Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis, and its treatment is essentially surgical for curves above 40 degrees. Posterior spinal instrumentation (PI) is the usual technique, while the vertebral body tethering (VBT) method is tested technique for this study as a new treatment option.

Objectives:
To compare postoperative pain outcomes between PI and VBT with mini-thoracotomy surgeries performed in AIS patients.

Study Design:
Prospective, randomized controlled study registered with the Clinical Trials Portal (NCT04822935).

Setting:
Department of Anesthesiology.

Methods:
We randomly divided 31 adolescents (28 women, 3 men) aged 11 to 18, with a diagnosis of AIS into 2 groups using computer software: the PI and the VBT groups. Postoperative morphine consumption and the Numeric Pain Rating Scale (NRS) scores at the 1st, 4th, 8th, 12th, 24th, and 48th hours and at 4 weeks were recorded. Length of hospital stays, length of intensive care unit (ICU) stays, duration of operation, postoperative patient satisfaction with the Likert scale, and complications such as bleeding and respiratory distress were recorded. Preoperative and follow-up Oswestry Disability Index (ODI) questionnaires were obtained to assess patient outcomes at 4 weeks postoperatively.

Results:
Postoperative morphine consumption and the NRS scores at the 1st, 4th, 8th, 12th, 24th, and 48th hours were significantly higher in group VBT ($P < 0.05$). The amount of bleeding was significantly higher in group PI ($P = 0.002$). The ICU and the hospital length of stays in the VBT group were significantly higher (respectively, $P = 0.011$; $P = 0.032$). Discharge NRS scores, ODI scores as well as patients’ satisfaction were similar in both groups ($P > 0.05$).

Limitations:
Firstly, this was a single-centered study with a small sample owing to the rarity of AIS surgeries. Moreover, double-blinding was not applied to the patients and doctors because of the surgery incision places.

Conclusion:
From our results, both techniques can be employed for AIS surgery, but a meticulous approach is essential for the prevention of acute pain for VBT.

Key words:
Adolescent idiopathic scoliosis, posterior spinal instrumentation, postoperative pain, mini-thoracotomy, spine

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Scoliosis is the 3-dimensional (3D) deformity of the spine characterized by an increase of the lateral curve with a Cobb angle of more than 10 degrees in the coronal plane (1). With a 2%-3% incidence, scoliosis is commonly observed in pediatric patients. The most common type is Adolescence Idiopathic Scoliosis (AIS), which includes 90% of all cases with idiopathic scoliosis (2).

In patients with Cobb angle of $25^\circ$-$40^\circ$, nonsurgical treatment options are recommended. Bracing is the most commonly used method with the aim of limiting the progression of the curve. However, those with an-
gles of 40° or more require surgical treatment. Posterior pedicle screw and rod fixation techniques are the most commonly used approaches (3). Growth-modulating fusionless surgeries are alternative techniques in skeletally immature patients. Among various techniques, vertebral body tethering (VBT) and vertebral body stapling are the most frequently performed surgeries (4). VBT is a technique performed thoracoscopically, and mini-thoracotomy and incisions are made smaller than the standard spinal fusion surgery (5).

In AIS surgeries underwent in a pediatric population, postoperative pain management, and complications should be considered meticulously. Treatment of pain in pediatric population can be very challenging, and under treatment may result in psychiatric trauma. Moreover, postoperative pain may cause delayed recovery, prolonged hospitalization, and decreased quality of life (6).

The aim of this study was to compare postoperative pain outcomes in patients who either underwent posterior spinal instrumentation (PI) surgery or VBT with mini-thoracotomy in AIS patients. Our secondary aim was to compare the amount of perioperative bleeding, patient satisfaction with postoperative complications, and preoperative/postoperative Oswestry low back pain disability score between the 2 surgeries.

**METHODS**

We adopted a randomized controlled design. The study was approved by the Clinical Research Ethics Committee of the Faculty of Medicine with protocol no. 2020/1561 and was registered with ClinicalTrials.gov (NCT04822935). The research was performed between June 2021-November 2021 at the Department of Orthopedics and Traumatology. All written and oral consent for the study was obtained from the parents of the patients prior to their involvement.

The patients included in this prospective randomized controlled study were aged 9-18 years (adolescent) with an ASA score of I-III, body mass index < 40 kg/m², patients diagnosed with AIS, and patients and their parents who agreed to join the study. We excluded patients with scoliosis due to neuromuscular disease, patients undergoing reoperation for correcting the deformity, patients whose Cobb angle was < 40°, patients who had hematological pathology which could affect coagulation, and patients with lack of cooperation as well as psychiatric disorders.

