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QUALITY ASSURANCE GUIDELINES FOR PERCUTANEOUS TREATMENTS OF INTERVERTEBRAL DISCS

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INTRODUCTION

Herniation of intervertebral disc is an important and common cause of low back pain which affects mobility, physical function, quality of life and costs highly to society [1, 2]. It is estimated that 70-90% of normal population will experience at least 1 episode of sciatica or lumbago during their lifetime [3, 4]. Intervertebral disc and discogenic pain have been identified as causative agents in 26-39% of patients with sciatica or lumbago [3-8]. The long-term outcomes, complications and occasionally suboptimal results which accompany open disc surgery in herniated discs have lead to the development of other treatment techniques that avoid an open surgery, through the spinal canal.

Percutaneous treatments are used in the therapy of small to medium sized hernias of intervertebral disks in order to reduce the intradiscal pressure in the nucleus and theoretically to create space for the herniated fragment to implode inwards, reducing thus pain and improving mobility and quality of life [9]. These techniques involve the percutaneous removal of the nucleus pulposus by using a variety of chemical, thermal or mechanical techniques [1, 9-13]. They are based on the study of Hijikata et all in 1975 concerning the role of intradiscal pressure which stated that: “Reduction of intradiscal pressure, reduced the irritation of the nerve root and the pain receptors in the annulus and peridiscal area” [1] and consist of removal of all or part of nucleus pulposus to induce more rapid healing of the abnormal lumbar disc.

These guidelines are written in order to be used in quality improvement programmes for assessing fluoroscopy- and/or Computed Tomography (CT)- guided percutaneous intervertebral disc ablative techniques.

DEFINITION:

Percutaneous ablative techniques of intervertebral discs are image guided therapeutic techniques for intervertebral disc hernia which use a trocar in order to puncture the outer annulus of the disc. Through this trocar a variety of chemical, thermal or mechanical ablative devices may be placed inside the nucleus pulposus assuring its partial removal. The nuclear material removal internally decompresses the disc with the least disruption of surrounding tissues.

- **Automated percutaneous lumbar discectomy (APLD):** a pneumatically driven, suction-cutting probe within a 2.8 mm outer diameter cannula, removes approximately 1-3 grams of disc material anterior to the herniation.
- **Intradiscal electrothermal therapy (IDET):** a flexible thermal resistive coil (electrode or catheter) coagulates the disc tissue with radiant heat (electrothermal energy). Although IDET is used for treatment of the annulus, and it is not per se a treatment of the nucleus, it is included in this document as an ablative technique for small contained hernias with ruptures of the annulus. Percutaneous intradiscal radiofrequency therapy may be considered an IDET variant where an electrode or catheter applies alternating radiofrequency current to the nucleus pulposus.
- **Percutaneous Laser Decompression:** laser energy vaporizes a small volume of nucleus pulposus reducing thus the intradiscal pressure.
- **Nucleoplasty:** a non-heat driven process where bipolar radiofrequency energy causes molecular dissociation and dissolves nuclear material creating a series of intradiscal channels.
- **Percutaneous disc decompression (PDD):** nuclear material extraction is achieved with a mechanical high rotation per minute device with spiral tips.
- **Ozon therapy:** the ozone's chemical properties and the reaction of hydroxyl radical with carbohydrates and amino acids leads to breakdown of nucleus pulposus with rapid disappearance of herniated material.
- **Discogel:** a chemonucleolytic agent (gelified ethanol) that causes dehydration of nucleus pulposus, resulting thus in retraction of intervertebral disc herniation

INDICATIONS

- Small to medium sized contained intervertebral disc herniation confirmed by Magnetic Resonance Imaging (MRI) [12-13, 14-15]
- Back pain of discogenic origin, sciatica or crural pain that limit activity for at least 6 weeks duration (leg pain should be of greater intensity than back pain) [12-13, 14]
- Specific dermatomal pain distribution [16]
- Neurologic findings referring to a single nerve root involvement (positive Laseque sign, decreased tendon reflex, sensation and motor response) [13]
- No significant improvement after conservative therapy (6 weeks of bed rest, analgesics, anti-inflammatory drugs, muscle relaxants and physiotherapy) [12, 13]. Significant improvement is defined as any pain reduction and mobility improvement greater or equal to 4 Visual Analogue Scale (VAS) units [17].
- Reproduction of patient's usual pain in the cases which provocative discography is performed prior to any percutaneous intervertebral disc ablative technique [12, 14, 15].

