

Conservative treatment for sciatica compare with surgical intervention: a multi-center cohort clinical study

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Abstract

The objective of this study is to compare between conservative and surgical intervention in patients with low back ache. A cohort clinical retrospective-prospective study is enrolling 75 patients with low back ache and diagnosed as sciatica in multi-center (Baghdad and Muthanna). The outcome of both procedures depends on the following measures: neurological deficit, Lasègue test, Sciatica Bothersomeness Index, contralateral Lasègue test. Paired t-test applied for efficacy within the group and Chi-square test to compare the efficacy of two groups. After 6 months there was significant difference between operated and non-operated patients related to Sciatica Bothersomeness Index ($p = \text{than } 0,01$), Lasègue test ($p=0,001$), neurological deficit ($p = 0,01$) and leg and back pain depending on the activity ($p=0,002$). There was no difference statistically difference between the groups related to contralateral Lasègue test ($p=0,206$). In conclusion, we expended formerly accepted operative indications. There were better treatment results in the surgical operated group. A fast reduction of symptoms is the main advantage of the operative treatment strategy. Patients whose pain is treated in process that is acceptable for them may decide to postpone surgery. Patient's preference for the type of treatment is crucial for an ultimate surgical decision in cases without widespread neurological deficits.

Keywords: Low back ache; Sciatica; Neurological deficit

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Introduction

Epidemiological view the back pain is extremely common, 60-80% of people report back pain at some time in their lives [1]. A population-based cross-sectional study of people aged 25 years and older found the one-month period prevalence of low back pain to be around 30%, peaking at age 41-50 years. The one-year prevalence of chronic low back pain is about 1% [2]. For most people, low back pain is

nonspecific and serious specific causes are rare [2]. Highly demanding jobs, prolonged standing and awkward lifting are the most consistent factors predisposing to low back pain [3]. Conservative treatment for sciatica is primarily aimed at pain reduction, either by analgesics or by reducing pressure on the nerve root. A recent systematic review found that conservative treatments do not clearly improve the natural course of

sciatica in most patients or reduce symptoms [4]. Adequately informing patients about the causes and expected prognosis may be an important part of the management strategy. However, educating patients about sciatica has not been specifically investigated in randomized surgical intervention for sciatica focuses on removal of disc herniation and eventually part of the disc or on foraminal stenosis, with the purpose of eliminating the suspected cause of the sciatica. Treatment is aimed at easing the leg pain and corresponding symptoms and not at reducing the back pain. Consensus is that a cauda equina syndrome is an absolute indication for immediate surgery. Elective surgery is the choice for unilateral sciatica. Until recently only one relatively old randomized trial was available that compared surgical intervention with conservative treatment for patients with sciatica [5].

A Cochrane review - albeit of a small number of trials - found spinal manipulation to be no better than other therapies [6]. However, a study of men and women aged between 18 years and 35 years with acute back pain found that chiropractic manipulative therapy in conjunction with standard GP care afforded significant advantages in decreasing pain and improving physical functioning compared to standard care alone [7]. The evidence base for the value of physiotherapy is surprisingly small. However, recent evidence suggests that its effectiveness can be increased when used in conjunction with a validated tool such as the Start Back screening tool developed at Keele University [8, 9]. This allocates patients to different treatment pathways based on their prognosis (low, medium, or high risk of

poor outcome) and is designed for ease of use in primary care [10- 15].

It is important to be active and positive to prevent back pain from becoming chronic. If it does, cognitive and behavioral therapy with relaxation therapy may be helpful. A Cochrane review reported that no type of behavioral therapy is better than any other [16-19]. The objective of this study is to compare between conservative and surgical intervention in patients with sciatica.

Methodology

Design

A multi-center prospective/retrospective cohort study of patients with back pain, diagnosed as sciatica. We are follow-up the patients over 6 months to compare the outcomes between those who have surgery and those with conservative management. The study protocol was approved by the University of Muthanna/Medical College and all patients provide written informed consent.

Patients

All patients between 35 and 65 years with low back ache and diagnosed as sciatica of more than 2 months duration are eligible for this study. Patients are recruited from three neurological and orthopaedic clinics in Baghdad medical center, Al-sadder medical city and Al-Husain hospital, these practices include nine surgeons who have referred patients to the study. We identify patients with predominant low back pain as a symptom confirmed by imaging, and a normal neurological exam as sciatica. Additional inclusion and exclusion criteria are listed in Table 1. These eligibility criteria mimic those of the European randomized trials of surgery for disc for

discogenic pain [21].

