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CASE SERIES

Learning curve for vertebral body tethering: analysis on 90 consecutive patients

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Abstract

Study design Retrospective study.

Objectives Vertebral body tethering (VBT) is raising interest for the treatment of adolescent idiopathic scoliosis (AIS), but many scoliosis surgeons have not been trained in anterior surgical approaches. We analyzed data of our first patients to define the learning curve for VBT.

Summary of background data VBT has shown encouraging results in the treatment of growing AIS patients, but there is a paucity of data and long-term results are not yet available. To our best knowledge, there is no published data regarding the learning curve for VBT.

Methods A retrospective analysis was performed, of all consecutive patients who underwent VBT at our Institution. Outcomes of interest were intubation time, surgical duration and estimated blood loss per screw and hospitalization length. For the statistical analysis, we referred to a linear model regression diagnostic and we used the Pearson product-moment correlation (r) for pairwise correlation. The final effect ranked between + 1 and − 1.

Results Data of 90 patients were analyzed, age 14.6 ± 1.8 years. On average, 9.4 ± 2.6 levels were instrumented. Per screw, mean intubation time was 33.1 ± 7.6 min ($r = -0.57$; $p > 0.0001$), mean surgical duration 21.3 ± 5.7 min ($r = -0.55$; $p > 0.0001$), mean estimated blood loss 21.3 ± 18.2 ml ($r = -0.66$; $p > 0.0001$). Mean hospitalization length was 8.3 ± 3.1 days ($r = -0.32$; $p = 0.002$). No intraoperative complications were reported.

Conclusion VBT has a rapid learning curve: the estimated blood loss per screw is expected to decrease by 60%, intubation time and surgical duration by over 50%, and hospitalization length by 32% for each treated patient.

Level of evidence III.

Keywords Non-fusion anterior scoliosis correction · Vertebral body tethering · Learning curve · Adolescent idiopathic scoliosis · Anterior approach

Introduction

Vertebral body tethering (VBT) represents a new, non-fusion option for the treatment of adolescent idiopathic scoliosis (AIS). This technique allows for curve correction while maintaining spine mobility, which is of particular relevance in the lumbar spine. VBT has been investigated with promising results [1–8], but further research is being conducted to define the role of VBT in the treatment of AIS and to identify the ideal candidate for this intervention. VBT was developed to employ the Hüter–Volkmann principle to modulate spine growth through a unilateral block of growth plates [9–11]. However, manual full curve correction can also be achieved in patients approaching skeletal maturity (e.g., Risser 4 and or Sanders 7) and advanced correction techniques can be performed in selected cases, which some authors describe as non-fusion anterior scoliosis correction (ASC). VBT requires an anterior approach to the spine: the lumbar spine is addressed through a mini-retroperitoneal approach, while thoracolumbar junction and thoracic spine are instrumented via a video-assisted thoracic surgery (VATS) [3]. Since the development of pedicle screws in the 90′, posterior approaches largely substituted anterior techniques

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[9]: thereby, many surgeons are not trained in anterior techniques. We conducted a study on the first 90 subsequent patients who underwent VBT at our institution to investigate intraoperative data and complications. The analysis of these parameters aimed to define the learning curve for VBT.

Materials and methods

Surgical procedure

All surgeries were performed in general anaesthesia after antibiotic prophylaxis with Cefuroxime or Clindamycin in case of allergy. For all patients, monitoring of motor evoked potentials was performed throughout surgery for detection of possible damage to the neural structures (neuromonitoring). A cell-salvage system was used for every patient. Patients were positioned on the side with the convex side of the curve facing up. Thoracic curves down to L1 were approached with VATS, with one or two intercostal incisions, about 6 cm each, and one or two thoracoscopic portals (Fig. 1). Lumbar curves were instrumented through a mini retroperitoneal approach. For patients requiring a bilateral correction, this was conducted in one stage with lumbar instrumentation performed first, as the authors feel instrumentation of the lumbar curve is mentally and physically more demanding. After suturing and dressing the wounds, patients were repositioned for thoracic instrumentation [2, 3]. The screws were placed bicortically following anatomic landmarks and under antero-posterior fluoroscopic control. After the first 60 patients, a double tether was added in lumbar curves to prevent tether ruptures. When intraoperative positioning and manual correction were not sufficient to achieve satisfactory correction on fluoroscopic control, disc releases were performed in few selected patients at the apex of thoracic curve to increase flexibility. We have not yet performed disc releases in the lumbar spine. Thoracoplasty was not performed in any of the patients of this cohort. The screws were connected with a polyethylene tether and curve correction was performed. Lastly, a chest drainage was placed and removed when the output was < 200 ml over 24 h. The last 50 patients included in the study received a Pectoralis major (Pecs) block for postoperative pain management.

