International Journal of Osteopathic Medicine (2015) 18, 181–188

International Journal of Osteopathic Medicine

www.elsevier.com/ijos

RESEARCH REPORT

Rehabilitation with osteopathic manipulative treatment after lumbar disc surgery: A randomised, controlled pilot study

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Received 22 April 2014; revised 2 October 2014; accepted 18 November 2014

KEYWORDS
Exercise;
Lumbar open laser microdiscectomy;
Osteopathic manipulative treatment;
Post-operative disability;
Residual pain;
Rehabilitation

Abstract *Background:* Despite growing evidence regarding the role of osteopathic manipulative treatment (OMT) for the management of low back pain, there is little evidence to support the use of OMT as a post-operative rehabilitation to improve the functional outcomes of lumbar disc surgery.
Objective: To assess the feasibility for a future definitive randomised control trial that would indicate whether OMT improves post-operative outcomes after lumbar microdiscectomy compared to a standard exercise programme.
Design: Randomised controlled pilot study.
Setting: Department of Spinal Surgery and Department of Spinal Rehabilitation at a major metropolitan spine surgery hospital, Seoul, South Korea.
Methods: Patients who underwent lumbar microdiscectomy due to low back pain with referred leg pain resulting from a herniated disc were enrolled in the study. Thirty-three patients aged 25–65 years were randomly assigned using a random number table to the OMT ($n = 16$) group or exercise group ($n = 17$). Patients received the allocated intervention twice a week for 4 weeks. Each session was 30 min. Primary outcomes were post-surgical functional disability and intensity of low back and leg pain. Outcome measures were assessed at baseline (2–3 weeks

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http://dx.doi.org/10.1016/j.ijosm.2014.11.003

after surgery) and post-intervention (7—8 weeks after surgery). Double blinding was not feasible in the study setting.
Results: Thirty-three participants were analysed. Both rehabilitation interventions improved all primary and secondary outcomes. Post-surgical physical disability improved more with OMT rehabilitation than the exercise programme (54% vs. 26%, $P < 0.05$). Residual leg pain decreased with OMT (53%) and exercise (17%). Post-operative low back pain decreased by 37% in the OMT group and 10% in the exercise group. Patients in both groups required less frequent use of medication and were highly satisfied with the rehabilitation interventions. No side effects or complications from any intervention were reported.
Conclusion: The current pilot study shows the feasibility of a future definitive randomised control trial investigating whether rehabilitation with OMT is a viable approach for post-operative management of a lumbar microdiscectomy.

Implications for practice

- OMT may be a feasible approach for post-operative management for lumbar disc surgery.
- OMT reduced early post-operative physical disability and residual pain, with less frequent use of analgesics.
- OMT combined with surgical care for lumbar disc patients would be an valuable integrative health care model.

Introduction

Low back pain is a worldwide health problem with a lifetime prevalence rate of 80%, which affects daily physical activities.[1] Lumbar disc pain accounts for <5—10% of low back pain, but is one of the most common reasons for lumbar spine surgery.[2,3] Although <1% of patients with low back pain require surgical intervention, lumbar discectomy is one of the most commonly performed operations because of its earlier effect of reducing physical disability and relieving nerve root pain, compared with other non-operative treatments.[4,5]

Despite the objectively successful outcomes of the surgery to remove the disc material causing the pain, patient-centred unsatisfactory outcomes have been sporadically reported. The main unsatisfactory complications observed in patients following lumbar discectomy are continued post-operative physical disability affecting daily activities and residual low back and leg pain.[6,7] Therefore, post-surgical rehabilitation has been considered important to optimise the surgical outcomes by minimising these post-surgical physical complications.

