RADIOFREQUENCY ABLATION OF THE BASIVERTEBRAL NERVE IN THE TREATMENT OF CHRONIC LOW BACK PAIN: ANALYSIS OF A SMALL CLINICAL SERIES

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Objective. To evaluate the efficacy and safety of radiofrequency ablation of the basivertebral nerve in the treatment of chronic low back pain associated with Modic I and II changes according to MRI data.
Material and Methods. The results of treatment of 19 patients with chronic low back pain syndrome in the lower back lasting 6 months or more were analyzed. Patients were treated with radiofrequency ablation of basivertebral nerve.
Results. The duration of the manipulation averaged 28.0 ± 4.8 min. In all patients, a decrease in the Oswestry index by an average of 24.3 points (21.7 ± 5.2) was observed at 6 months after ablation of the basivertebral nerve. The intensity of the pain syndrome decreased immediately after the manipulation to 2.1 ± 1.1 cm on average, that is, by 71.2 %. According to the Beck Depression Scale, the patients showed signs of mild depression (subdepression) before the procedure (13.8 ± 3.6 points). When examined after 12 months, the patients showed an improvement in their psychoemotional state up to the normal values (3.4 ± 2.7 points). Subjective assessment of the condition of patients compared with the baseline showed that 16 (84.2 %) of them assessed their condition as a significant improvement with a significant regression of pain by more than 50 % at all stages of follow-up, and two patients (10.5 %) reported only a slight decrease in pain syndrome immediately after the procedure, followed by its resumption to the initial level.
Conclusion. Using clear criteria for selection of patients for radiofrequency ablation of the basivertebral nerve, it can be argued that this method is effective in the treatment of chronic low back pain associated with Modic I and II changes according to MRI data. With the help of radiofrequency ablation, it is possible to achieve long-term remission of pain syndrome up to 12 months and more.
Key Words: radiofrequency ablation of the basivertebral nerve, chronic lower back pain.
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According to the definition proposed by the International Association for the Study of Pain (IASP), a chronic lower back pain syndrome is the one that lasts for more than 3 months and, as a rule, does not have an anatomical substrate [1]. In 30–40 % of cases, a chronic pain is of a neuropathic nature. It reduces the life quality, social adaptation, ability to work, and often does not well answer to treatment. A long-lasting pain syndrome results in functional changes in the nervous system, after which even a non-painful impulse is interpreted as pain. It is difficult to choose treatment techniques for chronic lower back pain, while there is often no specific diagnosis [2, 3]. This would further lead to excessive or insufficient treatment and, consequently, to high costs and poor results [4].

A chronic lower back pain is diagnosed in 10–13 % of the American adult population (30 million people in absolute terms). These data are derived from various epidemiological studies. The manifestations of the syndrome are noted in 19 % of German population; up to 20 % of the population of the EU and Northern Europe [5]. The incidence of chronic pain in elderly and senile patients is observed in 65–82 % of cases [6].

Despite the fact that the diagnosis of "vertebrogenic pain" is a relatively new clinical concept, today there is a considerable amount of fundamental research data verifying the role of vertebral end plates in the formation of chronic lower back pain [7–11]. The immunohistochemical studies have demonstrated that nociceptors from the vertebral end plates are drawn to the basivertebral nerve, which, in turn, is a branch of the synuvertebral nerve. The first mention of the basivertebral nerve was made by Antonacci et al. [6] in 1998. The dual role of the vertebral end plates (providing vertebra tropism and structural support of the spine) makes them more vulnerable in terms of the effect of the injurious factor. The injury of the vertebral end plate results in the onset of a chain reaction between the immunologically and biochemically active nucleus of the disc and the bone marrow of the vertebral bodies, causing chronic inflammation, which is well visualized on MRI [7]. This results in proliferation of nerve terminals and vessels of the vertebral end plate. In

turn, in the presence of chemical sensitization by biologically active substances of the degenerated disc nucleus and mechanical stimulation can cause the formation of pain signal. The latter is transmitted to the central nervous system via the basivertebral nerve, which interprets it as a lower back pain [4].

The degenerative changes of the vertebral end plates are easily identified by MRI. They are classified into 3 types, first described in 1988 [12]. Modic I, II changes are directly associated with degenerative disc disease and may manifest as persistent pain syndrome [13]. According to studies, patients suffering from chronic lower back pain with Modic I, II changes are clinically different from ones experiencing chronic lower back pain without Modic I, II changes [14]. The patients with Modic I, II changes reported a higher frequency and duration of chronic lower back pain episodes and more frequent applied to the hospitals [15]. Additionally, the findings of conservative [16, 17] and surgical [18] treatment of intervertebral disc herniations were worse in patients with chronic lower back pain and Modic I, II changes.