Postoperative care

Patients were monitored at the intermediate care unit until the chest tubes were removed. A thromboembolic prophylaxis was not administered. In the first 3–4 days after surgery intravenous pain management was performed with a PCA

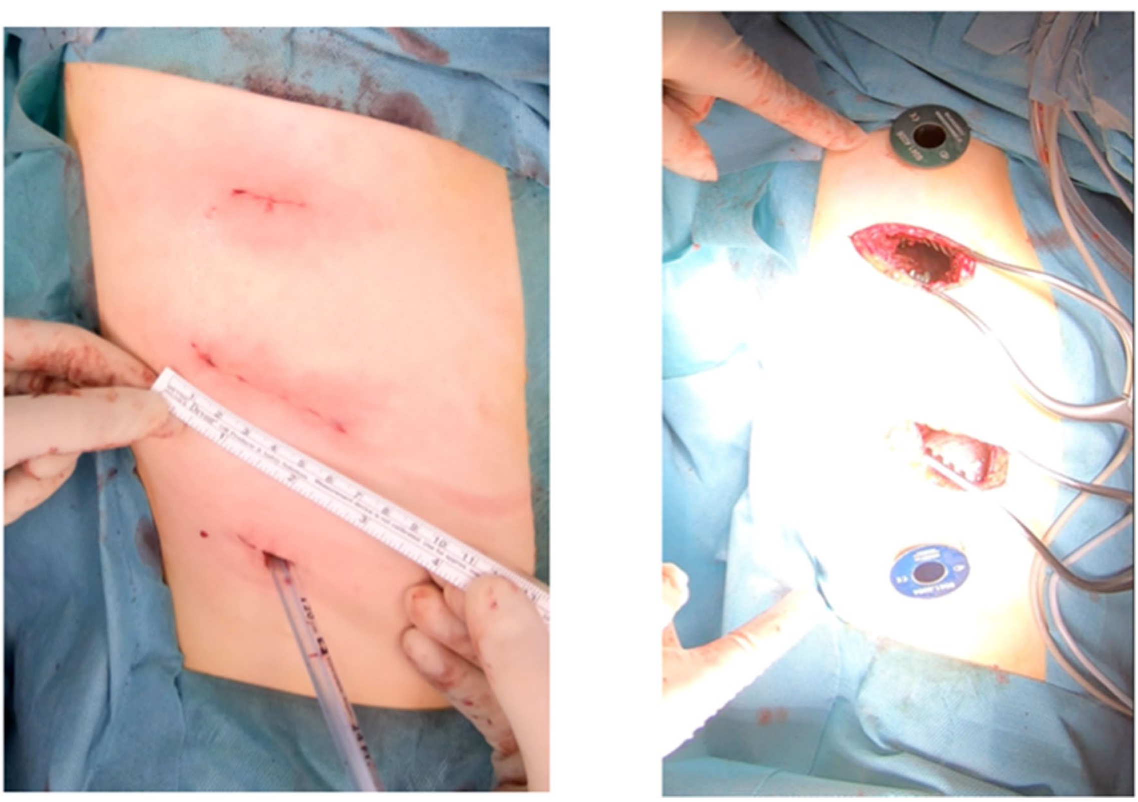

Fig. 1 Examples of thoracic incisions for short thoracic instrumentation (T6–T10, on the left) and long thoracic instrumentation (T5-L2, on the right). The pictures are oriented with the dorsal side on the left and ventral side on the right; cranial side is on the top of the images

(Patient-Controlled Analgesia) pump and oral administration of Ibuprofen and Paracetamol or Metamizol. The PCA pump was then discontinued and, when needed, substituted with a low dose of Oxycodon. There were no restrictions to mobilization, which the patients begun on the first postoperative day with physiotherapists and without walking aids. All patients were requested to be able to climb stairs before discharge.

