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RESEARCH PAPER

Inversion therapy in patients with pure single level lumbar discogenic disease: a pilot randomized trial

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Purpose: Backache and sciatica due to protuberant disc disease is a major cause of lost working days and health expenditure. Surgery is a well-established option in the management flowchart. There is no strong evidence proving that traction for sciatica is effective. We report a pilot prospective randomized controlled trial comparing inversion traction and physiotherapy with standard physiotherapy alone in patients awaiting lumbar disc surgery. This study sought to study the feasibility of a randomized controlled trial on the effect of inversion therapy in patients with single level lumbar discogenic disease, who had been listed for surgery. **Methods:** This was a single centre prospective randomized controlled trial undertaken at the Regional Neurosciences Centre, Newcastle Upon Tyne, UK. It was a prospective randomized controlled trial where patients awaiting surgery for pure lumbar discogenic disease within the ambit of the prestated inclusion/exclusion criteria were allocated to either physiotherapy or physiotherapy and intermittent traction with an inversion device. Post-treatment assessment made by blinded observers at 6 weeks for various outcome measures included the Roland Morris Disability Questionnaire (RMDQ) Score, Short Form 36 (SF 36), Oswestry Disability Index (ODI), Visual Analogue Pain Score (VAS), magnetic resonance imaging (MRI) appearance and the need for surgery. Avoidance of surgery was considered a treatment success. **Results:** Twenty-six patients were enrolled and 24 were randomized [13 to inversion + physiotherapy and 11 to physiotherapy alone (control)]. Surgery was avoided in 10 patients (76.9%) in the inversion group, whereas it was averted in only two patients (22.2%) in the control group. Cancellation of the proposed operation was a clinical decision based on the same criteria by which the patient was listed for surgery initially. There were no significant differences in the RMDQ, SF 36, ODI, VAS or MRI results between the two groups.

Implications for Rehabilitation

- Resolution of impairment and disability due to radiculopathy is the aim of any intervention.
- Avoidance of surgery meant satisfactory resolution of impairment and disability due to radiculopathy. This happened more often in the inversion group to the extent of reaching statistical significance.
- The 12-point improvement in disability by the Oswestry Disability Index in the inversion group suggests a role for this intervention in disability reduction.
- Inversion may form part of the conservative rehabilitation of patients with single level unilateral lumbar disc protrusion alongside other forms of physiotherapy.
- There is a potential secondary impact in the reduction of rehabilitation following surgery.

Conclusion: Intermittent traction with an inversion device resulted in a significant reduction in the need for surgery. A larger multicentre prospective randomized controlled trial is justified in patients with sciatica due to single level lumbar disc protrusions.

Keywords: Avoidance of surgery, inversion therapy, single level lumbar discogenic disease, traction

Introduction

Degenerative lumbar disease is a major cause of disability and health expenditure, especially in the industrialized world [1,2]. Compression of the nerve roots is often the cause of sciatica and, if sustained or severe, can result in neurological deficits. This can be caused by a degenerative disc protrusion

or by other processes like spondylolisthesis, spinal stenosis and arthritis of the spinal joints. Sciatica can be described as pain radiating down the leg(s) along the distribution of the sciatic nerve and is usually a sequel to mechanical compression or inflammation of the lumbosacral nerve roots [1].

The natural history of lumbar discogenic disease is well known. It is usually a benign self-limiting condition. Sciatica due to disc disease resolves without surgery in 1–12 months in the majority of patients [3]. Over a period of time, the protruded disc fragment decreases in size as the normal route of “nutrition” is impeded and the hydration is reduced. The relationship between the bulging disc and the adjacent nerve is not only very close, but the inflammatory changes in the root cause further reduction in the space for the nerve. With restriction of movement and activity coupled with reduction in disc size, the inflammation is also reduced and symptoms are sometimes alleviated. If this does not happen, a variety of interventions are available [4].

General Practitioners in Maastricht have reported that there was no difference in the outcomes when patients with lumbar discogenic backache were managed either with bed rest or no bed rest [5]. These results were confirmed in a later Cochrane review [6]. There is no evidence that one or the other type of conservative therapy is superior, including no treatment for patients with lumbosacral radicular syndrome [7]. There is no evidence for optimal sequencing of therapies or their efficacy in the treatment of sciatica [8].

