

Does Serial Casting Under General Anesthesia for Infantile Idiopathic Scoliosis Affect Childhood Behavior? A Prospective Investigation in Response to the New FDA Warning

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Background

- **Hundreds of infants are diagnosed annually with IIS; serial casting treatment has gained popularity due to reproducible success [1-9]**
- **2016 FDA warning: Gen anesthesia/sedation in pts < 3 yo for >3 hrs or repeated use may affect brain development [10]**
 - Clinical studies have been difficult to interpret and are ongoing but have suggested negative cognitive effects associated with repeated anesthesia exposure in patients <3 yo [11-18]
 - Multiple basic science and animal studies have linked anesthetic drugs to neurotoxicity and cognitive deficits in the developing brain [19-23]
- **Effects of serial casting under general anesthesia on these pediatric patients' behavior and cognitive psychology development is unknown**



Behavioral Assessment System for Children Second Edition: BASC-2

- Parent Rating Scale (PRS) for Preschool Age (2-5 yo) Children: “Comprehensive measure of child’s adaptive and problem behaviors in community and home settings”
- 134 questions, 4-choice response format, 10-20 minutes, written at 4th grade reading level
- Validated and normalized to large representative samples; output is Raw Scores, T-scores, & Percentiles
- T-scores have scale of 0-100, with mean of 50 and standard deviation of 10, normalized to population



BASC-2 PRS Subscales

Scale	Definition
Activities of Daily Living	Skills associated with performing basic, everyday tasks in an acceptable and safe manner
Adaptability	Ability to adapt readily to changes in the environment
Aggression	Tendency to act in a hostile manner (either verbal or physical) that is threatening to others
Anxiety	Tendency to be nervous fearful, or worried about real or imaginary problems
Attention Problems	Tendency to be easily distracted and unable to concentrate more than momentarily
Atypicality	Tendency to behave in ways that are considered “odd” or commonly associated with psychosis
Depression	Feelings of unhappiness, sadness, and stress that may result in an inability to carry out everyday activities or may bring on thoughts of suicide

Scale	Definition
Functional Communication	Ability to express ideas and communicate in a way others can easily understand
Hyperactivity	Tendency to be overly active, rush through work or activities, and act without thinking
Leadership	Skills associated with accomplishing academic, social, or community goals, including the ability to work with others
Social Skills	Skills necessary for interacting successfully with peers and adults in home, school, and community settings
Somatization	Tendency to be overly sensitive to and complain about relatively minor physical problems and discomforts
Withdrawal	Tendency to avoid others to avoid social contact

Example of Aggression Questions

Annoys others on purpose.

Argues when denied own way.

Argues with parents.

Breaks other children's things.

Bullies others.

Calls other children (adolescents) names.

Defies or teachers (or caregivers).

Disrupts the play of other children.

Hits other children (adolescents).

Is cruel to others.

Loses temper too easily.

Seeks revenge on others.

Teases others.

Threatens to hurt others.

- **Answer each question:**

- **Never "N"**

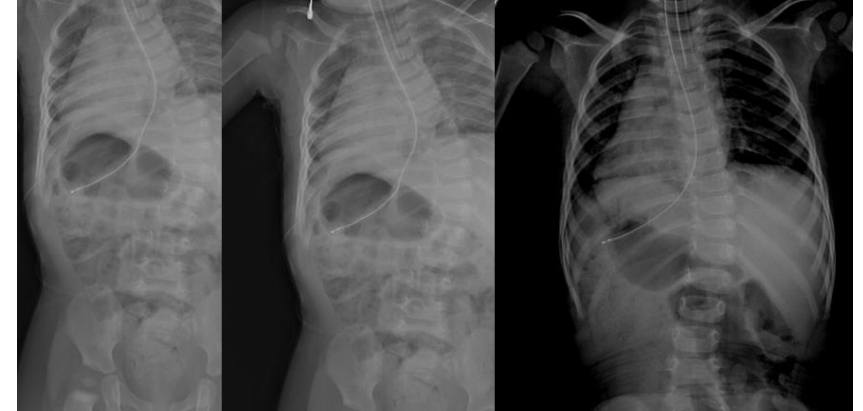
- **Sometimes "S"**

- **Often "O"**

- **Almost Always "A"**

Project Methods

- Prospective Comparative Study; Level of Evidence II
- Multi-center (CSSG sponsored); First patient enrolled 10/31/2013
- Pts undergoing serial casting completed validated Behavior Assessment for Children (BASC-2) at pre-casting visit, 1-year post-initiation of casting, and 2-years post-initiation of casting
- Statistical analysis included related-samples Wilcoxon signed rank test with Bonferroni correction (significance at $p < 0.017$).
- BASC-2 sub-scales with $n < 8$ or that have had their validity challenged in this age group due to questions related to communication/language skills were excluded
- ***Hypothesis:*** Serial casting under general anesthesia will negatively affect behavioral development of Infantile Idiopathic Scoliosis (IIS) scoliosis patients