Patient recruitment

The present study was conducted according to the strengthening the reporting of observational studies in epidemiology: the STROBE Statement [10]. Data of all consecutive patients were analyzed, who underwent single or bilateral VBT at our institution between June 2017 and August 2019. All surgeries were performed by one spinal deformity, (US) fellowship trained senior surgeon (PDT), who had limited previous experience with anterior approaches to the thoracic and lumbar spine. Anesthesia was performed by a limited number of senior anesthetists. All consecutive patients diagnosed with adolescent idiopathic scoliosis and showing flexible curves (< 30° on bending or traction X-rays) were included in this study. While skeletal maturity (Risser = 5, Sanders = 8) is per se not an exclusion criterion for VBT at our institution, we seldom perform VBT in skeletally mature patients and the vast majority of the subjects in this cohort were skeletally immature (Risser ≤ 4 and/or Sanders ≤ 7). A few surgeons have started to propagate VBT to be applicable in flexible curves for adult idiopathic scoliosis and, at our institution, VBT has been experimentally offered to selected mature patients (e.g., very flexible lumbar curves in active patients without degenerative changes). However, these patients were not included in this work. While research aimed to identify the ideal candidate for VBT is still ongoing, the authors developed a classification based on the benefits of VBT over fusion and on the magnitude and flexibility of the curve [2] (Table 1). This classification is employed for immature patients (Risser ≤ 4 and/or Sanders ≤ 7) with curves between 40° and 70°. This table has been developed over time following the learning experience we had with our first patients, so not all of the subjects of this cohort have been operated following this scheme. The goal is full intraoperative curve correction for Risser 2–4 or Sanders 5–7. The authors leave a minor curve of approximately 20° for Risser 0–1 and/or Sanders 3–5 patients and try to delay surgery for patients with open triradiate cartilage, to limit the risk of overcorrection. As this classification is solely based on clinical experience and has not been validated yet, the authors do not propose it as a guideline. Patients with (1) radiculopathy or other neurological symptoms deriving from spine pathology and/or (2) previous spine surgery are not eligible for VBT at our institution. Exclusion criteria for our study were (1) uncontrolled chronic disease (2) infections (3) malignancy (4) pregnancy (5) any blood anomalies (6) immunodeficiency (8) other omitted criteria that could influence the results of this study. A comprehensive physical and blood examination were performed pre-operatively. This study was approved by the ethic committee of the University of Aachen (EK 130/19).

Outcomes of interest

To analyze the learning process of VBT intubation time per screw, surgical duration per screw and estimated blood loss per screw were observed. Intubation time was considered as the time from the beginning of intubation to extubation of the patients. Surgical duration was calculated from the first incision until end of suturing. In case of bilateral correction, the time needed for repositioning and re-draping was not included in surgical duration. The number of intraoperative complications and screw misplacement was observed, with misplacement defined as a screw causing a neurological deficit or visceral or vascular damage. The hospitalization length from day of surgery to discharge was also evaluated. Furthermore, we analyzed the number of postoperative complications occurring within the first 6 weeks after surgery.

Table 1 Visualization of the authors' indication according to curve type and magnitude

Type/bending	> 50% less than 30°	< 50% but less than 30°	< 50% and less than 30°
Type 1 (lumbar curve)	Very good candidate	Good candidate	Bad candidate, could consider traction films under anesthesia to re-evaluate flexibility
Type 2 (double curve)	Very good candidate	Good candidate	Like above, disc releases optional for the thoracic apex
Type 3 (long thoracic curve)	Good candidate	Good candidate	Borderline candidate, could consider disc releases
Type 4 (short thoracic curve)	Good candidate	Borderline candidate, could consider disc releases	Bad candidate
Type 5 (curve with high proximal curve)	Bad candidate	Bad candidate	Bad candidate

