Could the clinical effectiveness be improved under the integration of orthotic intervention and scoliosis specific exercise in managing adolescent idiopathic scoliosis? -A randomized controlled trial study

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Abstract

Objective: To compare the effectiveness of the integration of orthotic intervention (OI) and scoliosis specific exercise (SSE) with orthotic intervention only via assessing the spinal deformity, back muscle endurance and pulmonary function of the patients with adolescent idiopathic scoliosis (AIS).

Design: It is a prospective randomized controlled study. Patients who fulfilled the SRS criteria for OI were randomly assigned to the OE group (combined orthotic and exercise intervention) or the OI group (orthotic intervention only). All the subjects were prescribed with a rigid thoracolumbosacral orthosis and SSE program was provided to the subjects in the OE group. Cobb angle, back muscle endurance and pulmonary function of subjects were measured at baseline, 1-month and 6-month follow-up visits.

Results: After 6 months of intervention, the subjects in the OE group showed better Cobb angle correction than those in the OI group. The back muscle endurance and pulmonary function decreased in the subjects of the OI group, while some improvement happened in the subjects of the OE group. Between-group statistical significance was detected at the 6-month follow-up among back muscle endurance time and parameters of pulmonary function.

Conclusion: In this study, OI combined with SSE offered better Cobb angle correction and improvement of the respiratory parameters and back muscle endurance of the patients with AIS as compared with OI only.

Keywords: Adolescent idiopathic scoliosis; Orthotic intervention; Scoliosis specific exercise; Spinal deformity; Back muscle function; Pulmonary function

Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity with unknown etiology that occurs in adolescents aged 10 years or older.[1] It is diagnosed in a standing posterior-anterior radiograph with a Cobb angle >10°. Treatment strategies for AIS include conservative treatments and surgery based on the severity of spinal deformity. Surgery is usually considered for the patients with spinal curvature >45°. The majority of patients with AIS receive conservative treatments with the goal to prevent and slow down the curve progression.[2] For the patients with curvature between 20° and 45°, orthotic intervention (OI) and scoliosis-specific exercise (SSE) are commonly recommended by the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT).[3]

The effectiveness of the rigid brace (TLSO) in the management of AIS was recently reported by a multicenter randomized controlled trial (RCT), which demonstrated that OI significantly decreased the progression of high-risk curves to the threshold for surgery compared to observation.[4] It is generally suggested to wear the rigid brace at least 23 hours per day for 2-3 years until the bone maturity of the patients, which may lead to some side effects:

the long-term orthosis intervention may restrict the rib-cage and decrease the lung volume,[5] its rigidity may also limit the activities of the back muscle leading to its decreased strength.[6]

SSE, as another conservative treatment, has been used commonly for the management of AIS.[7] Differing from OI, SSE allows patients to move without restrictions, thus less side effects were reported and some studies have reported that SSE is effective to decrease the progression of AIS.[7] In addition, there have been an increasing number of studies that demonstrated the positive outcomes of SSE on improving the pulmonary function and back muscle function of the patients with AIS.[8,9] SSE was therefore recommended by the SOSORT guideline as an add-on treatment for patients under OI, not only to enhance the orthosis effectiveness, but also to prevent or treat the side effect of OI.[3] However, these recommendations were mostly based on observational studies or experts' opinions. There have been no controlled studies which compare the effectiveness of SSE during OI with orthosis alone in patients with AIS. To test the hypothesis that SSE during bracing would achieve better correction of spinal deformity and more benefits on pulmonary function and back muscle endurance compared with orthosis only, this randomized controlled study was conducted to investigate the effectiveness of the integration of OI and SSE versus OI only via assessing the spinal deformity, pulmonary function and back muscle endurance in the patients with AIS.

