

Clinical Study

Brace treatment is effective in idiopathic scoliosis over 45°: an observational prospective cohort controlled study

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Abstract

BACKGROUND CONTEXT: Recently, positive results in bracing patients with idiopathic scoliosis (IS) above 45° who refused surgery have been presented in a retrospective study. Obviously, this can give only an efficacy (EA) analysis, as there is neither a control group, nor it is possible to know failures because of dropouts.

PURPOSE: To present the prospective results of bracing patients affected by IS above 45° and still growing.

STUDY DESIGN: Prospective study including all IS patients with 45° or more, Risser stage 0 to 4, who had their first evaluation in our institute, an outpatient clinic specialized in scoliosis evaluation and conservative treatment, from March 1, 2003 to December 21, 2010 and utterly denied any surgical intervention.

PATIENT SAMPLE: Of 59 patients, we excluded 2 patients still in treatment and 57 (11 males) patients were included. At the beginning of the study, they were 15 years 3±22 months of age, had 52.5° Cobb (range, 45°–93°), and Risser 2 (0–4). Thirty-nine accepted a full-time brace treatment (BG) to try avoiding surgery, 18 refused any treatment and served as controls (CG).

OUTCOME MEASURES: *Physiological measures:* radiographic and clinical data.

METHODS: *Treatment:* A year of full-time Sforzesco brace (23 hours/day) or Risser cast (8–12 months) and gradual weaning after Risser 3; all patients performed exercises; and International Society on Scoliosis Orthopaedic and Rehabilitation Treatment management criteria were respected. *Analyses:* EA in patients who completed treatment/observation (34 in BG and 10 in CG) and intent-to-treat (ITT) with worst case analysis in the whole population. Relative risk (RR) and 95% confidence interval (CI) have been computed.

RESULTS: Efficacy: failures were 23.5% in BG and 100% in CG. Intent-to-treat: failures were 20.5% in BG and 55.6% in CG. Relative risks of failure in CG were 4.3 (95% CI, 3.6–4.9) in EA and 2.7 (95% CI, 2.0–3.5) in ITT ($p < .05$). Percentage of patients (53.8%) improved: RRs of improvement in BG were 1.6 (95% CI, 1.46–1.9) in EA and 1.9 (95% CI, 1.6–2.2) in ITT ($p < .05$). Patients who joined the treatment achieved a 10.4°±10.7° Cobb improvement, an ATR reduction of 4.2°±4.3°, and an esthetic improvement of 2.8±1.9 of 12 points (TRACE). At the end, in BG, 24 patients were below 45° and 6 patients below 35°.

CONCLUSIONS: Through this study we can conclude that the conservative brace plus exercises treatment (if correctly performed and managed) is a suitable alternative for those patients who reject any surgical intervention for IS above 45°. But we could also conclude that a good brace treatment

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should be considered as the first choice to try avoiding fusion because of the high sanitary and social costs of surgery. © 2014 Elsevier Inc. All rights reserved.

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Background

The most widely accepted outcome criterion of adolescent idiopathic scoliosis (AIS) is Cobb angle [1,2]. Decisions on AIS treatment come from what we know about its natural history; below 30°, the risks of worsening (and other health problems) in adulthood are very low [3,4] and above 45° to 50°, these risks become almost certainties [5,6]. Consequently, the aims of AIS treatment are primarily to remain below 30° if possible and, most of all, to avoid progression above 45° to 50° [5,7] because surgery becomes the most commonly proposed treatment beyond 45° to 50° [5,8].

The best literature gives weak evidence in favor of bracing [2]. Brace treatment is believed by most authors incapable of reducing AIS curvature. In fact, the most accepted criteria for AIS outcome evaluation, proposed by the Scoliosis Research Society, consider only “avoiding progression” and not “reducing the curve” [9]. A consequence of this approach to AIS treatment is that above 45° of curve, attempts of brace treatment are generally considered at best, an almost desperate attempt and at worst, a waste of time [10].

In recent years, wide criticism has surrounded brace treatment [11], with some negative results presented in the literature [8,12]. Nevertheless, positive results of bracing have been documented as well, particularly by the experts of the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) [13–17]. In some of these articles and others [10,18], the possibility of reducing AIS curves has been documented; it is now also proposed as a possibility by the SOSORT guidelines [5]. If this is true, is it not possible to also treat curves above 45°?

Recently, this possibility has been documented in a retrospective uncontrolled cohort of 28 patients with at least one curve above 45° who refused surgery [10]. They were treated full time with Risser cast, Lyon, or Sforzesco braces plus exercises; SOSORT management criteria were applied. Six patients (21%) finished between 30° and 35° and 12 patients (43%) finished between 36° and 40°. Improvements were found in 71% of patients. It was concluded that future prospective controlled studies should be performed to check the hypothesis of the usefulness of conservative treatment in the specific population considered in the study.

