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Elastic Lumbar Support Versus Rigid Thoracolumbar Orthosis for Acute Pediatric Spondylolysis : A Prospective Controlled Study

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INTRODUCTION

Isthmic spondylolysis is the most common cause of low back pain among adolescent athletes, explaining up to 47% of their low back pain [1]. It is a stress fracture by nature, and it is treated with restriction of sports, physical therapy and often using a brace to immobilize the trunk. Previous studies [2-6] have shown good results concerning treatment of adolescent spondylolysis with different kinds of hard orthosis. Boston brace, a rigid thoracolumbar orthosis, is antilordotic to the lumbar spine, which is thought to be favorable for the treatment of adolescent spondylolysis [7]. A biomechanical analysis by Fujimoto et al. 2020 [8] revealed that a custom-made, rigid lumbo-sacral orthosis had the highest restriction in all directions compared to a soft lumbo-sacral orthosis, a custom-molded back cast-panel, a Damen type elasticity corset, and an off-the-shelf soft lumbo-sacral orthosis. On the other hand, soft brace is more comfortable to wear. The natural history of spondylolysis is unclear [9] and there is a lack of prospective comparative studies evaluating the effect of a rigid thoracolumbar orthosis compared to a soft brace on the healing of the defects of the pars interarticularis in pediatric population.

In this study we aimed to examine whether an individualized, custom-made rigid thoracolumbar orthosis (Boston brace) improves the bony union rates of isthmic spondylolysis or the health-related quality of life (HRQoL) outcomes when compared to a low-profile, elastic lumbar support (Porostrap) in acute pediatric spondylolysis. We also aimed to figure out factors that affect the bony union of pediatric spondylolysis. We hypothesized that treatment with a rigid thoracolumbar orthosis would improve the bony union rate of the spondylolysis and the HRQoL of patients as compared to treatment with an elastic lumbar support.

MATERIALS AND METHODS

Trial design

The study was designed as a randomized, non-blinded clinical trial comparing the outcomes of acute pediatric isthmic spondylolysis using a Boston brace or an elastic lumbar support. Sample size was calculated with the use of study power of 80% and a type-I error (alpha) of 0.05. The bony union rate of spondylolysis with a Boston brace was assumed to be 90% [3] and with an elastic lumbar support 58% based on our clinical experience. This led to sample size of 26 patients per group and to allow drop outs, a total of 57 patients were included.

The first 14 patients underwent randomization into these two groups (Randomized cohort). An independent observer provided sealed envelopes with the two treatment options and randomization was performed after informing the families about the study and when informed consent was obtained. During this initial enrollment period (June 2016-September 2018) it became quite clear that a large part of the patients and their families refused randomization (22%, 4/18) and wanted to choose the treatment method. To facilitate the recruitment process, the study was modified into a prospective patient preference study (Patient preference cohort, the remaining 43 patients), Figure 1.

Patients

Fifty-seven consecutive children with acute uni- or bilateral spondylolysis were prospectively recruited to this study between June 2016 and October 2020. All patients were examined by a professional due to low back pain. Inclusion criteria were an acute unilateral or bilateral spondylolysis with bone edema in the spondylolysis in the MRI as a sign of an active lesion, a lesion without bony sclerosis in the CT, and age between 8 and 18 years. Exclusion criteria included lesions with round edges or with bony

sclerosis, spondylolisthesis on a standing spinal radiograph, a systemic skeletal disorder or lack of interest.

Interventions

Patients were treated with a rigid thoracolumbar orthosis (individual Boston brace, Respecta, Finland) or an elastic lumbar support (Porostrap, Donjoy) 23 hours a day for four months. Boston brace is a custom-made, rigid brace, which gives a good immobilization of the trunk [8], where as an elastic lumbar support is a non-rigid textile corset and only slightly supports the trunk.
Additionally, all patients were instructed to avoid physical activities except walking and met a physiotherapist to receive advice on isometric abdominal and spinal muscle exercises.