All demographic data were recorded. NRS (numerical rating scale) and Oswestry disability index (ODI) for low back pain of the patients were recorded before the operation. The NRS score at the 1st, 4th, 8th, 12th, 24th, and 48th hours and 4 weeks postoperative, morphine consumption at the 1st, 4th, 8th, 12th, 24th, and 48th hours postoperative, ODI score in the preoperative, postoperative (before hospital discharge) and 4 weeks were recorded. Length of hospital stays, length of intensive care unit (ICU) stays, Cobb angle, operation times, and postoperative patient satisfaction were recorded. The patients were also evaluated in terms of complications such as bleeding and respiratory distress.

**Patient Assessment Scales**

Opioid consumption: the amount of morphine in milligrams from patient-controlled analgesia (PCA) + rescue analgesia. The dosage set for morphine PCA was: Demand dose: 1 mg + continuous infusion dose 0.5 mg/h + lockout interval: 10 minutes.

NRS is a commonly used pain assessment tool in patients. It is scaled between 0-10, where 0 is no pain and 10 is the worst pain possible.

ODI is an index derived from the Oswestry Low Back Pain Questionnaire used to quantify disability for low back pain. The questionnaire contains 10 questions, and each question is followed by 6 statements about the patients' life. Each question is scored on a scale of 0-5. We calculated the ODI scores using computer software.

Patient satisfaction was evaluated with a 5-level Likert scale. The questions included ‘Are you satisfied with the surgery?’ and patients responded in a Likert scale: 1-Strongly disagree, 2-Disagree, 3-Neither agree nor disagree, 4-Agree, or 5-Strongly agree.

The randomization was accomplished using computer software. After randomization, patients were divided into 2 groups: those who underwent posterior spinal instrumentation surgery (Group PI), and those who underwent vertebral body tethering surgery (Group VBT).

**VBT Group Surgery Technique**

For VBT surgery, the patient was placed in a lateral decubitus position convex side of the curve. The apex point of the curve was determined using radiological evaluation. A mini-thoracotomy was performed at the apex of the curve, and a 10-mm thoracoscopy port was inserted for T5 and T6 screw insertion. A second mini-thoracotomy was performed for screw insertion at T11 vertebra and below. For the lumbar portion, a mini-lumbotomy was performed for screw insertion.
A thoracal side single screw was inserted from T5 to T12, and a double screw was inserted from L1 to L4. All screws were inserted under fluoroscopic control through anteroposterior and lateral views. Tether was tensioned using derotation, and manual translation was performed under fluoroscopic anteroposterior control. A chest tube was placed, and the incision was closed after lung reinflation.

**Posterior Instrumentation Technique**

For posterior spinal fusion surgery, the patient was placed in a prone position. The standard approach using electrocautery was performed for all fusion surgery. A pedicle screw was inserted bilaterally for each vertebra under fluoroscopic control. Instrumentation level was determined according to Lenke through preoperative side bending X-ray. Translation was performed under traction for deformity correction. Segmental derotation was performed for each segment with compression and distraction. The incision was closed after the placement of one hemovac drain.

All surgery was performed by the same team, with one senior surgeon having 10 years of experience in spine deformity surgery. The indication for surgery was determined according to deformity magnitude measured as Cobb angle. A Cobb angle > 40 degrees was the main indication for surgery.

**Anesthesia Technique**

Patients were moved to the operating room after premedication. ECG, pulse oximetry, and blood pressure monitoring were performed in the operating room. The induction of general anesthesia was achieved with intravenous 0.05 mg/kg midazolam, 2 µg/kg fentanyl, 2 mg/kg propofol, and 0.6 mg/kg rocuronium. Cases in group PI were intubated by a single-lumen tube. Cases in group VBT were performed under general anesthesia with a right-sided double-lumen endotracheal tube for single lung ventilation. Invasive arterial cannulation and central vein catheterization were performed in all patients after anesthesia induction. Maintenance of anesthesia was provided by total intravenous anesthesia with propofol (100-150 µg/kg/min) and remifentanil (0.08-0.25 µg/kg/min) infusions. We managed propofol and remifentanil infusion doses to sustain a mean arterial pressure (MAP) in approximately the 60-65 mmHg range. The patients were operated on in the prone position, and neuromonitoring with somatosensory evoked potentials (SSEP) and motor evoked potentials (MEP) was performed in all patients throughout the operation. Also, we implemented a restrictive transfusion protocol when hemoglobin levels were below the 7 g/dL threshold, 10-15 mL/kg of erythrocyte suspension was applied. Intraoperative bleeding volume was calculated as follows: [blood volume on weighted gauze pads (volume of blood accumulated in the aspirator- minus irrigation fluid)].

