

Feasibility, safety and efficacy of an innovative Remote BioMonitoring (RBM) device to validate reported Kangaroo Mother Care(KMC) in hospital and community settings in southern India: a proof-of-concept study

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Background: Verification of reported KMC duration remains a key challenge.

Research objective: To evaluate a Remote BioMonitoring (RBM) device for tracking KMC adherence and neonatal temperatures in hospital and community settings

Design: Techno-feasibility study and Phase IIa clinical trial

Essential variables: Feasibility, safety and accuracy (KMC position and neonatal temperature)

Data collection tools: A battery-operated, wearable sensor secured 24/7 onto the neonate's epigastrium sensed skin temperature and KMC position (through skin touch and baby angle) at 6-minute intervals. Data was transmitted via bluetooth to a gateway cellphone onto the cellular network. A structured questionnaire administered obtained information on side-effects.

Statistical plan: Validation was by direct observation of KMC and comparison of time-stamped device temperatures against axillary thermometer readings. Test of significance between mean temperatures and percent agreement between KMC durations was calculated.

Results: Device-based data collection was possible in a set of 24 mother-baby dyads for upto 15 days (1-5 hospital-days and 1-14 home-days). Vital signs (heart rate and oxygen saturation) remained stable soon after strapping the device. No severe/moderate side-effects were reported; mild dermatitis was noted in upto 30% (7/24) of babies over 12% (7/59) person-days of observation; all side-effects resolved spontaneously. Device temperatures were 0.4°C lower than axillary temperatures ($p < 0.01$) and there was 90% agreement against direct observation of KMC. Self-reported KMC durations per day were double that captured by the device.

Discussion and conclusions: Remote, real-time biomonitoring of KMC position and temperature was feasible, safe and reasonably accurate. Further device refinements and clinical trials must continue.