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EFFECT OF BRACING ON DISABILITY IN PATIENTS WITH SPONDYLOLISTHESIS: A RANDOMIZED CONTROLLED TRIAL



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ABSTRACT

Background: Spondylolisthesis is now a days a well known condition related to low back pain induced disability. Among the various treatment options, bracing often advised to these patients. But the effectiveness of bracing in reducing disability is often debated. Aim of Study: To assess the effect of Bracing in limiting disability in patients with Spondylolisthesis. Method: This Randomized controlled trial was conducted on 70 patients of both sexes within the age group of 40-60 years with radiological grade1&2 spondylolisthesis. They were randomly divided in two groups of same number (35 in each group)- Group-1: managed with therapeutic exercises only and Group-2: managed with therapeutic exercises with bracing. Disability assessment was done with Oewestry Disability index. Data collected in predesigned pretested proforma during follow ups(visit1 to visit4) and analyzed accordingly. Result: For Oswestry Disability index, in group1, there was significant changes(p<0.001) noted only in visit 1 & visit4, whereas significant improvement (p<0.001) noted in all visits in group2. Conclusion: Therapeutic exercise with judicious bracing is more effective in limiting disability among patients with grade 1&2 spondylolisthesis.

KEYWORDS

OSWESTRY Disability index, Spondylolisthesis, Low back pain, Lumbo-sacral brace.

INTRODUCTION

Low back pain associated disability is increasing day by day in Indian population. Spondylolisthesis being one of the major causes of low back pain which is often associated with disability in many ways. ¹⁻³

Spondylolisthesis is the forward displacement of a vertebral body one over another. It is derived from the Greek word "olisthanein", which means "to slip". The diagnosis of lumbar Spondylolisthesis usually made on plane radiography in the course of evaluating a patient of low back pain and/or leg pain. Subsequent management depends on the age of the patient, the severity of the symptoms, the pathogenesis & natural history of slip and assessing the risk:benefit ratio of the available treatment modalities.⁴⁻¹⁰

The goal of treatment of patients with spondylolisthesis is pain and disability limitation and to restrict progressive slippage of vertebrae over one another. The treatment protocol for grade 1 and grade 2(radiological grading) spondylolisthesis patients remain conservative measures with therapeutic exercise with or without bracing. Contradictory results are obtained regarding the use of L-S Brace in these patients. There are some school of thoughts which consider bracing is not at all necessary as a conservative measure in patients with spondylolisthesis. But some literatures are in favor of Bracing for disability limitation in patients with spondylolisthesis. 24.8

Therefore, we have formulated this study to compare the disability limitation of two groups of patients of grade 1 or 2 anterolisthesis who were under similar pharmacological treatment, prescribed exercise only to one group and exercise with bracing to another. Disability assessment was done with OSWESTRY Disability index.

AIMS AND OBJECTIVES

 $Effect \, of \, Bracing \, in \, limiting \, disability \, in \, patients \, with \, Spondylolis thesis.$

MATERIALS AND METHODS

This Prospective randomized open level control trial was conducted in the Dept of Physical Medicine and Rehabilitation I.P.G.M.E&R, Kolkata after obtaining clearance from the institutional ethics committee.

Inclusion Criteria

Cases were selected from patients attending O.P.D in the Dept of Physical Medicine and Rehabilitation during the above mentioned period. Consequently 70 case were selected, all of them between 40-60 yrs having grade 1 or grade 2 spondylolisthesis (radiologically).

Exclusion Criteria

(i)Significant neurological complications, (ii) Grade 3 & 4

spondylolisthesis (Radiological grading), (iii) Retro or lateral listhesis, (iv) Spinal infection/malignancy, (v) Compressed fracture, pathological fracture, (vi) Patient having contraindication of therapeutic exercise and bracing, (vii) Pregnancy & lactating. mothers.

Study Population

Patients of radiological grade 1 & 2 spondylolisthesis with or without spondylolysis who are attending the OPD of Physical Medicine and Rehabilitation Department of I.P.G.M.E&R, Kolkata.

Study Period: February 2010 to July 2011: One and half year.

Study Tools

Oswestry Disability Index

The Oswestry Disability Index (aka:Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test has been around for 25 years and is considered the "gold standard" of low back functional outcome tools.