Methods

Subjects

The patients who fulfilled the subject selection criteria of the Scoliosis Research Society[10] for OI were enrolled from a local scoliosis clinic. The inclusion criteria were a) age of 10 or older; b) primary curve of 25°-40°; c) Risser grade of 0-2; & d) female with premenarchal or less than one year postmenarchal. Subjects with diagnoses other than AIS, contraindications to exercise (such as cardiopulmonary diseases, systemic infections, uncontrolled metabolic diseases, psychiatric problems, neuromuscular diseases and so on), or prior treatment were excluded from the study. Informed consent forms were signed once the eligible subjects agreed to participate in this study. Informed consent forms were signed once the eligible subjects and their parents agreed to participate in this study. This RCT study was approved by the Chinese Clinical Trial Registry (Granted number: ChiCTR1800014730), and confirmed to all CONSORT guidelines and reported the required information accordingly (see CONSORT

Checklist, Supplemental Digital Content 1). Ethical approval was obtained from the China Ethics Committee of Registering Clinical Trails, and all procedures were conducted in accordance with the Helsinki Declaration of 1975.

Sample size calculation

Sample size was calculated with the G*power 3.1.7 software using a priori power analysis, with power set at 0.80, type I error rate of 0.05 and an effect size d=0.8, on the basis of Cobb angle correction of orthotic intervention referred from the previous literature.[9] The estimated sample size would be 21 participants per groups, 25 subjects per groups were required for allowing 20% loss in follow-up visits.

Randomization and blinding assessment

The randomization sequence was generated using a computer program. Subjects were randomly allocated to the OE group or the OI group in the ratio of 1:1. The allocation information was sealed in envelopes. Once a patient consented to participate in, an individual administrator opened the envelopes in sequence and then informed the doctor with the allocated treatment regimen. Subjects and clinicians were not blinded, however investigators who collected and analyzed data were blind to treatment allocation.

Intervention for the OI group

All the subjects were prescribed with spinal orthosis (TLSO) and received preliminary assessment for orthosis design and fabrication at the first visit. Subjects were requested to wear orthosis 23 hours a day and 1 hour for personal hygiene and exercise activities. Subjects were followed up every 3 months for orthotic re-evaluation and modification.[11] For compliance monitoring, log-sheets were provided to the subjects and their parents for recording their wearing time in daily basis. In addition, interview for compliance study was launched when the subjects came to the scoliosis clinic for follow-up visits.

Intervention for the OE group

Subjects of the OE group received the Scientific Exercise Approach to Scoliosis (SEAS),[12] which consisted of: a) active self-correction exercise to restore movements of different planes as close to physiologically normal as possible; & b) spinal stabilization exercise to strengthen intrinsic muscles of spine to counteract of evolution of the curve. In addition, a specific breathing exercise was applied to improve lung capacity and rib mobilization. These exercises, individually prescribed according to subjects' scoliotic pattern as well as physical abilities, were taught to the subjects in scoliosis clinic every 2-3 months, followed by 40 minutes clinical treatment per week combined with a daily 10-15 minutes home exercise session. Clinical visits were recorded, including treatment date and duration, attendance or not and the reason for absence, and logbooks were used for self-recording of the subjects' home-exercise compliance.

Assessments

The treatment outcomes measured at baseline, 1-month and 6-month included: spinal deformities, back muscle endurance and pulmonary function of the subjects. All the data analyses in this study were performed by the research investigators, who were blinded to the treatment assignment and follow-up visits.

Spinal deformity

The "Cobb angle" method was used to quantify the degree of spinal deformities.[13] Cobb angles of the major curves were evaluated at the baseline and the 6-month follow-up. Each measurement was made by the same assessor with same protractor to minimize the measurement error.

Back muscle endurance

Back muscle endurance was assessed with the Biering-Sorensen test (BST).[14] It is a muscle performance test used to evaluate the isometric endurance of the trunk extensor muscles.[15] The subjects laid on the examining table in the prone position with the upper edge of the iliac crests in alignment with the edge of the table. The lower body was fixed with three straps which were located around the pelvis, knee and ankle level, respectively. The subjects were asked to hold on the upper body in a horizontal position with hands crossed over the chest. The time the subject could hold the horizontal position was recorded. Longer hold time would indicate better back muscle function. The test was validated for measuring back muscle fatigue.[16]

Pulmonary Function

Subjects were asked to remove the orthosis at least two hours before pulmonary function test. This test was performed with subjects in sitting position. Forced expiratory volume in the first second (FEV_1), forced vital capacity(FVC), FEV_1/FVC, were determined by static spirometry (MasterScreen CPX, CareFusion, Germany). Each pulmonary function test was repeated three times, and the mean values of each variable were used.

