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**Diagnostic accuracy of in-house developed indirect enzyme-linked immunosorbent assays for HPV16 and HPV18 high-risk human papillomaviral infections in oral and oropharyngeal cancer patients in Sri Lanka**

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Human papillomaviral (HPV) infection is recognised as a relatively novel major risk factor for oral and oropharyngeal cancers (OOPC). High-risk HPV types (HPV16 and HPV18) are known to be responsible for two thirds of all invasive OOPCs. HPV seropositivity reflects past or present HPV exposure and is associated with risk for OOPC. This case control study aimed to assay for HPV specific IgG antibodies for HPV16 and HPV18, in test and control serum samples, using in-house developed indirect ELISAs and to standardize these tests with diagnostic accuracy. The association of high-risk HPV in OOPC was assayed using the levels of anti-HPV IgG antibodies present in 100 OOPC patients and 100 age and gender matched non-cancer healthy control subjects. HPV 16 and HPV 18 virus like particles (VLPs) were used as antigen. Serologic response to both HPV16 and HPV18 infection showed a statistically significant difference between test and control groups ( $P < 0.05$ ). Anti HPV16 IgG antibodies were detected in 24% of OOPC patients as well as in 3% of non-cancer controls, while 19% of OOPC patients and 2% of controls harboured anti HPV 18 IgG antibodies. The test group was more likely to have had exposure to HPV 16/18 infections, with a 4 fold increased risk for developing OOPC (HPV 16: OR=4.3, 95%CI=1.225-17.446 and HPV 18: OR=4.0, 95%CI=1.114-17.341) compared with controls. Receiver Operating Characteristic (ROC) analyses using MedCalc; version 17.6 software standardized the two ELISAs. The anti HPV16 antibody ELISA showed 96% accuracy (sensitivity = 93%, specificity =94.4%, cut off  $\geq 0.134$ ) while the anti HPV18 antibody ELISA resulted in 91% accuracy (sensitivity = 87.2%, specificity =84%, cut off  $\geq 0.097$ ) in discriminating the test group from controls. Thus, these in-house developed ELISAs provide serologic diagnostic tools with high accuracy for the detection of high-risk HPV16 and HPV18 in OOPC.

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