The aim of this article was to verify through a prospective cohort controlled study the final outcomes in patients with AIS and juvenile idiopathic scoliosis above 45° Cobb at first evaluation at our institute independently of any previous treatment.

Materials and methods

Design

Observational controlled cohort study nested in a prospective clinical database including all patients treated in an outpatient facility devoted to conservative treatment of scoliosis.

Population

Inclusion criteria were idiopathic scoliosis, at least one curve of 45° or more, Risser stage 0 to 4, age above 10 years, first evaluation in our institute between March 1, 2003 and December 31, 2010, and surgical intervention refused.

The study was performed in August 2012. From a database including 8,717 patients, we found 59 patients meeting the inclusion criteria; 2 patients had to be excluded because they were still in treatment and 57 (11 males) were included. At the beginning of the study, they had an average age of 15 years and 3 months (standard deviation, 1.10), an average 52.5° Cobb (range, 45°–93°), and were Risser 2 (range, 0–4). Thirty-nine accepted a full-time brace treatment (BG) in an attempt to avoid surgery, whereas 18 did not accept the treatment or came for a second opinion only and served as controls (CG).

All patients signed a consent form to their clinical data management for research purposes.

Methods

All patients in the BG were individually checked. We telephoned patients who dropped out from the BG and all of those in the CG to verify whether they had been finally fused; if they had not been operated on, we asked them to come to our institute with an X-ray for a free follow-up. Unfortunately, all patients apart from one rejected this offer because they did not want to know anything about their scoliosis; they were simply waiting for the first symptoms before going directly to the surgeon for fusion.

After this telephone contact and/or the personal check, each patient was included in one of the following subgroups: fused, waiting for fusion, progressed 5° or more, unchanged, improved 5° or more, and not retrievable. The last subgroup included all patients who were not possible to reach for any reason (ie, they never answered phone calls or email messages).

Treatment

Patients who arrived in our institute for the first time in 2003 and 2004 were treated with either a Risser cast

followed by the Lyon brace or only the latter if they refused a cast; from 2005, patients were treated with the Sforzesco brace. The therapeutic approach has been already described [10]; it requires the brace to be worn full-time (24 hours per day for the Risser cast and 23 hours for the Lyon/Sforzesco brace [19–21]) for the first year, followed by a 1 hour reduction for 6 months, and then a weaning of 2 hours every 6 months.

Physiotherapy-specific exercises [5,22] were prescribed systematically to all patients that were to be performed twice a week. Patients were prescribed SEAS exercises [23,24] to be followed-up and updated regularly in our institute (every 3 months—exercised then performed autonomously at home or followed by a trainer); the final decision of the patients was between SEAS or usual physiotherapy (UP) with a physiotherapist not coming from our institute.

Outcome criteria and statistics

Because our main aim was improvement, we considered the percentage of patients to have radiographically improved above the measurement error (5°) [5] as the main outcome. We considered the main curve (if there was more than one curve, both were considered main curves if their difference was less than 11° Cobb) and the maximum curve.

We calculated the relative risk (RR), the absolute risk reduction, and the number needed to treat (NTT) for success (improvement of 5° or more) and failure (either progression of 5° or more or fusion); for all parameters we calculated and 95% confidence interval (CI). We performed in two analyses: efficacy (EA) (that considers only completers, ie, patients who reached the end of the treatment and/or were retrievable for follow-up) and intent-to-treat (ITT) (that includes all patients and also considers dropouts).

In the ITT, groups were assembled differently because in the control group we had the highest percentage of nonretrievable patients (11 in total, 3 in BG and 8 in CG) and we always considered the worst possible situation for the treated group (Table 1).

The Scoliosis Research Society outcome criteria (percentage of patients progressed or fused) [9] were calculated too, whereas the criterion of number of curves progressing to 45° was inverted in terms of number of curves that improved reaching a level below 45° . Secondly, we considered the clinical and radiographic results: TRACE [25] for esthetics, Cobb degrees, ATR, and plumb-line distances [26–28] for the sagittal plane.

Finally, we considered patient's referred compliance. At each visit, the patients and their parents were carefully inquired about how many hours per day she/he had used the brace and the average usage during the reported period. This was subsequently compared with the prescription so that a percentage of compliance was computed. Currently, sensors can be used in the brace [29,30] that detect temperature during brace wearing and provide more accurate data, but this was not possible for the patients considered in this study.