All operated AIS patients were extubated in the operating room and taken to the ICU for close follow-up. After the operation, all patients were given an intravenous PCA device for 48 hours. Rescue analgesia of 1 mg morphine was applied when NRS > 4 after each questioning, and pain monitoring continued till NRS < 4. Chest tubes of the patients in the VBT group were removed on the 2nd postoperative day. Both groups were given 4x15 mg/kg acetaminophen and 1x20 mg tenoxicam during all patients’ hospital stay.

**Statistical Analysis**

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) program was used for statistical analysis. Descriptive was employed (mean, standard deviation, median, frequency, percentage, minimum, maximum) while evaluating the study data. The conformation of the quantitative data to the normal distribution was tested with the Shapiro-Wilk test and graphical examinations. Repeated analysis of variance was performed to examine the effects of group and time on morphine consumption and NRS pain scores. Group and time were included in the analysis as independent variables, while morphine consumption and NRS measurements were included as dependent variables. Independent t-test compared 2 groups of normally distributed quantitative variables, and Mann-Whitney U test compared 2 groups of non-normally distributed quantitative variables. Dependent groups t-test was used for within-group comparisons of normally distributed quantitative variables. Wilcoxon signed-ranks test was used for in-group comparisons of quantitative variables that were not normally distributed.

Pearson chi-square test, Fisher’s exact test, and Fisher-Freeman-Halton exact test were used to compare qualitative data. Statistical significance was accepted as $P < 0.05$. We made the sample size analysis with the Power and Sample Size Program (PS version 3.1.2). With predicted alterations, the change in NRS values altered by 50% was predicted at least 26 patients were required to reject the null hypothesis at a power of 0.8 and at a confidence interval corresponding to 0.05. Prior data
define that the difference of matched pairs is normally distributed with standard deviation 2.2 and when the true difference in the mean response of matched pairs is 1.95. Considering a 20% dropout, at least 29 patients were required (7).

RESULTS

We included 38 patients in the study. Six patients were excluded: 2 refused to participate in the study, and 4 did not meet the inclusion criteria. One patient was excluded from follow-up due to missing data. Thus, 31 cases were included in the final analyses (Fig. 1). Study patients were 90.3% (n = 28) women, and the ages of patients ranged from 11 to 18 years, with a mean of 14.0 ± 1.69 years. Demographic data of the patients included in the study are displayed in Table 1.

In Table 2, a significant difference in the amount of bleeding according to the type of operation was demonstrated. The amount of bleeding in cases with PI was significantly higher compared to that in cases with VBT (P = 0.002). The ICU length of stay of cases in the VBT group was significantly higher (P = 0.011). The duration of hospitalization for cases in the VBT group was significantly higher (P = 0.032) (Table 2).

Morphine consumption amounts at the 1st hour, 4th hour, 8th hour, 12th hour, 24th hour, and 48th hour of the VBT group were significantly higher (P = 0.001) (Table 3, Fig. 2).

The NRS of patients in the VBT group at the 1st hour (P = 0.041), 4th hour (P = 0.007), 8th hour (P = 0.001), 12th hour (P = 0.001), 24th hour (P = 0.001), 48th hour (P = 0.001) were significantly higher (Table 4).

There was no statistically significant difference between the NRS measurements of the cases at the postoperative 3rd week according to the groups (P = 0.348) (Table 4).

Preoperative, postoperative, and 3rd week ODI measurements of the cases did not show a statistically significant difference according to the groups (P > 0.05) (Table 5).

In order to examine the effects of group and time on morphine consumption, a 2-factor repeated-measures analysis of variance was performed. The group was included in the analysis as an independent factor and time as an in-group factor. Morphine consumption value was included in the analysis as a dependent variable.

When the effects within the group were examined, the change in morphine values over time was found to be statistically significant (P < 0.001). The difference between the morphine consumption levels of the groups was also found to be statistically significant (P < 0.01). Time interaction with the group was also found to be statistically significant for morphine consumption (P < 0.01) (Table 6).
Repeated measures analysis of variance was performed to examine the effects of group and time on NRS value. The group was included in the analysis as an independent factor and time as an in-group factor. NRS value was included in the analysis as a dependent variable.