Surgery for sciatica due to disc herniation is well established [9], but costs more than a hundred million pounds per year in the United Kingdom alone. Surgery has been shown to reduce the time to recovery by about 50% but is associated with a complication rate of 1–3% [3]. The biggest challenge faced by clinicians in the management of these patients therefore is to optimize the use and timing of surgical intervention. Avoiding surgery (and that too within a reasonable waiting period as a significant outcome measure) has not been clearly addressed by earlier trials. The SPORT trial failed to show a benefit from surgery perhaps because of a high cross-over rate (30%) from conservative treatment to surgery [10].

Traction is a well-known treatment for lumbar discogenic disease used commonly in North America [11] and to a lesser extent in parts of Europe [12]. Traction may work by separation of vertebral bodies, distraction and gliding of facet joints, widening of the intervertebral foramen, straightening of the spinal curves and stretching of the spinal musculature [13]. By distracting the vertebral bodies, negative pressure could probably withdraw the protruding fragment back into the disc space. The futility of traction (continuous or intermittent) as a single treatment for low back pain [14] or radiculopathy [7] is highlighted in some systematic reviews while research is not infallible in definitively proving that there is “no effect” or “no difference” between two treatments [15]. Traction is more likely to work if there is radicular involvement [16–19] manifesting as sciatica [16,17].

Type of traction and traction dosage could influence effectiveness in sciatica. Traction can be continuous or intermittent and can be manual, mechanical or motorized. Traction forces

of less than 20% of the body weight have been described as placebo [20], whereas others claim that this can also be useful [16,21]. The importance of intradiscal pressure especially in relation to posture is well known [22]. Nachemson et al. [22] showed that a traction load of 60% of the body weight is sufficient to reduce the residual pressure of 25% caused by standing to zero. In “Inversion” or “Backswing”, a tilt table is used and the weight of the entire upper half of the patient’s body assisted by gravity acts as the traction. The traction forces here are likely to be more consistent and tailored to each patient than conventional traction.

The primary aim of the present study was to assess the efficacy of traction using an inversion device in alleviating symptoms due to lumbar disc protrusion and avoiding the need for surgery in patients with acute disc protrusions that had been offered microdiscectomy.

Methods

Patients

Recruitment and randomization were undertaken at the Regional Neurosciences Unit, Newcastle upon Tyne between February 2003 and September 2006. Approval from the Newcastle Local Research ethics committee was obtained in 2003. Patients eligible for inclusion were aged between 18 and 45 years (both inclusive), within 6 months of the first episode of symptoms caused by a single level unilateral lumbar disc protrusion causing the appropriate nerve root impingement and in whom a decision to operate was made. Patients were not considered eligible if there were any red flag features, increasing neurological deficits, significant cardio-respiratory disorder, pregnancy, weight more than 20% of ideal norms for height and age or more than 140 kg. Magnetic resonance imaging (MRI) evidence of a large sequestered disc fragment was also an exclusion criterion.

Written informed consent according to the prescription of the local research ethics committee was obtained in every patient.

Procedures

Sealed serially marked envelopes were used for randomization by the treating physiotherapist. All patients were given a standard regime of physiotherapy. One group had traction with standardized access and time on the inversion table for a period of 4 weeks whereas the other group did not have this. All patients were assessed by blinded observers after 6 weeks. The outcome measures used were Roland Morris Disability Questionnaire (RMDQ), Short Form 36 (SF 36), Oswestry Disability Index (ODI), Visual Analogue Pain Score (VAS), MRI appearance and need for surgery. An MRI done 6 weeks after the randomized treatment was commenced and the pre randomization and post-treatment MRI scans were compared. If the second MRI was worse, a score of –1 was given while it was 0 for an unchanged appearance. If the second MRI was better, but compression persisted, a score of +1 was given while total relief of compression earned +2. Patients who went on to have surgery were considered as treatment failures. In all patients, surgery

was initially considered the best option; but because of the waiting lists in the unit, a final decision about surgery was made by the treating surgeon preoperatively. The treating neurosurgeon was blinded to the allocation to inversion or not.

