The use of halo-femoral traction without anterior spinal release for treating severe adolescent idiopathic scoliosis

Abdulmonem Alsiddiky

Department of Orthopedic, College of Medicine, King Saud University, Riyadh, Saudi Arabia

Correspondence to Abdulmonem Alsiddiky, MD, Department of Orthopedic, College of Medicine, King Saud University, PO Box 55264, Riyadh 11534, Saudi Arabia.
e-mails: alsiddiky@gmail.com, alsiddiky@hotmail.com

Received: 5 May 2017
Revised: 28 May 2017
Accepted: 12 June 2017
Published: 22 June 2021

The Egyptian Orthopaedic Journal 2019, 54:325–329

Background
Treatment of severe and rigid idiopathic scoliosis is challenging because of severity of the deformity. With the introduction of several correction techniques, decision making became more complex.
Patients and methods
In this study, a trial was conducted comparing halo-femoral traction under anesthesia without anterior spinal release with the traditional technique involving anterior release. A single-center, open-label, two-group prospective randomized controlled trial was implemented. A total of eight patients was recruited in each group and allocated using a simple randomization method.
Results
Recent follow-up after surgery radiogram showed that the average primary curve Cobb's angle was 53° (51.2%) in group 1 and 48.6° (54.2%) in group 2. The average shoulder and pelvic balance in group 1 was 0.3° (range, 0–2) and 0°, respectively, and in group 2 was 0.3° (range, 0–2) and 0°, respectively. Postoperative thoracic kyphosis was 38.6° (range, 18–51°) in group 1 (45.3%) and 39° (range, 23–47°) in group 2 (36%). Postoperative lumbar lordosis was 44.2° (range, 30–53°) in group 1 (12.4%) and 49.8° (range, 40–58°) in group 2 (25.6%). Statistical analysis showed that there was no significant difference between correction of primary curve Cobb's angle, postoperative thoracic kyphosis, and postoperative lumber lordosis in both groups. This indicates that patients in both groups had almost the same outcomes, and there is no difference between both surgical techniques in terms of clinical results. Patients undergoing the new technique could overcome several complication and comorbidities that may result from excessive blood loss.
Conclusion
The use of halo-femoral traction without anterior spinal release for treating severe adolescent idiopathic scoliosis is an effective, safe, and efficient procedure with low comorbidity.

Keywords:
adolescent idiopathic scoliosis, halo-femoral traction, rigid scoliosis, severe scoliosis

Egypt Orthop J 54:325–329

1110-1148

Introduction

Known to be the most common form of scoliosis, adolescent idiopathic scoliosis (AIS) is a three-dimensional structural deformity of spine and trunk [1–3]. The disease is conventionally measured using the Cobb's angle technique, after which patients are diagnosed according to the severity of measured Cobb's angle. The treatment of severe and rigid idiopathic scoliosis is challenging because of severity of the deformity, as AIS is associated with a significant disturbance of body morphology, reduced thoracic volume, impaired spinal mobility and respiration, decreased trunk balance, increased rates of back pain, and serious aesthetic concerns, activity limitations, and decreased quality of life [3–5]. Furthermore, severe scoliosis is accompanied by a significant kyphotic component. Thus, correction of severe kyphoscoliosis is a great challenge for spine surgeon.

Although the introduction of sophisticated systems of malleable rods and pedicle screws aided scoliosis correction in three dimensions, decision making became more complex. Various correction methods have been developed, such as combined anterior and posterior surgical procedures with a period of halo traction after anterior release and combined anterior and posterior instrumentation [2]. The surgery aims to halt the progress of the disabling deformity, to reduce the size of the curve and to restore trunk balance while improving the patient's quality of life [6].

Commonly used technique is anterior spinal release through thoracotomy followed in the same day by

halo-femoral traction which gives traction force over spine and causes gradual correction and facilitates the second stage. A second surgery involves posterior spinal fusion and instrumentation of spine. Anterior release combined with posterior correction in one stage or two stages can achieve a correction rate of 40–50% in patients with severe scoliosis [1–4].