In 2017, Becker et al. were the first who published studies on the application of radiofrequency ablation of the basivertebral nerve [8]. They noted a positive outcome of treatment in 13 (81 %) of 16 patients. The authors described the method as promising in the treatment of this group of patients. The presented data suggested the effectiveness of radiofrequency ablation application of the basivertebral nerve in the treatment of chronic lower back pain of vertebrogenic origin associated with degenerative changes of vertebral end plates according to Modic I.

The papers concerning the presented subject are extremely few. As for the Russian literature, there are practically no publications. In contrast to the huge number of papers on radiofrequency ablation and chronic pain syndromes of arthropathies of various localizations, the studies are limited to small clinical series. there is no convincing data on the effectiveness and analysis of mistakes and complications after the procedures performed. The above-mentioned determines the relevance of our retrospective study.

The objective is to evaluate the efficacy and safety of radiofrequency ablation of the basivertebral nerve in the treatment of chronic low back pain associated with Modic I and II changes according to MRI data.

Material and Methods

The treatment results of 19 patients (12 men and 7 women) aged 52.6 ± 6.9 years with chronic lower back pain by radiofrequency ablation of the basivertebral nerve were analyzed. The pain syndrome lasts from 6 months up to a year. 14 (73.7 %) patients were observed, 1–2 years – 5 patients (26.3 %). Modic I changes according to MRI data were detected in 13 (68.4%) cases, Modic II – in 5 (26.3 %), Modic I–II – in 1 (5.3 %). The study was performed on the basis of the Institute of Traumatology and Orthopedics (Kiev) from December 2018 to April 2019.

The candidates for the procedure were chosen according to the following criteria [9]:

– manifestations of lower back pain from 6 months and more in patients who did not experience positive changes after conservative drug treatment;

– presence of closed growth regions in patients;

– the presence of a pathological MR signal from the bodies of L3–S1 vertebrae of Modic type I, II;

– Oswestry destabilization index ⩾30 points;

– pain intensity more than 4 cm according to VAS;

– the follow-up period after the procedure should be 12 months or more.

Exclusion criteria:

– radicular pain correlating with nerve compression (according to instrumental methods of diagnosis);

– surgeries on the lumbosacral spine (discectomy, laminectomy);

– clinically significant spinal stenosis, manifested by NIC syndrome and confirmed by instrumental methods of diagnosis (MRI and SCT);

– metabolic diseases of the bone;

– post-injury, fragility or Mts-compression fracture of the vertebral body;

– inflammatory changes of the spine;

– intervertebral disc extrusion that emerges into the canal by more than 5 mm;

– spondylolisthesis more than 2 mm;

– spondylolysis;

– pronounced arthrosis of the facet joints;

– depression on the Beck scale of more than 24 points;

– drug consumption.

The radiofrequency ablation of the basivertebral nerve was done in the operating room, under local anesthesia (Sol. Bupivacaine, 5 ml) and intravenous sedation. After surgical site treatment and skin infiltration, aponeurosis and periosteum with a solution of local anesthetic, a Bevel type G15 bone biopsy needle (beveled tip) was inserted at the level of the transverse process, 5–6 cm from the median line. The access point of the needle into the vertebral body was the isthmus (the place of intersection of the transverse and articular process). Under the fluoroscopy with the help of a surgeon mallet, the needle was inserted into the vertebral body so as to place its tip in the anterior-posterior projection on radiographs along the midline, and in the lateral projection 50-60% from the anterior surface of the vertebral body.

After reaching the correct location of the bone biopsy needle, the mandren was removed and a navigation needle was inserted. The bone biopsy needle was removed, and an isolated cannula (150 mm) with an active end (10 mm) and a diameter of G18 and a radio frequency electrode were inserted along the navigation needle. After performing sensory and motor stimulation, ablation of the basal and vertebral nerve was performed at a temperature of 85° for 15 minutes. 16 (84.2 %) patients underwent ablation of the basivertebral nerve in two adjacent vertebral bodies, and 3 (15.8 %) patients in three vertebral bodies. In 10 (52.6 %) cases, ablation was done in the L5–S1 segment, in 6 (31.5 %) – in the L4–L5 segment, in 3 (15.8 %) – in the L4–

L5 and L5–S1 segments. The procedure duration averaged 28.0 ± 4.8 minutes.

The assessment of treatment results using the VAS, the Oswestry questionnaire and the Beck scale was performed the next day, 3, 6 and 12 months after the procedure. The statistical data processing was done using the license program Statistics for Windows 13 (StatSoft Inc., no. JPZ804I382130ARCN10-J). The level of statistical significance $p < 0.05$ was used for all types of analysis, at which the differences were considered significant.

Results

The dynamics of clinical scores is given in Table. Six months after the procedure, all patients underwent a control MRI scan of the lumbosacral spine. In all patients (n = 19), the regression of changes in the vertebral bodies was viewed according to Modic I, II.