Many types of post-operative rehabilitation programmes following lumbar disc surgery have been implemented including home care training, behavioural graded activity, and exercise therapy.[8—11] These interventions have been heterogeneous with regard to the timing, duration, and intensity. Although the optimal rehabilitation intervention after lumbar disc surgery is unknown, exercise programmes have been the most commonly used post-operative rehabilitation and shown to be more effective than no treatment for the residual post-operative pain at short-term follow-up.[12] Studies of high-intensity exercise rehabilitation starting immediately or 4—6 weeks after surgery have indicated that such programmes have led to a faster decrease in disability and pain than no treatment or low-intensity programmes.[13—16]

Osteopathic manipulative treatment (OMT) has been used for the management of low back pain. OMT was recommended by a recent consensus guideline for improving physical disability caused by acute and chronic low back pain.[17—19] In addition, the long term analgesic effect of OMT on lumbar spine pain was reviewed.[20] Moreover, this hands-on treatment requires significantly less analgesic use and has higher satisfaction than that associated with the standard care for low back pain.[21]

Despite growing evidence regarding the role of OMT for the management of low back pain, there is little evidence to support the use of OMT as a post-operative rehabilitation intervention to optimise the outcomes of spinal disc surgery. We performed this pilot study comparing OMT with exercise following lumbar disc surgery to assess the feasibility for a future definitive randomised control trial.

Methods

Study design

This study was a prospective, randomised controlled pilot study. The study was conducted at a major metropolitan spine surgery hospital where all participants underwent lumbar microdiscectomy. Two research spinal surgeons registered in Korea and a research osteopath registered in the UK conducted patient recruitment and screening. The study protocol was approved by the institutional review board of the University of Korea, and all participants provided written informed consent.

Participants

Patients between 20 and 65 years of age who had low back pain and referred leg pain resulting from a herniated lumbar disc and underwent lumbar microdiscectomy were identified by hospital nurses. No formal sample size calculation was performed. Forty-eight patients who met the eligibility criteria and wanted to participate in the study were interviewed and screened by two research surgeons. Exclusion criteria included revision surgery or other forms of combined surgery, refusal to participate, or contraindication for participation including pregnancy, metastatic disease, or a mental disorder. Of the 48 patients, 15 were excluded and the remaining 33 were randomly allocated to either the OMT group ($n = 16$) or the exercise programme group ($n = 17$) (Fig. 1).

Procedure

The 33 patients who underwent lumbar microdiscectomy, which was performed by 2 neurosurgeons at the spine surgery hospital, returned to the hospital 2–3 weeks after the surgery for baseline measurements and the first rehabilitation intervention. Each participant was randomly assigned to one of two intervention groups. The allocations were conducted using simple randomisation with a random number table by a research physiotherapist at the hospital who was not involved in the intervention or measurement. The sequentially

