Are Outcomes Improving for AIS Following FDA HDE Approval?

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INTRODUCTION: The US FDA first approved VBT for AIS in August 2019. Published data thus far is from cohorts treated prior to approval 9/2019 with off label products (first generation data(1G)). We sought to evaluate second generation outcomes (2G) from 3 experienced centers using a consecutive series of AIS patients, within FDA indications, treated with VBT for AIS. We hypothesized that 2G results would be superior to 1G due to the use of an on-label device and instrumentation and experience at these centers.

METHODS: Multicenter retrospective review of perioperative and postoperative outcomes following VBT. Patient series were consecutive and from 3 experienced centers. Inclusion criteria were curves between 35-65 degrees, skeletally immature patients and minimum follow up (fu) of two years.

RESULTS:

A total of 98 subjects with 108 treated curves were included. Primary mean initial Cobb 52 (39-65) with mean fu 28 months (21-43). There were 98 thoracic, 11 thoracolumbar and 11 double curves (table 1). For the total group, mean coronal Cobb angles for the first post op visit, one and two year time points were 27 (10-46), 21 (0-41) and 23(-6-49) respectively. 17 patients with >3 year fu had a mean Cobb of 28 (5-40). At most recent fu 91% of curves were less than 35%. For doubles all curves were successful. First erect curve magnitude was associated with successful treatment $p<.01$. There were 2 fusions (2%), 4 reoperations after full or overcorrection, 4 reoperations for cord rupture and one aspiration for effusion for a reintervention rate of 11%. Suspected tether rupture rate 27%. There were no neurologic injuries or infections.

DISCUSSION AND CONCLUSION: For this series of 98 AIS patients treated with an FDA approved VBT device, 2-4 year post operative outcomes were improved compared to first generation studies with only a 2% fusion rate and with 91% of curves less than 35 degrees. Complications Occurred in 11% of patients which included 4 reoperations for full or overcorrection. Complication rate for other issues was 6% including 2 fusions. Initial correction on first erect radiograph appears to be a predictor for success. Second generation data shows promising improvements in outcomes and decreasing rate of complications/reoperations compared to the original first- generation cohorts. This is one of the first VBT studies to present 2-4 year second generation results with a cohort of patients that were all within FDA indications..