■ **SPINE**

Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis

A MULTICENTRE REVIEW OF 57 CONSECUTIVE PATIENTS

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Aims

Spinal fusion remains the gold standard in the treatment of idiopathic scoliosis. However, anterior vertebral body tethering (AVBT) is gaining widespread interest, despite the limited data on its efficacy. The aim of our study was to determine the clinical efficacy of AVBT in skeletally immature patients with idiopathic scoliosis.

Methods

All consecutive skeletally immature patients with idiopathic scoliosis treated with AVBT enrolled in a longitudinal, multicentre, prospective database between 2013 and 2016 were analyzed. All patients were treated by one of two surgeons working at two independent centres. Data were collected prospectively in a multicentre database and supplemented retrospectively where necessary. Patients with a minimum follow-up of two years were included in the analysis. Clinical success was set a priori as a major coronal Cobb angle of < 35° at the most recent follow-up.

Results

A total of 57 patients were included in the study. Their mean age was 12.7 years (SD 1.5; 8.2 to 16.7), with 95% being female. The mean preoperative Sanders score and Risser grade was 3.3 (SD 1.2), and 0.05 (0 to 3), respectively. The majority were thoracic tethers (96.5%) and the mean follow-up was 40.4 months (SD 9.3). The mean preoperative major curve of 51° (SD 10.9°; 31° to 81°) was significantly improved to a mean of 24.6° (SD 11.8°; 0° to 57°) at the first postoperative visit (45.6% (SD 17.6%; 7% to 107%); $p < 0.001$)) with further significant correction to a mean of 16.3° (SD 12.8°; -12 to 55; $p < 0.001$) at one year and a significant correction to a mean of 23° (SD 15.4°; -18° to 57°) at the final follow-up (42.9% (-16% to 147%); $p < 0.001$). Clinical success was achieved in 44 patients (77%). Most patients reached skeletal maturity, with a mean Risser score of 4.3 (SD 1.02), at final follow-up. The complication rate was 28.1% with a 15.8% rate of unplanned revision procedures.

Conclusion

AVBT is associated with satisfactory correction of deformity and an acceptable complication rate when used in skeletally immature patients with idiopathic scoliosis. Improved patient selection and better implant technology may improve the 15.8% rate of revision surgery in these patients. Further scrutiny of the true effectiveness and long-term risks of this technique remains critical.

Introduction

Modification of anterior spinal growth is becoming increasingly adopted as a form of treatment for patients with idiopathic scoliosis, given the reported long-term concerns of spinal fusion.[1–11] Anterior vertebral body tethering (AVBT) may be used in an attempt to correct the deformity and prevent progression of the curve by exploiting the Heuter-Volkman principle,[12] and has been shown to be efficacious in experimental studies.[13–21] To date, however, little has been published about its efficacy in the treatment of idiopathic scoliosis. The aim of our study was therefore to evaluate the clinical, radiological, and perioperative outcomes and complication rates to determine the safety and efficacy of AVBT in skeletally immature patients with idiopathic scoliosis.

Methods

Following institutional review board approval, we retrospectively reviewed all consecutive patients treated with AVBT who were enrolled in a longitudinal, multicentre, prospective database between 2013 and 2016. All patients had a diagnosis of idiopathic scoliosis. They were treated by one of two surgeons (MF, SP) working at two independent centres, and those with a minimum follow-up of two years were included in the analysis.

A total of 24 patients had started bracing therapy and had either progressive curves or were non-compliant. The decision to undertake surgery was based on progression of the deformity and the predicted risk of requiring a fusion by the time skeletal maturity was reached. All patients therefore had both options of anterior body tethering and standard fusion discussed and a collective decision was made with the patients and their families.

