

The GoMo study: a randomized clinical trial assessing neonatal pain with Gomco vs Mogen clamp circumcision

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Objective

Our objective was to compare the pain/stress levels of newborns among the 2 most common circumcision techniques after resident-wide education.

Study Design

The study period of this randomized control trial was October 2012 through March 2014. Following informed consent, full-term males from uncomplicated singleton pregnancies were randomized to Gomco (n = 137) or Mogen (n = 137) devices. Resident-wide education for an obstetrics and gynecology residency program at a single institution was performed to ensure standardized training. All infants received a subcutaneous ring block before the procedure and oral sucrose intraoperatively. The primary outcome was neonatal pain assessed physiologically by salivary cortisol levels (enzyme-linked immunosorbent assay) and clinically by a validated neonatal pain score (crying, requires increased oxygen administration, increased vital signs, expression, sleeplessness [CRIES]). Secondary outcomes were immediate complications, duration of procedure, and short-term outcomes as reported by mothers and pediatricians. A sample size of 274 (accounting for 20% loss of follow-up) was determined sufficient to detect a mean difference of 1.22 $\mu\text{g/dL}$ in cortisol levels (Gomco, SD \pm 3.34; Mogen, SD \pm 0.81) with 80% power, $P = .05$ level of significance.

Results

A total of 251 infants completed the protocol. There were no significant differences in maternal or neonatal demographics including preoperative heart rate and mean arterial pressure. In the Mogen circumcision, the percentage change of cortisol was significantly lower than Gomco (279.1 ± 498.15 vs 167.75 ± 272.22 ; $P = .049$). There were no differences in postoperative CRIES scores. Postoperative heart rate was higher in infants undergoing Gomco circumcision than Mogen circumcision (138.7 ± 16.5 vs 133.4 ± 17.5 ; $P = .015$) as was mean arterial blood pressure (63.3 ± 9.2 vs 60.4 ± 8.6 ; $P = .012$). Mogen circumcisions were shorter (7.00 ± 2.97 vs 3.65 ± 1.84 minutes; $P < .001$). There were no significant differences in bleeding complications. A total of 168 maternal surveys were completed, with 98.7% maternal satisfaction in Gomco vs 98.9% in Mogen. There were no reports of bleeding after discharge or circumcision revisions in either group to date.

Conclusion

Mogen clamp is associated with less neonatal pain physiologically by significantly lower percentage change in salivary cortisol, lower heart rate, and mean arterial blood pressure. There was no difference in CRIES scores. Mogen clamp circumcision duration is significantly shorter than Gomco clamp. Both methods demonstrate satisfactory maternal and pediatrician short-term follow-up.