Instructions:

Simply answer the below questions by choosing the 'best answer' that describes your 'typical' pain and/or limitations within the last week or two. You can only choose ONE answer. If your limitations fall in between two questions, pick the higher point value question. After finished the test, add up the points, divide that number by 50 and multiply by 100 to get the percent disability.

Study Design

After considering the inclusion and exclusion criteria, 70 patients were selected and divided into 2 groups of 35 patients randomly. First group (Group1) is given only therapeutic exercise while the second group (Group2) treated with therapeutic exercise with bracing; data collected in predesigned pretested proforma during follow ups and analyzed through appropriate statistical method.

RESULTS & ANALYSIS

During one and half year study period, all the data were recorded in predesigned and pretested proforma and analyzed by Statistica version 6 [Tulsa, Oklahoma: StatSoft Inc, 2001] and GraphPad Prism version 4 [San Diego, California: GraphPad Software Inc.2005]. Analysis was done by repeated measures ANOVA followed by Tukey's test as post hoc test when repeated measures ANOVA returns p value <0.05.

Oswestry Disability Index in Group1:

Tukey's multiple comparison test	Mean diff	q	P value	95% Cl off diff
V1 vs V2	2.4667	3.1467	>0.05	-0.44441-5.3777
V1 vs V3	5.7333	7.3139	< 0.001	2.8223-8.6444
V1 vs V4	8.9333	11.396	< 0.001	6.0223-11.844
V2 vs V3	3.2667	4.1672	< 0.05	0.35558-6.1777
V2 vs V4	6.4667	8.2494	< 0.001	3.5556-9.3777
V3 vs V4	3.2000	4.0822	< 0.05	0.28892-6.1111

P value < 0.001, number of groups=4, F 24.612

Significant changes with visit 1 & visit 4 as p<0.001.

Oswestry Disability Index In Group2:

Tukey's multiple	Mean diff	q	P value	95% Cl off diff			
comparison test							
V1 vs V2	4.8667	5.2478	< 0.01	1.4228-8.3105			
V1 vs V3	9.9333	10.711	< 0.001	6.4895-13.377			
V1 vs V4	16.333	17.613	< 0.001	12.889-19.777			
V2 vs V3	5.0667	5.4635	< 0.01	1.6228-8.5105			
V2 vs V4	11.467	12.365	< 0.001	8.0228-14.911			
V3 vs V4	6.4000	6.9012	< 0.001	2.9561-9.8439			

Pvalue < 0.001, number of groups = 4, F 56.903

There is significant statistical improvement during all visits.

DISCUSSION

The burden of Spondylolisthesis in our society is increasing day by day resulting in more & more disability. This prospective open level control trial, conducted in the Dept. Of Physical Medicine and Rehabilitation I.P.G.M.E&R, Kolkata during the period from Feb 2010 to July 2011 comprising 70 patients showed predominantly (55%) affected persons are within 40-50 yrs age group. In our study most of the victims of Spondylolisthesis are female (mostly housewives), with female :male ratio around 1.73:1. This corroborates well with the evidences which shows that the congenital & degenerative forms of spondylolisthesis have a female to male predominance of 2:1 and 5:1, respectively. Another interesting finding noted in our study that 43% patients were urban dwellers & most of them are active working.

In our study we have used the Meyerding classification system & exclude grade 3 & grade 4 spondylolisthesis cases. In our study sample grade 1 spondylolisthesis were more common than grade 2 (radiological) spondylolisthesis. It is also corroborating with the natural history of the disease as the incidence rate of grade 1 listhesis is more common than grade 2.

Patients of only Therapeutic exercise group showed improvement in the later half of the study in Oswestry scale in comparison with initial visit. In this group comparison with visit 1 to visit 4 shows statistically significant outcome (p<0.001). Whereas patients with bracing & exercise showed statistically very significant improvement in Oswestry scale and continued to show improvement till the last visit. Comparative study of both the group showed bracing are more effective to improve the pain & disability score both initially & after significant duration of time. As the previous studies though there is some improvement with bracing our study also supporting the fact & our patient group which are mainly the patients of degenerative spondylolisthesis responded well & in better ways with the exercise plus bracing combined therapy .

Limitations:

i)Small sample size, ii) Other contributory factors of LBP can not be ruled out completely, iii)Different working environment among the participants.

CONCLUSION:

Comparative study of both the group showed Therapeutic exercise with bracing is more effective to improve the pain both short and long term basis.

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