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Research Article

# Percutaneous Treatment of Degenerative Disc Disease with Radiopaque Gelified Ethanol (Discogel); Initial Experience in Iran

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## Abstract

**Background:** Minimally-invasive treatments of degenerative disc disease are becoming more popular. Various intra-discal procedures have been introduced since many years ago, with variable outcome. Discogel has been recently introduced with promising results.

**Purpose:** To present our initial experience with intra-discal injection of Discogel in Iranian patients, to evaluate its efficacy and safety.

**Material and Methods:** 100 Patients with symptomatic lumbar or cervical disc herniation who failed conservative nonsurgical treatment, were included into the study. Discogel was injected under controlled fluoroscopic/CT scan guidance using standardized techniques. For patient evaluation, regular follow ups were carried out for assessing pain intensity on visual analog scale (VAS).

**Results:** The procedure lasted from 15 to 90 minutes depend on the number of levels that must be injected, and the whole admission took from 3 to 24 hours. Median VAS score was 10 before injection, which dropped to 5 at 1 week post-injection, and 0 at 1 month post- injection. Only 3 patient reported significant remaining pain at 1 months of follow- up that underwent operation intervention. No complications were noted.

**Conclusion:** This preliminary study shows efficacy and safety of Discogel intradiscal injection in selected cases. Further long-term follow-up is needed to evaluate the results.

**Keywords:** Discogel; Disc Herniation; Radiopaque Gelified Ethanol

## Introduction

Minimally-invasive treatments of degenerative disc disease are becoming more popular. Various intradiscal procedures have been introduced since many years ago, with variable and inconsistent outcome. Discogel, a new similar substance composed of ethanol mixed with Ethyl cellulose and radiopaque material, has been recently introduced with promising results. In this study, we try to present our initial experience with intradiscal injection of discogel in Iranian patients, to evaluate its efficacy and safety.

## Materials and Methods

To evaluate the efficacy of radiopaque gelifield ethanol (Discogel) in cervical and lumbar intervertebral disc herniation, this prospective study was setup. The study protocol was approved by hospital ethical committee. We obtained informed consent from all patients, letting them know it is a new treatment with all details. We started our experience with discogel in Tehran, Iran from August 6$^{th}$ 2014 until December 31$^{st}$ 2014. 100 patients with symptomatic cervical or lumbar disc herniation, who failed conservative non-surgical treatment, were included into the study. Procedure were performed with local anesthesia in surgical condition and under digital fluoroscopic guidance [1,2].

All patients underwent to physical evaluation by Neurosurgeon, Interventional radiologist, Pain specialists or Spine surgeons, and neuroradiological examination with cervical or lumbar X-ray, MRI, CT-scan or both [3]. The exclusion criteria was asymptomatic disc bulging as incidental finding in MRI, canal and foraminal stenosis, spondylolisthesis, segmental instability/fracture, local and systemic infections, pregnancy, Cauda Eq. syndrome, large extruded disc specially noncontagious fragment and Efficacy of medical treatment.

According to standard protocols for intradiscal percutaneous technique in cervical disc herniation, positioning of patient is supine with a cushion under neck with hyperextension of the neck. Approaching to disc is from Right antero-lateral of the cervical disc. Before needle insertion, Carotid artery is detected by its pulsation and avoided, trachea and esophagus also pushed to remove them from pathway. Approaching to the lumbosacral disc required a cranial tilt of the C-arm at roughly 45 degree obtain good visualization of the disc space. Prone position is more stable for the patient (or lateral decubitus) [3,4]. A cushion was positioned under the abdomen to straighten the lumbar curve. The feet were rested on a pillow. A paramedian line 8 to 10 cm (12 cm) parallel and lateral to the midline was drawn depending to the patient corpulence [2].

A 20 gauge spinal needle was used for cervical Intradural disc herniation (IDH) and 18 gauge spinal needle for lumbar IDH and also a 22 gauge spinal needle for local anesthesia [2,3].

Injections performed in the middle of the nucleus pulposus paralleled at midway between two endplates [3].

