *et al.* analysed gait kinematics and activity of lower back muscle after radiofrequency ablation in a patient with L4-L5 facet joint pain (Stegemöller *et al.,* 2015). The measurements were performed during 15-minutes walking on a treadmill – before intervention and after 0, 8, 14, 28 and 58 days (Stegemöller *et al.,* 2015). The results showed an increase in speed and stride length after the procedure (Stegemöller *et al.,* 2015). The analysis with electromyography revealed a reduction of increased superficial muscle activity over the multifidus and erector spinal muscles with increasing speed and stride length during treadmill walking after radiofrequency denervation (Stegemöller *et al.,* 2015). Further research with EMG in patients treated with cryoablation is needed.

As the authors, we are aware of some limitations of the study. Firstly, according to the one-month follow-up, the results may only refer to short-term observation. We still do not know, how long the improvement in pain, disability and gait will sustain, and which factors will influence it. Secondly, the number of participants is relatively (to the high prevalence of low back pain) modest. This fact may limit the extrapolation of results to larger groups of LBP patients. Further, the gait analysis (eg. number of steps, distance) was performed on the treadmill – in "artificial environment" in a 6 MWT and it may not be related to the level of daily activity measured with the number of steps due to recommendations of WHO on physical activity in adults.

Our studies revealed that cryoablation as a minimally invasive method seems to be safe for patients with low back pain related to facet joint syndrome. This group of patients may benefit in crucial clinical aspects such as pain reduction, improvement of functional performance and gait. This method may be adequate if noninvasive treatment is insufficient.

Conclusions

1. Cryoablation seems to be a safe method for treatment of low back pain related to facet joint syndrome, if earlier conservative management failed.
2. The validated tools (NRS, RMDQ, RODI) and gait analysis are proper outcome measures

to observe changes in functioning of patients treated with cryoanalgesia.

3. The cryoablation is the effective method for pain reduction in facet joint syndrome, which improves the functioning and gait.

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