The efficacy of a preceding anterior release in AIS in terms of leading to a better curve correction as compared with a single posterior approach has not been proven, and therefore, the indication for the combined approach is still controversial. Anterior release in patients with severe scoliosis is not ideal, as these patients often experience cardiopulmonary limitations and significant pulmonary function compromise [1]. Moreover, patients with severe and rigid scoliosis usually have short stature, low body weight, and low tolerance for surgery. It is important to determine the safest and most effective method to treat this population. Therefore, it was always emphasized on correcting severe and rigid curves without encountering any of these complications.

As mentioned earlier, several studies have examined correction method for severe scoliosis, of which they have diagnosed as a measured Cobb's angle greater than 100° on average [1–5]. For this study, as per literature review, severe scoliosis was diagnosed as Cobb's angle over 90°. In this study, a trial was conducted comparing halo-femoral traction under anesthesia without anterior spinal release with the traditional technique involving anterior release, thus avoiding possible morbidity accompanied and reported using anterior release combined with posterior correction technique which is caused by anterior spinal release.

Patients and methods

A single-center, open-label, two-group prospective randomized controlled trial was implemented. The study was approved by the institutional ethics committee in the Orthopedic Department of Orthopaedic Surgery, king saud university, Saudia Arabia. The trial inclusion criteria were all adolescent patients diagnosed with severe idiopathic scoliosis more than 90°. The primary objective was to compare two surgical technique outcomes through validating the noninferiority of single-stage posterior approach surgery without any anterior approach in relation with anterior release followed by posterior approach. Primary curve Cobb's angle correction percentage was the trial primary outcome which was designed to detect a mean difference of 10°. A total of eight patients was recruited in each group to detect this mean difference with 5% significance level and 80% power. Subsequently, patients were allocated to the trial in two different groups using a simple randomization method. Group 1 procedure was a single-stage posterior approach surgery without any anterior approach (two stages; two operations). Then again, group 2 procedure was anterior release followed by posterior approach (two stages; three operations). Same traction technique was applied on patients in both groups after stage one. Demographic data (age and sex) were recorded at the baseline for each group. Primary and secondary outcomes were measured at baseline (preoperative), after applied traction, postoperatively, and 6, 12, 24, and 48 months from randomization by a trail reviewer at the same center. Only one surgeon was assigned for patients in both groups and all radiographic measurements were recorded by a blinded reviewer, thus minimizing potential bias. Secondary outcomes were kyphosis correction, lordosis correction, hospital stay, operation time, and blood loss. Baseline analysis was carried out to determine how different values of independent variables may affect the study outcomes. Moreover, this step will signify the effect of the used randomization method. The study primary objective was based on the intent-to-treat population where all randomized patients were included with last observation carried forward in case of missing data based on the assumption that data are missing completely at random. χ^2 test was used for categorical variables, whereas continuous variables associations were examined using t test. Independent t test was used to analyze the mean difference between the two trial arms. SPSS software, version 23 (SPSS Inc., Chicago, Illinois, USA) was used for data entry and analysis. All analyses were carried out at a 5% two-sided significance level, and results were reported as odds ratio with its 95% confidence intervals. In case of loss to follow-up, sensitivity analysis was performed to assess the effect on the final outcomes.

Results

The study included 12 females and four male adolescents who were randomized between the two arms of the trial. The average follow-up was 35 months for group 1 and 45 months for group 2, ranging from a minimum of 24 months to a maximum of 66 months. Table 1 illustrates the patients' demographic data in each group. At the time of surgery, the average primary curve Cobb's angle in groups 1 and 2 was 108.7° (range, 95–143°) and 105.1° (range, 92–119°), respectively. Preoperative bending radiogram in groups 1 and 2