Radiographic Measures

All patients underwent a standing lumbar radiograph (lateral), a lumbar spine MR images and a selected CT of the fractured vertebra. These images were blindly re-evaluated by an independent musculoskeletal radiologist. From these images spondylolisthesis was excluded, additional stress reactions were noted, and spondylolysis was graded. Grading was done according to Fujii et al. 2004 [10] from the CT images and according to Hollenberg et al. 2002 [11] from the MRI. Bony union was evaluated using a selected CT at four months.

Outcome parameters

The primary outcome parameter in this study was the bony union rate of the spondylolysis with a Boston brace and an elastic lumbar support at four months using CT. Secondary outcome parameters

were the HRQoL of the patients before and after the treatment and predictive factors for bony union of the spondylolysis.

HRQoL was measured with the Scoliosis Research Society-24 (SRS-24) outcome questionnaire. It is a questionnaire that Scoliosis Research Society (SRS) originally developed to measure HRQoL of adolescent scoliosis patients but it is widely accepted for use of evaluating HRQoL of other back conditions as well [6, 12, 13]. The questionnaire consists of twenty-four questions and measures seven domains: pain, general self-image, function from back condition, general level of activity, posttreatment self-image, posttreatment function and satisfaction. Every question is scored from one to five and the higher the score the better the outcome. The maximum total score of the questionnaire is therefore 120 points and it is divided by the number of questions resulting into maximum total score of 5.0. Questions from sixteen to twenty-four concern the treatment and can therefore be filled out only after the treatment.

Statistical analysis

Continuous variables were described as means with standard deviations or 95% confidence intervals (CI). Categorical variables were expressed as counts (n) and percentages. Associations between categorical data were analyzed with Fisher's exact test. Comparisons of continuous variables were performed with one-way analysis of variance (ANOVA).

Bony union rates were calculated using log-binomial models. Univariate analysis was performed for the brace type and possible predictive factors for bony union. Only one significant factor was found, and multivariate model was not constructed. Risk ratio for the stage of the spondylolysis in baseline CT

was not possible to estimate because all early defects healed. Hence Cochran-Armitage trend test was used to evaluate association between the stage of the spondylolysis in baseline CT and bony union. Different SRS scores were analyzed with a hierarchical linear mixed model with repeated measures including one within-factor (time), between-factor (group) and the interaction (time*group). Unstructured covariance structure was used for time and Kenward-Roger correction for degrees of freedom was performed. In addition, background characteristics were also examined in order to discover whether they had an effect on the mean change scores between the two measurement points. Univariate analysis was performed for the background characteristics. When only non-significant factors were found, the multivariate model was not constructed.

Posttreatment self-image and function had skewed distribution. Medians with 95%CI were reported, and they were analyzed with Mann Whitney U test. Whereas posttreatment satisfaction was normally distributed and mean with 95%CI reported and it was analyzed with ANOVA.

All tests were performed as two-sided with a significance level set at 0.05. The analyses were carried out using SAS System, version 9.4 for Windows (SAS Institute Inc., Cary, NC, US).

Ethical committee approval

Ethical committee approval was received from a local Ethics Committee for Human Sciences. All procedures were followed according to the Helsinki declaration of the World Medical Association.

A written informed consent from the patient and if needed from his guardians was required. Study was registered to ClinicalTrials.gov (NCT03675152).

RESULTS

Participants

A total of 57 patients participated into this study. One patient was lost to follow-up. Additionally, two patients were excluded, because they had a bilateral pseudoarthrosis with no bone edema in the MRI in the pars interarticularis leaving 54 patients (mean [SD] age at the beginning of the treatment 14.1 years [±1.68 years], 36 males) to be analyzed.

Twenty-nine (53.7 %) patients were treated using the Boston brace and twenty-five (46.3%) patients using an elastic lumbar support. Patients treated with Boston brace had symptoms 3.12 months (± 1.56 months) and patients treated with an elastic lumbar support 3.00 months (± 1.92 months). The clinical characteristics of the patients are shown in Table 1.