Typical indications for AVBT were skeletally immature patients with progressive major main thoracic and/or lumbar curves of ≥ 40°. Patients with a Risser score[22] of ≤ 3 and a Sanders score[23] of < 5 were considered skeletally immature and AVBT was offered. Thoracic tethers were performed thoracoscopically as previously described.[6] Thoracolumbar/lumbar tethers required a miniopen approach. Levels were typically instrumented from end vetebra to end vertebra and tension applied on the tether to bring the tilted discs into neutral alignment where possible.

All data were collected by independent researchers not involved in the analysis or care of the patients. Demographic and perioperative data were obtained from the medical records. Preoperative, first erect, and most recent x-rays were evaluated and all radiological measurements were made by an independent observer (LN, AS). Perioperative and immediate postoperative complications, and those at two-year follow-up were noted from the medical records. Clinical success was set a priori as correction of the major coronal Cobb angle to < 35° without any patients having undergone or awaiting fusion at the most recent follow-up, based on previously described criteria.[8,9] Tether breakage was suspected radiologically if there was increased convergence of vertebral body screws on interval radiographs. Rib hump and lumbar prominence was measured with a scoliometer.

Statistical analysis. Data were largely non-parametric. Analyses included between group comparisons using Mann-Whitney U tests. Wilcoxon signed rank tests were used to assess interval changes. Categorical variables were compared using chi-squared tests. All statistical analyses were performed with SPSS v22 (IBM, Armonk, New York USA), with $p < 0.05$ being considered significant.

Results

A total of 57 patients were analyzed. The mean age at surgery was 12.7 years (SD 1.5; 8.2 to 16.8) most (54/ 95%) were female. The mean Sanders score preoperatively was 3.3 (SD 1.2), and the mean Risser grade was 0.5 (SD 0.9; 0 to 3). The majority of curves that were treated were main thoracic curves (96.5%), two patients had lumbar tethers. The mean follow-up was 40.4 months (SD 9.3; 11 to 56) (Table I). The mean preoperative major coronal Cobb angle was 51° (SD

Table I. Patient demographics.

Variable	Value
Mean age at surgery, yrs (SD; range)	12.7 (1.5; 8.2 to 16.7)
Sex, F:M	54:3
Lenke curve type,[24] 1:2:3:4:5:6	48:6:1:0:1:1
Preoperative	
Mean Risser grade (SD; range)	0.5 (SD 0.9; 0 to 3)
Mean Sanders score (SD)	3.3 (1.2)
Premenarchal, n (%)	42/54 (78)
Mean height, cm (SD; range)	154.2 (8.5; 137.2 to 179.1)
Mean mass, kg (SD; range)	43.7 (10.2; 30 to 80.1)
Mean BMI, kg/m² (SD; range)	18.3 (3.1; 14.1 to 31.3)
Mean length of follow-up, mths (SD; range)	40.4 (9.3; 11 to 56)
Most recent follow-up	
Mean Risser grade (SD; range)	4.3 (1.02; 0 to 5)
Mean height, cm (SD; range)	162.3 (7.2; 148.7 to 184.0)
Mean mass, kg (SD; range)	55.4 (10.2; 38.6 to 92.9)
Mean BMI, kg/m² (SD; range)	21.1 (3.5; 13.4 to 36.2)
Tether location, n	
Thoracic	55
Lumbar	2
Vertebrae tethered, mean (SD; range)	
Thoracic tether	7.3 (0.7; 6 to 9)
Lumbar tether	5.5 (0.7; 5 to 6)
Mean operating time, mins (SD; range)	
Thoracic tether	221.9 (101.3; 110 to 505)
Lumbar tether	295.5 (30.4; 274 to 317)
Mean blood loss, ml/kg (SD; range)	
Thoracic tether	5.5 (3.8; 0.9 to 18.8)
Lumbar tether	6.1 (1.3; 5.2 to 6.96)
Mean length of stay, days (SD; range)	4.7 (1.4; 3 to 10)

BMI, body mass index.

10.9°; 31° to 81°), which corrected on side bending films to 30.5° (SD 13.8°; 4.2° to 65.4°), thus having a mean of 41.8% (SD 19.9%; 1.6% to 91.1%) flexibility preoperatively.