EVIDENCE & METHODS

Context

Recent studies have confirmed the efficacy of bracing for skeletally immature patients with adolescent idiopathic scoliosis and curves in the range of 20° – 40° . The question remains, however, whether bracing can still be efficacious for individuals with curves that exceed 45° for whom surgery is typically recommended. The authors performed a prospective observational study among an adolescent population with scoliotic curves who opted for brace management, or no treatment, despite a recommendation for surgery.

Contribution

In this small series of 57 patients (39 treated and 18 controls), failure, defined as curve progression of 5° or greater, occurred in 23.5% of patients treated with a brace and 100% of controls. Nearly 54% of treated patients demonstrated improvements in the scoliotic curvature of 5° or more and close to 62% of the treated group had a final radiographic result measured below the critical threshold of 45° . The risk of failure was more than four times higher among patients who refused brace treatment and findings did not change substantially using a “worst-case scenario” model that took into account patients lost to follow-up.

Implications

The authors' report provides potentially useful information for physicians who have patients with scoliotic curves exceeding 45° and who yet wish to avoid surgical intervention. The results provide some putative evidence that, in this population, an effective bracing regimen may be able to provide satisfactory short-term results. The authors correctly recognize that their study design creates the potential for confounding by indication, as all patients treated with bracing were highly motivated to avoid surgery, and this may impair the study's generalizability. In addition, the results presented are relatively short-term, and the authors are unable to comment on longitudinal levels of satisfaction, health care utilization, or the eventual need for spinal fusion. Moreover, the study's design obviates any possibility of comparisons with surgical intervention regarding efficacy and outcomes.

—The Editors

Results

At baseline there were no differences between BG and CG in all clinical and radiographic parameters. In the EA, there were 8 failures (23.5%; 95% CI, 9.3%–37.8%) in BG and 10 (100%) in CG (Table 2). Accordingly, the RR of failure in CG was 4.3 (95% CI, 3.6–4.9) ($p < .05$)

Table 1

Definition of success or failure of the results obtained according to the different statistical analysis performed (RR of progression/fusion and of improvement)

Outcome	Progression/fusion		Improvement	
	EA	ITT	EA	ITT
Fused	Failure	Failure	Failure	Failure
Waiting list for fusion	Failure	Failure	Failure	Failure
Progressed 5° or more	Failure	Failure	Failure	Failure
Unchanged	Success	Success	Failure	Failure
Improved 5° or more	Success	Success	Success	Success
Not retrievable	—	Success	—	Failure

RR, relative risk; EA, efficacy; ITT, intent-to-treat.

Note: In both cases an EA and an ITT analysis have been performed.

and the NTT was 1.31 (95% CI, 1.10–1.61) (Table 3). In the ITT analysis, we had 8 failures (20.5%; 95% CI, 7.8%–33.2%) in BG and 10 (55.6%) in CG. Accordingly, the RR of failure in CG was 2.7 (95% CI, 2.0–3.5) (p<.05) and the NTT was 2.85 (95% CI, 1.64–11.34). In practice, CG had a 4.3 (EA) or 2.7 (ITT) times higher probability of failure than BG; in terms of NTT, treating 1,000 patients for 5 years, 765 (EA) or 350 (ITT) would not fail.

Looking at the general results, 24 patients (61.5%) reached a final radiographic result below 45°: 6 patients (15.4%) were below 35° and 17 (43.6%) below 40°. There were 21 patients who improved by at least 5° (53.8%), but there were also 2 patients (5.1%) who improved by 20° or more (Table 4).

The RR of improvement was 1.6 (95% CI, 1.4–1.9) in the EA and 1.9 (95% CI, 1.6–2.2) in the ITT (both statistically significant), that is, BG had double the probability of improvement than CG.

Treatment lasted an average of 5 years and 3 months (standard deviation, 13 months). Referred compliance to treatment was 94.7% on average (range, 50%–100%). Patients joining treatment achieved on average an esthetic improvement of 2.8±1.9 out of 12 points (TRACE), a 10.4°±10.7° Cobb improvement, and an ATR reduction of 4.2°±4.3°.