To ensure adequate rest, the subjects had 25-30 minutes interval between the Biering-Sorensen test and the pulmonary function test.

Statistical analysis

Normality of each studies parameter was tested with the Shapiro-Wilks test. Data were expressed as mean values and standard deviation (SD), when the normality assumption was accepted. Independent sample t-test was used to determine statistical difference in the baseline demographics as well as each of the outcome measures between groups over time. Intra-group comparisons were carried out with one-way repeated measures ANOVA. Post-hoc tests were conducted with Bonferroni method. Statistically significant level was set at $p<0.05$. All statistical analyses were conducted using the SPSS statistics 20.0 software (IBM Corporation, USA).

Results

Between May 2017 and April 2018, eighty-six subjects were assessed for eligibility in the scoliosis clinic, fifty subjects met the inclusion criteria and agreed to participate in this study. Twenty-two subjects (mean age=12.13 yrs, range=10.0-14.0 yrs) with a mean (SD) Cobb angle of 28.64° (3.91)° (range=22.0°-36.0°) in the OI group and twenty-three subjects (mean age=12.22 yrs, range=10.0-14.0 yrs) with a mean (SD) Cobb angle of 29.13° (4.32)° (range=23.0°-37.0°) in the OE group completed 6 months intervention, and five subjects were lost to follow-up (2 preferred other interventions, 3 withdrew without reason) (Figure 1). The curve types of the subjects based on the Ponseti[17] classification were as follows: the OI group included 5 thoracic curves, 6 lumbar curves, 8 thoraco-lumbar curves, and 3 S-shaped curves, while the OE group consisted of 6 thoracic curves, 6 lumbar curves, 7 thoraco-lumbar curves, and 4 S-shaped curves. No statistical difference was detected in the comparison of demographic information and baseline measurements between groups (Table 1).

Spinal deformity

Intra-group and inter-group comparisons of spinal deformity were shown in Table 2. After 6 months intervention, the OE group showed a significant improvement in Cobb angle from 29.13°±4.32° to 24.26°±1.96° ($p<0.001$), a Cobb angle reduction was also observed in the OI group from 28.64°±3.91° to 26.59°±3.57°, but did not reach statistical significance ($p=0.053$). For inter-group comparison, subjects in the OE group showed a statistically significant better Cobb angle correction from baseline to 6-month follow-up than subjects in the OI group (4.87±3.83° vs. 2.05±4.68°, $p=0.032$).

Back muscle endurance and pulmonary function

Intra-group comparisons of BST time, FEV_1, FVC and FEV_1/FVC for two groups were shown in Table 3. Figure 2 presented inter-group comparisons of back muscle endurance and pulmonary function at baseline and follow-up periods.

The average BST time in the OI group showed significant deteriorations from the baseline to the 6-month measurement ($p<0.001$) as well as from the 1-month to the 6-month measurement ($p=0.002$), while it significantly improved in the OE group among all the comparisons of three visits. As compared to the OE group, the OI group had significant shorter hold time at both 1-month ($p=0.007$) and 6-month ($p<0.001$) follow-ups.

With regard to FEV_1, subjects in the OE group showed remarkable improvement after one month intervention (2.67L ±0.74L at baseline vs. 2.74L ±0.78L at 1-month, $p=0.007$), further significant improvements were obtained at 6-month, in relation to the baseline (2.93L ±0.6L at 6-month, $p<0.001$). However, there was a decline in the OI group for the first month (2.49L ±0.65L at baseline vs. 2.36L ±0.65L at 1-month, $p=0.007$), although a significant improvement was recorded between the 1-month and the 6-month follow-up (2.43L ±0.66L at 6-month, $p=0.009$), the average values of FEV_1 at the 6-month follow-up were still significantly lower than that at the baseline (p=0.020). In the inter-group analysis, statistically significant difference of FEV_1 was only detected at 6-month measurement (p=0.022).

In terms of FVC, the OE group demonstrated significant improvement from the baseline to the 6-month measurement (p<0.001) as well as from 3-month measurement to 6-month measurement (p<0.001). On the other hand, the OI group presented significant reductions in FVC after one month intervention (2.95L ±0.69L at baseline vs. 2.85L ±0.72L at 1-month, p=0.008), the results were maintained at the 6-month follow-up (p=0.845). Statistically significant between-group difference of FVC was detected at the 6-month follow-up (p=0.045), but was not presented at the 1-month follow-up (p=0.191).

