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Vertebral Body Tethering (VBT): Non-Fusion Surgical Treatment for Scoliosis. Our First 60 Patients

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Abstract

Present: Present our experience with the vertebral body tethering (VBT) technique in surgical treatment for scoliosis. Analyze its advantages, disadvantages, and complications.

Methods: A prospective case series, submitted to the VBT technique by our surgical team from September 2020 to March 2022 with a minimum follow-up of six months. Patients with flexible curves between 35º and 65º were operated on. The main thoracic and thoracolumbar/lumbar curves were evaluated with the Cobb method preoperatively, postoperatively, and at the last follow-up.

Results: In our series of 60 patients, 90% were female, with a mean age of 15.1 ± 2.9 years, and follow-up was 10.1 ± 4.7 months. The VBT technique was used to treat 53 (88%) patients with adolescent idiopathic scoliosis, 6 (10%) syndromic scoliosis, and 1 (2%) neuromuscular scoliosis. The mean preoperative main thoracic curve was 48.2º ± 9.4º and thoracolumbar/lumbar 47.8º ± 9.7º. The mean Cobb in the immediate postoperative was 19.2º ± 9.0º for the main thoracic curve and 9.4º ± 8.9º for the thoracolumbar/lumbar curve. The mean Cobb in the last follow-up was 22.8º ± 11.0º for the main thoracic curve and 12.7º ± 11.1º thoracolumbar/lumbar. Giving a final correction of 54% ($p < 0.0001$) in main thoracic curves and 71% ($p < 0.0001$) in thoracolumbar/lumbar curves. A 10% of complications (6) were reported, and hemothorax (4) was the most common.

Conclusion: We propose VBT as a safe and effective option, with good results, for treating scoliosis. To our knowledge, our study is the largest case series in Latin America and is the first published study using this surgical technique.

Level of Evidence: IV, Therapeutic Studies, Case Series

Introduction

Scoliosis is a deformity that affects 1 in 300 children[1]. It is defined by the Scoliosis Research Society (SRS) as: "Deformity in the coronal plane of the spine greater than 10º on a standing anteroposterior radiograph associated with variable rotation of vertebral bodies"[2]. It can cause pain, limitations in daily living activities, and psychological problems, among others[3].

In its etiopathogenesis, scoliosis is characterized by two stages. The first stage is when an alteration of the rotational axis occurs, which begins the curve and is considered idiopathic. The second is the progression of the curve, which Hueter and Volkmann's law explains. The curve generates an asymmetric distribution of the

load, which generates an asymmetric growth of the spine, and when it lasts over time, it behaves like a vicious circle[4].

Historically, the surgical gold standard approach is posterior spinal fusion, a reliable, predictable treatment, but not without negative consequences, such as loss of mobility and growth potential, among others[5].

In 2008, Newton et al. established the bases for spinal growth modulation by anteriorly fixing the thoracic vertebral bodies of male calves with flexible tether. They observed the formation of curves at six months of control. They concluded that the same force applied to the convexity of a curve corrects the deformity according to Hueter and Volkmann's law[6].

The VBT technique consists of the non-fusion fixation of the spine through the anterior approach on the convex side using screws. A polyethylene terephthalate (PET) cord is attached to these screws, which is then tensioned screw by screw, resulting in immediate correction and allowing residual growth of the concave side of the spine.

In 2010, Crawford and Lenke performed the first VBT surgery on an 8-year-old patient with a main thoracic curve of 40º, achieving an excellent result with a control curve of 6º at four years postoperatively[7]. Subsequently, Samndani et al. (2014)[8] and Newton et al. (2018)[9] showed their case series submitted to the VBT technique showing good results, both including patients with idiopathic scoliosis, older than 10 years, thoracic curves 35º–65º, flexible > 50%, with immature skeleton according to Risser 0–2, and Sanders < 4[10].

In 2019, the VBT technique was approved for use by the Food and Drug Administration (FDA) through Human Device Exemption (HDE)[11].