For the initial procedure, the mean operating time was 224.5 minutes (SD 100.5; 110 to 505). The mean blood loss was 231.5 cc (SD 140.8; 50 to 650), with no patients requiring a blood transfusion. The mean length of stay was 4.7 days (SD 1.4; 3 to 9). Most patients reached skeletal maturity with a mean Risser grade of 4.3 (SD 1.02) at final follow-up. All patients were discharged to full activity at three months following surgery.

Table II summarizes the radiological and surface measurement data. The mean preoperative major curve of 51° (SD 10.9°; 31° to 81°) significantly improved to a mean of 24.6° (SD 11.8°; 0° to 57°) at the first postoperative visit, with a mean percentage correction of 45.6% (SD 17.6%; 7% to 107%) (p < 0.001). From the first postoperative erect film a further significant correction was noted to a mean of 16.3 (SD 12.8; -12 to 55; p < 0.001) at one year follow-up. At the latest follow-up, the mean major coronal curve had a further small but significant increase to 23° (SD 15.4°; -18° to 57°) from one year postoperatively, but remained significantly improved from the preoperative value (p < 0.001), with a mean percentage correction of 42.9% (SD 30.3%; -16% to 147%).

Significant spontaneous compensatory curve correction was also observed in the uninstrumented curves by a mean 34.7%

Table II. Radiological and surface measurements.

Variable, mean (SD; range)	Preoperative	First erect	One year	Most recent follow-up
Coronal plane				
Tethered curve Cobb angle, °	51.0 (10.9; 31 to 81)	24.6 (11.8; 0 to 57)*	16.3 (12.8; -12 to 55)†	23.0 (15.4; -18 to 57)‡§
Tethered curve correction, %		45.6 (17.6; 7 to 107)	53.2 (22.3; 5.2 to 138.8)†	42.9 (30.3; -16 to 147)‡
Untethered minor curve Cobb angle, °	31.5 (9.5; 3 to 57)	21.9 (10.6; 0 to 52)*	20.6 (10.2; -8 to 50)†	22.3 (14.3; -11 to 62)§
Untethered minor curve correction, %		34.7 (23.9; -15.6 to 100)	37.6 (31.1; -15.4 to 188.9)†	41.8 (59.1; -48.2 to 222.2)
Sagittal plane				
Thoracic kyphosis T5-T12, °	18.7 (11.1; -8 to 45)	18.7 (12.01; -12 to 43)	17.3 (12.4; -14 to 47)	22.0 (13.3; -14 to 52)‡§
Lumbosacral lordosis L1-S1, °	-55.4 (11.3; -99 to -28)	-53.6 (11.6; -76 to -30)	-56.4 (11.5; -87 to -24)	-56.5 (12.1; -83 to -24)
Thoracic tether instrumented sagittal Cobb angle, °		16.2 (12.3; -12 to 50)	15.8 (12.8; -13 to 46)	17.2 (13.3; -12 to 51)
Lumbar tether instrumented sagittal Cobb angle, °		-4.0 (12.7; -13 to 5)	-5 (14.14; -15 to 5)	-5.0 (8.5; -11 to 1)
Surface measurements				
Rib hump, °	14.9 (5.49; 0 to 26)	8.3 (4.7; 0 to 22)*	8.4 (4.6; 0 to 25)	10.3 (5.6; 0 to 22)§
Lumbar prominence, °	3.5 (5.0; 0 to 20)	2.5 (3.8; 0 to 14)*	2.5 (3.7; 0 to 15)	2.3 ± 4.5 (0 to 18)§