Statistical analysis

For the statistical analysis we referred to the software STATA/MP 14.1 (StataCorp, College Station, TX). For the analysis, we referred to a linear model regression diagnostic. The confidence interval was set at 95% in every comparison. The unpaired *t* test was performed to compare the outcomes of interest among the first 20 and the last 20 treated patients. For the pairwise correlation, the Pearson Product-Moment Correlation Coefficient (PPMCC, ρ) was used. According to the Cauchy–Schwarz inequality, the final effect ranks between + 1 (positive linear correlation) and − 1 (negative linear correlation). Values of $0.1 < |\rho| < 0.3$, $0.3 < |\rho| < 0.5$, and $|\rho| > 0.5$ were considered to have small, medium, and strong correlation, respectively. The test of overall significance was performed through the χ^2 test. Values of $p < 0.05$ were considered statistically significant.

Results

Demographic data

In the observation period, surgery was performed on 91 patients. The follow-up ranged from 6 to 24 months. One patient was excluded from the study: for one girl with bilateral scoliosis, after successful instrumentation of the lumbar curve, anterior, dynamic correction of the thoracic curve had to be abandoned because of diffuse pleural scarring and a second-time thoracic spondylodesis was performed instead. Thus, the data of 90 patients were analyzed.

Of the 90 patients included in the study, 80 were females and 10 males. The mean age was 14.6 ± 1.8 years, Risser 2.3 ± 1.7, Sanders 5.1 ± 2. The mean height was 161 ± 10 cm, the mean weight was 52.7 ± 9.8 kg and mean Body Mass Index 20.3 ± 3.11 kg/m^2.

Before surgery, the mean Cobb angle of the instrumented curves in the whole cohort was 55.7° ± 13.5°. Considering the first 20 treated patients (8 thoracic, 4 lumbar and 8 double instrumentations), the mean Cobb angle of the instrumented curves was 58° ± 11° before surgery and 24° ± 13° at the first standing X-ray. Considering the last 20 treated patients (5 thoracic, 4 lumbar and 11 double instrumentations), the mean Cobb angle was 58° ± 11° before surgery and 24° ± 12° at the first standing X-ray.

Within 6 months from surgery, none of the patients required pain medication and all had returned to the daily activities and sports they were participating to before VBT.

Outcomes

On average, 9.4 ± 2.6 levels per patient were instrumented with 10.2 ± 3.3 screws. Apical thoracic disc releases were performed in few selected patients at three to five levels, with onedisc release requiring about 2–3 min. A double tether was used in seven patients from this cohort.

The mean intubation time per screw was 33.1 ± 7.6 min (range 15.4–61.6 min). Overall intubation time fell from 439.2 ± 52.8 min for the first 20 patients to 358.4 ± 83.4 min for the last 20 patients ($p = 0.0007$). Surgical duration was 21.3 ± 5.7 min per screw on average (range 9.4–44.8 min), overall surgical duration was 390 ± 267.3 min among the first 20 patients and 163 ± 57.7 min among the last 20 patients ($p = 0.0006$). The average estimated blood loss was 21.3 ± 18.2 ml per screw (range 100–6.6 ml), changing from 286.5 ± 86 ml for the first 20 patients to 188.8 ± 54.3 ml for the last 20 ($p = 0.0001$). Four patients received a transfusion from cell-salvage and three blood transfusions were performed: all these patients were among the first ten treated subjects. The mean hospitalization length was 8.3 ± 3.1 days on average (range 4–14 days), falling from 9.3 ± 2.1 days to 7.8 ± 1.6 between the two considered cohorts ($p = 0.01$). No intraoperative complications, neuromonitoring anomalies or screw misplacements were observed. Six patients in this cohort experienced pulmonary complications within the first 6 weeks after surgery. Five complications occurred after double VBT and one after thoracic VBT. Three patients were re-admitted to their local hospital for recurrent, right-side pleural effusion 2–6 weeks after surgery. Two patients were treated with chest-tube reinsertion, one patient underwent exploratory thoracotomy due to a bleeding from the right pulmonary ligament, but this lesion could not be repaired and a chest-tube was reinserted. One patient was admitted to her local hospital 2 weeks after surgery because of fever and dyspnea and was treated with antibiotics for 2 weeks after diagnosis of a “chest infection”. One patient suffered a minor pulmonary embolism after a 24-h flight and underwent intramuscular low-molecular-weight heparin therapy for 1 month [3]. One patient developed a persistent atelectasis of the lower left lobe on the second postoperative day after thoracic VBT from the right side. Since she did not tolerate non-invasive ventilation, intubation was required for 3 days. The symptoms resolved after bronchoscopic removal of a large mucus accumulation. All patients recovered well and without sequelae. Four of the reported complications were observed within the first 25 operated patients. No further complications were observed beyond 6 weeks after surgery.