Table 1

Selection criteria for trial eligibility

Inclusion criteria
• Age 35–65 year.
• Continuous back pain in the L4, L5 or S1 dermatome with or without mild neurological deficit
• Severe disabling leg pain of 6–12 weeks duration
• Evidence of a unilateral disc herniation confirmed on image
• Received consent from patients
Exclusion criteria
• Cauda equina syndrome
• Complaints of a lumbosacral radicular syndrome in the same dermatome within the past 18 months
• History of unilateral disc surgery on the same level
• Spinal canal stenosis
• Lytic spondylolisthesis
• Pregnancy
• Severe life-threatening and psychiatric diseases

In the initial analysis, the modified Roland Disability scale at 6 months will be compared between the surgical operable and non-surgical treatment arms using regression techniques to adjust for important baseline characteristics. Secondary analysis will include comparison psychological measures for the two treatment arms, and pain. To characterize time trends in the primary and secondary outcomes, we will use linear mixed models (or Generalized Estimating Equations in the case of categorical variables) to analyze the repeated measures obtained at all follow-up interviews. Lastly, we will investigate potential predictors of outcome, including disability, psychological factors, and image findings. The objective of this study is to identify subgroups of patients who respond well to surgery but not to non-surgical

therapy, or to non-surgical treatment but not surgery.

Results

Table 2, showed the overall surgical treatment and complications were similar between the two cohorts study. The average surgical operation time was longer in the randomized cohort (82.2 minutes randomized vs. 72.4 minutes observational, $p=0.031$). Median (interquartile range) values for surgical time were 72.2 minutes (53.1, 10.0) for the randomized and 68 minutes (54.0, 94.0) for the observational cohort. The average blood loss was 63.2ml in the randomized cohort vs. 58.0ml in the observational, $p=0.42$. Median (25th percentile, 75th percentile) for blood loss was 47ml in the clinical randomized cohort and 52ml in the observational study. Only 8

patients total required intra-operative transfusions.

The most surgical complication was dural tear (2% of cases). Re-operation occurred in a combined 4% of cases by 1.5 year, 9% at 2.5 years post surgery. The rates of reoperation were not significantly different

between the randomized and observational cohorts clinical study. 71 of the 93 re-operations noted the type of re-operation; approximately 58% of these were listed as recurrent herniations at the same level. Two death occurred within 4-months post-surgery related to heart surgery.

Items	Status	Difference between groups	N/group, 2-sided alpha = 0.05, power = 0.85
Functional Status	Difference in change in Roland score (0–23 scale, SD = 6.20)	2.2 points	112
		2.9 points	82
Clinical Symptoms	Improvement in pain (1 = gone, 5 = same, 7 = much worse) (SD = 1.620)	0.63 point	82
		0.8 point	47
Back to Work	Proportion currently employed	0.12	143

Discussion

The present study showed that patients with sciatica diagnosed by imaging and beside the clinical symptoms continue for at least 4-6 weeks, the operation surgery was more beneficial to patients than non-surgical management in relieving symptoms and improving function. The management effects for surgical operation was seen as early as 6 weeks, appeared to reach a maximum by 6 months. Under reasonable cases, these combined treatments can be expected to appear a bias toward the null in the intent-to-treat analyses [22-26]. The more effects benefits of treatment are seen

in the management analysis after adjustments for features of the crossover population suggest that the intent to treat and investigates the underestimates the true effect of surgical operation. The SPORT data are supported by the other studies mostly randomized clinical trial for sciatica [28-33]. In that analysis study, 39% of those clinical randomized to non-surgical treatment crossed over to surgical operation at about five months. This is nearly identical to SPORT, in which 38% had crossed into surgical operation by 6 months. The approximate estimated clinical improvements inform decreased the pain and general lifestyle 1 year after surgical

operation in these two studies were similar (Peul vs. SPORT): SF-36 BP 59.3 vs. 43.7; SF-36 PF 50.3 vs. 44.4; and Sciatica Bothersomeness -11.5 vs. -11.2. These results further validate the SPORT randomized cohort results but needs highlight the need to also consider the as treated analysis in present study patients to estimate the true effect of surgical operation and to prevent bias towards the null.

Competing interests

The author declares that they have no competing interests.

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