Six months after ablation of the basal and vertebral nerve, a reduction in the Oswestry index was seen by an average of 24.3 points (21.7 ± 5.2) in all cases. The pain intensity declined immediately after the procedure to 2.1 ± 1.1 cm on average, that is by 71.2 %. At the time of the last examination, it was 2.4 ± 0.9 cm.

A subjective assessment of the patients' condition compared to the base one showed that 16 (84.2 %) of them defined their condition as an improvement with a significant regression of pain syndrome (by more than 50 %) at all stages of follow–up; 2 (10.5 %) – only a slight decrease in pain syndrome immediately after the procedure, followed by its restoration to the base level.

According to the Beck Depression Scale, signs of mild depression (subdepression) were noted in patients before the procedure – 13.8 ± 3.6 points. When examined after 12 months, an improvement in the psychoemotional state to normal indicators was found – 3.4 ± 2.7 points.

In a single case, a negative result was achieved due to technical errors during the procedure. During the puncture needle stage, a. lumbalis sinistra was damaged at the level of the L4 vertebra. A hematoma formed from the affected artery in *m. Iliapsoas* (Fig. 1), which irritated the superior and inferior roots of the lumbar plexus and manifested itself as a pronounced polyradicular pain syndrome and a gradual increase in neurological manifestations in the right lower limb.

As an additional examination, an SCT angiography was performed, which revealed a defect in the artery wall and a hematoma in m. Iliapsoas. Endovascular shutdown of the artery by embolization with adhesive composite.

Discussion

The chronic low back pain mechanisms and pathways associated with degenerative changes in the intervertebral discs have been studied for more than half a century. Unlike specific pain with an obvious pathological cause, such as a herniated disc, spondylolisthesis or spinal stenosis, chronic lower back pain occurs during degeneration of the disc and vertebral end plate, which are caused by changes in their physiology and morphology. The studies have demonstrated that inflammatory mediators were released from the damaged disc. This resulted in a number of further inflammatory responses through the generation of cytokines [10]. The direct evidence that the vertebral body is the source of pain was given by Kuslich et al. [11]. These authors reported on a series of patients who underwent laminectomy under local anesthesia. Kuslich et al. observed that intraoperative mechanical irritation of the vertebral end plates in awake patients triggered a pronounced pain syndrome. The additional evidence of the role of vertebral end plates in the generation of pain signals was given by Lotz et al. [22]. These authors conducted a histomorphological study of the vertebral bodies and found nociceptors' induration of the vertebral end plates with increased disc degeneration [23]. Heggenes and Doherty [24] noticed that during the injection into the disc, as well as during the discography, there were changes in the vertebral end plates. This enabled the hypothesis to be put forward those changes in the vertebral end plates may explain the occurrence of pain experienced during the discography. After assuming that increased physical activity may cause disc degeneration, Adams et al. [25, 26] demonstrated that minor damage to the vertebral end plates may result in structural changes in adjacent intervertebral discs. Carragee et al. [27] determined that changes in the MRI signal from the vertebral end plates suggest intraosseous edema or inflammation and relate well to lower back pain.

Owing to the similarity of the MRI pattern of Modic I changes with spondylitis, there is a theory of its infectious origin [19]. Proceeding from this, Albert et al. [20] performed a double-blind randomized study of the effectiveness of pain syndrome treatment against Modic I bone edema by taking the antibacterial drug Bioclavid for 100 days. A group of patients receiving an antibiotic demonstrated significantly better treatment outcomes for chronic lower back pain both immediately after treatment and within 12 months. Regression of Modic I changes was also seen in the antibiotic therapy group according to the MRI scan. The disadvantages of this technique include a side effect to the gastrointestinal tract, which was observed by 65 % of patients.

The Korean surgeons demonstrated another destruction technique of the basivertebral nerve. It was done by transforaminal endoscopy using a 1414 nm Nd: YAG laser in a small series of 14 cases [21]. Notwithstanding the good treatment results (excellent and good MacNab results in 93 % of cases), the absence of complications and side effects, this technique seems to be quite complex and high-tech, requiring significant economic costs.

Fischgrund et al. [9] analyzed the treatment outcomes of 145 patients with chronic lower back pain associated with Modic I, II changes according to MRI scan by radiofrequency ablation of the basivertebral nerve. An analysis of long-term results (2 years) revealed a reduction in pain according to VAS and

Table
The dynamics of clinical indicators at the follow-up stages in the studied patients

Indicators	Before the procedure	After the procedure	After 3 months	After 6 months	After 12 months
VAS, cm	7.56 ± 2.5	2.1 ± 1.1	2.5 ± 1.1	2.3 ± 1.4	2.4 ± 0.9
Oswestry index, points	49.2 ± 14.8	27.1 ± 3.3	25.1 ± 3.3	22.3 ± 4.7	21.7 ± 5.2
Beck Depression Scale, points	13.8 ± 3.6	6.9 ± 3.1	4.3 ± 3.2	3.1 ± 2.4	3.4 ± 2.7

the Oswestry index by more than 50 % on average in the group.

