Prematurity and Low Birth Weight Effect on Reference Interval of DBS TSH and 17-Hydroxyprogesterone in Neonates From a Community in Pakistan

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Background: There are gaps in available neonatal reference intervals (RI) for use in Pakistan, where dried blood spot (DBS) testing is still not standard of care. Ascertaining RI in neonates and children is challenging.

Objective: To determine RI for thyroid stimulating hormone (nTSH) and 17-hydroxy progesterone (17OHP) using DBS from a cohort of neonates enrolled in the AMANHI (Alliance for Maternal and Newborn Health Improvement) Biorepository at the Aga Khan University, Pakistan.

Methodology:
Study Design: Cross-Sectional
Study Period: Nov 2017- Feb 2019
ERC Approval: was sought from AKU, ERC Committee

Study Subjects & Study Site:
• Neonates, from peri-urban communities of Ibrahim Hyderi & Ali Akbar Shah, Karachi located along the Arabian Sea coast covering an area of 6 sq. km with a population of 187 357, were included.
• Blood from neonates’ heel pricks were obtained within 24-72 hours of birth on filter paper.
• Samples were transported to University of Iowa for analysis in dry ice.
• nTSH and 17OHP were analysed on Perkin Elmer Auto Delfia.

Exclusion Criteria: All new-borns with high 17OHP (>33nmol/L) or high nTSH (>10 uIU/ml) were excluded.

Statistical Analysis: RI was calculated before and after adding small for gestational age (SGA) new-borns and premature (<37 weeks). CLSI recommended method was used for the determination of upper and lower end points covering 95% of the reference values of each analyte with respective 90% Confidence intervals.

Results:
• Maternal mean gestational age at the time of delivery was 38.4±1.5 weeks.
• Mean birth weight was 2789.9±468.3 gm.
• The nTSH-RI in 163 neonates was 2.2-8.1 uIU/mL and 17OHP-RI was 1.1-8.9 nmol/L.
• RI was recalculated after including all SGA and premature babies and no significant difference was found between the reference ranges (p value >0.05).
• The nTSH-RI in 297 neonates was 2.2-8.1 uIU/mL and 17OHP in 294 neonates was 1.2-9.4 nmol/L.

Conclusion No effect of SGA and prematurity was seen in neonates’ RI for 17OHP and nTSH.