The treatment protocol for both groups of patients included physiotherapy. Best practice physiotherapy remains to be established for radiculopathy [23–25]. Each patient was assessed for impairment and clinical findings and treated with a combination of education and advice [26], specific exercise for movement control [27] exercises for reduction of derangement [23] and manual therapy techniques [24,25]. Distraction techniques were not used with this group. In addition to physiotherapy, the inversion therapy group received mechanical inversion three times a week for 4 weeks. Each session comprised up to six 2-minute inversions within the tolerance of the patient. Guvenol et al. [28] inverted patients 10 minutes daily for 10 days, however poor tolerance due to anxiety was reported with this dose. Static inversion is reported to produce feelings of congestion and to avoid this Goldman et al. [29] suggest short periods within patient tolerance.

The patient completed outcome measures used in the study were SF 36, RMDQ, ODI and VAS. All four questionnaires have been used in the low back pain population. The RMDQ and ODI are recognized disease-specific measures of patient perception of disability [30]. The RMDQ [31] is a patient completed questionnaire developed from the Sickness Impact Profile. The 24-item scale covers a range of functional activities with higher scores representing worse dysfunction. The ODI [32] measures perceived disability in 10 activities of daily living. The scale produces a score out of 100% with a higher score representing increasing disability. The SF 36 [33] is a generic measure of eight dimensions of health status divided between physical and mental health. A score of 100% denotes the best health status possible. A VAS is a measurement instrument that measures a characteristic or attitude across a continuum of values.

Statistical analysis

Statistical analyses were conducted using SPSS 14.0 and WinPepi 6.3. Data were compared using Fisher Exact test, t-tests and Mann–Whitney U tests as appropriate.

Results

Twenty-six patients were recruited but two patients did not attend the physiotherapy department, and so 24 patients were randomized. Of these, all baseline and follow-up data were missing for one patient and one patient did not fulfill the inclusion criteria. Thus 22 patients were eligible for assessment. Of these, 13 patients were randomized to inversion while 11 were allocated to the group without inversion. The trial profile is shown as a flow chart in Figure 1 and details of all patients' age, sex and level of disc involved is given in Table I.

Surgery

Surgical intervention was avoided in 10 patients (76.9%) among the inversion group, while it was avoided in only two

patients (22.2%) among the no inversion group. Cancellation of the proposed operation was a clinical decision based on the same criteria by which the patient was listed for surgery initially. This is statistically significant (Figures 2 and 3). Avoidance of surgery thus has to be considered as a treatment success.

MRI

Post-treatment MRI scans were available for 21 patients. One patient who had surgery before the treatment was completed because of worsening symptoms. The majority of the patients in both groups (53.8% for the inversion group and 54.5% for the control group) had unchanged images. The number of patients in whom a change was seen either for the better or worse was not statistically significantly different and the same was true when the two groups were compared (Figure 4).

Roland Morris Disability Questionnaire

This was available for 12 subjects in the inversion group and 7 patients in the other group. Table II displays the median and range of Roland Morris scores at baseline and follow-up for each group and change over time. A higher score implies the disability is greater and a negative change score implies the improvement over time. There are no statistically significant differences between the two treatments.

SF 36

This was available for 12 subjects in the inversion group and 7 patients in the other group. Table III displays the mean and standard deviation of each component of SF 36 at baseline and the change over time between baseline and follow-up. The higher the score at baseline, the better the health status and the more positive the change over time the greater the improvement. The change in health measure ranges from 1 to 5 and a score of 1 indicates that the patient feels they are much better now than they were a year ago whereas a score of 5 indicates that they are much worse now. A negative value for change in health status implies improvement and a positive value implies the patient is reporting being worse. Comparisons between the two treatment groups have been made using the t-test.

Patients in both groups show a poor health status on most components at baseline. These values are similar to those reported in other studies. There is little difference between the two groups. On average, the patients improve over time but again there is no difference between the two groups in the degree by which they improve although this study is not powered to be able to show a difference.

Oswestry Disability Index

This was available for eight subjects in the inversion group and three patients in the other group. Table IV displays the median and range of Oswestry scores at baseline and follow-up for each group and the change in score. A higher score at baseline or follow-up implies a greater disability. A negative change in score implies an improvement over time. There is no difference in score at baseline but patients in the inversion therapy