When the effects within the group were examined, the change in NRS values over time was found to be statistically significant (P < 0.001). The difference between the NRS measurements of the groups was also statistically significant (P < 0.01). However, it was determined that the time interaction with the group was insignificant (P > 0.05) (Table 7).

**DISCUSSION**

In this study, we observed a significant reduction in pain scores and opioid consumption rate of the PI group at the early postoperative period (48 hours). In the VBT group, we observed significantly less bleeding, and longer hospital and ICU stay. However, pain scores at discharge, ODI scores at all time periods, and patients’ satisfaction with surgery were similar in both groups. There are few studies in the literature that compare the postoperative pain outcome of VBT and PI in a randomized controlled fashion.

Curves greater than 300 are 10 times more common in women (8). This was reflected in our study as
90.3% consisted of women and 9.7% consisted of male patients.

In a retrospective study comparing 49 patients who underwent either VBT or PI, there was no difference in pain and patient satisfaction outcomes between the groups using the SRS-22 test (9). VBT was performed through a thoracoscopic approach. Similar to Newton and his colleagues, there was no difference in patient satisfaction between the VBT and PI groups, but there was a significant difference between the groups in terms of pain. The differences in results could be explained by the fact that our VBT group was performed through a mini-thoracotomy.

In our institution, an open mini-thoracotomy approach was used for the operation of our AIS patients. This technique was preferred because it allows for surgical correction of larger curves, though it can cause a higher degree of acute postoperative pain, possibly because of its larger incision compared to the thoracoscopic model (10). Recently, 2 cases of successful continuous erector spinae plane block catheters and one intercostal nerve block were described. They also

![Fig. 2. Distribution of morphine consumption by groups.](image)

### Table 3. Evaluation of morphine consumption by groups.

<table>
<thead>
<tr>
<th>Morphine Consumption (mg)</th>
<th>Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VBT (n = 14)</td>
<td>PI (n = 17)</td>
</tr>
<tr>
<td>1.hour</td>
<td>Mean ± SD</td>
<td>4.82 ± 2.01</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>4.6 (1.9-8.3)</td>
</tr>
<tr>
<td>4.hour</td>
<td>Mean ± SD</td>
<td>9.48 ± 3.66</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>8.2 (4.3-14.5)</td>
</tr>
<tr>
<td>8.hour</td>
<td>Mean ± SD</td>
<td>16.29 ± 5.4</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>17.3 (6.2-24.9)</td>
</tr>
<tr>
<td>12.hour</td>
<td>Mean ± SD</td>
<td>24.47 ± 7.87</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>25.6 (9-37.1)</td>
</tr>
<tr>
<td>24.hour</td>
<td>Mean ± SD</td>
<td>41.15 ± 15.16</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>48.2 (15.7-62.9)</td>
</tr>
<tr>
<td>48.hour</td>
<td>Mean ± SD</td>
<td>64.83 ± 15.72</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>71.2 (32-83.3)</td>
</tr>
</tbody>
</table>

*Student t-test
*Mann Whitney U Test
**P < 0.01
VBT, Vertebral Body Tethering; PI, Posterior Instrumentation; Max, maximum; Min, minimum; SD, standard deviation.

### Table 4. Evaluation of NRS by groups.

<table>
<thead>
<tr>
<th>NRS</th>
<th>Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VBT (n = 14)</td>
<td>PI (n = 17)</td>
</tr>
<tr>
<td>1.hour</td>
<td>Mean ± SD</td>
<td>8.36 ± 2.59</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>9 (0-10)</td>
</tr>
<tr>
<td>4.hour</td>
<td>Mean ± SD</td>
<td>7.07 ± 2.84</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>8 (0-10)</td>
</tr>
<tr>
<td>8.hour</td>
<td>Mean ± SD</td>
<td>6.57 ± 2.47</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>7 (1-9)</td>
</tr>
<tr>
<td>12.hour</td>
<td>Mean ± SD</td>
<td>6.21 ± 2.61</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>7 (0-8)</td>
</tr>
<tr>
<td>24.hour</td>
<td>Mean ± SD</td>
<td>5.14 ± 1.51</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>5 (3-8)</td>
</tr>
<tr>
<td>48.hour</td>
<td>Mean ± SD</td>
<td>4.5 ± 1.61</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>5 (2-8)</td>
</tr>
<tr>
<td>3.week</td>
<td>Mean ± SD</td>
<td>1.64 ± 0.63</td>
</tr>
<tr>
<td></td>
<td>Median (Min-Max)</td>
<td>2 (1-3)</td>
</tr>
</tbody>
</table>

