**CASE SERIES**



# **Defning the learning curve in CT‑guided navigated thoracoscopic vertebral body tethering**

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## **Abstract**

**Summary** Estimated blood loss (EBL), anesthesia time, operative time, and length of stay decreased over 67 navigated vertebral body tethering (VBT) surgeries performed in a 5-year period, indicating a steep learning curve.

**Design** Retrospective review of prospectively collected data.

**Hypothesis** There would be a signifcant improvement in the performance of VBT procedures over time at a single tertiary center in terms of perioperative and postoperative outcomes.

**Purpose** Learning a new procedure for surgeons takes time, and previous studies have described improved efficiency as experience grows. VBT procedures are increasingly being performed in the US, but there is limited data regarding the learning curve specifcally regarding the use of CT-guided navigation. We sought to assess the learning curve of VBT with respect to estimated blood loss, anesthesia time, operative time, length of stay, percent correction of the major curve at frst follow-up. We further sought to characterize change in rates of 90-day complications.

**Methods** Pediatric scoliosis patients who underwent thoracic or lumbar CT-guided navigated VBT with a consistent surgical team at a single tertiary referral center between 2015 and 2020 were included. Student *t-*test was used to assess change in perioperative parameters over time, and also results between frst and latest group of 20 patients were compared.

**Results** 67 patients met inclusion criteria. Estimated blood loss (EBL), operative time, anesthesia time and length of stay signifcantly decreased over the 5-year study period. Specifcally, on comparison of our frst 20 patients with our last 20, the former had greater EBL (282 vs 116 ml, *p*=0.0005; 8.5% vs 3.6%, *p*=0.0024), operative time (4.8 h vs. 3.3 h, *p*<0.001), anesthesia time (7.4 h vs. 5.7 h,  $p = 0.0001$ ), and length of stay (3.7 days vs. 3.2 days,  $p = 0.019$ ). We also found significant reduction in EBL, operative time, anesthesia time and LOS in patients who underwent VBT surgery after 2019.

There was no signifcant change in the percent correction of the major Cobb angle at frst erect imaging or 90-day complications over the 5-year study period or between the various cohorts.

**Conclusion** This series has demonstrated improvements in surgical efficiency for VBT including reduced EBL, operative time, anesthesia time and hospital stay over a 5-year period. This indicates improved surgical technique and outlines the signifcant learning curve for surgeons who wish to perform this procedure. Improved surgeon training programs and newer instrumentation may reduce this learning curve.

**Take home point** 67 cases in a 5-year period, VBT procedures performed at a single center had signifcantly decreased EBL, anesthesia time, operative time, and length of stay, indicating a steep learning curve.

**Keywords** Vertebral body tethering · Scoliosis · Learning curve

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# **Introduction**

Surgical management for pediatric scoliosis is indicated in patients with progressive severe curves. The goals of surgery are to correct the deformity and prevent progression of the curve. The traditional surgical treatment for scoliosis is posterior spinal fusion (PSF) with instrumentation, but due to concerns regarding restricted motion and growth,

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other treatment approaches such as vertebral body tethering (VBT) are increasing in popularity [[1](#page-7-0)[–4](#page-7-1)].

Vertebral body tethering (VBT) is a non-fusion surgical technique for the treatment of progressive scoliosis in growing children. It was frst described by Crawford and Lenke in 2010 and has been introduced as an alternative to PSF [\[5](#page-7-2)[–7](#page-7-3)]. The current indications for this technique include moderate to severe scoliosis curves in skeletally immature patients. Leveraging the Heuter-Volkmann law where compression when applied on the concave side slows physeal growth while longitudinal growth is accelerated on the convex side, after VBT the curve may gradually correct over time. The potential advantages of this non-fusion technique are that it is minimally invasive, retains mobility of the spine, permits ongoing spinal growth and may decrease the risk of arthritis of the segments adjacent to the fusion sites  $[6-11]$  $[6-11]$ .

Learning a new procedure for surgeons takes time, and previous studies have described improved efficiency and outcomes as surgeon experience grows [[12](#page-8-1)]. A learning curve describes the surgeon's performance over the time and outlines the number of cases required for a surgeon to become skilled at a novel procedure. Variables that can describe the learning curve include operative time, anesthesia time, estimated blood loss (EBL), and length of hospital stay, as well as rates of morbidity or adverse events.