For FEV_1/FVC, significant differences were observed in the OE group between the baseline and the 1-month measurement (p=0.013) as well as between the baseline and the 6-month measurement(p=0.003), while results did not differ significantly across all three time points in the OI group. The FEV_1/FVC values in the OE group were significantly higher than that in the OI group at the 1-month (p=0.006) and the 6-month follow-up (p=0.007).

Discussion

This RCT study compared the clinical effectiveness of SSE combined with OI versus OI only on Cobb angle, pulmonary function and back muscle endurance in the patients with AIS. The results showed that SSE combined with OI tended to be superior to OI only in the correction of spinal deformity. In addition, the patients with AIS received both SSE and OI showed significantly better improvements in terms of pulmonary function and back muscle endurance.

The effectiveness of spinal deformity correction is one of the major considerations for clinicians to prescribe intervention to the patients with AIS. After 6 months intervention, Cobb angle decreased averagely 4.87° in the OE Group, while only 2.05° in the OI group, which meant the correction of Cobb angle was significant more in the OE group (p=0.032). These results substantiated the findings of an early cohort study,[18] which showed that exercise combined with orthosis increased the proportion of patients with Cobb angle improvement ⩾ 6° by 6% compared with that of OI only. The exercise programs performed in the above two studies were both SSE. They followed the similar principles and shared common goals to help orthoses to take effects. Specifically designed training included in the SSE grogram, such as kyphotisation and rotation training, were performed during OI, which allowed additional forces to be acted on the soft tissues and through them to increase the pressure that orthoses exerted on the spine.[19] In addition, mobilizing training was taught to the patients aiming at improving the mobility and plasticity of the spine, allowing the orthoses to achieve the better corrective results[12,20].

The effectiveness of orthotic intervention on preventing the deformity progression and reducing the need for surgery has been demonstrated in recent studies.[4,21] There were various orthotic designs available in the management of scoliosis, differing in building method, rigidity, mechanism of action and plane of action. The Boston brace (a commonly used TLSO) is an individually fitted orthosis with corrective pads placed on the convexity of the curve and relief points, which prevents progression through applying three-point pressure to the spinal curvature.[22] SpineCor is a flexible orthosis that provides dynamic de-rotation straps rather than rigid thermoplastic shell and it seems more acceptable to patients because of its fabric material, however, its failure rate was found significantly higher than that of the rigid brace.[23] Charleston brace is designed to be worn during sleeping hours with the patient arranged in the supine bending position. Katz et al.[24] retrospectively compared 319 patients with AIS treated either a Charleston brace or a Boston brace patients, 83% of Charleston brace patients had curve progression of > 5°, whereas only 43% of Boston brace patients progressed. Each type of spinal orthosis has its characteristics and target population, and none was distinctly superior to the others with regard to curve progression, psychological impact or need for surgery. The commonly used TLSO was prescribed in the current study. In order to achieve better therapeutic outcomes, patients were generally required to wear the orthosis full time for 3-4 years till skeletal maturity. Long-term orthosis wearing may unavoidably bring about the immobilization of trunk and disuse of back core muscles.[25] However, less attention has been paid to back muscle function of patients with AIS, and little was known about the influence of OI on back muscle function. Danielsson et al.[26] evaluated the back muscle function and found that patients treated with orthosis presented reduced muscle endurance of both lumbar flexors and extensors even 20 years after the intervention. The results of current study were consistent with their findings, patients treated with orthosis only showed a significant decrease in back muscle endurance after 6 months intervention. Back muscle weakness caused by OI should not be ignored, since back muscle was essential to maintain spinal alignment and stabilize the body postures. More importantly, the combination of back muscle weakness and asymmetry of trunk muscle has been considered to serve an important role in the development of spinal deformity.[27] The effects of SSE on back muscle function of AIS patients was firstly investigated by

