Pediatric Oncology Procedures: Sedation versus General Anesthesia

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Introduction: Children with acute lymphocytic leukemia (ALL) undergo repeated lumbar puncture (LP) and bone marrow aspiration (BMA). Sedation (S) and general anesthesia (GA), among other techniques, are commonly employed to facilitate these invasive and otherwise painful procedures (1-4). Few studies have comprehensively compared S versus GA approaches. We conducted a pilot study to examine the following hypotheses: compared to S, GA :1) decreases procedure time and difficulty, 2) decreases recovery time and total time to disposition, 3) does not increase the incidence of side effects, and 4) reduces patient distress and pain.

Methods: After Children's Hospital of Philadelphia (CHOP) IRB approval, we enrolled children aged 1-18 years with newly diagnosed ALL. Ten patients for the S arm and 9 for the GA arm were enrolled and successfully completed the study. For day 7 LP/BMA, subjects were initially randomly assigned to either S or GA. Enrollment slowed dramatically as parents increasingly preferred and requested one technique or the other. After 4 years only 12 subjects had been recruited and the protocol was changed to allow randomization opt-out, which 9 subjects elected. Sedation subjects received a standard regimen of midazolam 0.025-0.05 mg/kg IV (max 2.5 mg/dose; 10 mg total) and fentanyl 1 mcg/kg IV (max 50 mcg/dose; to be repeated once if needed) in accordance with the CHOP conscious sedation protocol. Monitoring was performed by a nurse and included level of consciousness, respiratory rate, SpO2, heart rate and blood pressure. Patients assigned GA underwent anesthesia induction with lidocaine 1 mg/kg IV and propofol 3-5 mg/kg IV. Anesthesia was maintained by mask with isoflurane or sevoflurane and nitrous oxide in oxygen. Additional monitoring included end-tidal CO2 and temperature. Preoperatively, patients were assessed using the modified Yale Preoperative Anxiety Scale (mYPAS). Room entry time, procedure start and finish times, and time to meet standard discharge criteria were recorded. Assessment of technical difficulty was made by asking the operator to rate the degree of difficulty using a 10 cm visual analog scale. Parents were asked to rate both their perception of the child's comfort level and their overall satisfaction with the procedure using 10 cm visual analog scales. Presence of common side effects such as nausea/vomiting, sore throat, and headache were recorded.

Results: Procedure time was significantly longer for the S group (19.4 min S vs. 8.1 min GA, p= 0.005). (Table) In addition, the performing clinician rated the procedures performed under S as significantly more difficult than those performed under GA (4.2 vs.

0.8, p= 0.03). GA did not result in a decreased recovery time and time to discharge readiness. Neither parental perception of child comfort nor overall parental satisfaction differed significantly between groups. There were no cases of nausea/vomiting, sore throat, or headache reported in either group in the immediate post-operative period. There was one case of failed sedation requiring conversion to GA.

Discussion: While GA improved operative conditions and allowed for greatly reduced LP/BMA procedure times, it did not seem to alleviate the mild to moderate anxiety the children experienced, nor did it contribute to any improved comfort or satisfaction outcomes. GA may decrease variability in recovery time, but it did not reduce average discharge readiness time. We attribute the recovery findings in part to the use of fentanyl instead of morphine sulfate in S, as had been used in previous years. We intentionally used an anesthetic that included potent agent to compare S against a GA technique that covered extremes, acknowledging the potential for longer recovery time and increased side effects over other techniques (2). The major limitations of these data include small sample size and, ultimately, a cohort design. The latter would mitigate differences in outcomes such as perceived comfort and satisfaction as parents were generally happy that familiar expectations were met in the study arm of their choice.

	Sedation (n=10)	General Anesthesia (n=9)	P value
Age (months)	84.5 (±45.7)	65.5 (±32.6)	0.17
MYPAS score	9.8 (±4.2)	11.4 (±3.2)	0.34
Procedure time (min)	19.4 (±8.8)	8.1 (±5.9)	0.005
Procedure difficulty	4.2 (±4.4)	0.8 (±0.7)	0.03
Time to discharge readiness (min)	25 (±21.1)	34.1(±9.2)	0.28
Parental perception of child's comfort level	6.9 (±3.6)	7.6 (±0.7)	0.67
Parental satisfaction with procedure	9.0 (±1.6)	8.9 (±1.0)	0.87

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