VBT is a promising technique but its use is currently limited. Though the number of vertebral body tethering procedures being performed is steadily increasing, it is technically demanding and requires additional specifc training. Most centers perform this technique under fuoroscopic guidance for vertebral body screw placement. At our center, we routinely use CT-guided navigation for posterior spinal fusion procedures and had signifcant experience with a navigated technique. Thus, we developed a novel CT-guided navigation technique for anterior vertebral body screw placement. The purpose of this study was to review the learning curve of the navigated VBT technique at a single tertiary center. We hypothesized that over time, surgeon skill would improve, resulting in decreased operative time, length of stay, estimated blood loss and improved correction of the major curve. We also evaluated the rates of 90-day complications over time.

## **Methods**

This study was conducted at a single tertiary referral center. Institutional Review Board (IRB) approval was obtained for all aspects of the study. We conducted a retrospective review of pediatric scoliosis patients who underwent thoracic or thoracolumbar/lumbar VBT between 2015 and 2020. Curves which were instrumented below L1 were considered thoracolumbar/lumbar. Patients between the ages of 10–16 years

with at least 1–2 years of growth remaining underwent VBT. Patients with at least 90 day follow-up were included in the study. Children with neuromuscular scoliosis, patients with nonfexible curves with bending flms showing residual  $curves > 40^\circ$  and those with history of previous spinal surgery or an underlying neuromuscular disease were excluded. To maintain a consistent patient population, all patients who underwent tethering of the right thoracic and left lumbar spine in a single operative setting were excluded from the study.

All surgeries were performed by the same two experienced fellowship-trained pediatric orthopedic surgeons in conjunction with one of two approach surgeons and a consistent surgical team. The two pediatric orthopedic surgeons have ample experience in pediatric spinal surgeries including thoracoscopic anterior spinal fusion surgeries. Prior to performing this procedure, one surgeon performed a site visit to another hospital to observe the procedure. Both surgeons participated in cadaveric labs to rehearse the specifc technique and to select appropriate navigated instrumentation and the best anchor point for the reference frame. The two approach surgeons have subspecialized practices focusing on thoracoscopic surgery.

Of the 79 consecutive patients who underwent VBT during this time period, 67 patients met the inclusion criteria for this study. 57 patients (85%) had a major right thoracic curve while 10 patients (14.9%) had a major thoracolumbar/ lumbar curve. 6 patients were excluded due to both a right thoracic and left lumbar VBT procedure performed on the same day. 4 patients were excluded because they had a history of prior spine surgery or underlying neurologic diagnosis, and 2 patients lacked follow-up. Data extracted from the hospital electronic medical record system were utilized in this study including the preoperative and 90-day radiographs and complications.

Statistical analysis was performed using the JMP 14 statistical analysis tool from the makers of SAS. Analysis of continuous variables was carried out using a Student *t*-test. For discrete variables, a chi-squared test was used. Preoperative and follow-up major Cobb angles were compared. Significance was set at  $p < 0.05$ .

#### **Surgical technique**

The surgery is performed via a routine thoracoscopic approach for all thoracic and L1 screws. For cases requiring instrumentation at L2, L3 or L4, either a mini-open retroperitoneal approach with typically a 6 cm incision or a minimally invasive direct lateral approach using a tube was utilized. The vertebral body tethering surgical technique performed was as described by Joshi et al. [\[9\]](#page-8-2). Surgical set up includes standard video-assisted thoracic surgery (VATS) equipment, double-lumen tube intubation, ultrasonic scalpel,

neurologic monitoring of motor evoked and somatosensory-evoked potentials (MEPs and SSEPs), and intraoperative computed tomography guided navigation (O-arm and Stealth, Medtronic).

Anesthesia is performed with a double-lumen endotracheal tube using total IV anesthesia to facilitate neuromonitoring. The patient is placed in a lateral decubitus with the apex of the curve facing up. The lung ipsilateral to the convexity of the curve is defated at the initiation of the surgery to allow access to the anterior vertebral bodies.

