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

Alexander J. Adams, BS; Sumeet Garg, MD; Jason B. Anari, MD; Peter F. Sturm, MD; Joshua M. Pahys, MD; Robert Murphy, MD; John M. Flynn, MD; Children’s Spine Study Group; Patrick J. Cahill, MD

The Children’s Hospital of Philadelphia
Perelman School of Medicine at University of Pennsylvania
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

- 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

<table>
<thead>
<tr>
<th>Scale</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Activities of Daily Living</td>
<td>Skills associated with performing basic, everyday tasks in an acceptable and safe manner</td>
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<tr>
<td>Adaptability</td>
<td>Ability to adapt readily to changes in the environment</td>
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<tr>
<td>Aggression</td>
<td>Tendency to act in a hostile manner (either verbal or physical) that is threatening to others</td>
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<tr>
<td>Anxiety</td>
<td>Tendency to be nervous fearful, or worried about real or imaginary problems</td>
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<tr>
<td>Attention Problems</td>
<td>Tendency to be easily distracted and unable to concentrate more than momentarily</td>
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<td>Atypicality</td>
<td>Tendency to behave in ways that are considered “odd” or commonly associated with psychosis</td>
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<tr>
<td>Depression</td>
<td>Feelings of unhappiness, sadness, and stress that may result in an inability to carry out everyday activities or may bring on thoughts of suicide</td>
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<tr>
<td>Functional Communication</td>
<td>Ability to express ideas and communicate in a way others can easily understand</td>
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<tr>
<td>Hyperactivity</td>
<td>Tendency to be overly active, rush through work or activities, and act without thinking</td>
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<tr>
<td>Leadership</td>
<td>Skills associated with accomplishing academic, social, or community goals, including the ability to work with others</td>
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<tr>
<td>Social Skills</td>
<td>Skills necessary for interacting successfully with peers and adults in home, school, and community settings</td>
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<tr>
<td>Somatization</td>
<td>Tendency to be overly sensitive to and complain about relatively minor physical problems and discomforts</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>Tendency to avoid others to avoid social contact</td>
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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).
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

AGGRESSION T-SCORE

PRE-CASTING 1 YEAR POST-INITIATION OF CASTING

ATTENTION PROBLEMS T-SCORE

PRE-CASTING 1 YEAR POST-INITIATION OF CASTING

SOMATIZATION T-Score

PRE-CASTING 1-YEAR POST-INITIATION OF CASTING

p = 0.018

p = 0.058

p = 0.673
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
References