In 2019, Khalil et al. [28] released the results of a prospective randomized placebo-controlled trial of 140 patients. They were examined and treated at 20 American hospitals by radiofrequency ablation of the basivertebral nerve. In the main group, the authors observed a significant decrease in pain at all stages of follow-up compared to the control group.

The guide by Lorio et al. [29], whose task was to identify the optimal treatment technique for chronic lower back pain associated with Modic I, II changes, confirmed the high level of evidence for radiofrequency ablation of the basivertebral nerve and a sizeable reduction in medical costs for this group of patients.

After the radiofrequency ablation of the basivertebral nerve, the regression of changes in the vertebral bodies according to type Modic I, II was seen in all patients (n = 19) (Fig. 3).

We did not find any literature data concerning complications caused by this procedure. Nevertheless, our experience leads to the conclusion that radiofrequency ablation may be a source of serious complications. That is why it is essential to perform it in specialized spinal centers of neurosurgical or orthopedic type.

Conclusions

Thorough clinical and radiation comparison provides for the identification of potential sources of chronic lower back pain with high accuracy. It may cause degenerative inflammatory changes in the vertebral end plates in a number of patients. Using clear criteria for selection of patients for radiofrequency ablation of the basivertebral nerve, it can be argued that this method is effective in the treatment of chronic low back pain associated with Modic I and II changes according to MRI data. With the help of radiofrequency ablation, it is possible to achieve long-term remission of pain syndrome. The possible risks of potential complications and side effects demand this procedure to be performed in highly specialized spine surgery centers.

Limitations of the research. Limited sampling size.

The study had no sponsors. The authors declare that they have no conflict of interest.

Fig. 1
SCT angiography of *a. lumbalis sinistra IV* perforation

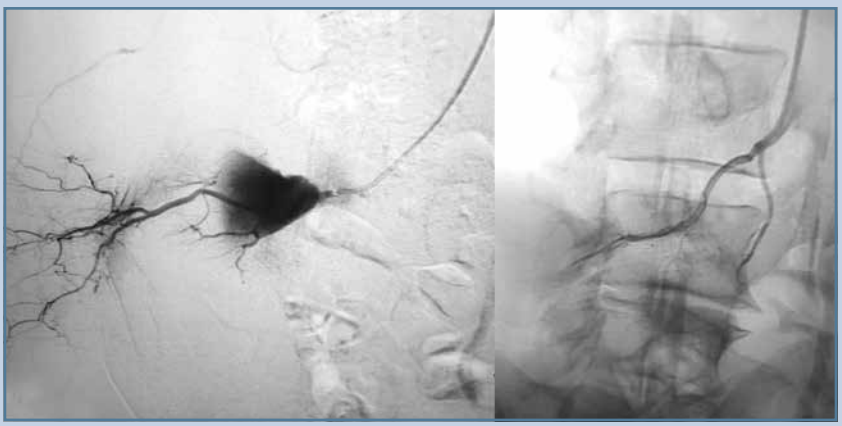

Fig. 2
Endovascular embolization of *a. lumbalis sinistra V* by adhesive composite

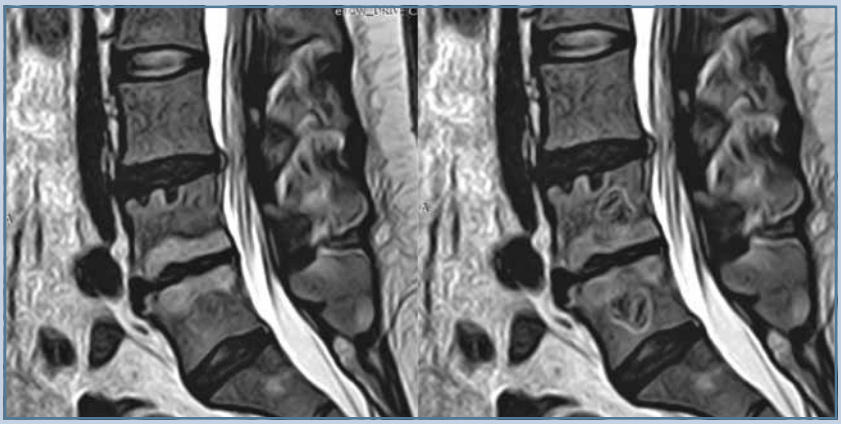

Fig. 3
MRI of the patient before radiofrequency ablation of the basivertebral nerve and within 6 months after the procedure.

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