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# Clinical trial result of FocalPoint Screening system in Uterine Cervical Cytology

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Background : The concordance of FocalPoint guided GS review system with manual screening for identifying atypical cells in Liquid based cervicovaginal cytology preparation(SurePath) was evaluated. The FocalPoint guided GS review system is an automated device which was designed for initial screening of Liquid-Based Uterine Cervicovaginal Cytology(SurePath). The FocalPointed GS review system have been used as a method of quality control in many hospitals, specially in United kingdom. The screening process is going through two stages. The Surepath slides are run through a FocalPoint GS automated imager. Each is scanned and using a series of algorithms which divide those scanned slides into 5 quintiles with each slide having 10 FOV(field of view) that the FocalPoint GS system has detected as may have possibile abnormalities. Then these divided five slide groups are review on the location guided screener. At previous setting system, the FocalPoint GS system used a specific setting algorithm identifies up to 25% of a standard population which require "no further review". All slides which were randomly sampled are equally processed and divided into 5 groups. The Group 4 and 5 means comparative lower possibility of abnormalities in those processing slides. The group 3 has a borderline possibility. The group 1 and 2 means comparative higher possibility of abnormalities.

Aims: we evaluated the false negativity and the concordance of 5 quintile grouping from the FocalPoint guided GS review system and cytologic results from professional cytologists.

Material and Method: Two hundred twenty six slides of liquid based cervical cytology(SurePath System) which were randomly sampled and screened manually were evaluated. By using the FocalPoint GS system, we localized the atypical cells as 10 fields of view(FOVs), which were reexamined by professional cytologists for two times.

Result: Two hundred twenty six slides were categorized into Process review, No further review and each 5 groups by possibility of abnormalities in this population. The process review cases which means unevaluable slides were 10 out of 226 cases(4.4%). No further review cases were 38 out of 226 cases(16.8%) Among them 4 cases were false negative (LSIL 3 cases, ASCUS 1 case). Therefore, the false negative rate of the FocalPoint system was measured 1.8%(4 out of 216 cases). The false negative rate of the Surepath review

system only was measured 5.3%(12 out of 226 cases). The false negative rate was reduced 3.5% by using the FocalPoint system.

In each group, group1 was 35 cases,(15.5%), group2 35 case(15.5%), group3 36 cases(16.0%), group4 35cases(15.5%), group5 37cases (16.4%). The group1 showed 42.8 %(15/35) in LSIL, 40%(14/35) in HSIL, 17%(6/35) in SCC. The group2 showed 5.7 %(2/35) in ASCUS, 40%(14/35) in LSIL, 37.1%(13/35) in HSIL, 14.2%(5/35) in SCC and 2.8%(1/35) in Adenocarcinoma. The group3 showed 27.7%(10/36) in normal cytology, 2.7 %(1/36) in ASCUS, 52.7%(19/36) in LSIL, 8.3%(3/36) in HSIL, 8.3%(3/36) in SCC. The group4 showed 34.2%(12/35) in normal cytology, 2.8%(1/35) in ASCUS, 2.8%(1/35) in ASC-H, 40%(14/35) in LSIL, 17.1%(6/35) in HSIL, 2.8%(1/35) in SCC. The group5 showed 62.1 %(23/37) in normal cytology, 8.1%(3/37) in ASCUS, 24.3%(9/37) in LSIL, 2.7 %(1/37) in HSIL, 2.7 %(1/37) in SCC.

Conclusion: The FocalPoint GS system reduced false negativity of liquid based cervical cytology comparing with manual review system using SurePath system. It can be an efficient screening system to localize atypical cells and reduce the false negativity.