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CONTRAINDICATIONS:

Absolute:

- Sequestered (free) disc fragment [14]
- Segmental instability (spondylolisthesis) [14, 17]
- Stenosis of neural foramen or spinal canal [14, 18]
- Asymptomatic intervertebral disc bulging discovered as incidental finding in Computed Tomography (CT) scan or Magnetic Resonance Imaging (MRI) [14]
- Untreated, ongoing, active infection and/or discitis [12]
- Pregnancy (radiation exposure of the fetus must be avoided) [15]

Relative:

- Hemorrhagic diathesis (should be corrected before the operation) [7, 12]
- Anticoagulant therapy (should be interrupted before the operation) [19]
- Severe degenerative disc disease with more than 2/3 of disc height decrease [16, 20]
- Medical record of intervertebral disc operation at the same level [17]
- Primary or metastatic malignancy

PATIENT SELECTION:

Characteristics for the ideal candidate include a single level, symptomatic, contained disc herniation with leg greater than the back pain. These candidates do not belong in the most severe surgical disc disease spectrum and they have a good chance of achieving significant pain reduction with conservative therapy therefore, a 4-6 weeks course of conservative treatment should be the first step [14].

Preoperative imaging planning begins with plain films of the spinal column which are promptly available and not expensive [20]. These are obtained in order to provide information about spinal bony elements and possible vertebral misalignment excluding thus other potential sites and causes of pain origin including facet arthropathy, spinal canal stenosis and fracture [21]. Magnetic Resonance Imaging (MRI) with T1- and T2-weighting sequences should be systematically performed before any percutaneous intervertebral disc decompression technique. Computed tomography may be performed for a more thorough bone evaluation [20].

TECHNIQUE:

Percutaneous ablative techniques of intervertebral discs are performed under fluoroscopy-, CT-, or dual (CT and fluoro)-guidance with the patient in prone (when thoracic or lumbar spine is concerned) or in supine (when cervical spine is concerned) position. Although there are reports of Magnetic Resonance guidance concerning infiltrations of facet joints and selective neural root blocks, this modality is rarely if ever used for the guidance of percutaneous intervertebral disc treatments.

Appropriate preoperative preparation, draping and strict sterilization of the area of interest are one of the most important points of these techniques. An iodine solution (the use of extra solution containing alcohol varies among different centers) is used for rigorous and extensive skin disinfection, and all the instruments and materials used (forceps, sterile gauze swabs) should be included in a sterile set. Pre-procedural antibiotic therapy administration at least 1 hour prior to the procedure is optional. Some authors prefer intradiscal antibiotic treatment [22].

Trocar positioning is performed under local anaesthesia (skin and subcutaneous tissues). In order to avoid an accidental puncture of the nerve root without patient reaction, the nerve root itself should never be anesthetized.

Trocar positioning at the cervical spine [1]

With the patient in supine position, under A-P fluoroscopy, the selected disc is recognized and aligned, a projection to the skin is marked and an anterior approach is performed. Under continuous fluoroscopic control and subluxation of the larynx, advancement of the trocar is performed between larynx and jugular-carotid vessels, until the trocar tip reaches the anterior longitudinal ligament. The right side is usually preferred, since the oesophagus is located on the left side.

Trocar positioning at thoracic spine [1, 16]

A lateral oblique projection (35-40° rotation of the tube) is used for disc space definition at the thoracic level. The target point is situated between the superior articulation of the lower vertebral body on the lateral side and the head of the ipsilateral rib on the medial side. Tube rotation greater than 35-40°, will block the entry point by means of costovertebral joint presence.

Trocar positioning at lumbar spine [1]

Concerning the lumbar spine, intervertebral disc of interest should be aligned in antero-posterior (A-P) projection. Rotating the tube at 45° will send the spinous process towards the controlateral facet joint, producing thus, the “Scotty dog” projection (take care to preserve open the intervertebral disc’s anterior part). Trocar advancement is performed under fluoroscopic control at the “Scotty dog” projection. Annulus fibrosus puncture can be both felt as well as seen under fluoroscopy. A curved trocar can be used when necessary for the L5-S1 intervertebral disc [13].