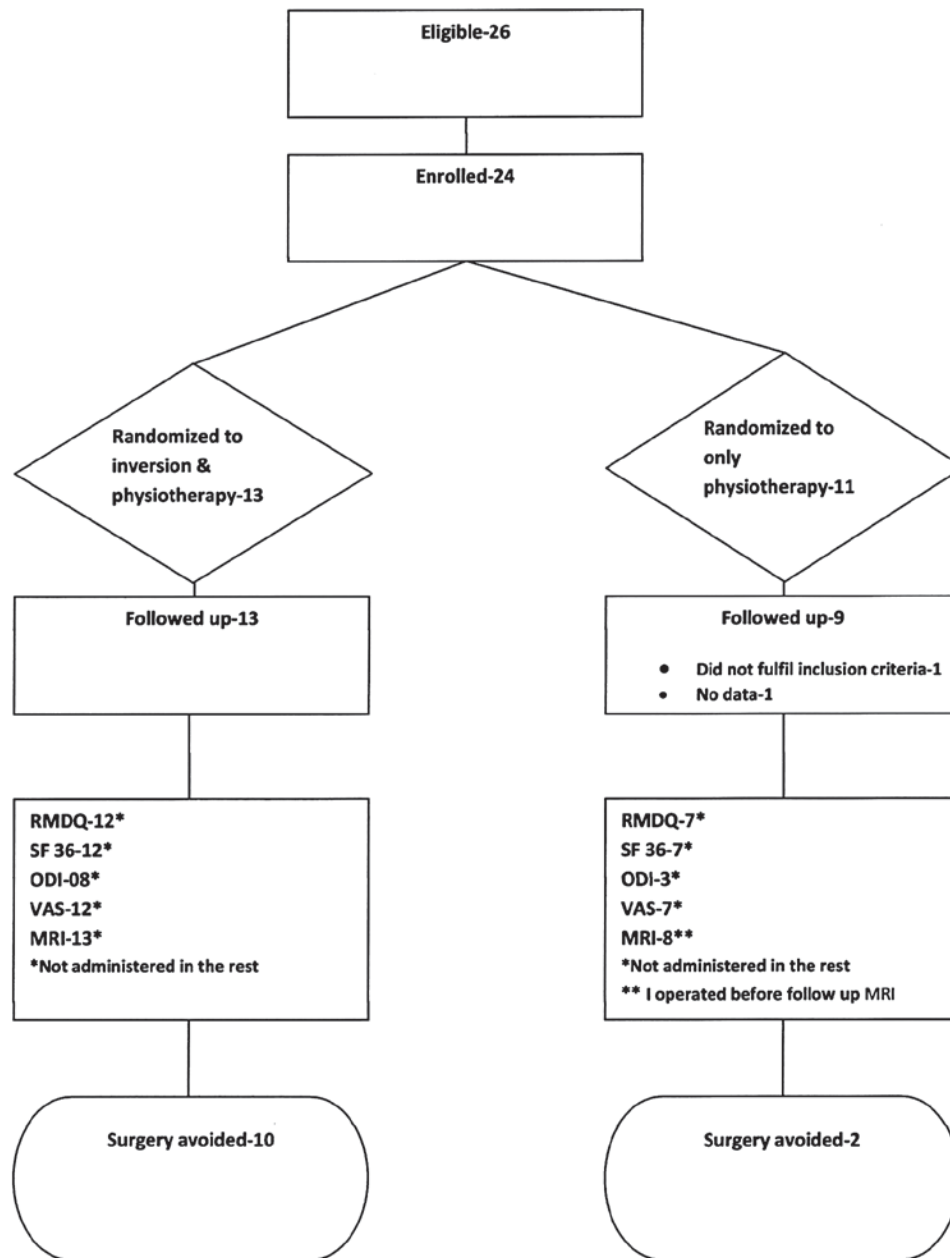


Figure 1. Trial profile.

group tend to have less disability at follow-up and the change in score between baseline and follow-up almost reaches statistical significance (using Mann-Whitney U test). Patients in the inversion therapy group have a median improvement of 12 percentage points while those in the physiotherapy group have a median improvement of 0 percentage points.

Visual Analogue Pain Score (VAS)

Though the VAS was available for 12 patients in the inversion group before and after treatment, one in each of the before and after cohort groups was not available at the other time point and therefore the mean and median was calculated for 11 subjects. In the control group, data were available for seven patients, before and after treatment. A negative change over a period of time indicates improvement. Figure 5 gives details of the VAS before and after treatment in the two groups. The

change was not statistically significant in either group. In the control group, the median VAS changed from 2.8 to 3.0 (t-test $p=0.697$) and for the inversion group it changed from 3.2 to 0.9 (t-test $p=0.078$).