Data analysis

There was evidence of a negative correlation between growing number of patients and the intubation time ($\rho = -0.57$; $p < 0.0001$), surgical duration ($\rho = -0.55$; $p < 0.0001$), total estimated blood loss ($\rho = -0.66$; $p < 0.0001$), hospitalization length ($\rho = -0.32$; $p = 0.002$). These results are shown in Fig. 2.

Discussion

The main findings of this paper are that there is a statistically significant and rapid decrease in all the considered outcomes of interest with time. Intubation time and surgical time per screw are expected to decrease by over 50% for each treated patient and the estimated blood loss per screw is expected to drop by 60% per treated patient. The hospitalization length is also expected to drop by 32% for each treated patient. There were no observed intraoperative complications and no misplaced screws. The analyzed data suggest that, even if the surgeon has limited experience with anterior approaches, VBT is a safe procedure and that increasing experience quickly reflects on both intraoperative parameters and hospitalization length. Notably, there is a difference between the average number of instrumented level (9.4 ± 2.6) and the average number of screws per patient (10.3 ± 3.4). This difference is due to the use of a double tether for the correction of lumbar curves after the first 60 patients: to avoid a bias in the outcomes of interest, we decided to analyze intubation time, surgical time and estimated blood loss per screw and not per instrumented level. Double tether was adopted as a high rate of tether rupture was observed during follow-up (28 patients), most of all in lumbar curves. While only three of the 28 patients with tether rupture required revision surgery for loss of correction, the second tether may provide more stability to the construct. Data regarding the rupture rate with double tether are not yet available, but preliminary results showed how the introduction of double tether did not have a negative impact on lumbar lordosis [11]. Apical disc releases were also performed in few selected thoracic curves. This includes cutting a window into the near annulus (on the convex side), while the nucleus is left untouched. We found that this procedure facilitates compression on the convex side and less tether tension is required for correction. On intraoperative fluoroscopy, we did not observe any loss of disc height and we believe that, by compressing the convex side, the displaced nucleus will centralize. Obviously, this is only possible if the opposite annulus is not too rigid. We do not