*Changes from preoperative to first erect: denotes significance; tethered curve Cobb/ tethered curve correction/untethered minor curve Cobb/rib hump all p < 0.001, lumbosacral lordosis p = 0.01, lumbar prominence p = 0.004. (Non-significant: thoracic kyphosis p = 0.6).
†Change from first erect to one year: denotes significance; tethered curve Cobb/tether curve correction/ instrumented Cobb/untethered minor curve Cobb/untethered minor curve correction all p < 0.001. (Non-significant: thoracic kyphosis p = 0.3; lumbosacral lordosis p = 0.2; thoracic tether instrumented sagittal p = 0.8; lumbar tether instrumented sagittal p = 0.5; rib hump p = 0.3; lumbar prominence p = 0.9).
‡Change one year to most recent follow-up: denotes significance; tethered curve Cobb/tethered curve correction/instrumented Cobb/ thoracic kyphosis all p < 0.001. (Non-significant: untethered minor curve Cobb p = 0.4; thoracic kyphosis p = 0.2; lumbosacral lordosis, thoracic tether instrumented sagittal p = 0.3; lumbar tether instrumented sagittal p = 0.1; rib hump p = 0.6; lumbar prominence p = 0.5).
§Change from preoperative to most recent follow-up: denotes significance; tethered curve Cobb/untethered minor curve Cobb/thoracic kyphosis/ rib hump all p < 0.001, lumbar prominence p = 0.003. (Non-significant; lumbosacral lordosis p = 0.8).

(SD 23.9%; -15.6% to 100%) at the first postoperative visit with further significant correction by a mean of 41.8% (SD 59.1%; -48.2% to 222.2%) at the latest follow-up (p < 0.001).

The rib hump significantly improved from a mean of 14.9° (SD 5.49°; 0° to 26°) preoperatively to 8.3° (SD 4.7°; 0 to 22°) at the time of the first erect film (p < 0.001), with a further small increase to a mean of 10.3° (SD 5.6°; 0° to 22°) at most the recent follow-up ; however, significant improvement from the preoperative value was still maintained (p < 0.001). Lumbar prominence improved from a mean of 3.5° (SD 5°) preoperatively to a mean 2.5° (SD 3.8°) at the time of the first erect film and to a mean 2.3° (SD 4.5°) at the most recent follow-up.

The mean preoperative T5-T12 kyphosis of 18.7° (SD 11.1°; -8° to 45°) was stable to one year, after which there was a small but significant increase at the most recent follow-up to 22° (SD 13.3°; -14° to 52°) (vs preoperative; p < 0.001). Despite this, the kyphosis across the instrumented levels in thoracic tethers remained stable during the study period. No significant overall change was seen in lumbosacral lordosis (p = 0.803).

Clinical success, as defined above was achieved in 44 patients (77%). The overall complication rate was 28.1% with a 15.8% rate of unplanned revision surgery. There were 16 complications reported with eight patients requiring nine additional unplanned revision procedures; one patient required arthroplasty for tether breakage, one for extension of the tether and this patient subsequently required a fusion, and one for overcorrection; five additional patients underwent fusion for insufficient correction and progression of deformity (Table III).

Of the seven complications not requiring reoperation or readmission to hospital, one patient had persistent pain in the hip and shoulder, one superficial infection was treated with oral antibiotics and dressing changes, and four patients had respiratory

Table III. Complications and revision procedures.

Nature of complication/revision operation	Cases, n	Revision operations, n
Perioperative		
Pulmonary		
Atelectasis	3	N/A
Pneumonia	1	N/A
Superficial wound infection	1	N/A
Hip and shoulder pain	1	N/A
Numbness in the arm and breast	1	N/A
Prompting revision of tether		
Overcorrection (loosening tether)	1	1
Tether breakage (replaced)	1	1
Adding on (extension of tether)	1	1
Prompting fusion		
Insufficient correction of tethered curve and progression of deformity	5	5
Adding on	1	1

N/A, not applicable.

issues, for which two required bilevel positive airway pressure, and two simple observation. One additional patient complained of continued numbness in her arm and breast (Table III).

