Preliminary study for analysis of modification of disk volume and disk fragment in patients with lumbar contained disk herniation treated with CT-guided ozone-oxygen injection

Poster No.: B-0343
Congress: ECR 2015
Type: Scientific Paper
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Keywords: Interventional non-vascular, Musculoskeletal spine, Neuroradiology spine, CT, MR, Puncture, Computer Applications-General, Hernia
DOI: 10.1594/ecr2015/B-0343

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Purpose

Low back pain (LBP) is a major cause of absence from work and need of healthcare service; the incidence increases with age [1]. In a large part of the population LBP is associated with herniated disc [2]. Radicular pain can be mechanically generated or have an immune-mediated inflammatory origin [3-6].

When medical treatment fails infiltrations play a role [7].

The aim of this study was to quantify the modification of lumbar disk herniation after treatment CT guided with O₂-O₃ gas mixture. In particular we want to study the volume modification of entire disk [8] and the only portion migrated.

In addition we want to correlate this value with the symptoms according to the rating scales of pain [9].

Intradiscal O₂-O₃ mixture injection produces some effect: first the ozone mixture had a well-known anti-inflammatory and analgesic properties due to the activation of cytokines in plasma [10-11] in addiction the biochemistry action produces a chemodiskolysis that determinates a mechanical effect of disk shrinkage[12-13]. Many studies in the past have shown that treatment with intradiscal oxygen ozone mixture results in a change of the volume of the disc [14-15].
Methods and materials

We enrolled all patients consecutively treated with O\textsubscript{2}-O\textsubscript{3} gas mixture (including patients already undergone on hemilaminectomy) with these features:

- they had signed an informed consent
- they performed laboratory tests (thyroid function, coagulation factors, G6-PDH) which showed no infiltration contraindications
- they executed lower limbs electromyography exam (EMG)
- the lumbar MRI that showed focal or broad-based lumbar disk herniation with migration of disk material (contained disk herniation)[16].
- medical therapy was not decisive.

Exclusion criteria comprised pregnancy, deficit of G6-PDH, patients with disk sequestration; important lumbar osteoarthritis - degeneration, and with a documented microinstability.

TECHNICAL EXECUTION

The patient is placed in the prone position with hands on their face (Fig.1) on a 16 slice CT scanner. CT protocol expected a small package (3 sl acquisition) with low-dose reconstruction (DLP 130 mGy / cm) (Fig.2). The images acquired are necessary to visualize the discoradicular conflict and to determine the best route of the needle to reach the discal nucleus (Fig.3- 4). A 22G needle is used, this gauge is considered optimal by several authors [17]. The intradiscal injection of O\textsubscript{2}-O\textsubscript{3} gas mixture were administrated with paravertebral (Fig.5), interlaminar (Fig.6) approach. The type of approach was chosen by the operator on the basis and on the type of hernia.

Infiltrative treatment was guided by CT images before treatment (to make a mark on the skin), after placement of the needle inside the disk (to document the right position of the needle) and post treatment to document the correct distribution of intradiscal gas (Fig 7). All patients were treated with intradiscal O\textsubscript{2}-O\textsubscript{3} mixture with a standardized protocol of 8-10 ml of O\textsubscript{2}-O\textsubscript{3} gas mixture with ozone concentration of 30 µg/mL.

The control MR images were acquired with TSE-T2 images on sagittal (TR 3500, TE 120) and axial (TR 2000, TE 120) plane (using 1.5 T scanner with coil plugs surface), thickness of layer 4 mm, 0.4 mm gap; FOV of 15 cm for axial, 30cm for sagittal sequences. Axial
images were obtained using as a reference the sagittal image and was acquired using a plain parallel to the lower endplate.

We arbitrarily divided the patients in two groups: patients evaluated with lumbar MRI at 3 months (group A) and 6 months (group B) after O$_2$-O$_3$ diskolysis. These two groups were found to be statistically homogeneous for the examined characteristics of hernia and symptoms.