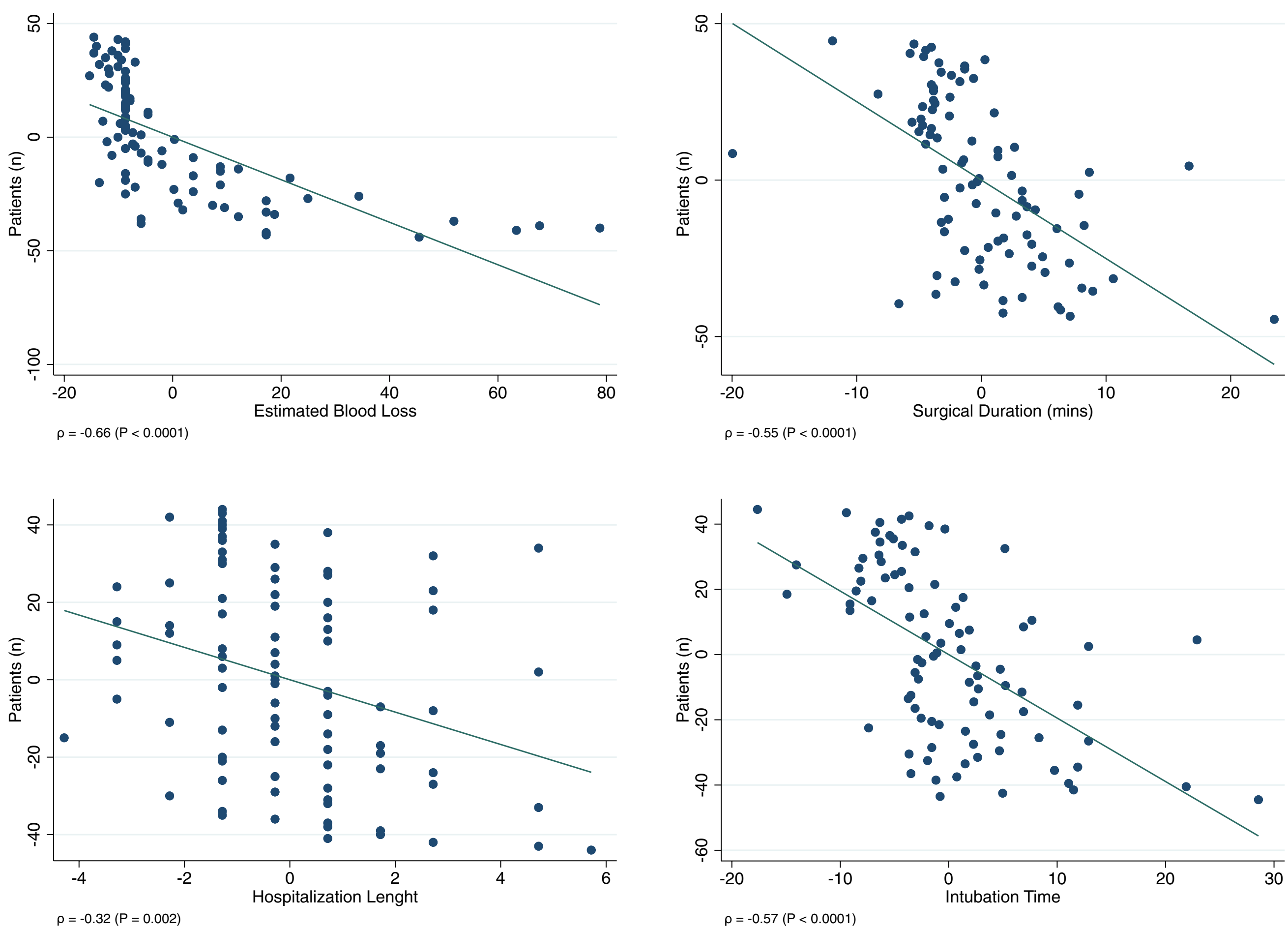

Fig. 2 Overall results of the pairwise analyses

perform discectomies. Further studies will be required to investigate the role of disc releases in curve correction and their long-term effects. While we do not currently recommend the use of VBT in mature patients, we believe that advanced intraoperative correction techniques such as disc releases or double cord will allow expanding the use of VBT to Risser 5 and/or Sanders 8 patients with flexible curves. Tissue remodeling following Wolff's law may be the principle behind the application of VBT to skeletally mature patients. However, further research will be required to investigate the possible use of VBT in this group of subjects.

While there seem to be no difference in the results between the first and last 20 subjects, we performed surgery on, the authors believe that the modifications in surgical technique and patient selection will be more relevant in the long-term follow-up, resulting in a reduced rate of revision and tether rupture. These factors, along with the effect of disc releases on curve correction and disc degeneration, and with the effect of curve type on correction, deserve a separate analysis when long-term follow-up will be available.

To our best knowledge, this is the first paper to describe the effect of learning curve for VBT. There was a significant improvement of all observed parameters in the comparative analysis of our first 20 and last 20 patients. Regarding the intubation time, $r = -0.57$ indicated a strong inverse correlation between number of operated patients and intubation time. This value was statistically significant ($p = 0.0001$). According to this correlation, the intubation time per screw is expected to decrease by 57% for every operated patient. In our cohort, intubation time has not yet reached a plateau, with values ranging between 31.2 and 15.4 min per screw among the last ten treated subjects. Thus, a further decrease in intubation time is to be expected in the future.

For surgical duration, $r = -0.55$ also showed a strong inverse correlation between number of treated patients and surgical time. This parameter was statistically significant ($p = 0.0001$). In this case, the surgical time is expected to be halved for every patient. Even for this parameter, a plateau has not yet been reached and a further decrease in surgical time is to be expected.