Since its approval by the FDA, its use has increased. Although good results have been published highlighting the little pain, better ranges of mobility, better self-image in score SRS 22, and early return to daily living and sports activities, it is not free of complications where pleural effusion, PET cord breakage with loss of correction, over-correction, and increase in the distal curve stand out[12-16].

We present the preliminary experience of the first 60 cases submitted to the VBT technique by our surgical team. No fusion, with minimally invasive approaches, and allowing continuous spinal growth.

Methods

A prospective case series, submitted to the VBT technique by our surgical team from September 2020 to March 2022 with a minimum follow-up of six months. Patients aged 10–25 years were included, with main thoracic and thoracolumbar/lumbar curves of 35º–65º measured with Cobb's method, all flexible (> 50% reduction in traction radiographs)[16]. Skeletal maturity was assessed using the Risser and Sanders scale[10]. Surgical time, intraoperative bleeding, days of hospitalization, use of Foley catheter and pleural drainage, complications, and reoperations were documented. The main thoracic and thoracolumbar/lumbar curves were evaluated with the Cobb method preoperatively, postoperatively, and at the last follow-up. At the last follow-up, the SRS 22 score was performed[17].

The study was approved by the Institutional Review Board, and the informed consent form was signed by the patients or their legal guardians. The advantages and consequences of VBT were explained in detail to the family members, and the patients were made aware of the possible scenarios. All information can be found in the patient file.

Surgical Technique

Anesthesia

General anesthesia with a double-lumen bronchial tube, allowing us to collapse the lung on the side where we are operating on the thoracic spine. Monitoring includes an arterial line, Foley catheter, and neuromonitoring.

Positioning

The patient is placed in a lateral decubitus position towards the concave side of the curve. Pressure points are protected. The ipsilateral leg is positioned on a support cushion with 45º abduction and slight knee flexion. Pressure points in the knees and ankles of both lower limbs are protected.

Approaches

For patients with thoracic curves requiring correction, a mini-open incision of 5 cm is made at the 9th intercostal space along the midaxillary line. Two additional 1.5 cm portals are created for video-assisted thoracoscopy and instrumentation at the 5th and 10th intercostal spaces.

For lumbar vertebra instrumentation, a 5 cm retroperitoneal approach is made below the T11 costal arch. The psoas muscle is identified and retracted posteriorly using blades.

Thoracic approach: Can sometimes extend down to L2.

Lumbar approach: Typically extends up to L1.

Usual limits:

Thoracic procedures: Up to L1

Lumbar procedures: Up to L2

Instrumentation

Under thoracoscopic vision and fluoroscopic guidance, AP and Lateral view, clips and screws are positioned

on the lateral aspect of the vertebral body. Our limit for instrumentation levels were considered as follows: Upper limit: Maximum at T4; Lower limit: Up to L4; Limit for double cord / double screws: T7.

A PET cord is placed with tension applied between the screws, tension starts with 100N and can reach 400N according to the immediate correction observed under fluoroscopy, evaluated segment by segment. The amount of correction goes according to skeletal maturity. There was not a fixed formula to determine the exact tension (N).

Single vs. Double Cord Technique

Double cord is preferred whenever possible, depending on flexibility. When the patients presented very immature skeletons, the single cord procedure was performed. When facing cases when the patients presented more mature skeletons, high tension and double cord are applied.

Pleural Drain

A pigtail drain is used with suction for 24 hrs.

Surgical Time

Initial surgeries to correct only thoracic deformity used to dure around 8 hours. Along the learning curve done for the surgeon for those procedures, the current standard times stablished around: Thoracolumbar surgery: 3 hours; Thoracic-only or lumbar-only: 2 hours 30 minutes and 2 curves: 6 hours.

Statistical analysis

All statistical analyses were performed with PRISM® statistical software (GraphPad, Inc). The student t-test for independent samples and the one-way ANOVA test for samples related to Welch's correction were used to observe the statistically significant difference when comparing means.