Outcomes

The bony union rates of the spondylolysis (primary outcome) with either a Boston brace or an elastic lumbar support treatment are shown in Table 2. There was no statistical difference in the union rates of spondylolysis treated with a rigid thoracolumbar orthosis or an elastic lumbar support. In 69.0% (20/29) of the Boston brace group and in 60.0% (15/25) of the elastic spinal support group patient had a unilateral defect that healed, or a bilateral defect of which both sides healed (RR 1.14, 95%CI 0.44, 2.98, p=0.785).

In univariate analysis factor that predicted bony union of the spondylolysis (secondary outcome) was the stage of the spondylolysis in baseline CT ($p<0.001$) whereas patient's age, gender, laterality of the spondylolysis, level of the spondylolysis or brace type did not affect bony union ($p=0.785$, all comparisons collected to Table 3).

The HRQoL at baseline did not differ in any domain of the SRS-24 between treatment groups. At the end of the treatment the HRQoL of the patients (secondary outcome) was similar in both treatment groups in all domains of the SRS-24 (Table 4). Total SRS-24 score at 4 months was a mean (95% CI)

3.73 (3.59, 3.86) in patients treated with a Boston brace and a mean (95% CI) 3.85 (3.74, 3.96) in patients treated with an elastic lumbar support (MD 0.128, 95%CI -0.052, 0.308, p=0.159).

The impact of the bony union of the spondylolysis to the HRQoL was evaluated and the results of the SRS-24 scores in patients who did not achieve bony healing of a unilateral defect or both sides of a bilateral defect (non-union group) and in patients who did (union group) are seen in Table 5. The SRS-24 scores at the end of the 4 months treatment in all domains of the questionnaire were at similar level in patients who achieved bony union and who did not (results not shown). When comparing SRS-24 scores before and after the treatment it was noted that pain domain raised in all patients ($p<0.001$) and additionally activity domain raised in patients who achieved bony union of the defect ($p=0.021$) (Table 5).

DISCUSSION

Comparison with existing literature

To our knowledge, this is a first prospective, comparative study of a rigid thoracolumbar orthosis and an elastic lumbar support for treatment of acute pediatric spondylolysis. Treatment of adolescent spondylolysis varies worldwide between institutions. Other providers use brace treatment while others do not. Treatment methods have not been based on literature but more on clinical practice. Effectiveness of rigid brace treatment remains unproven in the current study. Earlier studies have shown good union rates with various kinds of rigid orthosis used for the treatment of adolescent spondylolysis. In previous study done by Virkki et al. [6] bony union rates with a Boston brace were 82.6% for incomplete fractures and 28.9% for complete fractures. This is in line with previous publications, where a rigid thoracolumbar orthosis achieved bony union of the spondylolysis for 94% of the early lesions and 37.1-80% of the progressive lesions [3, 4, 5]. Treatment of pediatric spondylolysis with a soft brace is studied mostly with a Damen soft corset, and with it the union rates have been reported to be 62-87-%

for the early lesions and 32% for the progressive lesions [10, 14]. However, studies comparing brace treatment efficiency with standardized treatment protocols are scarce. In this study we could not show any difference in the healing rates when pediatric spondylolysis was treated with a rigid thoracolumbar orthosis or an elastic lumbar support. A low-profile, elastic lumbar support does not give much spinal support and therefore is quite close to the natural history of the spondylolysis. Based on this study a rigid thoracolumbar orthosis is not necessary for treatment of acute pediatric spondylolysis.