Table 1 Patient data

Characteristic	Group 1 (*N*=8)	Group 2 (*N*=8)
Male [*n* (%)]	2 (25)	2 (25)
Female [*n* (%)]	6 (75)	6 (75)
Mean (SD) age at time of surgery	15.9 (2.8)	17.2 (4.9)

revealed an average flexibility of 93° (14.4%) and 82.5° (21.5%), respectively. Preoperative thoracic kyphosis in groups 1 and 2 was 70.6° (range, 45–113°) and 61.8° (range, 15–80°), respectively. Preoperative lumbar lordosis in groups 1 and 2 was 50.5° (range, 32–72°) and 67° (range, 57–85°), respectively. The average preoperative coronal balance and sagittal balance in group 1 were 2.8 cm (range, 0.6–6.8 cm) and 2.6 cm (range, 0.2–10.4 cm), respectively, and in group 2 were 1.4 cm (range, 0.1–2.1 cm) and 2.4 cm (range, 0–7.2 cm), respectively. Average hospital stay for group 1 was 13.2 days compared with 15.1 days for group 2. The first operation time average was 28.7 min for group 1 and 125 min for group 2. Postoperative thoracic kyphosis was 38.6° (range, 18–51°) in group 1 (45.3%) and 39° (range, 23–47°) in group 2 (36%). Postoperative lumbar lordosis was 44.2° (range, 30–53°) in group 1 (12.4%) and 49.8° (range, 40–58°) in group 2 (25.6%). Recent follow-up after surgery radiogram showed average primary curve Cobb's angle was 53° (51.2%) in group 1 and 48.6° (54.2%) in group 2 (Table 2). The average shoulder balance and pelvic balance in group 1 were 0.3° (range, 0–2) and 0°, respectively, and in group 2 were 0.3° (range, 0–2) and 0°, respectively. Baseline demographic data and measured variables in both groups were tested for any significant difference. From baseline analysis, both groups showed no significant difference associated with sex, age, preoperative primary curve Cobb's angle, preoperative kyphosis, and preoperative lordosis angle (Table 3). Statistical analysis between groups 1 and 2 revealed no significant difference in correction of primary curve Cobb's angle ($P>0.05$, independent t test). Mean difference between groups 1 and 2 in thoracic kyphosis was 8.8°, which was measured using independent t test to be not significant ($P>0.05$). Likewise, lumbar lordosis mean difference of 16.5° between groups 1 and 2 did not show any statistical significance ($P>0.05$). During the first operation, group 1 did not record any blood loss owing to the nature of the procedure discussed earlier compared with average blood loss of 145 ml (range, 80–200 ml) in group 2 (Table 2). The operation time mean difference was statically significant between groups 1 and 2 ($P<0.0001$, independent t test). As expected, a statistically significant difference was measured for the amount of blood loss between groups 1 and 2 ($P<0.0001$, independent t test). The immediate postoperative primary curve Cobb's angle was 50.8 (17.3) in group 1 and 52.5 (6.3) in group 2. There was no neurologic deterioration or mortality after surgery. There were no cases of postoperative wound infection, screw loosening, or implant failure. In both groups, none of patients required postoperative ICU care or ventilator support. Although pulmonary complications are the most commonly encountered, especially in group 2 procedure, no complications were recorded for both groups.

Table 2 Postoperative angle measurements

Outcomes	Results	Group 1 (*N*=8) [*n* (%)]	Group 2 (*N*=8) [*n* (%)]
Immediate postoperative	Primary curve Cobb's angle correction percentage	50.8 (17.3)	52.5 (6.3)
	Secondary curve Cobb's angle correction percentage	56.2 (25.9)	64.6 (14.0)
	Kyphosis angle correction percentage	42.2 (12.6)	26.5 (25.1)
	Lordosis angle correction percentage	11.3 (16.1)	22.9 (13.9)
Final follow-up	Primary curve Cobb's angle correction percentage	51.2 (11.3)	53.5 (5.3)
	Secondary curve Cobb's angle correction percentage	59.3 (21.9)	65.7 (16.0)
	Kyphosis angle correction percentage	43.3 (15.6)	28.6 (34.1)
	Lordosis angle correction percentage	10.2 (14.1)	24.6 (11.9)
	Days of hospital stay	13.2 (0.9)	15.1 (1.1)
	Operation 1 time (min)	28.7	124.6
	Operation 2 time (h)	3.6	3.9

