PREVALENCE OF HIGH RISK HPV GENOTYPES IN ONTARIO WOMEN DETERMINED BY AMPLICOR® HPV PCR AND LINEAR ARRAY OF SUREPATH® PAP SAMPLES

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OBJECTIVES: The AMPLICOR HPV PCR [AMP] and Linear Array HPV genotyping tests [LA] from Roche have recently been approved for the diagnosis of HPV in Canada. There is limited published data on their performance on liquid-based SurePath Pap samples [L-Pap]. We tested L-Pap samples from women seeking routine cervical cancer screening using AMP and LA to determine concordance for HR types, reproducibility of AMP results between two laboratories and distribution of genotypes in the population.

METHODS: Samples from patients attending Ontario medical clinics were Pap-tested and within 1 week the residual L-Pap fluid from patients with abnormal cytology were extracted in QIAamp MinElute columns. Amplification and detection of HR HPV and beta-globin DNA were performed according to the package inserts. For the reproducibility protocol the two laboratories extracted and tested a panel of samples. Analysis was performed using SPSS software.

RESULTS: A total of 325 women have been enrolled [49% >30 yr]. Sixty-five percent [212] contained HR types. The following genotype prevalences were found: 16 [24%], 18 [8%], 51 [11%], 52 [10%], 39 [9%], 56 [8%], 31 or 58 [6%], 33 [4%], 35, 45 or 68 [3%], 59 [2%]. Of the 212 samples containing an HR genotype, 44 had 2, 17 had 3, 7 had 4, and 1 had 5 different types. HPV DNA was detected in 100% [15/15] samples with HSIL, 83.0% with ASCUS [78/94] and 81.7% with LSIL [107/131]. In patients <30 years of age, types 16 or 18 were found in 38.9% of ASCUS, 46.2% of LSIL and 80% of HSIL compared to 27.8%, 14.7% and 33.3% respectively in those >30. The tests agreed 79.7% of the time with the AMP test finding more positives due to a higher analytical sensitivity. The 2 laboratories agreed on positives and negatives 76.2% of the time.

CONCLUSIONS: This ongoing study showed that although infections with types 31, 39, 51, 52, 56 or 58 were prevalent in 52% of the positive samples, they were often accompanied by types 16 and 18, which were more often associated with cytological diagnoses of ASCUS or HSIL. Results of AMP testing between laboratories may be due to differences in extraction and/or performance of the assay.