EVALUATION OF THE PERFORMANCE OF Sacace HPV Genotypes 14 Real-TM Quant AND careHPV AGAINST LINEAR ARRAY IN DETECTION OF HUMAN PAPILLOMA VIRUS GENOTYPES IN WOMEN FROM WESTERN KENYA

ABSTRACT

Cervical cancer (CC) is common among women, with global estimates of over 530,000 new cases and over 270,000 deaths annually. Human papilloma virus (HPV) infection increases the risk for CC development while high HIV prevalence predisposes individuals to persistence infection of the high risk (HR) HPV. Western Kenya is a region with the highest HIV prevalence in Kenya. Detection and distribution of HPV genotypes in regions of high HIV transmission is critical in identification of target HPV proteins that would help in rational design of globally effective HPV diagnostic tools and vaccines. Currently, there is incompatibility in the detection of HPV genotypes when gold standard (Linear Array®) (LA), Sacace™ HPV Genotypes 14 Real-TM Quant (Quant) and careHPV™ assays are used separately. Misdiagnosis may occur if one method with low sensitivity and specificity is used. It is therefore imperative that a tool which detects most HR HPV genotypes is applied during diagnosis. This cross-sectional study compared the performance of the two assays against LA in the detection of the 14 HR HPV genotypes and ascertained the optimal tool for HPV detection. Specifically, it determined the prevalence and distribution of HPV; sensitivity, specificity and concordance of Quant and careHPV™ as compared to LA in detecting HPV genotypes in women from western Kenya. Archived cervical swab specimens from 179 women from Moi Teaching and Referral Hospital in western Kenya were used. DNA was purified from the cervical swab specimens and genotyping assays performed according to the manufacturers protocols. Using LA, the overall HPV prevalence was 50.28% and HR-HPV was 36.87%. HPV 16, 52, 58 and 66 were the dominant HR-HPVs when tested by LA. The sensitivity of careHPV™ and Quant in overall population was 53.03% and 92.86% against LA respectively, with specificity of 80.90% and 79.31 respectively (McNemar's test, P = 0.061 and P = 0.004, respectively). The sensitivity of careHPV™ and Quant in the detection of 14-HR-HPV in women with abnormal cervical cytology was 74.07% and 94.12% and specificity of 65.22 and 71.43%, respectively (McNemar's test, P = 1.000 and P = 0.125, respectively). The overall agreements of careHPV™ and Quant against LA were 69% and 84.61% respectively (kappa statistic = 0.349 and 0.691 respectively) indicating moderate and substantial agreement with LA respectively. The high HR HPV prevalence calls for early treatment and management of women from western Kenya. The presence of HPV 66 in western Kenya supports its inclusion to the future vaccines. The good sensitivity, specificity and concordance of Quant tests makes it a reliable and suitable options for CC screening. Accurate tools will be helpful in early detection of HPV hence early management and prevention of CC development. Detection of HR genotypes is of great importance in providing the knowledge on HR-HPVs distribution that may increase the chance of individuals exposed to high HIV prevalence to CC. This may also inform incorporation of these genotypes into future vaccine development that would decrease HR HPV infections in populations exposed to high HIV transmissions.