Preliminary Results

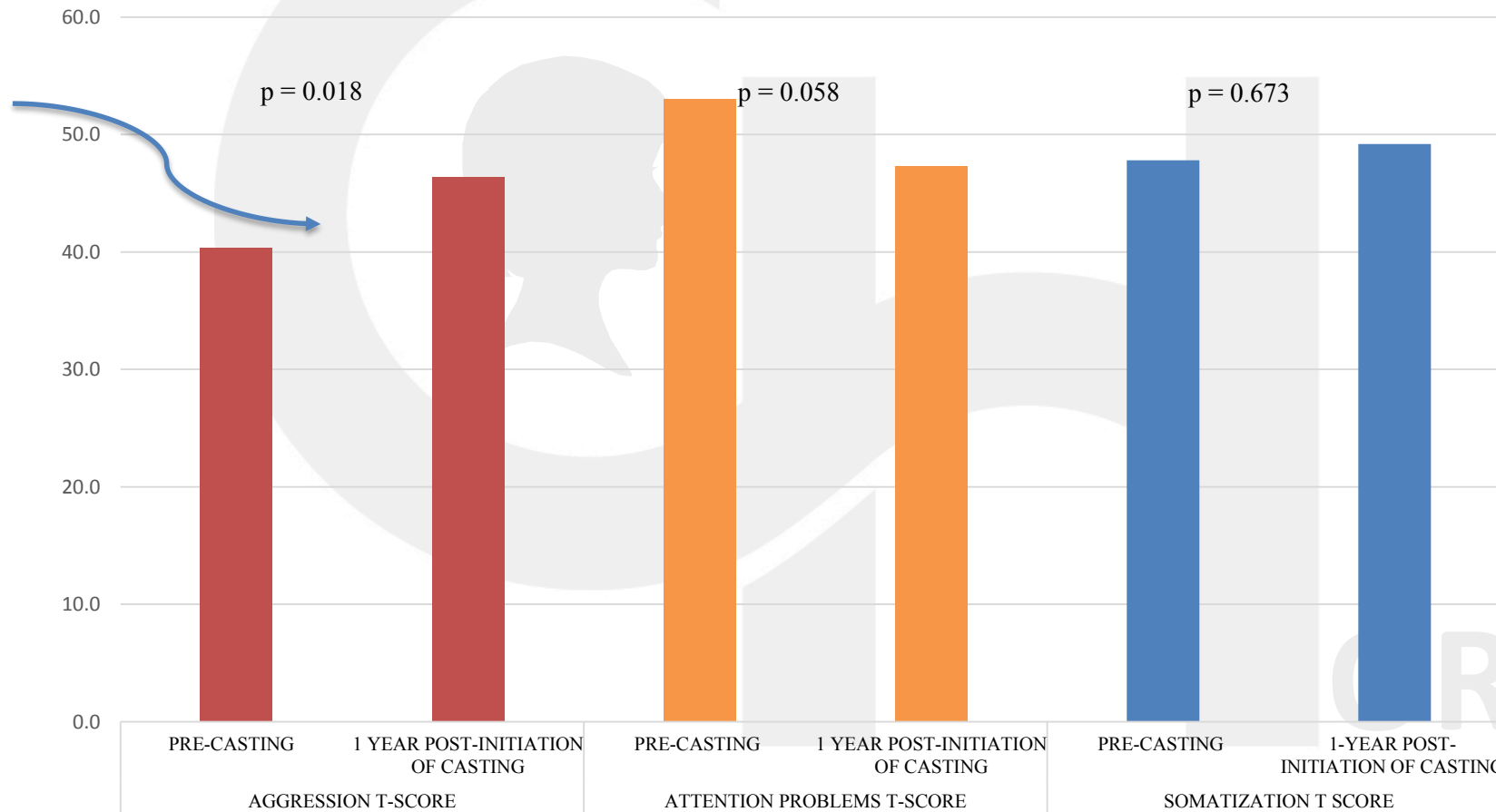
- 10 patients were available to study at pre-casting and 1-year post-initiation of casting
- Results included T-scores for the BASC-2 subdomains of Aggression (n=8), Somatization (n=8), and Attention Problems (n=10)
- Mean age at pre-cast was 15.4 ± 6.4 months and at 1-year post-initiation of casting was 27.0 ± 4.3 months
- Aggression increase ($p=0.018$) closely approached statistical significance. Attention Problems and Somatization did not ($p=0.058$, $p=0.673$, respectively)



Graph

BASC-2 Subscale T-Score Averages Pre- and 1-Year Post-Initiation of Serial Casting For Infantile Idiopathic Scoliosis Patients

Represents +0.6 St Dev,
Both within 1 St Dev of
Population Norm



Limitations

- **Sample Size & Power**
- **Cannot separate serial anesthesia and long-term body casting as separate variables to assess which correlates with increased behavioral aggression**
- **BASC-2 has only been validated for 2-year-olds (our participants age at pre-casting is mean 15.4 +/- 6 months)**
 - **BASC-2 strongly correlates with other infant/ toddler assessment, (Achenbach system), validated for children as young as 1.5 years [24]**



Conclusions

- IIS requires tx to prevent pulmonary function loss, disfigurement, and decreased life expectancy
- To our knowledge this is the first study evaluating the psychological and behavioral impact of serial casting treatment
- Although the data is limited, a slight increase in BASC-2 Aggression scores suggests casting may negatively impact behavior and emotional status in children
- Future Directions: Additional data collection and incorporation of control group undergoing serial casting without general anesthesia



ORTHO

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