

KASADHA RICHARD (2019/MMLS/016/PS) ABSTRACT

Background: Diagnosis of extra pulmonary tuberculosis is still a challenge and this is due to few bacilli in tissues. Poor diagnosis of this TB increases the infection rates which can lead to high death rates. There are latest molecular methods used in diagnosis of EPTB and since on many occasions, tissues are submitted in Histopathology Lab while fixed in formalin, therefore it was important to explore the use of Xpert® MTB/RIF assay on formalin fixed paraffin embedded tissue biopsies in diagnosis of extra pulmonary Tuberculosis (EPTB).

Objective: The aim of this study was to determine the diagnostic utility of Xpert® MTB/RIF assay on formalin fixed paraffin embedded tissue biopsies in diagnosis of extra pulmonary Tuberculosis (EPTB) using ZN and H and E staining as composite reference standard at Mbarara University Pathology Laboratory, south western Uganda.

Methods: 89 archived FFPE tissue cases with histological features of tuberculosis were purposively selected and included in the study. ZN and H & E staining were performed on tissue sections (3µm thick) as composite reference standard. Tissue sections (10µm thick) were subjected to the Gene Xpert® MTB/RIF assay as diagnostic test after deparaffinisation, tissue digestion and lysis. Information recorded on data sheet was entered in excel for completeness and the dataset was imported into STATA software version 17.0 for analysis.

Results: The overall sensitivity, specificity, PPV, and NPV of Gene Xpert were 48.94% (95% CI: 38.55% –59.32%), 90.48% (95% CI: 84.38 – 96.57%), 85.19% (95% CI: 77.80% –92.57%) and 61.29% (95% CI: 51.17% –71.41%) respectively. In lymph nodes tissues, the sensitivity, specificity, PPV, and NPV of Gene Xpert were 52.94% (95% CI: 39.98% - 65.90%), 82.61% (95% CI: 72.77% - 92.45%), 81.82% (95% CI: 71.81% - 91.83%) and 54.29% (95% CI: 41.35% - 67.22) respectively and in non- lymph nodes tissues, the sensitivity, specificity, PPV, and NPV of Gene Xpert were 38.46% (95% CI: 21.61% - 55.32%), 100% (95% CI: 100% - 100%), 100% (95% CI: 100%- 100%) and 70.37% (95% CI: 54.55% - 86.19%) respectively.

Conclusion: Gene Xpert MTB/RIF assay is a potential assay for diagnosing EPTB in FFPE tissues and could be used as an alternative or additional test for the detection of *M. tuberculosis* in formalin fixed tissues. We recommend use of Gene Xpert assay in diagnosis of EPTB in FFPE tissues and also formation of algorithm is recommended.