Regarding estimated blood loss, PPMCC measured $r = -0.66$, again showing a strong inverse correlation between number of treated patients and estimated blood loss. This data were statistically significant ($p = 0.0001$). For this parameter, a decrease by 66% is to be expected for every treated patient. A plateau for blood loss was observed among our last 32 patients, with an average estimated blood loss per screw of 10.7 ± 2.2 ml in this restricted cohort: this translates into an estimated blood loss of 80–100 ml for unilateral approaches and 150–200 ml for bilateral surgeries. This values are coherent with other published data [12].

The last considered outcome was hospitalization length. The PPMCC was $r = 0.32$, indicating a medium inverse correlation between numbers of treated patient and hospitalization length. This correlation was statistically significant ($p = 0.002$). The hospitalization length is expected to decrease by 33% for every treated patient. A plateau has not yet been reached, but the hospitalization length for VBT is already shorter than the average stay for posterior fusion for AIS in Germany (13 days, InEK GmbH, Siegburg, updated 2019). Comparing hospitalization length in patients undergoing VBT and posterior fusion, Chen et al. also observed a reduction in in patients undergoing VBT [12].

Posterior fusion with pedicle screws still represents the gold standard for treatment of AIS [9]. Retrospective studies aiming to measure the accuracy of pedicle screws for AIS during the learning curve showed an accuracy above 80%, with no neurological or visceral complications reported [13, 14]. Similarly, no neurological or visceral complication were reported, confirming the safety of VBT during the learning curve. As reported for posterior fusion, surgical time and estimated blood loss decrease as the surgeon gains experience [15, 16]. Surgical duration per screw seemed to be longer for VBT in comparison to the data showed by Lonner et al. (21 min for VBT vs 25 to 11 min for posterior fusion) [17]. Since we have not reached a plateau for surgical time per screw yet, we expect this parameter to further decrease in the future. Comparing the total estimated blood loss, this appeared to be considerably lower for VBT than for posterior fusion (188 ml vs 774 ml at the end of the learning curve) [17], with no patients requiring cell-salvage blood or blood transfusions shortly after the beginning of the learning curve. Regarding the rate of perioperative complications, the most frequent one was recurrent pleural effusion in patients undergoing bilateral VBT. While the rate of pulmonary complications was comparable to that of other studies [18], the protocol for chest tube removal for all patients was modified aiming for a further reduction in the rate of recurrent pleural effusion. Initially the chest tube was removed when the output was below 200 ml in 24 h, and later on this threshold was decreased to 100 ml. Recurrent pleural effusion may be caused by manual retraction of the lungs when these are not sufficiently deflated, thus particular care should be taken when timing chest-tube removal in these patients [3].

The main limitation of our study was the bias created by performing disc releases. This controversial procedure is only needed in selected patients and, among these, there is variability in the number of disc releases needed: for this reason, it is not possible to quantify the effect of this procedure on the surgical duration. An analysis of the outcomes of interest by treated level was also not performed. Furthermore, we have not yet reached a plateau in intubation time, surgical duration and hospitalization length. A longer observation period would be useful to measure the plateau values for these parameters. In this work, radiologic data were not analyzed, as no influence of the learning curve on scoliosis correction was observed. This was probably due the heterogeneity of the treated curves. Further radiologic studies with a longer follow-up are required to analyze the results of VBT.

Conclusion

Our study shows a steep learning curve for VBT, with all observed parameters rapidly decreasing with the experience of the surgeon. Intubation time and surgical time per screw decrease by over 50% for each treated patient and the estimated blood loss by 66%. The hospitalization length stay drops by 32% for each treated patient. Furthermore, the hospitalization length after VBT is shorter than the mean German hospitalization length after posterior fusion. No intraoperative complications or screw misplacement were observed in this study. These data are encouraging for surgeons willing to perform VBT but have limited experience with anterior approaches.

Author contributions AB: conception, data interpretation, draft and revision, final approval of the work. PDT: data interpretation, revision, final approval of the work. FM: data analysis and interpretation, draft and revision, final approval of the work.

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Compliance with ethical standards

Conflict of interest AB: none. PDT: consultant, paid lectures—globus medical. FM: none.

Approval of the ethics committee EK 130/19, RWTH Aachen University, Aachen, Germany.

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