Discussion

This prospective controlled cohort study confirmed that brace treatment can be useful for patients with curves above

Table 2

Results in the two considered groups and in the total population

Outcome	Treated		Controls		Total	
	N	%	N	%	N	%
Fused	0	0	4	22.2	4	7.0
Waiting list for fusion	6	15.4	6	33.3	12	21.0
Progressed 5° or more	2	5.1	0	0	2	3.5
Unchanged	5	12.8	0	0	5	8.8
Improved 5° or more	21	53.8	0	0	21	36.8
Not retrievable	5	12.8	8	44.4	13	22.8
Total	39		18		57	

Table 3

Relative Risks of Failure/Improvement according to the two analyses performs (Efficacy and Intent-to-treat)

	Failure			Improvement		
	Relative Risk	95% CI		Relative Risk	95% CI	
Efficacy analysis						
Relative risk	4.3	3.6	4.9	1.6	1.4	1.9
Absolute risk reduction (%)	76.5	62.2	90.7	61.8	45.4	78.1
Number needed to treat	1.31	1.10	1.61	1.62	1.28	2.20
Intent-to-treat analysis						
Relative risk	2.7	2.0	3.5	1.9	1.6	2.2
Absolute risk reduction (%)	35.0	8.8	61.3	53.8	38.2	69.5
Number needed to treat	2.85	1.63	11.34	1.86	1.44	2.62

CI, confidence interval.

45° Cobb and still growing (Risser 0–4 at start). The probability of failure is greatly decreased by bracing, whereas the probability of success (reduction of at least 5° of the curve) is doubled.

Bracing EA has been questioned for many years [8,11,12]. Recently, a wide observational controlled study, including also a randomized arm, has shown the effectiveness of bracing in adolescent patients with Risser grading 0 to 2 and scoliosis curves between 20° and 40° [31]. These results strengthen those published by Nachemson and Peterson [32], contributing to the best actual evidence for this specific population [2]. Adolescents with curves above 45° to 50° Cobb, that is considered the surgical threshold [31], are not included in these studies; in fact, since bracing is considered unable to correct and reduce scoliosis curves [9], the only therapeutic option generally accepted for this specific population is surgery. Nevertheless, some results question this null hypothesis, bracing reduced a percentage of curves above 30° Cobb [13–18], but also, according to a single retrospective study, scoliosis above 45° [10].

The prospective design of the study presented here allowed us to perform not only an EA but also an ITT analysis. The former confirmed previous results from a retrospective study [10]; however, the percentages of success were reduced because of the inclusion of drop-outs. The ITT analysis gave the real possibilities of this treatment independently by indicating adherence to therapy.

Table 4

Results of the patients who improved (these were present only in the treated group)

Improvement	Patients in the treated group	
	N	%
5° or more	21	53.8
10° or more	14	35.9
15° or more	4	10.3
20° or more	2	5.1

In this case, an EA analysis has the ability to determine the probability of success in patients accepting and performing the entire treatment, whereas the ITT gives the actual overall EA of this conservative approach.

The study was performed in patients who completely refused surgery; this was unavoidable for ethical reasons. It must be recognized that the aim of avoiding an invasive procedure like spinal fusion can give these patients the highest motivations and this unavoidably results in high compliance rates. In any case, it must be stated that comparably high compliance rates can also be achieved with other means, as has been proposed [5,33] and also proven recently [34]. Nevertheless, also in this highly motivated population, there are many patients who are either not able to perform/complete treatment (dropouts) or who reject not only surgery but also conservative therapy (CG).

Compliance could be only one explanation of these results; a good and efficacious brace in terms of technical construction is also important [33]. In fact, in-brace X-rays results and compliance are among the main determinants of the results because of bracing [29,35,36].

While this is the first study to prospectively show the possibility of reducing AIS in high degree curves, there are some limitations:

- Patients self-selected treatment: this gives a high ecological reliability and generalizability to the study but in theory reduces its scientific strength; nevertheless, a randomized controlled study could not be applied without previous prospective results; moreover, ethical issues could be raised because the investigated treatment was less invasive than the actual gold standard (fusion);
- It was not possible to physically assess all patients; in fact, even if their parents were ready to accept further evaluations after some years, the patients themselves rejected any other medical and radiographic evaluation because of psychological issues; all of them stated that they were simply waiting for progression or quality of life reductions to be fused; this limitation was unavoidable.
- We lack a long-term follow-up, which could show, in some of the positive results of this study, a progression requiring fusion; this will be evaluated in future studies on this same cohort.

A consequence possibly arising from this study is that brace treatment for curves above 45° could be considered not only as an alternative for patients who utterly reject surgery but also as a possible first choice in an attempt to avoid fusion. In fact, carefully considering sanitary and social costs of surgery [37–43], conservative alternatives should be regarded favorably. Overall, personal preferences because of the high personal costs of bracing [5] cannot be neglected.

Conclusions

Through this prospective controlled cohort study, brace treatment proved to be useful for patients with curves above 45° Cobb and still growing who were attempting to avoid surgery, provided that a good brace can be offered and a very good compliance is achieved. In this situation, patients need to know that a treatment of almost 5 years is offered. The only alternatives are surgery or waiting for symptoms or health problems in adulthood finally resulting in fusion.

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