A longitudinal incision is made over the spinous process at the apex of the curve and a reference frame is clamped to the apex of the spinous process to facilitate CT navigation during vertebral instrumentation. A 2-cm muscle-sparing incision in made in the fourth intercostal space. A diaphragm retraction stitch is used to improve exposure to the T11, T12, and L1 vertebrae if needed. The ultrasonic scalpel is used to dissect the pleura off a 1 cm longitudinal band of the lateral vertebral body and to ligate the segmental vessels. Approximately two to three vertebral bodies can be instrumented by one 15-mm port site made in the midaxillary line. Depending on the number of instrumented segments, three to four ports are needed to place screws. The navigated probe is used to identify the vertebrae and screw trajectory (Fig. [1](#page-2-0)). A navigated awl is used to start the entry hole followed by a staple held on its applicator which is then tapped into the entry hole. A navigated tap is used to access the contralateral cortex, followed by a ball tipped probe to ensure that a bicortical tract has been developed. The screw length is measured on the navigated image and 4 mm is added to account for height of the staple and bicortical fxation in the contralateral side (Fig. [2](#page-3-0)). A hydroxyapatite coated titanium screw is then placed. This process is repeated for each vertebra included in the tether. The polyethylene terephthalate tether cord is then introduced. The cord is tensioned to correct the deformity by manual compression on the chest wall as well by use of an extrathoracic tensioner. Segmental tensioning is performed at each level and the cord secured with a set screw.

A chest tube placed prior to lung re-expansion. All incisions are closed in layers and covered with a sterile dressing. Postoperatively patients receive a multimodal pain management protocol. The chest tube is removed when 24 h output is less than 100–150 cc. Mobilization is allowed as tolerated.

#### **Learning curve outcomes**

Various parameters were collected including EBL, operative time, anesthesia time, length of hospital stay, mean postoperative pain scores, 3-month SRS-22R scores, percent correction of major curve at 3 months, and 90-day complications. To assess our learning curve for the procedure with respect to study timeline, we categorized our patients as those who underwent VBT surgery prior to 2019 and those who had surgery after 2019 since more procedures were performed in the last 2 years of the study We then analyzed and compared the continuous outcomes variables for these two groups using Student *t*-test. We also assessed changes in continuous outcomes over time using linear regression analysis. Finally, perioperative and 3-month outcomes in our frst 20 VBT patients were compared to our last 20 patients to assess our performance and hence the learning curve for this procedure. A  $p$  value < 0.05 was considered statistically significant.

<span id="page-2-0"></span>**Fig. 1** A posterior incision is made over an apical spinous process to accommodate the fber optic reference frame needed for the navigated scan. Navigated instruments are used to plan the laterally based incisions. Typically, 2 to 3 screws can be placed through each incision through separate fascial incisions. Two smaller anterior incisions provide access for exposure, camera visualization, and placement of chest tube at completion of the case





<span id="page-3-0"></span>**Fig. 2** When using navigation, the image of the instrument is projected onto the intraoperative CT scan. This helps determine how deep to tap, the length of the screw, and the trajectory of the screw.

## **Results**

A total of 67 skeletally immature scoliosis patients who underwent thoracic or thoracolumbar/lumbar vertebral body tethering met the inclusion criteria. Mean age at surgery was 13.2 years (SD 1.4). There were 57 females (85%) and 10 males (15%). With respect to surgical timeline, 23 (34.3%) patients underwent VBT surgery prior to 2019 and 44 (65.7%) patients underwent surgery in 2019 and 2020. Demographically, these two cohorts of patients were similar with respect to age, gender, Risser score and Sander skeletal maturity score. The two cohorts were also similar in terms of number of patients with major thoracic curves or major thoracolumbar/ lumbar curves, preoperative major Cobb angle, preoperative SRS-22R score and number of instrumented levels (Table [1](#page-4-0)).

Comparing results from cases performed before 2019 to cases performed in 2019/2020, we found that EBL, operative time, anesthesia time and length of stay signifcantly decreased (Table [2](#page-4-1)). There was no signifcant change in the percent correction of the major Cobb angle at frst

The preferred screw tract is in the middle 1/3 of the vertebral body away from the rib head and spinal canal

erect imaging (46% vs  $44\%$ ;  $p = 0.95$ ) as well as the mean postoperative Numeric Pain Intensity Scale (NPIS) score or 3-month SRS-22R score before or after 2019 (Table [2](#page-4-1)).

