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Sex-specific full blood count reference intervals in the Jaffna population using *refineR*

Dohidha P¹, Kishamini V¹, Mauran S¹, Nilmini H², Karunaithas R^{1*}

¹Faculty of Allied Health Sciences, UoJ, Sri Lanka

²Regional Blood Bank, Teaching Hospital Jaffna, Sri Lanka

*karunaithas@univ.jfn.ac.lk

Introduction: Reference intervals(RIs) are vital for interpreting clinical laboratory results and guiding patient management. As RIs vary with demographic, genetic, and environmental factors, population-specific establishment is necessary for clinical accuracy. Refining hematological RIs is complex, requiring careful data selection, statistical analysis, and validation, typically achieved via the direct method. Indirect methods offer a cost-effective alternative, but their applicability in the Jaffna population remains unclear.

Objectives: This study aimed to establish sex-specific RIs for Full Blood Count (FBC) parameters in the Jaffna population using the indirect *refineR* algorithm.

Methodology: A retrospective cross-sectional study was conducted from July 2023 to July 2024 using routine FBC data from the Laboratory Information Systems of Base Hospitals in Thellipalai and Point Pedro. Data were curated to exclude pathological values and stratified by sex. RIs were estimated using *refineR*, an open-source R package that uses inverse modelling to identify non-pathological distributions within mixed datasets. Established RIs were compared with direct-method RIs using the bias ratio, with values ≥ 0.375 indicating significant differences.

Results: During the study period, 43,638 FBC records were collected, of which 15,844 (6,537 male and 9,307 female) non-pathological data met the criteria for RI calculation. Sex-specific RIs for 13 FBC parameters were established for the Jaffna population, with 95% inclusion: WBC (3.61–10.7 vs 4.06–10.8 ×10°/L), neutrophils (1.53–7.44 vs 1.46–7.46 ×10°/L), lymphocytes (0.97–3.67 vs 1.00–3.78 ×10°/L), monocytes (0.19–0.72 vs 0.15–0.69 ×10°/L), eosinophils (0.16–0.63 vs 0.03–0.60 ×10°/L), basophils (0–0.05 vs 0–0.05 ×10°/L), RBC (3.94–5.64 vs 3.46–5.01 ×10¹²/L), hemoglobin (11.3–16.7 vs 9.78–14.2 g/dL), hematocrit (34.8–47.8 vs 28.9–42.0%), platelets (130–399 vs 146–408 ×10°/L), MCV (75.9–97.2 vs 74.2–95.3 fL), MCH (27.0–32.2 vs 24.2–32.6 pg), and MCHC (32.3–35.7 vs 31.9–35.3 g/dL) for males and females, respectively. Furthermore, bias ratio comparison with the direct method showed comparable results in 8 parameters for males and 9 for females.

Conclusions: Sex-specific RIs for 13 FBC parameters were established for the selected Jaffna population using *refineR*, with most parameters showing good agreement with direct-method RIs, supporting its utility for accurate clinical interpretation.

Keywords: Full Blood Count, Jaffna, Reference intervals, *refineR*, Population-specific, Sex