*Student t Test
*Mann Whitney U Test
**P < 0.05  **P < 0.01
VBT, Vertebral Body Tethering; PI, Posterior Instrumentation; Max, maximum; Min, minimum; SD, standard deviation, NRS, Numerical rating scale.
encountered high levels of pain when VBT was accomplished through a mini-thoracotomy.

There is no consensus on the management of postoperative pain due to VBT. A retrospective study comparing the efficacy of thoracic paravertebral catheter with lidocaine infusion in AIS patients reported improved opioid requirement and length of stay (11). Techniques involving regional analgesia prove to be useful in VBT techniques involving mini-thoracotomy. However, more randomized controlled trials are needed to demonstrate the efficacy of regional blocks in AIS surgery.

The rate of complications was similar between both groups in our study as opposed to findings in a systematic review of 24 studies comparing the AVBT and/or PSF procedures where greater rates of complications and reoperations were observed in patients who underwent an AVBT (12). We think that this difference arises from the longer follow-up time of the latter study.

Growth-modulated techniques are on the rise, as early fusion encountered after posterior instrumentation in children is known to have a poor quality of life and adverse effects (13). Intravenous opioids remain the mainstay of postoperative analgesia but have several adverse effects. Thus, postoperative pain, especially in children, is an issue that needs to be handled considerately. In this study, we compared postoperative pain outcomes between the PI and VBT groups using the NRS score and total morphine consumption with PCA. The NRS score at the 1st, 4th, 8th, 12th, 24th, and 48th hours was higher in the VBT group. Since NRS is a subjective parameter, opioid consumption, which gives the most optimal results at the present time, was evaluated. Likewise, morphine consumption at the 1st, 4th, 8th, 12th, 24th, and 48th hours was higher in the VBT group. Although opioids are the mainstay in the relief of postoperative pain in both surgeries, they have minor side effects such as nausea and constipation, which are common, as well as serious side effects such as respiratory depression, which are often rare. The side effects of opioids are thought to be related to the total dose consumed (14). In our study, we observed that 5 patients (29.4%) had nausea and vomiting in Group VBT as well as 4 (28.6%) in Group PI. There were no serious side effects.

Bleeding has been shown to be the most common perioperative complication for both surgical methods (15). In our study, the amount of bleeding and the amount of erythrocyte suspension given was higher in those who underwent posterior instrumentation surgery. In a study of 1039 pediatric scoliosis-correction surgeries, Dick et al showed that 24.4% of patients received a perioperative blood transfusion, and the mean transfusion amount was 4.7 units (16). Similar to our results, we observed significant reductions in the VBT group in the meta-analysis carried out by Shin and his colleagues (12).

In our study, we employed the ODI score in order to assess the quality of life. In a retrospective case series examining the quality of life of non-operated AIS patients, the ODI score provided information about the course of the disease (17). Preoperative, postoperative 24th hour, and postoperative 3rd week ODI scores were the same between PI and VBT groups.
In a study involving 84,320 patients, the most common postoperative complications were wound infection, newly developed neurological deficit, and implant-related complications (18). In our study, it was shown that the incidence of short-term postoperative complications and the durations of the operation were similar across the 2 groups. The length of stay in the intensive care unit and the hospital was longer in the VBT group, though not significant (18). These results were also similar to our findings as we detected longer hospital and ICU stays for VBT patients.

The main limitation of our study was in its small sample. A higher number of patients can increase the reliability of our results; but this was because of the nature of AIS operations is less than other surgery types. This study is single-centered and limited to only one hospital’s clinical experience. Finally, we could not blind the patients and the doctors in the study design because of the presence of incision scars.

**CONCLUSIONS**

From our results, a regional block should be considered for the management of VBT with mini-thoracotomy patients because of the high level of pain we encountered during the acute postoperative period. More randomized studies are needed to compare the postoperative pain and the regional techniques that may be applied, and complications between the 2 surgical methods, since VBT is a surgical method on the rise in all centers. From our results, we think that both techniques can be used for AIS surgery, but a meticulous approach is essential for the prevention of acute postoperative pain of VBT.

**REFERENCES**