Next, we evaluated change in perioperative parameters over time. We found that over the 5-year study period, EBL (total EBL and % estimated blood volume), operative time, anesthesia time and length of stay signifcantly decreased (52 ml reduction per year,  $p = 0.0007$ ; 1.3% reduction per year, *p* = 0.0072; 0.6 h reduction per year, *p* < 0.0001; 0.69 h reduction per year,  $p < 0.0001$ ; 0.25 days reduction per year,  $p = 0.0007$ , respectively) (Fig. [3](#page-5-0)). Interestingly, even after the 5-year study period, our group continued to show improvements without plateauing. There was no signifcant change in the percent correction of the major Cobb angle at frst erect imaging (improvement in correction by 1.06%;  $p = 0.46$ ). On assessing the postoperative NPIS score and the 3-month SRS-22R scores, we found no signifcant improvement in the scores from 2015 to 2020 (NPIS score reduction by 0.41 per year;  $p = 0.16$ , 3-month SRS-22R score improvement by 0.02 per year;  $p = 0.66$ ).

 $(L)$ 

#### <span id="page-4-0"></span>**Table 1** Demographics of patient cohort before and after 2019



(SD 0.35)

<span id="page-4-1"></span>**Table 2** Learning curve parameters of patient cohort before and after 2019

(SD 0.36)



Comparing our most recent 20 VBT patients to the frst 20 VBT patients, we found signifcant reductions in EBL (total EBL and % estimated blood volume), operative time, anesthesia time and LOS (116 ml vs 282 ml,  $p = 0.0005$ ; 8.5% vs 3.6%; *p*=0.0024, 3.3 h vs 4.8 h; *p*<0.0001, 5.7 h vs 7.4 h; *p*=0.0001 and 3.2 days vs 3.7 days; *p*=0.019). However, there was no signifcant change in the mean postoperative NPIS score, 3-month SRS-22R score and percent correction of major Cobb at 3 months (Table [3](#page-5-1)).

No signifcant intraoperative neuromonitoring changes were noted in any patient, and no patient had a neurologic deficit post-operatively. No patients required blood transfusion. Among the 90-day complications recorded, 1 patient developed pleural efusion within 30 days of surgery, which resolved with pig-tail catheter placement. This patient underwent VBT in 2016 and was among our frst 20 patients. Thus, there were no 90-day complications after 2019 or in our last 20 patients. No other 90-day adverse events were noted in this study.

#### **Discussion**

The learning curve of a procedure is governed by the number of cases required for a surgeon to independently perform a procedure with a predictable outcome. It is also a tool for trainers and instructors in identifying focus areas to direct educational resources and to improve perfor-mance [[13](#page-8-3)]. Literature suggests that there is a learning curve for spinal surgeries. Minimally invasive spine surgery (MIS) has been gaining popularity in recent times since, as compared to the conventional open spine surgery techniques, it preserves the natural anatomy and may be associated with fewer postoperative complications. However, a review by Sharif et al. has shown that MIS also requires a longer learning curve [\[13\]](#page-8-3), with surgical experience was inversely related to operative time and length of hospital stay. They conclude that inexperienced surgeons would beneft from an organized training program which

(SD 0.36)



<span id="page-5-0"></span>**Fig. 3** Over the 5-year period of the study, estimated blood loss, operative time, anesthesia time, and length of stay decreased as surgeons and team members became more experienced with the procedure

<span id="page-5-1"></span>**Table 3** Learning curve parameters of 1st 20 versus last 20 patients



may include cadaveric training, proctoring, and guided practice by an experienced surgeon. Other elements may impact the learning curve, such as knowledge of appropriate instrumentation, presence of a skilled radiographer, and use of a trained surgical team [[13](#page-8-3)].

Video-assisted thoracoscopic surgery (VATS) for anterior disc release has been widely accepted for the treatment of severe and/or rigid pediatric spinal deformities that cannot be corrected with posterior surgery alone. Newton et al. demonstrated that VATS is a safe and efective technique for performing anterior thoracic release and fusion in pediatric patients with spinal deformities. The learning curve for this technique is substantial and required the surgeon to invest a signifcant amount of time during the training period. In their series, the average operative time for the procedure and the average operative time per disc decreased as the series progressed. No change in the average blood loss was found while complications were uniformly distributed throughout the series [\[12](#page-8-1)].

