Evaluation of a real-time, optoelectronic device 'TruScreen' as a primary screening tool for cervical cancer

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Purpose

The purpose of this study was to evaluate 'TruScreen' as an improved primary screening tool for cervical cancer by assessing its clinical performance against traditional methods.

Materials & Methods

A population-based, cross-sectional screening study was conducted on 391 women aged 20-67 in Shenzhen City, China during the period March 2007 to December 2007. A real-time optoelectronic device ('TruScreen') was used for primary cervical cancer screening.

Following the TruScreen procedure, a colposcopy was performed (3—5% aqueous acetic acid and Lugol's iodine solution) with the colposcopist blinded to the TruScreen result. The colposcopy results were recorded, and clinicians were encouraged to take a cervical biopsy on any colposcopically suspicious area.

In addition, cytology samples from all subjects were collected for liquid-based cytology ('LCT') and Hybrid Capture 2/high risk HPV DNA ('HPV') testing.

Histology was used as the gold standard against which the three methods (TruScreen, LCT, HPV) were evaluated.

If the subject did not have a biopsy at the initial screen and 'abnormality' was indicated by one or more of the screening methods then colposcopy was repeated in 3 months. The 'abnormality' results criteria used was (1) HPV positive and LCT ≥ ASCUS or (2) LCT ≥ LSIL or (3) TruScreen = positive.

Results

187 biopsy specimens were obtained. Histology reported 5 cases of cervical cancer, 12 cases of High Grade Squamous Intraepithelial Lesion ('HSIL') (including 7 cases of Cervical Intraepithelial Neoplasia ('CIN') III, 5 cases of CIN II), 110 cases of Low Grade Squamous intraepithelial Lesion ('LSIL') (including 14 cases of CIN I, 96 cases of HPV infection and Condyloma Acuminatum), 59 cases of chronic cervicitis and metaplasia of squamous epithelium. The positive rates of the TruScreen, LCT and HPV tests were **28.16%, 23.27% (7.42%) and 34.27%** respectively.

The sensitivity, specificity and positive predictive value of TruScreen were **76.47%, 77.27%, 13.27%**; those of LCT were **88.24%, 79.68%, 16.48%** (⩾ASCUS is positive result); **70.59%, 95.72%, 42.86%** (⩾LSIL is positive result, ASCUS is border-line), and those of HPV were **94.12%, 68.45%, 11.94%** respectively.

Conclusion

The study indicates that the performance of TruScreen is similar to that of the traditional methods, liquid-based cytology and Hybrid Capture 2/high risk HPV DNA. Due to the time and logistical issues associated with the LCT and HPV testing process, TruScreen offers an improved primary screening solution for cervical cancer.

Key Words: Cervical intraepithelial neoplasia (CIN), Liquid-based Cytology, Hybrid Capture