A Clinical Evaluation of Percutaneous Hydrodiscectomy

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Objective

To summarize and report on the clinical data available to date on the SpineJet™ Hydrodiscectomy System (HydroCision, N. Billerica, MA, USA) for the treatment of herniated nucleus pulposus.

Methods

An independent clinical consultant reviewed all of the clinical data obtained from published literature, pending publications, and data not published on file with Hydrocision, for percutaneous hydrodiscectomy.

Quality analysis was conducted using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, developed by the US Preventive Services Task Force[1], as illustrated in Table 1 below.

Table 1. *Quality of Evidence developed by USPSTF.*

I	Evidence obtained from at least one properly randomized controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomization
II-2	Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of penicillin treatment in the 1940's) could also be regarded as this type of evidence
III	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees

Evaluation of the effectiveness of percutaneous hydrodiscectomy was determined based upon improvement in radicular symptoms. Short-term success was defined as $\leq$ 6 months relief and long term success was defined as > 6 months of pain relief based on the criteria used by Parr[2] and Manchikanti[3] in their systematic reviews of lumbar epidural steroid injections.

Evaluation of the safety of percutaneous hydrodiscectomy was based upon the absence of device related serious adverse events as defined by the International Standard ISO 14155:2011.

Results

A total of 10 data sources were available for review: Level I quality of evidence, n=1, Level II-3 quality of evidence, n=4 and Level III quality of evidence, n=5. A total of 309 patients were treated with percutaneous hydrodiscectomy and available for the clinical summary. A summary of study characteristics and results of the review are tabulated in Table 2.

The most important data set for contributing to the overall performance of the SpineJet Hydrodiscectomy System is the Level I and II-3 quality of evidence data with long-term follow-up. The 3 studies comprised of 119 patients, demonstrate consistent long-term success rates ranging from 73- 98.6% and no device related adverse events. [4,5,6]

The short-term follow-up data consists of 3 Level II-3 and 3 Level III quality of evidence data sets for a total of 191 patients with consistent success rates of 88-94% and no device related adverse events [7, 8, 9, 10, 11]

Two Level III case reports on 2 patients demonstrate short-term effectiveness and positive safety results.

Table 2. *Characteristics of studies of percutaneous hydrodiscectomy for Lumbar HNP*.

Study/Methods	Patient Population	Results	Conclusion(s) *Effectiveness* Short-term relief ≤ 6 mos. Long-term relief > 6 mos. *Safety* No device related SAEs
Cristante, et al. 2013.[4] Level I: Randomized, controlled trial	40 pts. with MRI evidence of minor disc herniation or protrusion at a single level randomized to open lumbar microdiscectomy or percutaneous hydrodiscectomy.	Statistically significant improvement in ODI and leg VAS, non-statistical improvement in back VAS at 12-month f/up. Four of 16 (20%) patients had subsequent intervention. 1 post-op infection and 1 death related to complications from baseline illness (HIV).	80% Long-term effectiveness and positive safety profile.
Wang et al. 2010[5] Level II-3: Retrospective, multi-center	69 pts. with confirmed diagnosis of uncomplicated lumbar disc herniation in accordance with McCulloch criteria and MRI or CT. Mixed type canal stenosis, lumbar spondylolisthesis and migrated nucleus pulposus excluded.	98.6% excellent and good response based on MacNab criteria at 9 months post-op. 1 case of post-op infection.	98.6% Long-term effectiveness and positive safety profile.
Jasper 2013[6] Level II-3: Retrospective, observational, single center, two physician	30 pts. with dominant symptom of leg or back pain and disc herniation at 1-3 levels confirmed by imaging . Excluded sequestered herniation, disc height loss of >50%,	Statistically significant improvement in NRS at 12-month follow-up. 73% excellent and good based on MacNab criteria. Pain medications significantly reduced by 53% and 43%	73% Long-term effectiveness and positive safety profile.

	severe DDD or osteophytic spinal stenosis and spinal instability.	for opiods and NSAIDs respectively ($p<0.2$). No complications reported.	
Han et al. 2009[7] Level II-3: Retrospective, multi-center	13 pts. with soft disc herniation; 12 with LBP & radiculopathy, 1 with back pain only.	Statistically significant improvement in ODI, leg and back VAS at mean f/up of 5.5 months. 12 pts excellent and good results based on Odam's criteria. No complications reported	92% short-term effectiveness and positive safety profile.
Hardenbrook et al. 2013[8] Level II-3: Retrospective, multi-center	50 pts. with radiculopathy secondary to lumbar HNP confirmed by MRI at 1-2 levels. Free fragment, central stenosis or bony impingement excluded.	94% improvement in back pain and radiculopathy at mean f/up of 4.6 months. 3 patients had recurrent herniation after successful treatment. No complications reported.	94% short-term effectiveness and positive safety profile.
Lo 2012[9] Level III: Retrospective, case series	97 pts. with contained lumbar disc herniation < 6mm and radiculopathy confirmed by imaging. Excluded extruded and sequestered herniation.	Statistically significant improvement in ODI, leg and back VAS at mean f/up of 6 months. 88% excellent and good based on MacNab criteria. 90% returned to work < 2weeks. No complications reported.	88% short-term effectiveness and positive safety profile.
Borschenko, et al. 2010[10] Level III: Retrospective, case series	16 pts. with confirmed disc bulging (protrusion or small disc extrusion) at a single level.	Statistically significant improvement in SF36, leg and back VAS at mean f/up of 6 months. 88% excellent and good based on MacNab criteria. No complications reported.	88% short-term effectiveness and positive safety profile.
Kowalkowski 2013[11] Level III: Retrospective, case series	15 pts. with radiculopathy secondary to subligamentous lumbar HNP at a single level	Statistically significant improvement in VAS and ODI at mean f/up of 4 months. 93% improvement in symptoms.	93% short-term effectiveness and positive safety profile.
Jasper, et al. 2005[12] Level III: Case Report	1 pt. with LBP greater than leg pain due to large left paracentral L5/S1 disc herniation.	Remains pain free at 6 months. No complications reported.	Short-term effectiveness and positive safety profile.
Gerges, et al. 2013[13]	1 pt. with LBP and radicular pain due to L5/S1 moderate left	At 2 weeks back pain reduced from 5/10 to 1/10 and leg pain completely	Short-term effectiveness and positive safety profile.

Level III: Case Report	lateral disc protrusion compressing on L5 nerve root.	resolved. No complications reported.	

Conclusion

The safety and effectiveness data for the percutaneous hydrodiscectomy studies are consistent across all data sources. There are no device related complications and success rates ranged from 73–98.6%. The high success rates combined with the positive safety profile associated with the use of the device are acceptable when weighed against the benefits to the patient. The reported clinical data support the use of the SpineJet Hydrodiscectomy System in the treatment of lumbar herniated nucleous pulposus in this select group of patients.

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