Dual guidance (rotating fluoroscope and CT) provides three-dimensional imaging with exact differentiation of intervertebral disc from the surrounding structures [13].

In general, under every approach and guidance and for any of the ablative/decompressive devices used (except IDET), the inserted trocar must be inside the nucleus pulposus (projecting in PA view near the midline) parallel to and at midway between the two endplates. However, the trocar’s final position depends on the ablative/decompressive device used [13]. Once the trocar is found in the desired position, any of the above mentioned devices is inserted through it. Ablation (either thermal or mechanical) reduces the intervertebral disc volume with no surrounding spinal structures damage. IDET is placed circumferentially in the annulus pulposus, remaining in the midway between the two endplates [12].

POST-PROCEDURE CARE:

In the absence of complications, hospitalization is not necessary. Non steroid anti-inflammatory drugs and muscle relaxants could be prescribed, but this is optional and practice differs on each centre. A follow-up phone call is performed the next morning following disc decompression and then the patient is clinically examined one week later [15, 23].

Post-procedure restrictions should include rest during the first days after the procedure whilst prolonged sitting position should be avoided. Neither heavy lifting, twisting or forward bending, nor strenuous body activity are permitted during the first post-operative period. One week after the procedure light housework is allowed, whilst on the second week walking and progressive exercise may begin. Weightlifting is allowed after 3 months [12].

COMPLICATIONS:

Intra-operative complications are related to the technique itself as well as the instrumentation (eg catheter breakage, nerve root injury), whilst post-operative complications include bleeding, infection and other general

complications [19]. Discitis is the most common complication of percutaneous disc decompression techniques occurring in up to 0.24% per patient and 0.091% per disc of patients followed in sequence of appearance by epidural abscess [14, 23-28]. Less frequently encountered complications of the technique include reflex sympathetic dystrophy, puncture of thecal sac with accompanying headache, haemorrhage and neurologic injury, allergic reactions to any of the agents used during the procedure, pneumothorax (in case of thoracic intervertebral disc decompression) and vasovagal reactions (in case of cervical intervertebral disc decompression) [13, 23-25, 29]. In addition, material failure, resulting to open surgery has been described [30]. Finally, there is a case of cauda equine syndrome reported by Onik and Maroon due to improperly placed nucleotome but this was related to an interlaminar approach [31].

OUTCOME MEASURES (Table 1):

METHOD	SUCCESS RATE	COMPLICATION RATE
Automated Percutaneous Lumbar Discectomy (APLD)	75% [32, 33]	Technical failure rate 2.6% Mild muscle spasm 9% Functional lower limb paresis 0.4% [34]
Percutaneous Laser Decompression	63-89% [13, 35-37]	Intra-operative 1.1% Post-operative1.5% [38, 39] General complication rate 0.5-1% [40]
Intradiscal electrothermal therapy **(**IDET)	64-75% [12, 28, 41-43]	Transient and mild adverse events (radicular pain, paresthesia numbness) 0-15% [44] Serious adverse events (cerebrospinal fluid leak, cauda equine syndrome, vertebral osteonecrosis) <0.5% [44] General complication rate from meta-analysis 0.8% [28]
Discogel	91.4% [51]	<0.5% [51]
Intervertebral Disc Nucleoplasty	79% [17]	<0.5% [44]
Ozon therapy	70-85% [45]	<0.5% [46-48]
Percutaneous disc decompression (PDD)	60-85% [49, 50]	0.5% [20]

Table 1: Outcome measures (success and complication rates) of percutaneous intervertebral disc therapies

QUALIFICATION AND RESPONSIBILITIES OF PERSONNEL:

Percutaneous ablative techniques of intervertebral discs should be performed by an experienced interventional radiologist trained adequately in the procedures. The pre-procedure setup, the post-procedure care and the patient's follow-up are all included in the operator's general responsibilities. Proper patient selection, strict sterility measures during the procedure, adequate follow-up and patient's obedience to given restrictions will result to higher success rates and even lower complication rates.

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