Schreiber et al.[28] Patients showed better back muscle endurance when SSE was added to the standard care (OI or observation) for patients with AIS. While their study could not identify the effects of exercise combined with orthosis on patients' back muscle endurance, because observation was also included in the standard treatment. Only orthosis treated patients were enrolled in this study, patients treated with OI and SSE showed better back muscle endurance than those received OI only at both 1-month and 6-month follow up. These findings suggested that exercise is effective in improving back muscle function of patients undergoing OI. SSE applied in the OE group were based on an active self-correction technique, with the purpose of utilizing the intrinsic muscles of the spine as much as possible. The deep core muscles (i.e. transversus abdominis and multifidus) could be activated and trained to achieve the goal of improving the negative effects of orthosis on muscles.

Potential respiratory alteration caused by OI is another concern. Kennedy's team reported OI could significantly decrease lung volumes in patients with scoliosis (16% reduction in total lung capacity, 18% reduction in FVC).[5] In the current study, significantly decreases of FEV_1 and FVC were also found in the OI group after one month intervention. Differed from previous studies, the present study found a trend of improvement on the parameters of pulmonary function from the 1-month to the 6-month assessment. This might be explained by the physical adaption to the restriction of OI, reduced pulmonary function could recover through some respiratory compensatory mechanisms.[29] However, pulmonary function of the patients treated with OI only at the 6-month follow-up was lower than that at the baseline, which meant 6 months OI still negatively affected the pulmonary function of patients with AIS. Despite there was no symptom occurred in the early stage, the impairment of lung function could be aggravated by the long-term orthotic intervention, leading to loss of lung elastic recoil, weakness of respiratory muscle and obstruction of the airways. In order to avoid the further deterioration of pulmonary function, specific intervention is needed. In the current study, patients in the OE group performed a specific breathing exercise and presented better pulmonary function at the 6-month evaluation than patients treated with OI only. This breathing training is different from conventional exercise as it is designed for patients treated with orthotic intervention through improving rib mobilization to release orthosis restriction on respiratory excursion.[30]

Several arrangements have been in place for reducing the potential bias of this study such as the prospective randomized control design, strict implementation of inclusion and exclusion criteria and blinded analyses. The relatively short follow-up period could be considered as one of the limitations of the current study. Although correction of Cobb angle after 6-month intervention is statistically significant, a long-term clinical significance is needed to be further studied. Additionally, the radiographic outcome was presented in terms of the pre- and post-treatment difference in Cobb angle. The number of patients who improved by > 5° (success rate) or progressed by > 5° (failure rate) would be more persuasive to reflect the effectiveness of an intervention in the long-term follow-up.[10] Furthermore, compliance to bracing and exercise was not scientifically recorded (by self-reporting only), which could affect the actual results.

This study was application of a full conservative strategy in management of the patients with AIS, including not only bracing but also specific exercises. The combination of bracing and exercises resulted in a significant improvement of spinal curvatures. This is in line with the findings of Hedayati et al.[31] that not only reduced scoliosis Cobb angle but also increased patient satisfaction were observed when bracing was combined with grouping exercises. Both studies provided experience and references for the clinical application of exercise during orthotic intervention for AIS. Furthermore, the accurate and comprehensive assessments of the respiratory function and back muscle function for the patients treated with orthosis would certainly add value to the general understanding of the possible negative effects of orthotic intervention.

As this study was based on a group of AIS patients with moderate curvature (25-40°), the generalization of the current findings to the patients with mild or severe spinal deformity remains an important extension of this research.

Conclusion

In this study, orthotic intervention combined with scoliosis specific exercise offered better Cobb angle correction and improvement of the respiratory parameters and back muscle endurance of the patients with AIS as compared with orthotic intervention only. However, a long-term study with more subjects are deserved for confirmation of the current findings.

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Figure legends

Figure 1. Flowchart of patients participating in this study.

Figure 2. Inter-group comparisons of a) Biering-Sorensen test (BST) time, b) forced expiratory volume in first second (FEV1), c) forced vital capacity(FVC), and d) FEV1/FVC at baseline, 1-month and 6-month follow-ups. OI: the orthotic intervention only group; OE: the orthosis combined with exercise group; The results were shown as the mean and 95% confidence interval. *: $p<0.05$; **: $p<0.01$; ***: $p<0.001$.