Results

The sociodemographic characteristics of our series of 60 patients submitted to the VBT technique can be seen in Table 1. Mean age was 15.1 ± 2.9 years (range 10–25 years), minimum mean follow-up time was 10.1 ± 4.7 months (range 6–24 months) with skeletal maturation Risser scale 2.2 ± 1.9 (range 0 - 5) and Sanders 5.1 ± 2.1 (range 2–8).

The VBT was performed on one side in 45 patients (75%) and on both sides in 15 patients (25%) (Table 2). The VBT performed on both sides presented longer surgical time, bleeding, and a higher percentage of complications (Table 2)—only three patients operated on both sides required transfusion.

In our radiological measurements (Table 3), the mean main thoracic preoperative curve was 48.2º ± 9.4º and thoracolumbar/lumbar 47.8º ± 9.7º. The mean Cobb in the immediate postoperative period was 19.2º ± 9.0º for the main thoracic curve and 9.4º ± 8.9º for the thoracolumbar /lumbar curve. The mean Cobb at the last follow-up was 22.8º ± 11.0º (54%) for the main thoracic curve and 12.7º ± 11.1º (71%) for the thoracolumbar/lumbar. Giving a final correction of 54% ($p < 0.0001$) in the main thoracic curve and 71% ($p < 0.0001$) in the thoracolumbar/ lumbar curve. Both curves achieved a statistically significant correction.

The SRS-22 was performed in the last follow-up (Table 4), with good results in all domains.

Table 1: Sociodemographic and clinical characteristics of the included patients

Baseline characteristics	n = 60	%
Sex		
Men	6	10
Women	54	90
Age (years)		
10-15	35	58.3
16-21	23	38.3
≥ 22	2	3.4
$\underline{x}$ ± SD	15 ± 2.9	
Risser scale		
$\underline{x}$ ± SD	2.2 ± 1.9	
Sanders scale		
$\underline{x}$ ± SD	5.1 ± 2.1	
Pre-surgical diagnosis		
Adolescent idiopathic scoliosis	53	88.3
Lenke 1	20	33.4
Lenke 2	2	3.4
Lenke 3	7	11.7
Lenke 4	1	1.6
Lenke 5	19	31.6
Lenke 6	4	6.6
Non-idiopathic scoliosis		
Neurofibromatosis	7	11.7
Marfan syndrome	1	1.6
Down syndrome	1	1.6
Chromosomapathy	1	1.6
Noonan syndrome	1	1.6
Loeys-Dietz syndrome	1	1.6
Neuromuscular scoliosis	1	1.6

Table 2: Postoperative results according to surgical techniques

Variable	One side (n = 45)	Both sides (n = 15)
Surgical time (min)	265 ± 74	518 ± 98
Blood loss (ml)	213 ± 85	395 ± 112
Hospitalization (days)	4.5 ± 1.3	5.4 ± 1
Complications	(n = 5)	(n = 1)
Pleural effusion	3	1
Wound infection	1	0
Cord rupture with loss of correction	1	0
Need for transfusion	0	3

Table 3: Variation in thoracic and thoracolumbar/lumbar curves according to follow-up

	Preoperative	Postoperative (4-5 days)	Postoperative (12 months)	Postoperative correction	p-value
	$\underline{x}$ ± DS	$\underline{x}$ ± DS	$\underline{x}$ ± SD	%	
Main thoracic curve (Degrees)	48 ± 9.5	19 ± 8.9	23 ± 11	54	< 0.0001
Thoracolumbar/lumbar curve (Degrees)	48 ± 9.8	9.5 ± 9.9	13 ± 11	71	< 0.0001

Table 4: Results of the postoperative SRS 22 questionnaire according to type of procedure

Domain	Vertebral body tethering
	$\underline{x}$ ± SD
Pain	4.4 ± 0.76
Activity	4.6 ± 0.53
Self-image	4.3 ± 0.52
Mental health	4.0 ± 0.83
Satisfaction	4.8 ± 0.84

Complications

Complications were reported in six (10%) patients (Table 2): four patients had pleural effusion (hemothorax) and required reoperation, and one patient had wound infection with a history of severe ichthyosis and required surgical cleaning.