The data analysis was performed using the program OsiriX. Herniated disk volumes were calculated manually by defining regions of interest (ROIs) on sagittal images. The contours of the various ROI have been calculated considering all margins of the disk (Fig.8). The volumes of the disks analyzed before and after the ozone treatment are defined in cm$^3$.

The volumes of migrated disk were calculated in the sagittal images upon confirmation of axial images (Fig.9).

All patients were undergone on international scales of pain (Visual Analog Scale VAS, Numerical Rating Scale NRS and the Oswetry Disability Index ODI).
Fig. 2: CT protocol expected a small package (3 sl acquisition) with reconstruction low-dose (DLP 130 mGy / cm).

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Fig. 3: Image processing for needle placement.

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**Fig. 5:** The image shows the paravertebral approach

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Fig. 6: Interlaminar approach

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**Fig. 7:** The O2-O3 mixture is distributed inside the disk

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Fig. 8: Sagittal T2-w sequence. Total disc volume. These volumes were calculated manually by defining regions of interest (ROIs) on sagittal images. The contours of the various ROI have been calculated considering all disk margins. The volumes of the disks analyzed before and after the ozone treatment are defined in cm³.

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Fig. 9: Volume of the migrated disk. The volumes were calculated in the sagittal upon confirmation of axial images

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Fig. 1: The patient is placed in the prone position with hands on their face. Placement of the finds skin

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Fig. 4: Preliminary image to decide the right needle access.

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Results

We treated 2.5% of lumbar disc herniation (1 disc) at level L3-L4, 50% (20 disc) at level L4-L5 and 47.5% (19 disc) at level L5-S1.

Initial disc volume was 15.30 cm³ (median; range 7.5, 21.9 cm³), initial migrated disk material was 0.93 (median; range 0.21, 1.96 cm³).

All patients present a reduction of disk volume and group A showed disk volume reduction of 16.1% (median; range -6.5%, -25.7%) (Fig 10-11), while the group B showed a reduction of 7.3% (median; range -4.9%, -19.5%) (Fig.12-13).

The migrated disk material shrinkage in the group A was of 35.6% (median; range -21.4%, -49.8%), in the group B was of 40.8% (median; range -13.0, -68.6%). Study results were found to be statistically significant (pvalue <0.05).

We also evaluated the reduction of symptoms with VAS/NRS assessed in 32.1% in group A, 25.8% in group B; Owestry 72.2% of group A and 73.4% in group B. Finally, we calculated that reducing intake of drugs reaches 66.7% at three months and 80% at 6 months. Both groups showed a positive correlation with improvement of symptoms (pvalue <0.05).

This means that the treatment is perceived as effective three months in a greater than six months while not showing big changes compared to the functional limitations assessed by Owestry.

LIMITS and prospects OF THE STUDY

This is a preliminary study and we want to explain our experience but there are some limitations: first the lack of control group not treated.

On the second we realized that there was a great difference of reduction of disk volume on the basis of the size and type of the disc herniation [18], for this reason in the future we want to make the homogeneous subgroups. In addiction we would like to make a much more bigger group of patients.

In our experience 7 patients refused to do an MRI control.
Fig. 10: Patient of group A(Evaluated after 3 months)

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**Fig. 11:** Patient of group A (Evaluated after 3 months)

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Fig. 12: Patient of group B (Evaluated after 6 months)

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**Fig. 13:** Patient of group B (Evaluated after 6 months)

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Conclusion

In our study, ozone-oxygen nucleolysis provides a statistically significant reduction of the volume of the disk, migrated disc material and symptoms. The migrated disc material is the most sensitive portion to change in the first period, continuing its slow dehydration in the further 3 months.

Patients shows a reduction of the need of drugs taken daily. This leads us to suggest the oxigen-ozone treatment before recourring to surgery.
References


