Abstracts

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A PROSPECTIVE STUDY TO EVALUATE THE AGREEMENT OF HIGH-RISK HUMAN Papillomavirus DETECTIONS BY VAGINAL SELF-SAMPLING AND PHYSICIAN-SAMPLING

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Introduction/Background Various human papillomavirus (HPV) testing using physician-collected cervical samples have been approved for cervical screening. The COVID-19 pandemic highlights the need of self-sampling test for high-risk patients who are unwilling to participate routine screening program. The aim of clinical trial is to introduce a new ‘Hygeia Touch Self Sampling Kit for Women’ and evaluate the agreement of high-risk human papillomavirus (hrHPV) detections between vaginal self-sampling via Kit by patients and physician-collected cervical sampling.

Methodology Women aged 21–65 years without hysterectomy were enrolled by stratification: normal population and participants with Pap smear ≥ASCUS or cervical biopsy ≥ CIN 1 (ratio=1:10). All the participants had video-guided self-collected vaginal sampling, then physician-collected cervical sampling. The hrHPV types include types16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. The primary endpoint is to evaluate the agreement of hrHPV detection between self-sampling via Kit and physician-cervical sampling using Cohen’s kappa statistic, and the sensitivity and specificity of detection methods were also compared.

Results There were 1170 eligible participants. For the detection of hrHPV and any specific HPV type of 27 types, the concordance between self-collected sampling and physician was high (Cohen’s kappa 0.75, 95% CI 0.72–0.79 and 0.75, 95% CI 0.71–0.79, respectively). The detection rate of ≥ cervical intraepithelial neoplasia 2 (CIN2+) via HPV testing between self-collected vaginal samples and physician-collected cervical samples were similar in sensitivity (85% vs 89%, relative accuracy 95%), specificity, positive predictive value, and negative predictive value. Two participants had mild anxiety and seven participants had mild perineal pain, and the symptoms subsided after sampling. The adverse event is 0.7%.

Conclusion These results demonstrate good agreement for detecting hrHPV and HPV between self-collected vaginal swabs and physician sampled cervical specimens in detecting CIN2+ lesions.

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CONSERVATIVE MANAGEMENT OF CIN-2: A RETROSPECTIVE, SINGLE-CENTRE STUDY

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Introduction/Background Past management of cervical intra-epithelial neoplasia-2 (CIN-2) has centred around treatment via excision. Contemporaneously, more onus has been placed on conservative management of this disease in women of reproductive age. This is namely to prevent future preterm birth.

Methodology A retrospective analysis was completed of patients undergoing conservative management of biopsy confirmed CIN-2 between 2017–2021 in a single tertiary centre. This included 6 monthly colposcopic assessment for a total 24 months with either smear or biopsy alternatively. Excision was offered in the event of progression or patient choice. Primary outcome was divided into successful regression and discharge back to routine monitoring, progression or persistence requiring intervention, and patient adherence (drop-out or loss to follow-up). Further secondary measures were also examined, including pregnancy outcomes, and a sub-group analysis of smokers and those aged over 35 years old. Statistical analysis was completed using R Studio Ver 1.2.5033.

Results A total of 100 patients underwent conservative management. Primary outcomes are summarised in figure 1. A total of 18 women were treated with LLETZ, including 6 for patient choice. No women had progression of disease to malignancy, and 5 progressed to CIN-3. The average time to dropout was 12.42 months (1–22). Smokers and those over 35 were not significantly more likely to require intervention then the rest of the population (p=1.0000 and p=0.5936 respectively). 15 women became pregnant either during or after management. A total of 12 live births occurred, and 3 losses between 6–12 weeks gestation. A single preterm delivery occurred due to other reasons.

Conclusion • Conservative management represents a safe management to those of reproductive age. • Therefore, critical reductions in preterm birth and pregnancy loss are possible.