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ORIGINAL ARTICLE

Bracing adults with chronic low back pain secondary to severe scoliosis: six months results of a prospective pilot study

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Abstract

Purpose Adult scoliosis is sometimes associated with back pain and severe curves can progress over time. Despite scoliosis has been estimated to affect up to 68% of the population over 60, there is scant literature about conservative treatment for adult scoliosis. Recently, we tested a new brace designed to alleviate pain for adult patients with chronic pain secondary to scoliosis. The study aims to test the efficacy of a prefabricated brace in reducing pain in adult scoliosis patients.

Methods Twenty adults (age 67.8 ± 10.5, curve 61.9 ± 12.6° Cobb) with chronic low back pain (cLBP) secondary to Idiopathic Scoliosis (IS) were included. Patients were evaluated at baseline immediately before starting with the brace and after 6 months. Outcome measures were GRS, Oswestry Disability Index (ODI), Roland Morris Questionnaire (RM), COMI. The paired *t* test, ANOVA and Wilcoxon tests were used for statistical analysis

Results At six months, worst pain, leg pain and back pain were significantly improved: from 7.15 to 5.60, from 5.65 to 4.35 and from 6.55 to 5.25 ($p < 0.05$). Sixty-five percent of patients achieved the minimal clinically important difference of 2 points for worst pain and leg pain, 55% for back pain. RM and COMI improved ($p < 0.05$), no differences for ODI.

Conclusion The prefabricated brace showed a significant improvement at 6 months of worst, leg and back pain in most patients in a group of adult women with IS and cLBP. The quality of life didn't change in a clinically significant way even if the patients reported satisfaction with the treatment.

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Keywords Adult scoliosis · Chronic pain · Low back pain · Conservative treatment · Spinal orthotics

Introduction

The impact of spinal deformities in adult and elderly people is completely different compared with growing patients [1]. While during growth the main concern is aesthetic, with a quite good quality of life and pain is quite unusual [2], backache characterizes adult scoliotic patients, whether or not associated with the progression of the deformity, both in the sagittal and in the coronal plane [3–5]. The evolution of the adolescent idiopathic scoliosis in adulthood is reported especially in scoliosis more severe than 50°, while the risk of progression starts to increase as the curve grows above 30° [6]. The evolution of the "de novo" scoliosis is less linked to curve magnitude thresholds and is characterized by rapid changes with rotatory dislocation; nevertheless this form is frequently symptomatic [7]. Independently from the type of scoliosis, pain and progressive functional limitations are the main reasons for seeking treatment during adulthood [8, 9]. Poor Health-Related Quality of Life (HRQoL) scores are correlated with age, degenerative scoliosis disease, and positive sagittal balance [10, 11].

For back pain, one of the main issues faced by scoliosis patients, scoliosis-specific exercises have shown efficacy in reducing pain and improving HRQoL in case of minor curves of 30° on average [12] and dropping the progression of the deformity in more severe curves [13]. According to the current guidelines, bracing is another option, even if the evidence for adults is of very low quality [1]. For adult patients, the guidelines concerning the treatment of idiopathic scoliosis are less stringent since the evidence is much

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lower from the scientific perspective. Data about bracing come from some case reports, studies with a low level of compliance and are based mainly on custom-made braces on [14–16]. Moreover, the main outcome has usually been progression, with not much attention being paid to pain and quality of life [15].

Recent published data have shown that also prefabricated spinal orthosis can be helpful to quickly improve pain at 1 month in patients with chronic low back pain secondary to scoliosis [17]. The aim of the present study is testing the efficacy of this spinal orthosis to reduce back pain in adult scoliosis patients after six months of part time brace wear.

Methods

Study design A follow-up of a prospective experimental cohort study has been designed according to the STROBE guidelines. The methods, already described elsewhere [17], are briefly reported here.

Setting Tertiary referral outpatient center for scoliosis and low back pain.

Inclusion criteria Idiopathic or degenerative scoliosis of 30° Cobb or more suffering from chronic low back pain (cLBP—lasting for at least the last 3 months), 18 years of age or more.

Exclusion criteria Secondary scoliosis, previous spine surgical procedures.

Population Between April 1 and November 1, 2015, a group of consecutive adult patients with back pain secondary to idiopathic scoliosis or degenerative scoliosis were recruited [17].

Outcome measures

Primary the variation from baseline to 6 months follow-up of the worst pain, back pain and leg pain measured with the Graphical Rating Scale (GRS) [18].

Secondary the variation from baseline to the end of the 6 months of follow-up of disability and function, these outcomes were assessed using the Roland Morris Questionnaire (RM) [19], Core Outcome Measurement Index (COMI) [20], and Oswestry Disability Index (ODI) [21].

Protocol After a baseline clinical and radiological evaluation including ATR and Cobb angle measure [22], if considered eligible, the patients were invited to participate in the trial. Following acceptance, all participants had been evaluated at 1 month and then after 6 months of brace wear. They were prescribed to wear the brace at least 2–4 h per day, since this was the minimum amount of time that showed some benefit in pre-trial enrolled patients. At each evaluation, they had to complete self-administered questionnaires and scales: GRS, Roland Morris Questionnaire, ODI and COMI.