The vertebral body tether device has received humanitarian device exemption (HDE) (Zimmer Biomet The Tether™—Vertebral Body Tethering System H190005) approval for AIS from the US FDA in August 2019. Since FDA approval, this technique has been gaining popularity in the surgical management of progressive idiopathic thoracic, thoracolumbar and lumbar scoliosis in growing children as it corrects the scoliosis curve while preserving spinal mobility and growth potential and also avoids adjacent segment degeneration and arthritis. Early studies on 1- to 4-year postoperative results have reported VBT to be an efective and safe spinal growth modulation technique with optimistic functional results and signifcant patient satisfaction [\[6](#page-7-4), [7,](#page-7-3) [14](#page-8-4), [15](#page-8-5)].

Nonetheless, VBT is a technically demanding procedure with surgical challenges including determining the number of vertebrae to be included in the construct, safe exposure of the vertebral body for anterior screw placement, optimal screw size and trajectory, extent of tension to be applied across the tether segment and a transdiaphragmatic approach in the case of a lumbar tether  $[15]$  $[15]$ . Reported complications include screw breakage or pullout, undercorrection of the deformity, and curve progression. Complications from the approach include atelectasis, chylothorax, pneumothorax, hemothorax, pleural effusion, chest wall/shoulder/hip pain, superficial wound infection, dural leak, injury to spinal cord, viscera, vasculature and lumbosacral plexus [[6,](#page-7-4) [7](#page-7-3), [14](#page-8-4)[–17](#page-8-6)]. Currently, our center has unique experience using CT-guided navigation for vertebral body screw placement. Our center had previously conducted a study on CT-guided navigation for pedicle screw placement which found reduced pedicle screw malposition and reduced return to OR for a malpositioned screws with the use of navigation [[18\]](#page-8-7). As VBT surgery was added to our practice, we integrated CT-guided navigation for screw placement, following the experience with placement of navigated pedicle screws. The low-dose intraoperative imaging provides confirmation of levels, axial measurement of vertebral body width, and information regarding starting point and trajectory for the screw. Use of a spinous process clamp generates an extra incision, but does provide patient- and position-specifc axial information to guide screw placement. CT-guided navigation in VBT provides additional axial data to guide screw placement, thus reducing risk of screw malposition and avoids injury to major thoracic structures and vessels during screw placement.

Previous reports evaluating VBT learning curve have focused on an open or mini-open approach without navigation. Our series refects navigated VBT performed exclusively through a thoracoscopic approach and MIS retroperitoneal approach for L2, L3, L4. Baroncini et al. reported on their VBT learning curve by retrospectively analyzing 90 patients who underwent surgery at a single center in Ger-many [[19\]](#page-8-8). This study differed from ours in various ways. The surgical technique adopted by Baroncini et al. included one or two 6 cm intercostal incisions and placement of bicortical vertebral body screws following anatomic landmarks and fuoroscopic guidance. Disc releases were performed in thoracic tethers when adequate correction was not achieved. The surgeons also included double tethers in the study. 6 patients developed complications within 6 weeks of surgery, of whom 5 had double tether procedures. Complications included 3 pleural effusions, 1 pulmonary embolism, 1 suspected chest infection and 1 persistent atelectasis [[19\]](#page-8-8). This current study included thoracoscopic portal incisions which were 2 cm. All vertebral body screws were placed under CT-guided navigation. We also do not perform disc release as there is no current evidence or long-term studies on the outcome of this procedure on disc health. We also did not include double tethers as this would affect patient consistency. Among our 90-day complications we had 1 case of pleural effusion within 90 days of surgery which resolved with thoracentesis. The learning curve for thoracoscopic anterior fusion instrumentation has also been described over the course of 57 procedures, which resulted in the operative time decreasing from 6.2 to 5.3 h [\[20\]](#page-8-9). In our series, the operative time decreased from 4.8 to 3.3 h, and in the Baroncini et al. publication operative time decreased from 6.5 to 2.7 h, with shorter overall times than anterior fusion procedures likely because discectomies are not required for VBT [\[19](#page-8-8)].