The quantity of discogel injected per disc varies between 0/5-0/6 ml for cervical disc and 0/8 - 1/6 ml for lumbar disc, under controlled fluoroscopic/CT scan guidance using standardized techniques [1-3,5]. Discogel was well shaken for 5 minutes before aspiration and refrigerated just prior to injection for increasing the viscosity. Procedure performed with local anesthesia (5 ml Liducaine 2%) in surgical condition and under digital fluoroscopic guidance [1,2]. It injected very slowly for prevention of increasing in disc space pressure (0/1 ml every 30 seconds) [3].

Once discogel was injected, the needle remains in place for 5 - 10 minutes. Then, intradiscal injection of 1 to 3 mg of Gentamycin was performed at the end of procedure in all cases for prevention of infection [1,4]. Then, intra-articular steroid (20 mg Triamcinolone) was injected in the adjacent facet joint in all patients to help reduce inflammation [1,3]. In case of bilateral symptomatology injection was done in both facet joints (20 mg each). Three hours after injection, all patients had a thin slice computed tomography (CT scan) of treated level. The scan showed the discogel distribution in the nucleus pulposus in its herniated section [1,3].

Patients discharged from the hospital with analgesic and anti-inflammatory drug until the follow-up consultation after 7 days. For patient evaluation during the course of treatment, these follow ups were carried out at first day and also at first, fourth, sixth, eighth, and twelfth week assessing pain intensity on visual analog scale (VAS), with limitation on physical activity for 3 weeks. Although some physical maneuvers were recommended, Medical treatment modified depending on the residual symptom. All patients were visited 6 weeks after treatment.

## Results

100 patients were injected, aged 20 - 78 (mean = 44.4 ± 9.7). There were 29 cervical and 71 lumbar cases. The length of Symptomatic period before treatment was 2 months - 10 years. This was the first intervention for all patients except for 3 of them that had a history of previous surgery in another levels.

The procedure lasted from 15 to 90 minutes depend on the number of levels that must be injected, and the whole admission took from 3 to 24 hours. None of the patients undergo general anesthesia. There were no neurologic deficit, fever, allergic reaction, infection and any medical or surgical complications.

Median VAS score was 10 before injection, which dropped to 5 at first week Post injection, and zero at first month post injection. Only 3 patients reported significant remaining pain at one month of follow up that underwent operative intervention. Initial results indicating more than 96.5% good and very good results. No complications were noted.

## Discussion

Gelified ethyl alcohol (Discogel) is a sterile viscous solution. According to Prof. Theron's study, 96% pure ethyl alcohol could produce a local necrosis of nucleus pulposus and dehydration of the turgescent and protruding disc compressing the peripheral nerves of the spine and causing extreme pain [1,3]. Among percutaneous intervertebral disc therapies (Automated Percutaneous Lumbar Discectomy (APLD), Percutaneous Laser Decompression, Intradiscal electrothermal therapy (IDET), Intervertebral Disc Nucleoplasty, Ozone therapy and Percutaneous disc decompression (PDD) ), discogel has the most success rate and the least complication rate [6,7].

In the "Image-Guided Interventions" book, success rate is between 89% and 91% of cases, with no minor or major complications [8]. Initial results of our study indicating more than 96.5% good and very good response which is compatible with recent studies in this field.

Discogel consist of contrast agent (tungsten powder) that makes us able to monitor spreading of it with fluoroscopy through cracks and tearing while injecting [9]. The addition of Ethyl cellulose permits to get a viscose product and prevent leakage. It is also conceivable a direct effect of ethanol on the disc pain receptors by turning out the nervous endings. Freemont [3,10] and Coppes [3,11] demonstrated the presence of nerve fibers into the inner layers of the

annulus fibrosus and in the nucleus pulposus in degenerative painful discs and not in normal discs. In contact with the disc, Discogel changes quickly into a substance of a consistence close to a piece of cotton moistened with alcohol. This modification succeeded in the creation of a kind of soft intradiscal prosthesis that permits to deposit the product in the disc without significant leak toward the epidural space or nerve root and maintaining the height of intervertebral disc [12]. It also allowed us to get a more concentrated action of pure ethanol staying in the place for a minimal quantity of injected substance [1]. These topics should be confirmed by further larger studies.

## Conclusion

In conclusion this preliminary study shows efficacy and safety of Discogel intradiscal injection in selected cases. Further long-term follow up is needed to evaluate the results.

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