The brace is the Peak Scoliosis Bracing System™ (Aspen, USA), now called Aspen Tri-Point™ FSO, has been used (Fig. 1). This is a prefabricated adjustable brace that addressed postural correction in the frontal and sagittal plane mainly. It presents an adjustable thoracic pad to prevent the lateral collapse by making a 3-point system together with an adjustable trochanter pad on strut that allows a three-point contact. The belt is made to restore and support the lumbar lordosis, thus improving the sagittal balance. The authors were provided with braces to fit some patients before the study began but were not involved in the development of the brace.

Sample size

The sample size was calculated in the previously published prospective observational cohort study. The primary outcome was pain changes over time, the effect size was calculated from data collected during the development of the brace in the US, and the first two patients fitted in Italy. The estimated effect size, coming from literature on pain scales [18], was an improvement of about 2 points in the Graphical Rating Scale (GRS) of pain over the follow-up period. In order to be able to detect a minimum difference of 2 points at the GRS after six months of brace wear we need 16 subjects acting as their own controls from baseline to end of follow-up, at a power of 80% and a 2-tailed significance level < 0.05. Experiences from everyday practice indicate

Fig. 1 The Peak Brace from the back and the side

25% lost to follow-up for 6 months. Based on the power calculation ($n = 16$) we will enroll a total of 20 individuals.

Statistical analysis

For normally distributed continuous variables a 2 tailed paired *t* test was applied; otherwise, Wilcoxon test for ordinal data and not-normally distributed data was used. The alpha level of significance was set at 0.05.

Proportion of subjects reaching the MCID of 2 points at the GRS, were reported.

This study respected the principles of the Helsinki Declaration and was approved by the local ethics committee. All patients signed a written informed consent.

Results

Twenty female patients were recruited. The mean age was 67.8 ± 10.5, the mean curve magnitude was 61.9 ± 12.6° Cobb, and the average body mass index (BMI) was 24.07 ± 3.65. The three osteoporotic patients continued the pharmacological treatment. No other musculoskeletal conditions were detected. Six patients were performing scoliosis-specific exercises according to the SEAS protocol since at least three years and their pain condition was stable over time at the beginning of the study. They didn't change their standard level of activity during the study. The study included only female patients due to the convenience sampling of consecutive patients we recruited. The 20 patients recruited for the previous study continued wearing the Peak Scoliosis brace for 2–4 h a day, in agreement with the prescription, every day for 6 months, and there were no loss to follow-up [17].

At the end of the six months follow-up, all pain measures on GRS improved significantly with respect to baseline: worst pain, leg pain and back pain were all improved, changing, respectively, from 7.15 to 5.60, from 5.65 to 4.35 and from 6.55 to 5.25 (Table 1). Examining in details, 65% of patients reported improved worst pain and leg pain, 55% improved back pain (slightly inferior to the one month results that was 75% worst pain and leg pain and 65% back pain).

Considering the MCID for pain of 2 points at the pain scales[18], 55% of patients achieved the minimal clinically significant difference of 2 points for worst pain (that was only 30% at 1 month), 50% for leg pain (that was 60% at 1 month), and 40% for back pain (that was only 25% at 1 month). In the disability questionnaires, both RM and COMI continue to improve in a statistically significant way, while ODI did not, even if the changes were not clinically significant (Table 1). Most patients continue to be satisfied with the result on pain and wearing the brace. The few criticisms reported are that it is a bit cumbersome (often referred to by those who must wear any type of brace).

Discussion

Conservative treatment for adult scoliosis is challenging. Quality of life and pain are the main reason for seeking treatment. Part-time bracing and physiotherapeutic scoliosis-specific *exercises (PSSE)* could give pain relief and prevent progression [13]. PSSE have proven to be superior to natural history, especially in patients who refuse scoliosis surgery [13]. Specific exercises have the task of recovering postural collapse, postural control and spinal stability through active self-correction [1]. Postural integration is a key element, including neuromotor integration of correct postures and an ergonomic education program [23]. Braces in adults are not so frequently used, unlike children, perhaps mainly due to comfort issues, but can be integrated with exercises to achieve better results [24]. Few studies showed the effect of bracing in adult patients; they refer to custom-made polyethylene braces. One reported the effect of the combination of an asymmetric custom-made brace and PSSE on pain, posture and appearance, a second one analyzed the effect of a plaster cast for 3 weeks followed by a rigid polyethylene

Table 1 Outcome measures at baseline, 1 month and 6 months and statistical differences

