P1610

Testing For Oncogenic HPV in Pap Liquid Preservative Fluid (Tripath SurePath™) Correlates With Cytopathology and Digene Sampler Results

J. Kapala[1], M. Chernesky[2], J. Patel[1], S. Chong[2], D. Jang[2], K. Biers[1], J. Mahony[2]

Gamma-Dynacare Medical Laboratories, Brampton, McMaster University, St. Joseph's Healthcare[2], Hamilton, Ontario CANADA.

REVISED ABSTRACT

Objective: Recent approval by the FDA of adjunctive screening for high risk (HR) HPV with Pap testing led us to examine (a) the utility of the Digene HCII HR-HPV test on specimens collected by the Digene sampler (DS) vs. residuum from the SurePath™ liquid preservative (LP) after Pap testing (b) correlation of HR-HPV test results with Pap cytopathology.
Methods: A total of 320 women consented to the collection of an LP followed by a DS. Samples from Group I (n=106) were tested unfrozen. Discordant samples were freeze-thawed and re-tested twice. Samples from Group II (n=214) were freeze-thawed before testing. Patients were considered infected when positive for HR-HPV in LP and DS, or positive in one sample 2 of 3 times. For LP, a volume of 2ml was used for testing with 90 minutes denaturation.
Results: In group I, 20 were positive in both samples. Retesting 20 discordants increased the positives to 27 and suggested a benefit of freezing to reduce discordancy. In group II, 50 positives matched and 28 were discordant. After discordant analysis, 65 patients were considered positive. Combining the positives of both groups, the LP detected 92.4% (85/92) and DS 83.7% (77/92). Normal cytology was observed in 81.9% (186/227) of the patients negative for HR HPV in contrast to 37.6% (35/93) of those positive for HR-HPV. In the group of women less than 30 years of age (n=87), 50.6% were HR-HPV positive. Of those, 70.5% (31/44) had an abnormal Pap compared to 25.6% (11/43) from the HPV-negative group. Twenty-one percent (49/233) of women ≥ 30 years of age were HPV positive, of which 2 (41%) had carcinomas, 8 (16.3%) HSIL, 8 (16.3%) LSIL, 5 (10.2%) BBC and 22 (44.9%) had a normal Pap. In contrast, HPV negative women in this age group had mostly normal (83.6%) or BCC (11.4%) Pap results. Eleven of 16 women with ASCUS were ≥ 30 years of age but 50% (8/16) were in HPV-infected women.
Conclusions: HR-HPV testing on LP identified most of the infected women. Infection with HR-HPV correlated with cervical abnormalities and demonstrated a potential benefit of HPV testing with Pap to manage ASCUS and other cervical abnormalities.

INTRODUCTION

- On March 31/03, the US-FDA approved high-risk (HR) HPV DNA adjunctive screening for women 30 years and older.
- The DNA with Pap strategy is a combination of Digene's HCII HR-HPV test and a Pap test (conventional or liquid)

OBJECTIVES

1. To compare detection of HR-HPV in SurePath™ liquid preservative Pap residuum to the Digene cervical sampler.
2. To examine the correlation of the HPV test results with the Pap cytopathology according to age.

METHODS

- The Digene Hybrid Capture II assay was used to detect HR-HPV DNA using 2 ml volume.
- The Digene Cervical sampler was collected after the Pap sample.

PATIENT ENROLMENT: 320 women.
Group I (n=106), the samples were tested unfrozen.
Group II (n=214), the samples were tested after a freeze-thaw

A patient was considered infected with HR-HPV if the test was positive in both samples (SurePath™ and Digene Sampler) or repeatedly positive in one of the samples after discordant repeat testing

RESULTS

Table 1: HR-HPV Positives (%) in Two Groups of Women Before and After Re-testing

GROUP	NO.	POS. IN BOTH SAMPLES (%)	DISCORDANT	POS. AFTER RETESTING
I	106	20 (18.8)	20 (18.8)	7 (6.6)
II	214	50 (23.4)	28 (13.1)	15 (7.0)
	320	70 (21.8)	48 (15.0)	22 (6.8)

Total Positives = 92 (28.8%)

Table 2: Detection of HR-HPV Positive Patients

	Positives Detected (%)	
SurePath™ Liquid Pap preservative	85/92	92.4%
Digene sampler specimen	77/92	83.7%

Table 3: Distribution of Pap Results According to Age and HR-HPV Infections in 320 Canadian Women

Pap Results	<30 Years		≥ 30 Years	
	HR-HPV POS	HR-HPV NEG	HR-HPV POS	HR-HPV NEG
Carcinoma	0	0	2 (4.1)	0
HSIL	5 (11.4)	0	8 (16.3)	0
LSIL	21 (47.7)	2 (4.6)	8 (16.3)	2
ASCUS	4 (9.0)	1 (2.3)	4 (8.2)	7
BCC	1 (2.2)	8 (18.6)	5 (10.2)	21 (11.4)
Normal	13 (29.5)	32 (74.4)	22 (44.9)	154 (83.6)
Totals	44	43	49	184

HSIL = High grade squamous intraepithelial lesions
LSIL = Low grade squamous intraepithelial lesions
ASCUS = Atypical squamous cells of undetermined significance
BCC = Benign cellular changes

Table 4: Cytology of 48 Women with Original Discordant HR-HPV Results

Pap Reading	Number (%)
Carcinoma	0 (0)
HSIL	0 (0)
LSIL	4 (8.3)
ASCUS	3 (6.2)
BCC	3 (6.2)
Normal	38 (79.2)

SUMMARY

1. The HR-HPV HCII test performed comparatively on specimens collected by the Digene sampler and the SurePath™ liquid preservative residuum.
2. Most of the uninfected women and those with discordant results had normal cytology.
3. Most of the HR-HPV infected women were recorded with cervical abnormalities, with greater severity in women ≥ 30 years of age.
4. Based on our HPV results, 9 instead of 18 patients with ASCUS could be referred to colposcopy.