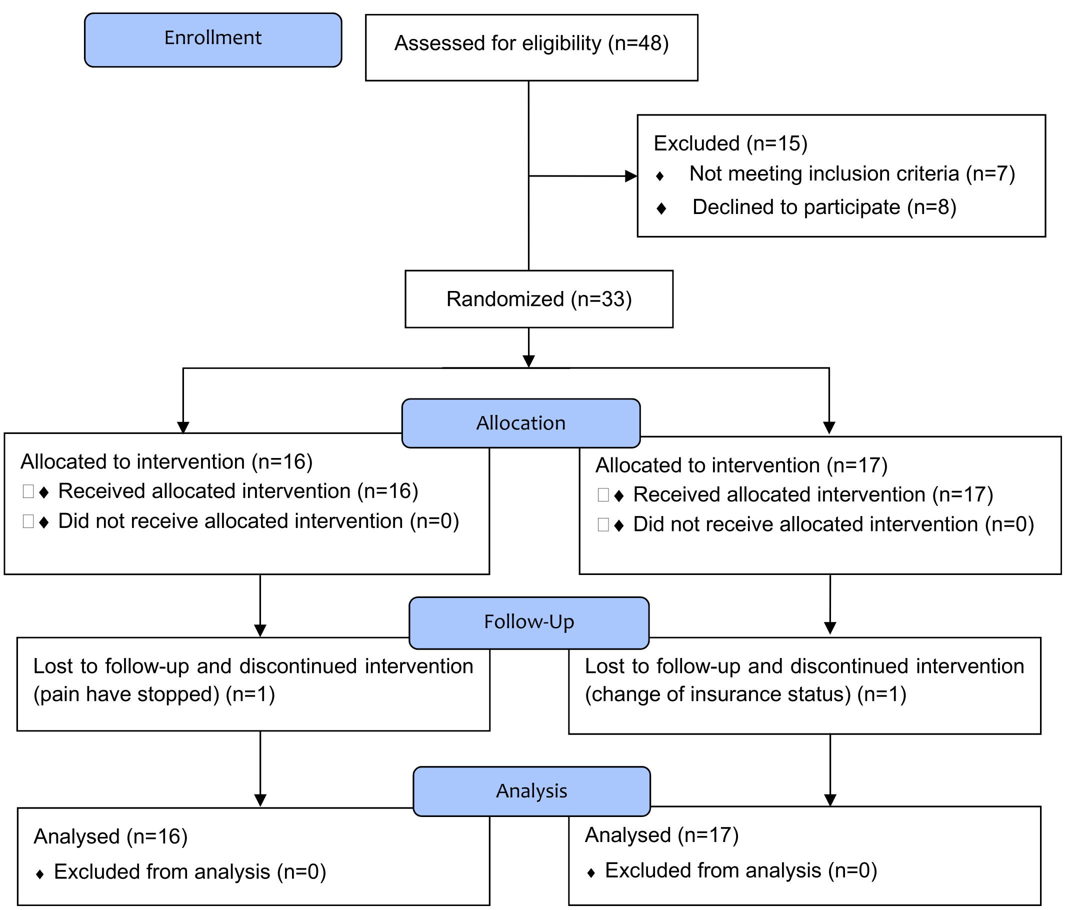

Fig. 1 The flow of participants throughout the study.

numbered, sealed envelopes were used for allocation concealment and were opened sequentially. Blinding of participants and clinicians was not considered to be feasible because this was a pragmatic open pilot study. Blinding the participants to allocation to either OMT or the exercise programme was not possible. We took steps to blind the evaluation of outcomes by having questionnaire responses in sealed envelopes. Outcome measures were assessed by a physiotherapist who was not involved in any intervention and was blinded to the group assignment. Both interventions consisted of eight individual sessions performed twice a week for 4 weeks. Each session was 30 min. All patients in both groups were prescribed supplementary anti-inflammatory medication, analgesics, and a muscle relaxant by surgeons.

Intervention

OMT rehabilitation

All patients underwent physical assessment prior to each intervention. The same practitioner applied a combination of techniques in the standardised protocol for the OMT (Fig. 2), but the intensity and sequence of the techniques were modified for each patient depending on their tolerance to treatment and other post-operative physical conditions. The protocol did not include spinal high-velocity, low-amplitude thrust (HVLAT) manipulation of the lumbar segments where the surgery was performed. The focus of the OMT protocol was to reduce biomechanical overload on the lumbar spine by functionally improving the motion of adjacent spinal segments or joints including the thoracic and cervical segments and the sacroiliac joint. The protocol included techniques applied to myofascial structures to reduce post-operative physical tension and stiffness generated in the body. Each OMT intervention was performed by two osteopathic students under the supervision of a qualified osteopath. Each treatment process was documented and reviewed by an allocated research osteopath and surgeon.

Exercise

Each individual exercise session was also conducted within the protocol. The programme aimed to improve spinal mobility and stabilise the lumbar segments. For the first week, practitioners focused on stretching exercises for the back and abdominal muscles with the patient in the supine position. In the next 2 weeks, practitioners focused on isometric strengthening exercises for the back and hip extensors with the patient in the prone position or sitting on a gym ball. In the final week, the intensity of the previous exercises was increased and back stability exercises were performed using a Pilates exercise apparatus.