	Baseline (T0) Mean/median (SD/95%CI)	1 Month (T1) Mean/median (SD/95%CI)	6 Months (T2) Mean/median (SD/95%CI)	*P* value T0-T1	*P* value T1–T2	*P* value T0–T2
Worst pain (back or leg)	7.15 ± 2.03	5.85 ± 2.81	5.6 ± 2.13	0.011*	0.71	0.007*
Back pain	6.55 ± 2.37	5.25 ± 3.21	5.25 ± 2.69	0.049*	1.00	0.06
Leg pain	5.65 ± 3.03	3.55 ± 3.33	4.35 ± 2.66	0.003*	0.28	0.04*
RM	12.50 (11.45–15.84)	11.50 (8.42–13.67)	10.85 (8.48–13.21)	0.018*	0.87	0.004*
COMI	5.67 (5.11–6.79)	4.82 (3.76–5.84)	4.18 (3.34–5.02)	0.035*	0.17	0.002*
ODI	33.00 (25.26–38.43)	30.00 (21.05–35.74)	33.05 (26.30–39.79)	0.06	0.14	0.96

*Statistically significant

bivalve overlapped brace worn for at least 4 h per day on progression of spine deformity in terms of Cobb angle and postural balance [24, 25]. Our study shows data concerning a prefabricated brace. An advantage of this brace that it is highly adjustable depending on the patient. Not only based on the sizes, but also with the adjustable tension straps and struts, which optimize the angle from which the tension is applied. In addition, there was the possibility of adding or removing the lateral support, which could be adjusted according to the patient's needs, then placed anywhere on the belt to optimize support.

Considering the average values of pain pre and post treatment, we have fund that there was a statistically significant improvement reaching the MCID in most of the subjects. Most of the changes happened in the first month and then the results were maintained. This is very interesting especially if we consider that LBP in these patients it's quite stable, as demonstrated by the data coming from the control group reported by of Monticone, in which, over a one year follow-up during which the patients were treated with generic exercises the pain scores remained stable [12].

Almost all the patients reported satisfaction with the easy wearing of the brace and the experienced good comfort. In addition, the patients reported pain relief: a further improvement compared to that recorded after one month of treatment. Two out of three patients achieved some pain relief, slightly less than one month's wear. However, the percentage of patients who achieved clinically significant improvement of 2 points on the GRS scale arose. Fifty-five percent of patients reduced the worst pain which was only 30% to 1 month, so it could be that a continuous wearing of the corset helps to further improve the pain and activities of daily life. We enquired also about the use of drugs, and patients reported they have reduced the need for NSAIDS. About their usual physical activity and exercises, they reported no changes, so we can state this was not connected to the improvements in pain.

The quality of life didn't change in a clinically significant way even if patients reported satisfaction with the treatment. It's possible that a higher dosage would guarantee a better effect, and it would be important to determine the features of responders with respect to non-responders in a larger study. A possible explanation of these limited results relies on the low daily dosage prescribed, even if the choice was made according to preliminary clinical reports of patients. Moreover, we included only very severe scoliosis, with and average Cobb angle of 62°, and it's possible that lower degree curves better results. It's also possible that the scales we used, that were developed to evaluate disability and quality of life in non-specific cLBP patients are not informative in a group of scoliosis patients. Maybe the limitations in everyday life and the benefits of the treatment are not well captured by these scales.

Previous reports describe mainly results in terms of prevention of progression [15], with scant attention to pain and quality of life [14]. Nevertheless, these are frequently significant problems for patients that may be hard to be treated effectively, especially when exercises are not enough, and surgery is prevented due to a poor general health.

The brace is helpful when it's regularly used. We do not think we can expect these results to be maintained over time in case the treatment is abandoned. No data are available on this topic, so we can only argue that a continuous treatment will be needed. We feel also that patients accept this principle, and when they decide to start using a brace are conscious that it will be always necessary. Considering that the extension of follow-up produced improved results, our recommendation could be to pursue this part time brace wear permanently. Starting with such a short period of brace wear (2–4 h per day) would also allow the expert clinicians to increase the dosage in case of need.

This study has some shortcomings: including a limited number of females only patients, as well as not having a control group. It would have been interesting to compare this group with those who refused to wear the brace or to another similar group that only did exercises, but this was not cost-effective, for an exploratory study. However, a comparison to literature data is provided. Unfortunately, there are few studies in the literature investigating the effect of braces in adult scoliosis, experimental designs are expensive, require time and expose to ethical concerns. Larger cohort of adult subjects observed prospectively for longer period will produce interesting insight on this topic and will provide data for comparisons of different subgroups of patients.

Conclusion

This new prefabricated scoliosis brace showed improvement in pain adult women with scoliosis and cLBP in the very short term. After six months of follow-up further improvements in pain were seen. The improvement of pain exceeded the 2 point minimally significant difference in more than 50% of cases. Although the quality of life remained stable over time, patients reported satisfaction with brace wear. Further studies are needed to verify the effectiveness of this specifically developed brace, in larger groups and longer follow-up to allow comparison with a control group and subgroup analysis.

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Declarations

Conflict of interest Stefano Negrini holds ISICO stocks.

Ethical approval The study respected the principles of the Helsinki Declaration and was approved by the local ethics committee. Comitato Etico Milano Area B parere 156_2015bis.

Consent to participate All patients signed a written informed consent.

Consent for publication All patients gave informed consent for publication.

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