The six patients who required fusion had a mean preoperative major coronal Cobb angle of 60.8° (SD 18.5°) with correction to 44.3° (SD 13.1°) on the first erect film with an increase in mean major coronal Cobb angle to 47.2° (SD 9.5°) at the most recent follow-up. The mean preoperative flexibility of these patients was 28.9% (SD 12.2%), which was significantly less than the mean preoperative flexibility of the entire cohort of 41.8% (SD 19.9%; p < 0.001). These patients were skeletally more immature than the larger cohort at a preoperative Risser score of 0.2 (SD 0.4), and all but one of these six patients

were pre-menarchal. Two of them had extension of the tether distal to the lowest instrumented vertebra with persistent right-sided coronal decompensation warranting fusion, and the other four had inadequate correction of the curve at the most recent follow-up necessitating fusion.

Given the loss of correction seen between one year and the most recent follow-up, patients were evaluated to identify the influence of tether breakage. Two patients had confirmed tether breakage, one verified at tether arthroplasty and one at fusion. In addition, 22 had radiographical evidence suggestive of tether breakage with splaying of the tulip heads noted at the most recent follow-up. Thus, 24 patients (42%) had a confirmed or suspected tether breakage. The most common sites for breakage were T9/10, T10/11, and T11/12 occurring in five, 11, and five patients, respectively. Tether breakage was noted on radiographs taken at a mean of 32.5 months (SD 6.2; 19 to 43) postoperatively. In the 22 patients with suspected tether failure, there was a mean increase in the tethered Cobb angle by 5.5° (SD 3.6°) from the first erect film (mean 23.5° (SD 7.4°)) to the most recent follow-up (mean 29.1° (SD 11°)).

Discussion

This study represents the largest cohort of prospective patients with a minimum two-year follow-up treated with AVBT. The retrospective review demonstrated a clinical success rate of 77% at this time in 57 patients with idiopathic scoliosis treated in this way. Of the 16 complications which were recorded, eight patients required revision surgery within the follow-up period. The fact that there was progressive correction of deformity during the first year confirms that growth is modified, validating the use of this technique in skeletally immature patients.

Physeal growth arrest due to compressive forces and a secondary acceleration of growth due to distractive forces across a growth plate has been well described in animal studies and felt to be related to the progression of scoliosis[12–14] Stokes et al[12,13] clearly demonstrated the application of the Heuter-Volkman principle to vertebral growth, illustrating differential growth by asymmetrical loading of rat-tail vertebrae resulting in both the creation of a deformity and its subsequent correction.[12–14] Other basic science models have also been used to demonstrate this phenomenon in animal vertebrae with a variety of mechanical implants which have been either a shape memory alloy staple, a staple/screw device, or a flexible tether.[15–21] The authors of these experimental studies have subsequently described the health of the discs in the tethered segments and found no evidence of irreversible injury to physeal cartilage or disc.[25–28]

More recently, clinical proof of the concept,[3] as well as single case series,[6–11] has sparked interest in AVBT as a potential treatment for patients with idiopathic scoliosis. Correction of deformity resulting from the modification of growth using this technique, however, is not uniform in the series which have been reported. Samdani et al[6] first reported favourable clinical results in a series of 11 patients with two-year follow-up. Their cohort had a mean preoperative age of 12.3 years (SD 1.6) with a mean Risser score of 0.6 (SD 1.1), and coronal curve improvement from a mean of 44.2° (SD 9.0°) to 20.3° (SD 11°) on the first erect radiograph, with subsequent further correction to a mean of 13.5° (SD 11.6°) (70%) at two-year follow-up. Samdani et

al[7] followed 25 patients after treatment with AVBT to skeletal maturity, also reporting acceptable correction of deformity by a mean of 66.1%. The mean Cobb angle improved from 40.9° (SD 7.1°) preoperatively to 20.1° (SD 8.4°) on the first erect radiograph with further improvement to a mean of 14.0° (SD 11.1°) at skeletal maturity. Although no patients were reported to have required fusion, two required subsequent surgery for over-correction necessitating loosening of the tether. Corbetto et al[10] reported progressive correction in 20 patients from a mean of 59° preoperatively to 27° immediately postoperatively and 23° at two years. Although Newton et al[9] noted no significant improvement in the main thoracic Cobb angle after the first erect radiograph in a skeletally immature group of 23 patients, the amount of improvement varied between patients. Wong et al[11] using a technique which avoided intraoperative tensioning of the tether also saw a mixed response in their five patients. All were Risser 0, but progressive correction was seen only in two patients with open tri-radiate cartilages at the time of surgery.[11]