Discussion

Our pilot trial has shown that intermittent extreme traction with an inversion device has resulted in a significant reduction in the number of patients requiring surgery for radicular symptoms due to lumbar disc protrusion.

Traction for sciatica

Some systematic reviews have highlighted the ineffectiveness of traction in low back pain [14] and radiculopathic pain like sciatica [7], whereas a number of other reports have

Table I. Patient details.

SINo	Age	Sex	Level	Treatment	Scan outcome	Surgery
1	33	M	L5-S1	Inversion	1	0
2	40	M	L4-5	Control	0	1
3	29	M	L5-S1	Inversion	1	0
4	28	M	L4-5	Inversion	0	1
5	34	M	L4-5	Control	2	1
6	25	M	L5-S1	Inversion	1	1
7	38	F	L4-5	Control	0	0
8	36	F	L4-5	Inversion	0	0
9	34	M	L5-S1	Inversion	0	1
10	38	F	L4-5	Inversion	0	0
11	38	F	L5-S1	Control	0	1
12	43	M	L4-5	Inversion	-1	0
13	41	F	L5-S1	Control	1	0
14	44	F	L5-S1	Inversion	2	0
15	28	F	L5-S1	Control	0	0
16	43	F	L5-S1	Control	0	1
17	31	M	L5-S1	Control	OPERATED	1
18	35	F	L5-S1	Control	0	1
19	31	F	L5-S1	Inversion	-1	0
20	40	F	L4-5	Inversion	0	0
21	32	M	L5-S1	Inversion	0	0
22	43	M	L5-S1	Control	0	1
23	35	F	L5-S1	Inversion	0	0
24	31	F	L5-S1	Control	0	1

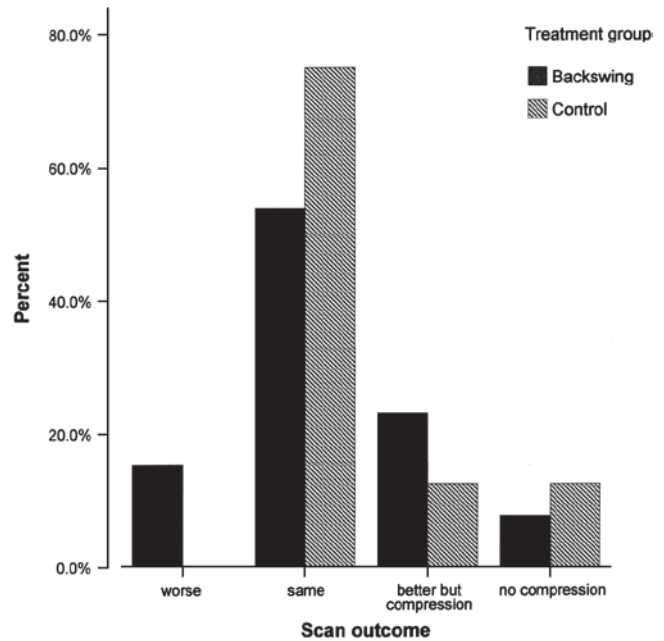


Figure 4. MRI scan outcome.

Type of traction

Inversion or Backswing is a form of traction where the patient is strapped at the ankles in a tilt table. The patient is then gradually tilted to a head down position. This results in a form of extreme traction where the traction force is created by the weight of the upper half of the patients' body and gravity. This brings in a sort of standardization as the traction is dependent on the patient's own body weight. Inversion is used as intermittent traction with each patient having standardized access and time with the device spread over a specified period of time. Our study looked at the specific subset of patients with radicular symptoms with the traction group receiving intermittent inversion.

Sheffield [34] surmised that the beneficial effects from adapting the tilt table for traction resulted from stretching of paraspinal muscles, ligaments and intervertebral discs. Another study showed that gravity assisted traction was more effective than other forms of traction [35]. Studying the effects of gravity assisted traction on intervertebral dimensions of the lumbar spine, it has been shown that this form of traction produced significant intervertebral separation between the lumbar vertebrae [36,37].

Decline in electromyographic (EMG) activity (which is thought to be an indicator of muscle pain) was consistently demonstrated with the use of the inversion device [37,38].

Traction dosage

Using gravity and the weight of the patient's own body, a consistent and reproducible traction can be administered. These factors influence the traction dosage as well.