When comparing patients HRQoL at the end of the treatment we could not prove that treatment method or achieving a bony union of the spondylolysis would affect it. There is very limited data of the HRQoL of pediatric spondylolysis patients. Zusman et al. 2020 [13] compared adolescent spondylolysis patients' HRQoL with age-matched controls and preoperative adolescent idiopathic scoliosis patients and noticed that spondylolysis patients have lower scores in pain, function and self-image domains of the SRS-22 compared to other two groups. However, they measured spondylolysis patients' HRQoL only before possible treatment for spondylolysis. Miller et al. 2004 [15] studied the functional outcome of 40 young athletes with early detected spondylolysis. In their study most of the patients (91%) had an excellent functional outcome based on low back outcome score an average of nine years after the treatment of spondylolysis. Bony union of the spondylolysis was reported in only eleven patients of their cohort. Achieving bony union may have implications in the long-term, such as preventing development of spondylolisthesis known to be associated with more back pain especially when above the L5 level (Frennered K. Isthmic spondylolisthesis among patients receiving disability pension under the diagnosis of chronic low back pain syndromes. Spine (Phila Pa 1976) 1994 Dec 15;19(24):2766-9.).

Strengths and Limitations

There are limitations in this study. Ideally, the effect of a rigid thoracolumbar orthosis on the healing of spondylolysis should be confirmed with a randomized clinical trial. This study was started as a randomized study, but study design was changed after a while due to patient refusals because of the randomization. Blinding was not possible in the randomized cohort as both treatment options were introduced to the adolescents and their families before informed consent. However, radiologist was blinded to the brace type. Similar problem with randomization was in the BRAIST trial [16] that compared the effect of a rigid orthosis on the progression risk of adolescent scoliosis. In the BRAIST trial the randomized trial arm was ended before the inclusion requirement was fulfilled because patients wanted to decide themselves between the brace treatment and observation. Patient's choice of brace type was based on various factors. However, based on the comparison of clinical characteristics of the patients both study groups were similar in terms of age, duration of symptoms, baseline health-related quality of life, and type of lesion. Patient cohort of 54 patients is considered as sufficient, but a larger study comparing brace treatments would bring more data of this topic.

Another limitation of this study is the follow-up time of four months. It is ideal for evaluating the healing of the spondylolysis but relatively short to evaluate the long-term HRQoL. Sakai et al. 2017 [4] treated adolescent spondylolysis patients with a thoraco-lumbo-sacral-type trunk brace (Sairyo-model hard corset) and followed up patients using monthly MR images after the first presentation and confirmed bony healing with a CT scan. In their study the average time for achieving a bony union of the spondylolysis was 2.5 months for very early lesions, 2.6 months for early lesions and 3.6 months for progressive lesions. Therefore, the treatment time of four months in our study can be considered as sufficient.

We did not have monitoring device inside the braces or the elastic supports. Therefore, their actual use remains somewhat uncertain, although compliance (good / poor) as reported by the patients themselves was recorded at 4 month follow-up. 19 / 21 (90%) of the patients in the Boston and 14/15 (93%) in the elastic support group reported good compliance. We hypothesize that as all of our adolescents were active in sports and they were highly motivated to use the prescribed immobilization to get back to the field as soon as possible.

In all patients, a selected CT was performed after 4 months' immobilization and this represents the gold standard to define bony union of the spondylolysis. Other strengths of this study include a prospective nature of the study, a standardized treatment protocol and a standardized and validated SRS-24 questionnaire to evaluate the HRQoL.

CONCLUSIONS

A rigid thoracolumbar orthosis did not improve the likelihood of achieving bony union for acute pediatric spondylolysis. Therefore, based on this study a rigid thoracolumbar orthosis is not necessary for the conservative treatment of acute pediatric spondylolysis. An even larger, randomized trial comparing the methods of spinal immobilization in treatment of spondylolysis would be needed. A long-term evaluation might reveal, how many of these adolescents will develop spondylolisthesis during remaining growth. The HRQoL of spondylolysis patients was not dependent of the treatment type or bony union of the pars defect. A long-term, prospective cohort study would bring more information of the HRQoL of pediatric spondylolysis patients.