Outcome measures

Outcome measures were assessed at baseline (2—3 weeks after surgery) and post-intervention. The post-intervention evaluation was conducted a week after the final rehabilitation session (7—8

OMT Techniques *	Rationale for Use
Soft Tissue and Joint mobilisation	For functional improvement of lumbar spine
To cervical spine and paraspinal muscles	For functional improvement of lumbar spine
To thoracic spine and paraspinal muscles	
Myofascial Release	For functional improvement of lumbar spine
To illiotibial band and tensor fascia lata	For releasing fascial restriction over lumbar spine
To thoracolumbar fascia	For improving coactivation with lumbar paraspinal muscles
Neuromuscular Technique	For improving coactivation with lumbar paraspinal muscles
To quadratus lumborum	
Muscle Energy Technique	For improving coactivation with lumbar paraspinal muscle
To transverse abdominis	For improving motion of lumbar spine
To psoas muscles	
Craniosacral Release	For better balance and parasympathetic function
To suboccipitalis	
Rib raising and mobilisation	For functional improvement of spinal muscles attached to ribs
To vertebrochondral joint	For improving sympathetic tone

* The protocol did not include spinal high-velocity, low-amplitude thrust (HVLAT) manipulation of the lumbar segments where the surgery was performed.

Fig. 2 Summary of osteopathic manipulative treatment (OMT) techniques applied in the post-operative management after a lumbar discectomy.

weeks after surgery). Primary outcome measures were the evaluation of post-operative disability and residual pain in the legs and low back using the Roland—Morris Disability Questionnaire with a 24-point scale (0—24, 0 = best)[22] and the Visual Analogue Scale (VAS, 0—100) with 0 indicating 'no pain' and 100 indicating 'the worst pain." Secondary outcomes included lumbar range of motion (ROM), use of medication, and patient satisfaction. The lumbar spine ROM at which the patients could move without pain was measured with a double inclinometer by a physiotherapist who was not involved in any intervention. The number of supplemental medications taken per week was used to assess medication consumption. The patient's satisfaction was measured at the final evaluation by using a self-grading questionnaire that indicated 'dissatisfaction', 'moderate satisfaction' and 'total satisfaction'. Patients were also asked whether they would recommend the rehabilitation intervention they received to a family member or friend with a similar condition.

Statistical analysis

Outcome measures were analysed using the intention-to-treat principle (with the last observation carried forward where necessary). The Shapiro—Wilk test was used to assess normality of distribution of the data. Numerical variables were summarised as means ± SD or medians, whereas categorical variables were given as frequencies and percentages. Medians are shown for the ROM of lumbar extension and left side-bending, and for the number of times medication was used. The categorical data were analysed using the chi-square test or Fisher's exact test to account for baseline variations. The Student's *t*-test or the Mann—Whitney *U* test was applied to compare the differences between the groups at baseline. Primary analyses were the comparisons of between-group differences of the outcome measures by using an analysis of covariance (ANCOVA) with baseline values as covariates. SPSS statistical software (Version 12.0, SPSS Inc., Chicago, IL) was used for the analyses. Two-sided tests and a significance level of 0.05 were used for all statistical analyses.

Results

Subjects

Of the 48 patients deemed eligible for inclusion, 69% (33 of 48) were enrolled and randomly allocated to either the OMT ($n = 16$) or exercise group ($n = 17$). There were no significant differences in baseline characteristics (Table 1) and baseline measures (Table 2) between the two groups. The primary reason for non-enrolment was lack of interest in participation. Of the enrolled patients, 6% were lost to follow-up at the primary study endpoint (2 of 33, 1 in each group). All the patients ($n = 33$) who were randomly assigned to a group were analysed on an intention-to-treat basis.

Outcomes

Primary outcomes

OMT and the exercise programme improved all primary outcomes. Post-surgical physical disability was more improved by OMT rehabilitation (54% vs. 26%, $P < 0.05$). Residual leg pain after the lumbar discectomy decreased in the OMT group with a 53% reduction from baseline compared to the exercise group which had a 17% reduction. Residual low back pain also decreased in both interventions with a 37% reduction in the OMT group and a 10% reduction in the exercise group (Table 2).

Secondary outcomes

There was overall improvement in lumbar spine ROM at which patients could move without pain in OMT group and exercise group (Table 2). Patients in the groups required less frequent use of medication; 87% reduction in the OMT and 73% in the exercise (Table 2). All patients in both groups responded that they were highly satisfied with the post-operative rehabilitation and answered that they would recommend the post-operative rehabilitation to a family member or a friend undergoing

Table 1 Characteristics of the patients at baseline.