Finally, one patient presented PET cord rupture, according to radiological measurements, an increase of > 5° of angulation between two adjacent screws (with loss of reduction, Cobb angle 18º in the postoperative, and 46º in the last follow-up, the patient is clinically well and does not wish to operate)[9,12,18].

Discussion

The VBT technique has been shown to achieve good corrections of the main thoracic and thoracolumbar/lumbar curves, avoiding segments fusion and modulating spinal growth according to Hueter and Volkmann's law[4,8,9,19].

Although it is a relatively new technique, there are studies with follow-ups from two to five years where good results have been maintained and correction losses have been slight[9,18,20].

In our case series, the main thoracic curve, such as the thoracolumbar/lumbar curve, corrected more than 50%, which is comparable to the corrections achieved with traditional surgery, without having significant correction losses; however, since this technique is without fusion, we must analyze it in the longer term. The surgical time reported in our study is longer than that reported in other series, due probably to the learning curve and that in our patients from the D8 to distal vertebra, we are placing two screws per vertebra[9,12,20,21].

The days of hospitalization and the use of pleural tubes are similar to published studies worldwide[21-23]. Six patients presented complications: four hemothorax, one wound infection, and one PET cord rupture, aligning with the most frequent complications reported in the literature[9,12,20]. No correction was reported, and to date, no patients have required subsequent fusion.

Comparing VBT and posterior fusion, VBT has achieved better lumbar mobility range and lumbar muscle endurance and better results on the SRS 22 and SF-36 questionnaires, mainly in the self-imaging domain[13]. Regarding surgical time, bleeding, need for transfusion, and days of hospitalization, VBT has demonstrated better outcomes than posterior fusion[9,12,15,24].

Historically, posterior fusion has been the gold standard for scoliosis management. While VBT has demonstrated advantages, posterior fusion has always reported a higher percentage of correction and a lower rate of complications and reoperations[12,25].

There is a lack of studies with more years of follow-up and a more reliable way to predict the final correction of the curve using VBT[26]. The VBT technique is reliable and of low morbidity, including surgeries with entry into the thoracic cavity[27,28]. In recent years, it has been used for managing non-idiopathic scoliosis[29] and in patients with a mature skeleton[14,18], as long as the curves are flexible.

Our series used VBT in seven non-idiopathic patients and ten patients with mature skeletons, Risser 5 and Sanders 8.

In the last follow-up, the SRS 22 scores of our series are comparable to published studies that used the VBT technique with similar results as patients operated with posterior fusion (Table 4)[13,14,30].

Limitations

In our series, 11 patients only attended their first post-operative check-up and were not located for radiological and SRS-22 score follow-up.

Our mean follow-up of ten months is lower than most case series published in the literature[12,20]

Conclusion

In our preliminary results, the VBT technique achieved good correction on the thoracic and thoracolumbar/lumbar curves compared to other studies, which included patients submitted to classic techniques[30-32], with a complication rate similar to that published worldwide. Although studies

with longer follow-ups are necessary, VBT is a technique with good results for the surgical management of scoliosis in patients with flexible curves. It should be considered an option in our environment where the state guarantees the surgical management of scoliosis to people under 25 years of age[33].

According to our knowledge, our study is the largest case series in Latin America and is the first published study using this surgical technique.

Declarations

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Funding

No funding was received for this study.

Availability of Data

The authors confirm that the data supporting the findings of this study are available within the article. Furthermore, the data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Code Availability

Not applicable

Ethics Approval

This study was approved by the Hospital Direccion de Prevision de Carabirenos de Chile under the number 18.

Authors' Contributions

Andres Chahin Ferreyra: Conceptualization, data curation, Supervision, Project management

Diego Villagrán Prado: Research, Writing - original draft, Methodology

Per Trobisch: Formal Analysis, Validation, Proofreading and editing

Juliana Mauad: Formal Analysis, Programs, Methodology, Validation, Writing - Original Draft

Rafael Lindi Sugino: Formal Analysis, Resources, Visualization, Writing - Proofreading and Editing

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