

Evaluation of Hologic Genius Digital Diagnostic System Six Months After Implementation in An Academic Medical Center

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Introduction

Cervical cytology (Pap tests) has been considered one of the most successful cancer screening tests in medical history. However, currently microscopic examination for Pap tests is largely manual and time-consuming. In addition, strict regulations and nationwide workforce shortages further limit the evaluation of Pap tests. Hologic Genius Digital Diagnostic System (HGDDS) is the first FDA approved AI-assisted system for clinical use in screening for cervical cancers. This study evaluates the performance of HGDDS by comparing cytologic diagnoses and quality assurance parameters before and after implementation in our institution.

Material AND Method

Cervical cytology cases examined six months before and after the implementation of HGDDS were extracted from our LIS system. Cytologic diagnosis, atypical squamous cells to squamous cell intraepithelial lesion (ASC/SIL) ratio, abnormal rate, and high-risk HPV status were compared. Pearson's chi-square tests with Bonferroni correction were performed to compare overall rates of diagnoses and HPV status as well as subgroup analysis before and after HGDDS implementation.

Results

A total of 6,280 and 8,487 cervical cytology cases were identified for the periods before and after implementation of HGDDS, respectively. There was no significant statistical difference across the cytologic diagnostic categories except for unsatisfactory cases which were increased after the implementation ($p < 0.001$). ASC/SIL ratio was 2.9 and 2.6, and the abnormal rate was 9.8% and 10.5% before and after the implementation, respectively. There was no significant statistical difference in high-risk HPV status in each diagnostic category. Pap test turnaround time reduced from average 5 days to 2 days.

Table 1. Comparison of the cases distribution in each cytologic diagnostic category pre- and post-HGDDS implementation

Diagnosis	Pre-HGDDS	Post- HGDDS	<i>p-value</i>
NILM/NILM>45	5558 (88.5%)	7371 (86.9%)	0.504
ASCUS	396 (6.3%)	552 (6.5%)	1
ASC-H	43 (0.6%)	60 (0.7%)	1
AGC	24 (0.4%)	30 (0.4%)	1
LSIL	133 (2.1%)	195 (2.3%)	1
HSIL	20 (0.3%)	43 (0.5%)	1
SCC	1 (0.02%)	2 (0.03%)	*
ADC	0	5 (0.06%)	*
UNSAT	105 (1.7%)	229 (2.7%)	<0.001
Total	6280	8487	

Table 2. High-risk HPV status in each cytologic diagnostic category pre- and post-HGDDS implementation

Diagnosis	HPV Positive		<i>p-value</i>
	Pre-HGDDS	Post- HGDDS	
NILM/NILM>45	446 (8.0%)	592 (8.0%)	1
ASCUS	171 (43.2%)	252 (45.7%)	1
ASC-H	38 (88.4%)	52 (86.7%)	1
AGC	4 (16.7%)	7 (23.3%)	*
LSIL	102 (76.7%)	132 (67.7%)	1
HSIL	19 (95.0%)	43 (100%)	1
SCC	1 (100%)	2 (100%)	*
ADC	0	1 (20.0%)	*
UNSAT	6 (5.7%)	11 (4.8%)	1
Total	787	1092	

Conclusion

HGDDS significantly improved screening efficiency with no significant differences in the case distributions in each cervical cytologic diagnostic category except for unsatisfactory cases. This increase in the unsatisfactory rate was likely due to the more accurate cell counts provided by HGDDS over manual microscopic examination. HGDDS may be a good solution for institutions seeking to improve screening efficacy without compromising diagnostic accuracy