Traction of less than 25% of body weight has been described as low dose or sham traction [39]. A traction load of 60% body weight was found to cause a reduction of the residual intradiscal pressure of 25% standing body weight to zero [22]. Inversion devices can easily achieve this.

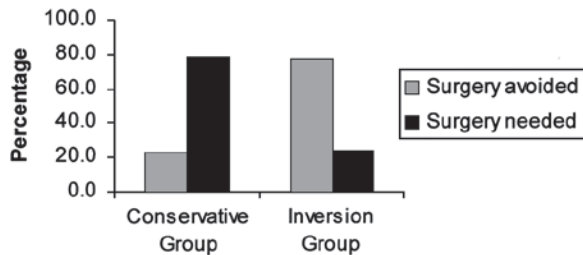


Figure 2. Avoidance of surgery.

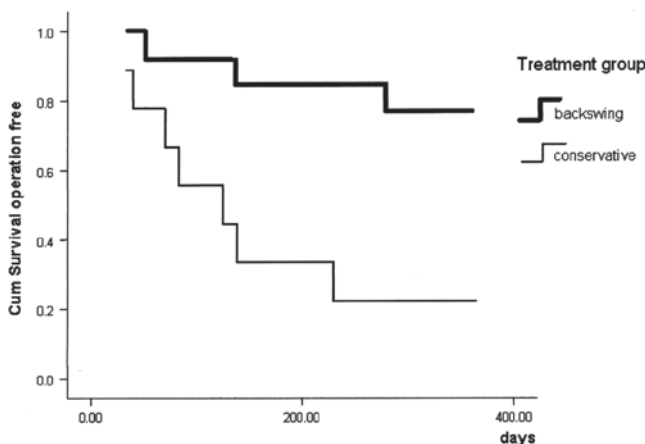


Figure 3. Duration of Avoidance of surgery.

contradicted this, especially when used for disability and pain due to radiculopathy [16-19].

This study was therefore undertaken in patients listed and waiting for an operation to relieve root compression due to lumbar disc disease.

Table II. Roland Morris disability questionnaire assessment.

	Inversion + physiotherapy N = 12	Physiotherapy N = 7	Significance
Baseline Roland Morris	12.5 (1–20)	10 (1–19)	0.475
Follow-up Roland Morris	7.5 (0–20)	11 (2–21)	0.552
Change ill Roland Morris	–1 (–13 to 4)	–1 (–5 to 8)	0.441

Table III. SF 36 scores.

	Inversion + physiotherapy N = 12	Physiotherapy N = 7	Significance
Baseline			
SF 36 physical function	43.5 (27.5)	35.7 (20.1)	0.521
SF 36 role – physical	17.3 (37.3)	32.1 (47.2)	0.449
SF 36 bodily pain	29.8 (23.7)	26.3 (9.3)	0.710
SF 36 general health	59.0 (13.2)	71.7 (12.4)	0.065
SF 36 vitality	39.2 (12.7)	44.3 (6.7)	0.344
SF 36 social function	44.2 (22.0)	53.6 (25.7)	0.404
SF 36 role – emotional	46.2 (46.2)	42.9 (53.5)	0.887
SF 36 mental health	54.1 (19.3)	61.7 (22.0)	0.436
SF 36 change in health	4.3 (0.8)	3.3 (1.0)	0.032
Change			
SF 36 physical function	9.2 (15.3)	8.2 (18.3)	0.901
SF 36 role – physical	10.4 (24.9)	7.1 (31.3)	0.804
SF 36 bodily pain	12.5 (24.6)	15.6 (15.5)	0.771
SF 36 general health	2.8 (15.1)	0.0 (13.4)	0.705
SF 36 vitality	11.3 (16.0)	0.5 (12.9)	0.148
SF 36 social function	15.6 (28.3)	2.5 (30.6)	0.824
SF 36 role – emotional	13.9 (54.0)	23.8 (41.8)	0.682
SF 36 mental health	10.0 (14.6)	–2.3 (14.2)	0.092
SF 36 change in health	–0.7 (0.9)	0.2 (1.3)	0.151

Table IV. Oswestry disability index.

	Inversion + physiotherapy N = 5	Physiotherapy N = 3	Significance
Baseline oswestry	50 (22–78)	48 (38–56)	0.644
Follow-up oswestry	31 (14–74)	54 (32–56)	0.298
Change in oswestry	–12 (–26 to 0)	0 (–6 to 6)	0.064

Administration of consistent and effective traction dosage could thus be achieved by using inversion as an intervention in this study.