Table 3 Mean angle measurements

Achievement	Mean difference	Significance *P* value (2-tailed)
Primary curve Cobb's angle correction percentage	2.3	0.604
Secondary curve Cobb's angle correction percentage	6.5	0.574
Kyphosis angle correction percentage	14.7	0.285
Lordosis angle correction percentage	14.4	0.065

Discussion

Severe and rigid idiopathic scoliosis is known to be a spinal deformity affecting the thoracic cage; disturb skeletal, muscular, and diaphragmatic function; and reduce respiratory system compliance [5]. In a previous

retrospective study, it was determined that patients with AIS did not exhibit clinically significant respiratory symptoms until their curves were 60–100°, so they defined severe scoliosis as Cobb's angle larger than 60° [5]. However, other studies have defined AIS as Cobb's angle more than or equal to 80° [2–7]. Consequently, there were conflicting data regarding the correct identification of severe and rigid curves [7]. In this study, severe scoliotic patients have been diagnosed as having a Cobb's angle more than or equal to 90°.Several correction methods have been developed to treat severe and rigid scoliosis. These methods involve diverse surgical techniques such as anterior release with halo traction followed by posterior correction with instrumentation. Other techniques range from single-stage posterior circumferential vertebral column resection (PVCR) to anterior release combined with posterior correction in one stage or two stages [8–11]. Literature review has revealed numerous studies that published clinical comparisons between these different surgical techniques. Of which, their main goals were reducing morbidity rates, surgical time, and blood loss through developing and comparing different techniques. Retrospective studies have reported a correction percentage achieved by PVCR for severe and rigid scoliosis to be between 51 and 59% [1–4]. However, they discovered that intraoperative massive bleeding and operative trauma might result in deterioration of neurological or cardiopulmonary function. Thus, one-stage PVCR may not be an ideal choice for patients with severe and rigid scoliosis [5]. Furthermore, anterior release combined with posterior correction in one stage or two stages can achieve a correction rate of 40–50% in patients with severe scoliosis [12]. Yet, patients with severe scoliosis undergoing operations that involve anterior spinal release often experience cardiopulmonary limitations and significant pulmonary function compromise.

A different approach was used to examine these techniques through this prospective study. A single-surgeon, single-center randomized controlled trial was conducted comparing halo-femoral traction under anesthesia without anterior spinal release with the traditional technique involving anterior release. Patients were allocated randomly to one of the study arms; procedures were controlled to ensure that all patients in study groups were treated the same, and 2-year follow-up data were analyzed. After explicit statistical analysis, baseline data showed no significant difference between both study groups. Thus, potential confounding factors were of no effect on the statistical inference. Being able to eliminate confounding bias is considered as one of the main advantages and strong points of this study. Further statistical analysis proved that there was no significant difference between correction of primary curve Cobb's angle, postoperative thoracic kyphosis, and postoperative lumber lordosis in both groups. This indicates that patients in both groups had almost the same outcomes, and there is no difference between both surgical techniques in terms of clinical results. Thus, bearing in mind the rigid study design, a confident decision could be taken regarding whether discarding anterior spinal release in adolescent patients with severe and rigid scoliosis might affect the outcome or not. Furthermore, operation time mean difference was statistically significant between both groups, in which operation time for group 2 was much shorter than for group 1. This finding was expected, relying on the fact that no anterior spinal release was done for the patients of group 2. In this manner, it was considered a success, as one of the study's target goal in introducing and applying the new technique is to reduce the overall operation time burden on scoliotic patients. Moreover, a statistically significant mean difference was measured for amount of blood loss between groups 1 and 2, in which blood loss in group 2 patients was much less than group 1 patients. As a result, patients undergoing the new technique were able to overcome several complication and comorbidities that may result from excessive blood loss. These previous advantages that were acquired by the intervention group can support the domination of the technique where halo-femoral traction is applied under anesthesia without anterior spinal release followed by posterior release at another scheduled operation time. According to the statistical analysis, noninferiority assumption of the new applied technique was proved. In that way, patients in both groups had almost the same clinical outcomes. Moreover, by applying halo-femoral traction without anterior spinal release, the surgeon will be able to decrease or almost eliminate the risk of certain reported comorbidities and complications. As a result, this new technique could serve as an effective and efficient surgical protocol to be chosen when dealing with severe and rigid scoliotic patients. Other centers are encouraged to apply this protocol in cases of severe and rigid scoliosis.