Characteristics[a]	Osteopathy ($N = 16$)	Exercise ($N = 17$)
Age, yr	46.4 ± 12.3	46.6 ± 11.9
Sex, no. (%)		
Male	6 (38)	5 (29)
Female	10 (62)	12 (71)
Endoscopic laser microdiscectomy Level, no. (%)		
L3-4	0 (0)	2 (12)
L4-5	8 (50)	6 (35)
L5-S1	3 (19)	6 (35)
Multi-levels	5 (31)	3 (18)
Post-operative days for rehabilitation	16.1 ± 3.7	14.1 ± 2.3

[a] There were no statistically significant differences between the groups.

Table 2 Primary and secondary outcomes before and after interventions.

Measure	OMT	Exercise	*P* value
Primary outcome			
Physical Disability (RDQ)			
Pre intervention[a]	6.7 ± 5.5	8.8 ± 4.4	>0.05
Post intervention	3.1 ± 2.8	6.5 ± 4.8	
Change scores	3.6 ± 5.1	2.2 ± 4.5	0.048
Residual Leg Pain (VAS)			
Pre intervention[a]	35.6 ± 27.1	44.7 ± 26.4	>0.05
Post intervention	16.9 ± 14.9	37.4 ± 28.5	
Change scores[b]	18.8 ± 33.6	7.4 ± 22.2	0.81
Residual Low Back Pain (VAS)			
Pre intervention[a]	29.1 ± 27.1	31.8 ± 17.1	>0.05
Post intervention	18.1 ± 12.8	28.5 ± 19.2	
Change scores[b]	10.9 ± 25.3	3.2 ± 18.1	0.29
Secondary outcome			
Flexion (ROM)			
Pre intervention[a]	27.1 ± 11.7	22.5 ± 12.9	>0.05
Post intervention	34.0 ± 11.3	28.5 ± 13.2	
Change scores[b]	6.9 ± 9.5	6.0 ± 7.4	0.51
Extension (ROM)			
Pre intervention[a]	8.3 ± 5.8 (8)	8.2 ± 8.9 (5)	>0.05
Post intervention	11.7 ± 7.3 (13)	8.9 ± 6.5 (6.5)	
Change scores[b]	3.3 ± 8.5 (1)	0.7 ± 5.3 (0)	0.24
Right Side Bending (ROM)			
Pre intervention[a]	13.5 ± 14.9	11.4 ± 6.8	>0.05
Post intervention	14.9 ± 8.2	14.8 ± 7.8	
Change scores[b]	1.4 ± 6.7	3.5 ± 1.0	0.76
Left Side Bending (ROM)			
Pre intervention[a]	13.1 ± 6.6 (16)	11.2 ± 6.6 (10)	>0.05
Post intervention	16.6 ± 7.9 (16)	12.9 ± 6.8 (12.5)	
Change scores[b]	3.5 ± 7.6 (1)	1.6 ± 7.7 (0.5)	0.25
Medication Use (weekly)			
Pre intervention[a]	13.8 ± 1.0 (14)	13.4 ± 1.5 (14)	>0.05
Post intervention	1.8 ± 4.8 (0)	3.7 ± 4.5 (1.5)	
Change scores[b]	12 ± 4.7 (14)	9.8 ± 5.1 (11.5)	0.28

All values are means ± SD or median in the brackets.
RDQ, Roland–Morris Disability Questionnaire (0–24, 0 = best).
VAS, Visual-Analogue Pain Scale (0–100, 0 = best).
ROM, Range of motion of lumbar spine in degrees (from 0, 0 = worst).
Medication use, number of times consumed per week (0–14, 0 = best).
[a] Student's *t*-test or the Mann–Whitney *U* test.
[b] ANCOVA with baseline values as covariates.

spinal surgery. No side effects or complications from any intervention were reported.

Discussion

In this pilot study, we showed the feasibility of OMT for post-operative rehabilitation after lumbar disc surgery compared to an exercise programme. The early post-operative physical disability and residual pain in the low back and legs were reduced by both rehabilitation interventions. These two post-operative cares also improved the active range of motion of the lumbar spine and were shown to be a safe approach without side-effects and high satisfaction.

