

A Comparison of Indomethacin and Ibuprofen for PDA Closure in ELBW

Infant:A Randomized Trial

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Background and Objectives: There has been no head to head control study to compare indomethacin and ibuprofen therapy for PDA closure in ELBW infant. A randomized trial was undertaken to compare the efficacy of ductal closure, side effects, and urinary prostaglandin (PG) between indomethacin and ibuprofen.

Method: One hundred and forty four infants who had clinically significant PDA were randomly assigned into 2 groups, 73 received indomethacin (0.2 mg/kg, 0.1 mg/kg and 0.1 mg/kg iv every 24 hours) and 71 received ibuprofen (10 mg/kg, 5mg/kg and 5 mg/kg iv every 24 hours).

Results: The two groups were comparable in birth weight (mean±SD, 812 ± 160 v s 801 ± 156 g), gestational age (26.3±1.6 v s 26.2±1.7 weeks) and in baseline cardiopulmonary status. Indomethacin group had a significantly lower urine output (54±16 v s 67±24 ml/kg/d, p=0.015), lower GFR (8.9±2.1 v s 17.8±10.4 ml/min/1.73m² p=0.004) on day 1, higher serum creatinine on day 1 (p=0.024) and day 2 (p=0.031), lower urine PG on days 2,3,5, and 7 (p=0.045, p=0.018, p<0.001, p=0.026 respectively) than the ibuprofen group. The two groups were comparable in renal tubular functions and in rate of ductal closure (55/73 or 75% v s 46/71 or 65%), ductal reopening (8/55 or 14% v s 11/46 or 23%), and in mortality and BPD, IVH and NEC morbidity.

Conclusion: In ELBW infant, ibuprofen was associated with similar efficacy of ductal closure as indomethacin but with less renal PG inhibition and less decreases in urine output and GFR.