The FLACC Pain Scale

	SCORING		
CATEGORIES	**0**	**1**	**2**
FACE	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin,
LEGS	Normal position or relaxed.	Uneasy, restless, tense.	Kicking, or legs drawn up
ACTIVITY	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
CRY	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging or talking to, distractible	Difficulty to console or comfort

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Figure 1. The presently applied FLACC observational pediatric postoperative pain scale (15).

postoperative bladder spasms, PONV, and pruritus were recorded by the bedside nurse on a dedicated study data collection sheet. The occurrence of any postoperative excessive sedation, respiratory depression, hypotension, and/or bradycardia, requiring medical intervention, was also noted. The initiation of clear liquid and solid food oral intake, the date and time of the removal of the Foley bladder catheter, and the patient's subsequent discharge home were all recorded.

All continuous group sample data were compared using a one-way analysis of variance (ANOVA) with Tukey HSD *post hoc* comparisons performed between group means. Kaplan–Meier survival curves of the elapsed time to the first postoperative morphine dose were compared using a log-rank test. Dichotomous group sample data were compared using a χ^2 test. The FLACC scale pain score data (with a discrete 0–10, minimum to maximum range) were deemed to be ordinal; all of the sequentially obtained individual patient pain intensity score data were aggregated by study group and compared using a nonparametric Kruskal–Wallis test with a Bonferonni correction of α. Levene's test (with $P < 0.05$) was used to confirm the homogeneity of group sample data variance. The Shapiro–Wilk test was applied to assess the normality of the continuous variable data. Any variable found to lack normality was subjected to logarithmic transformation before group mean comparisons. The positive effect of this data transformation on normality was visually confirmed using q-q plots. The collected study data were initially entered into a Microsoft Access database; all statistical analyses were subsequently performed using SPSS 14.0 (SPSS, Chicago, IL) with a $P < 0.05$ considered significant.

An *a priori* study sample size calculation was performed based upon our previous retrospectively observed 31% difference in the incidence of PONV in patients receiving a single caudal dose of clonidine versus morphine[1]. Applying an uncorrected χ^2 test with an α of 0.05, a sample size of 30 would be expected to have an 80% power to detect a minimum 30% difference in the incidence of PONV between two such treatment groups. Block randomization was applied so that a preliminary analysis of the primary side effect data could be performed after 60 patients had been enrolled. Based upon this preliminary analysis, enrollment in the study was terminated after 60 patients.

RESULTS

Complete study data were collected on all 60 initially enrolled patients (Fig. 2). While none of the 60 attempted caudal blocks was perceived as being a failed attempt, an intention-to-treat approach was applied that assumed successful caudal block placement. Patient demographics were similar among the three study groups (Table 1). The intraoperative clinical profile was likewise similar among the three study groups (Table 2). Specifically, no significant group difference was observed in the maximum maintenance end-tidal concentration of sevoflurane; the incidence of intraoperative hypotension, bradycardia, or delayed emergence; or the anesthesia emergence time.

There were no observed group differences in either the aggregate postoperative FLACC pain scale scores or the total amount of morphine administered postoperatively via proxy NCA (Table 3 and Fig. 3). While the mean elapsed time from PACU admission to the first required postoperative dose of IV morphine did not differ between the CR group and MR group ($P = 0.06$) (Table 3), a significant fraction of patients in the MR group experienced postoperative analgesia that

[1]Annual Meeting of the American Society of Anesthesiologists (2005). A1336: A Comparison of Single-Dose Caudal Clonidine Versus Morphine in Pediatric Ureteral Reimplant Patients.