Randomized controlled trails are most known for their rigorous way of determining whether a cause-effect relation exists between treatment and outcome. Accordingly, an assertive conclusion, to be relied on, could be established based on the powerful study design results shown earlier. However, caution should be

practiced with the generalization of the study results, as the sample size is one of the study limitations. One of the study recommendations is further investigation, perhaps with a larger sample size, on comparing halo-femoral traction with anterior spinal release in severe scoliotic patients with other surgical techniques.

Conclusion

The use of halo-femoral traction without anterior spinal release for treating severe AIS is an effective, safe, and efficient procedure with low comorbidity and favorable outcomes.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Suk SI, Kim JH, Cho KJ, Kim SS, Lee JJ, Han YT. Is anterior release necessary in severe scoliosis treated by posterior segmental pedicle screw fixation?. Eur Spine J 2007; 16:1359–1365.

2 Bullmann V, Halm HFH, Schulte T, Lerner T, Weber TP, Liljenqvist UR. Combined anterior and posterior instrumentation in severe and rigid idiopathic scoliosis. Eur Spine J 2006; 15:440–448.

3 Qiu Y, Liu Z, Zhu F, Wang B, Yu Y, Zhu Z, *et al.* Comparison of effectiveness of Halo-femoral traction after anterior spinal release in severe idiopathic and congenital scoliosis: a retrospective study. J Orthop Surg Res 2007; 2:23.

4 Zhou C, Liu L, Song Y, Liu H, Li T, Gong Q, *et al.* Anterior release internal distraction and posterior spinal fusion for severe and rigid scoliosis. 2013; Spine 38:E1411–E1417.

5 Hu HM, Hui H, Zhang HP, Huang DG, Liu ZK, Zhao YT, *et al.* The impact of posterior temporary internal distraction on stepwise corrective surgery for extremely severe and rigid scoliosis greater than 130. Eur Spine J 2016; 25:557–568.

6 Koller H, Zenner J, Gajic V, Meier O, Ferraris L, Hitzl W. The impact of halo-gravity traction on curve rigidity and pulmonary function in the treatment of severe and rigid scoliosis and kyphoscoliosis: a clinical study and narrative. review of the literature. Eur Spine J 2012; 21:514–529.

7 Koptan W, ElMiligui Y. Three-staged correction of severe rigid idiopathic scoliosis using limited halo-gravity traction. Eur Spine J 2012; 21:1091–1098.

8 Li M, Ni J, Li Y, Fang X, Gu S, Zhang Z, Zhu X. Single-staged anterior and posterior spinal fusion: a safe and effective alternative for severe and rigid adolescent idiopathic scoliosis in China. J Pediatr Child Health 2009; 45:246–253.

9 Sturm PF, Anadio JM, Dede O. Recent advances in the management of early onset scoliosis. Orthop Clin N Am 2014; 45:501–514.

10 Suk SI, Chung ER, Kim JH, Kim SS, Lee JS, Choi WK. Posterior vertebral column resection for severe rigid scoliosis. Spine 2005; 30:1682–1687.

11 Suh SW, Modi HN, Yang JH, Song HR, Jang KM. Posterior multilevel vertebral osteotomy for correction of severe and rigid neuromuscular scoliosis: a preliminary study. Spine 2009; 34:1315–1320.

12 Ren C, Liu L, Song Y, Zhou C, Liu H, Li T. Comparison of anterior and posterior vertebral column resection versus anterior release with posterior internal distraction for severe and rigid scoliosis. Eur Spine J 2014; 23:1237–1243.