The use of OMT for post-operative care after other surgeries has been observed. Jarski et al.[23] and Licciardone et al.[24] found that OMT rehabilitation is a feasible approach to improve physical function and pain management after knee or hip arthroplasty. Moreover, several studies have shown the beneficial effects of OMT in the post-operative recovery of patients who have undergone coronary artery bypass graft operation.[25,26] However, there has been no trial to determine the use of OMT for post-operative recovery after lumbar disc surgery despite growing evidence supporting the role of

OMT for the management of low back pain and post-operative rehabilitation after various surgeries. The present study, to our knowledge, is the first pragmatic, randomised, controlled pilot trial to assess the feasibility of OMT for post-operative rehabilitation after lumbar disc surgery. The present pilot study also showed the applicability of the combination of lumbar disc surgery and OMT rehabilitation in a pragmatic setting where the medical professionals including spinal surgeons, physiotherapists, nurses and an osteopath were involved in the study procedure.

The current study has several limitations. It is difficult to determine whether the post-operative outcomes of OMT rehabilitation can be maintained long-termly because of a short follow-up duration. However, the information regarding the short-term beneficial effect of the early applied rehabilitation would be important because the main expectations of patients undergoing lumbar microdiscectomy are early return to work or normal daily activities after disc surgery.[27,28] Osteopathy is a patient-centred system of healthcare with individualised diagnosis and treatment. The manipulative techniques are only part of a philosophy of care. Therefore, the unavailability of fully trained osteopath but osteopathic students to perform OMT intervention was also a study limitation. However, the intensity, sequence and selection of the treatment techniques were individualised to each patient depending on their physical conditions such as tolerance to treatment on the day of the intervention within the standardised OMT protocol. The research osteopath who was fully trained and registered and surgeon reviewed the each assessment for the treatment and supervised the OMT rehabilitation when required.

The lack of blinding was also a methodological weakness. In the pragmatic study, however, it was not possible to prevent the patients from knowing the rehabilitation interventions. We explained the type of rehabilitation being used upon inquiry. In particular, the patients allocated to the OMT group were not familiar with osteopathic treatment. Since the lack of a placebo control group, the study result is limited to determine whether the post-operative outcomes were improved by the interventions themselves or whether they were related to other aspects of the interventions. Factors such as time spent with patients or frequency of patient's visits may represent placebo effects. However, it was not desirable to use a sham treatment or no treatment because of ethical considerations concerning loss of chance for patients to improve the early post-operative outcomes. In addition, it is difficult to develop an OMT placebo at a pragmatic setting.

The results presented in this pilot trial comparing OMT with exercise will be valuable because the exercise programme we applied in the study has proven to be more effective rehabilitation to improve early post-operative disability and pain than no treatment, or other types of interventions such as self-homecare or programmes focusing on behaviour treatment.[10–13] Regarding timing and intensity of the rehabilitation, Kjellby-Wendt and Styf[15] found that an intensive programme starting immediately after lumbar discectomy had better short-term outcomes such as pain reduction and increased range of lumbar motion than less active programme. This was further confirmed by experimental studies[8,16] showing that vigorous exercise started 4–5 weeks postoperatively reduced physical disability and residual pain after lumbar disc surgery.

Findings from the present study are limited but support the feasibility for a future definitive trial. The future well-designed, adequately powered trial will require a larger sample size and long-term follow-up periods to confirm the effect of OMT rehabilitation. The use of fully trained and experienced osteopaths for the intervention should be considered in future research assessing the post-operative effect of OMT. The post-operative pain and its associated physical disability were more reduced in OMT, which required less use of medication; therefore a cost-effectiveness analysis should be perform.

Conflict of interest

None declared.

Ethical approval

Trial registration: 1040548-KU-IRB-13-26-P-1.

Funding

None declared.

Acknowledgments

The authors are indebted to the clinical staffs at the rehabilitation centre, Seoul Chuck Hospital for their tireless support in scheduling and guiding patients, without whom the study could not have been completed.

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