Newton et al's[8] description of 17 patients treated with AVBT illustrates a cautionary tale of this technology. Although they noted in their series modifiication of growth correcting the mean coronal Cobb angle by 8° (SD 17°) at a mean follow-up of 2.5 years, eight patients (47%) required subsequent surgery for overcorrection, broken tether, addition of a lumbar tether and conversion and/or awaiting fusion. Their patients were more skeletally immature (Risser 0) and younger (mean age 11 years) than those reported by others.[6,7] Many patients in their study had open tri-radiate cartilage, and thus were also likely to be more skeletally immature than our multicentre cohort, possibly explaining the differences in outcomes.

The "clinical success" in our series compares favourably with that reported by others. The definition of success, however, used in this study is debatable. We chose to mirror the work of Newton et al[8,9] to allow easy comparison, but note that a curve of < 50° at skeletal maturity is also an important metric, as these patients generally do not subsequently require fusion.[29] The study by Newton et al[9] reported that 12 of 23 patients (52%) had curves of < 35° and 17 of the 23 patients (74%) having curves of < 50° at a mean follow-up of 3.4 years (SD 1.1). In comparison, 77% of patients in our series had curves of < 35° and 89% had curves of < 50° at the most recent follow-up.[9] Samdani et al[7] reported that none of their 11 patients required fusion; all had residual curves of < 35° at follow-up of two years. Two of five patients reported by Wong et al[11] required fusion after > four years follow-up, with two of the remaining patients having residual curves of > 35° but < 50°. The variation of the success and reoperation rates in previous studies may reflect patient selection with a wider spectrum of skeletal immaturity, magnitude of initial Cobb angle, different follow-up, and surgical technique (such as intraoperative tensioning or selection of level).

This study has limitations. We analyzed lumbar and thoracic tethers together for clarity. As numbers grow further work is needed to determine if their responses to AVBT differ. We also analyzed radiological parameters and lack any functional health-related quality of life assessments. Our concern for the latter was that patient-reported outcome measures (PROMs) in these patients could be misleading as many presented with the

desire to undergo AVBT and this thus introduces a significant bias when evaluating treatment effect using PROMs. We felt that the cognitive dissonance would greatly skew any meaningful interpretations of PROMs.

In addition, a minimum two-year follow-up is not an adequate benchmark for these patients and clearly longer follow-up is required to make any definitive statements about the true value of this technique. This study is strengthened by the large sample size and the combined work of two independent centres and so the results may be more generalizable. Given the increased interest in AVBT from both patients and surgeons globally, we feel strongly that these data, despite their limitations, need to be disseminated to the readership and added to the paucity of literature so that the efficacy and true impact of this technique can be rigorously evaluated prior to its widespread adoption.

This study represents the largest series of patients treated with AVBT currently available. In showing progressive correction of deformity during the first postoperative year, it confirms the modification of growth , validating the premise of its use in skeletally immature patients. Most outcomes were considered successful with 77% having a major coronal Cobb angle of < 35° and 89% remaining without fusion at > two-years follow-up. However, the outcome varies within the cohort with 28.1% of patients having a complication and a 15.8% requiring further surgery at a mean follow-up of 40.4 months. Further scrutiny of the effectiveness and long-term risks of the use of this technique in the management of patients with idiopathic scoliosis remains critical.

Take home message
- Anterior vertebral body tethering is effective in modulating spinal growth.

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