

Medium to long-term functional outcome of patients after chemonucleolysis

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Chemonucleolysis is an established modality in the treatment of lumbar disc prolapse and has been widely used for over 39 years since its introduction by Lyman Smith in 1963. We report the medium to long-term functional outcome of patients who had chemonucleolysis for single level disc prolapse. One hundred and twelve patients were reviewed retrospectively with a mean follow-up of 9.5 years. The Oswestry Disability Index questionnaire was used to estimate the functional outcome of chemonucleolysis. An excellent or good response occurred in 79 patients (70.5%) while 12 patients (10.7%) showed moderate response with minimal disability. Treatment failed in 21 patients (18.5%) who showed poor response and 12 of these 21 patients went for surgery within a mean period of 6 months. One patient had surgery at a different level than chemonucleolysis. There was only one incident of procedure termination because of epidural contrast leak. There was no case of anaphylaxis or discitis. We concluded on the basis of our results that in carefully selected patients, chemonucleolysis is a safe and effective treatment modality for lumbar disc herniation with good medium to long-term functional outcome.

INTRODUCTION

In 1941 Jansen and Balls (5) first isolated chymopapain which is a proteolytic enzyme contained in crude papain, a mixture derived from the papaya plant. Lyman Smith and Joseph Brown first used chymopapain in 1963 as an intradiscal injection for removing the nucleus pulposus of degenerate and protruded intervertebral herniated disc and hence formulated the term 'Chemonucleolysis' (14, 15). It

is suggested that chymopapain causes hydrolysis of non-collagenous protein and inhibits the ability of proteoglycan to bind with water, which then leads to breakdown of cartilage (16). Controversy regarding chemonucleolysis started when a study demonstrated no statistical difference in improvement between a placebo and the chymopapain group (12). However critical analysis of the study later showed that the placebo was poorly selected, insufficient doses of chymopapain were given and there was lack of technical expertise among the investigators (2). In 1983 the first multi-centre, double blind study performed by Javid *et al* demonstrated a 75% response to chymopapain as compared to 45% to placebo (6). Another double blind study by Gogan and Fraser (4) also showed positive results for chemonucleolysis.

Chemonucleolysis should only be offered to those patients who have sciatica due to disc prolapse and also, otherwise would undergo surgical removal of the prolapsed disc. This selection of patients is vital for the success of chemonucleolysis. Relative contraindication of chymopapain

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use includes iodine allergy, rupture of the annulus fibrosus, previously operated discs or paediatric age group, while specific contraindications to its use include known papaya sensitivity, severe spondylolisthesis, severe progressive neurological deficit or paralysis, evidence of spinal cord tumour / cauda equina syndrome, injection above cauda equina level (L2 level) and pregnancy.

We conducted this study to investigate the medium to long-term functional outcome of patients after single level chemonucleolysis.

METHODS

We present here our experience with chemonucleolysis at a regional orthopaedic centre. The aim of this retrospective study was to analyse the medium to long-term functional outcome of patients who were treated with chemonucleolysis for single level herniated lumbar discs at Merlin Park Regional Hospital, between 1988 and 1996 by a single surgeon (MFXG).

McCulloch's clinical criteria (8) were used for patient selection. CT scans were also performed to confirm the clinical findings. Conservative treatment was tried for at least six weeks for all the patients before they were listed for chemonucleolysis. Only patients with single level disc involvement were included in this study. No patient in this series had multiple injections and none of these patients had previous chemonucleolysis or laminectomy.

Image intensifier was used for the chemonucleolysis, which was performed with a standard posterolateral approach. Patients were discharged the following day with back care instruction and were advised not to work for three weeks after chemonucleolysis. Physiotherapy to the back was not a routine after the procedure. All the patients were assessed with postal questionnaire using Oswestry disability index (3). An Oswestry disability index calculates scores on the scale of 0 to 100, where 0 to 20 indicates minimal disability, 21 to 40 is for moderate disability, score of 41-60 signify severe disability and 61 to 80 is for completely disabled patients. A score higher than 81 means that the patient is bed bound.

RESULTS

The total number of patients who had chemonucleolysis between 1988 and 1996 was 131. Of the 131 patients, 112 patients (85.5%) completed and

Table I. — Demographics

Total number of patients	131
Followed up patients	112
Lost to follow-up	19
Mean follow-up	9.5 years
Mean Age	35 years (22-68)
Number of Females	36 (32%)
Number of Males	76 (68%)

returned the Oswestry disability index questionnaires and were included in this study. A disc herniation was found at L5/S1 level in 51.7%, L4/L5 level in 39.6% and 1.7% disc herniation were at L3/L4 level. We failed to inject 6.8% of the patients.

In evaluating these questionnaires, any surgical treatment irrespective of the level excised was counted as a failure of chemonucleolysis. Out of 112 patients, an excellent or good response occurred in 70.5% while 10.7% showed moderate response with minimal disability. Treatment failed in 18.5% patients who showed poor response. Sixty six percent of the patients with poor response required surgery within a mean period of 6 months after chemonucleolysis. One patient had surgery at a different level than chemonucleolysis. There was one case of epidural contrast leak, where the procedure was abandoned. Two patients developed back spasm after the procedure, which was resolved in two days time. No case of anaphylaxis or discitis was seen in our series.

DISCUSSION

Chemonucleolysis is a minimally invasive therapy for intervertebral disc prolapse that still provokes controversy, though it has been thoroughly studied, evaluated and analysed. When compared with laminectomy, at 1 to 4 years follow-up, an overall success rate of 86.5% for chemonucleolysis and 83.8 % for laminectomy was seen (7). Another study comparing chemonucleolysis with percutaneous lumbar discectomy showed that at one year, an overall success rate for the percutaneous lumbar discectomy group was 37% while that in the che-

Table II. — Results

Oswestry Disability Index at Follow-Up			
Response	Number of Patients (%)	Mean Response (Weeks)	Mean ODI at follow up
Excellent	44 (39%)	5	0
Good	35 (31%)	9	8.5
Fair	12 (10.7%)	16	24
Poor (No Surgery)	7 (6%)	No response	35
Poor (Underwent surgery)	14 (12.5%)	No response	44

monucleolysis group was 66%. Within 6 months of treatment, 7% of the patients in the chemonucleolysis group and 33% in the discectomy group underwent subsequent open surgery (11).

It is also a common opinion that chymopapain results in more complications than open surgery. Actual comparison of usual complications however reveals that laminectomy has a 17 times higher infection rate, 6 times more neurological and vascular problems and 3 times more overall mortality as compared to chemonucleolysis (9).

We have used the Oswestry Disability Index for the functional outcome. Our study showed that at a mean follow-up of 9.5 years, an excellent or good response occurred in 70.5% of the patients and another 10.7% of the patients showed moderate response with minimal disability. The results reported here in our study are similar to those reported by others and confirms previously published data regarding improvement and cure percentages (1, 10).

Adverse effects observed in our case series have been reported in the past (9). Leakage of chymopapain into the epidural space has occurred in a single patient and back spasms were reported in a further two, but besides that we did not come across any other complications such as discitis or anaphylaxis.

As recommended in the literature (8, 13), chemonucleolysis was only offered to those patients who had sciatica due to disc prolapse and also, otherwise would have undergone surgical removal of the prolapsed disc. This selection of patients is vital for the success of chemonucleolysis. We conclude that chemonucleolysis is a simple, safe and effective modality in the treatment of lumbar disc herniation

in carefully selected patients with good medium to long-term functional outcome.

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