Possible effects

The most striking feature in this study was the statistically significant higher rate of avoidance of surgery in the inversion group. The other domain where the change due to inversion was noteworthy was in the ODI. A 12 point improvement was seen in this scale, suggesting a useful role for inversion in reducing disability. This almost reached statistical significance when compared with the “no inversion” group. Fritz and Irrgang [40] used a modified ODI and found that an improvement of 6 points or more made a clinical difference.

Surgery only addresses neural compression by disc material, but this is seen in a number of asymptomatic individuals as well. Pain and disability in lumbar discogenic disease might be due to mechanical, inflammatory

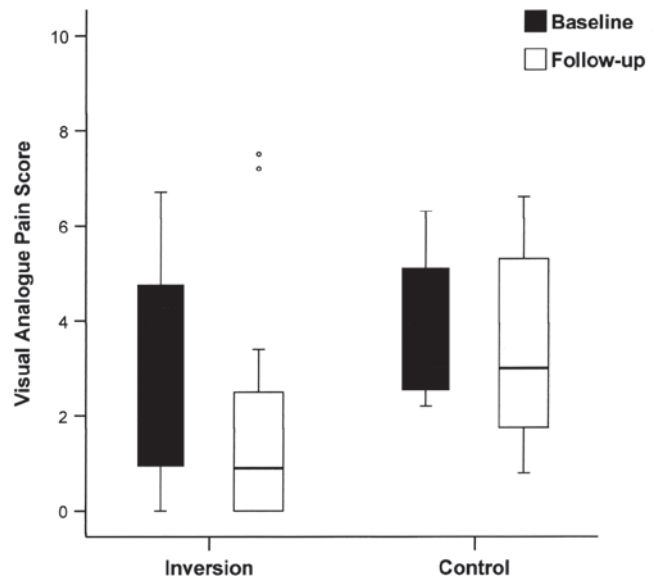


Figure 5. Visual analogue score.

and immunological causes and not just due to compression [41]. Sheffield [34] surmised that the beneficial effects due to inversion resulted from stretching of paraspinal muscles, ligaments and intervertebral discs whereas other studies have demonstrated decline in EMG activity (which is thought to be an indicator of muscle pain) with the use of the inversion device [37,38]. These observations might explain the significant benefits due to inversion as assessed by ODI and avoidance of surgery even though the appearance on MRI was not congruent.

Changes in practice

Some surgeons in this centre now offer inversion therapy as standard initial treatment to patients awaiting surgery for pure single level lumbar discogenic sciatica within the ambit of the inclusion/exclusion criteria used in this trial.

Adverse effects

No serious adverse effect was noted in either group in this trial. This was noted from a process of reporting adverse events by exception. The available literature shows that there is no clear reporting of adverse events with traction in general and inversion in particular [14].

Economic impact

Again, the costs of treatment with traction or the price of any adverse event thereof is not clearly seen in the available literature. Looking at costs for intermittent inversion, costs for lumbar disc surgery and the demonstrated reduction in the number of operations from our own data, savings in excess of a hundred million pounds per year can be expected if we assume that around 15,000 operations are done in the UK every year for lumbar discogenic disease.

Further research

The available literature does not provide evidence of efficacy from traction. However, traction as a single treatment

for low back pain also cannot be recommended at present [7,14]. Heterogeneity of patient populations in terms of type and duration of symptoms, non standardization of traction, variations in duration of follow-up and outcome measures used and lack of power are all contributory factors for lack of strong evidence regarding the use of traction [42,43]. This should encourage researchers to organize trials of high quality incorporating these points.

Conclusion

Our hypothesis was that inversion therapy would reduce the need for a surgical procedure in subjects with sciatica due to single level disc protrusion. The results of this study do support this; surgery was avoided in 77% in the inversion group while it was averted in only 22% in the non inversion group. Avoidance of surgery did not prejudice other outcome measures and vice versa. The study demonstrated the feasibility of a randomized controlled trial of the impact of an inversion device on various outcome measures in single level discogenic disease. Previous trials of traction have not reported on avoidance of surgery as an outcome measure and this trial has addressed that issue. The economic impact is very significant and a larger multicentre prospective randomized control trial is justified.

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