Our study analyzed important VBT surgical indicators (EBL, operative time, anesthesia time, hospital stay, % correction of major curve at 3 months and 90-day complications) which refect the learning curve for this procedure. Several factors contribute to a decrease in operative time. These include improvement in surgical skill of the surgeons and familiarity with the procedure as well as improvement in the skill of the surgical team which includes the approach surgeon, anesthesiologist, surgical assistants and operative room team.

On assessment of percent major Cobb correction at frst erect, we did not fnd a signifcant change over the study period or among our cohorts. This may be due to the fact that most of correction is obtained from patient positioning on the table and governed by preoperative curve fexibility [[21\]](#page-8-10). There were also no signifcant changes noted in the immediate postoperative NPIS pain score or 3-month SRS-22R scores over the course of the study. With respect to 90-day complications, 1 patient developed pleural efusion within 30 days of surgery. This occurred following a weekend trip during which the patient was quite active. Patient developed sudden onset shortness of breath and a CT angiogram revealed a pleural efusion. The efusion resolved with pig-tail catheter placement. Patient has now returned to all activities and has remained symptom-free.

Limitations of this study include the retrospective nature of the study and a small sample size. Further long-term prospective follow-up studies with at least 2 years postoperative follow-up and larger study cohort will be used to assess curve correction over time and establish fnal outcomes of this navigated VBT technique. Also, it should be noted that our center has extensive experience with the use of CT-guided navigation for pediatric and adult posterior spinal procedures, with an in-house team of 4 technicians

who run the navigation equipment for multiple operating rooms per day. Thus, our described learning curve would best apply to teams already experienced in the use of intraoperative navigation. Further, we do not have a comparison group of patients treated with fuoroscopic or freehand thoracoscopic screw placement. Although we believe that intraoperative axial imaging allows for superior placement and length selection of vertebral body screws, additional research should be undertaken on this topic to study potential benefts from a navigated technique. In contrast to fuoroscopy, intraoperative navigation spares the surgical team from occupational exposure to radiation. An intraoperative low-dose CT scan results in approximately 0.65 mSv of radiation exposure to the patient, which is on the order of 85 s of fuoroscopy so may be similar to a fuoroscopic technique depending on the surgeon's fuoroscopy time for the procedure [\[22](#page-8-11), [23](#page-8-12)].

In summary, our series of skeletally immature pediatric patients with idiopathic scoliosis has demonstrated that VBT is a surgical option in patients with signifcant progressive yet fexible scoliosis. The study noted improvements for VBT surgery over time including decreased operative time, anesthesia time, blood loss and length of hospital stay over a 5-year period. Furthermore, of the 67 patients analyzed, only 1 patient had a major complication within 90 days of surgery. This study thus outlines a signifcant learning curve for surgeons who wishes to adopt VBT surgery in their practice. Improved surgeon and surgical team training programs and newer instrumentation may reduce the impact of this learning curve.

# **Key points**

- Vertebral body tethering procedures performed using CTguided navigation over a 5-year period had signifcant decrease in estimated blood loss, anesthesia time, operative time, and length of stay.
- Decrease in estimated blood loss, anesthesia time, operative time, and length of stay were noted on comparing our frst 20 patients to our last 20 patients.
- Decrease in estimated blood loss, anesthesia time, operative time, and length of stay were also noted on comparing surgeries performed before 2019 to those performed in 2019 or after.
- One patient early in the series had readmission due to recurrent pleural effusion.

data: SM, TAM, DDP, ANL; Drafting the work or critically revising it for important intellectual content: SM, TAM, DDP, ANL; Final Approval of the version to be published: SM, TAM, DDP, ANL; Responsible for content and accuracy of the entire manuscript: SM, TAM, DDP, ANL; The order and inclusion should be decided by consensus among the authors and acknowledged in writing: SM, TAM, DDP, ANL.

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# **Declarations**

**Conflict of interest** Outside of the study, Dr. Milbrandt reports consulting activities with Orthopediatrics, Medtronic, Zimmer and stock ownership in Viking Scientifc. Dr. Larson reports consulting activities with Orthopediatrics, Medtronic, Zimmer, and Globus. Dr. Potter reports consulting activities with Medtronic.

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**Author contributions** Substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of

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