ASCCP2018 Late-Breaking Abstracts

Oral Abstract Presentations

Anal/Perianal

Persistent anal HPV16/18 infections as predictors of anal histological HSIL in older MSM

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Background: To assess anal cytology and high-risk HPV testing strategies to predict anal hHSIL in older MSM.

Methods: 183 MSM from a nested cohort anal health substudy of the Multicenter AIDS Cohort Study, had an anal swab tested for cytology and 37 HPV types (Linear Array PCR test) from 2+ visits. Afterwards, all had high-resolution anoscopy (HRA) with biopsy, classified as hHSIL vs. <hHSIL. Multivariable logistic regression models assessed five hHSIL screening test strategies: any abnormal cytology (abCyt), persistent positivity (positive at >2 consecutive visits) for HPV16/18 (pHPV16/18+), and persistent positivity for Group 1 hrHPVs (pGroup 1+) [i.e., HPV16/18/31/33/35/39/45/51/52/56/58/59]; two combined serial strategies were assessed: abCyt & pHPV16/18+, and abCyt & pGroup 1+.

Results: Men were, on average, 59 (+8) years old, HIV-infected (58%), and White, non-Hispanic (87%); and 54% had hHSIL. 73% of all men had abCyt, 44% had pHPV16/18+ and 87% had pGroup 1+ by their HRA visit. Multivariable models showed men with abCyt had 2-fold higher odds of hHSIL (OR=2.2 (95% CI: 1.1, 4.7)), men with pHPV16/18+ had 3.6-fold (1.8, 7.2) higher odds, and pGroup 1+ was not associated (OR=1.5 (0.6, 3.7)). Combined positivity for abCyt and pHPV16/18+ had 3.6-fold (1.7, 7.3) higher odds of hHSIL; positivity for abCyt and pGroup 1+ yielded 2.3-fold (1.2, 4.6) higher odds.

Conclusions: Strategies with persistent PCR-based HPV16/18 testing appear similarly effective as strategies with abCyt for detecting hHSIL in older MSM. High prevalence of hHSIL is consistent with high rates of anal cancer in HIV-infected MSM, suggesting more research is needed to improve screening.

Pilot study of markers for high-grade anal dysplasia in a southern cohort from the Women's Interagency HIV Study (WIHS)

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Background: Anal cancer rates have increased in HIV+ women. Factors associated with anal cancer precursor high-grade squamous intraepithelial lesions (HSIL) in HIV+ and at-risk-HIV- women were assessed.

Methods: HIV+ and HIV- women from the Atlanta WIHS cohort were enrolled in a cross-sectional pilot study. All anal (AS) and cervical (CS) swab samples were analyzed for HPV-genotyping (Linear-Array® HPV-Genotyping Test, LA-HPVGT) and FAM19A4 and microRNA-124-2 promoter methylation. All women underwent high resolution anoscopy with biopsy of suspicious lesions and anal cytology (AC) collection. Logistic regression was conducted with anal HSIL histology (A-HSIL) as the dependent variable.

Results: 75 women were enrolled: 52(69%) were HIV+ with 3/4 having undetectable viral load, 64(86%) Black, with mean age 49. 44(59%) AC samples were ASCUS/+hrHPV or higher, 38(51%) of all AS were +hrHPV by LA-HPVGT.13 anal biopsies were confirmed A-HSIL. 69(95%) AS and 19(26%) CS tested positive for hypermethylation, respectively. A-HSIL model included ASCUS/+hrHPV or greater on AC and cervical hypermethylation as covariates (Table 1). AS hypermethylation was not associated with A-HSIL.

Table 1. Logistic regression model for anal HSIL histology					
Variable	**Estimate**	**SE**	**p-value**	**OR**	**OR 95%CI**
Anal cytology: ASCUS/+hrHPV or greater (ref: NILM or ASCUS/-hrHPV)	1.56	0.71	0.0283	4.78	1.18-19.31
Cervical hypermethylation	1.62	0.68	0.0174	5.03	1.33-19.04

Conclusions: Our results suggest AC with hrHPV testing and/or cervical gene promoter hypermethylation measurements as promising non-invasive screening strategies for A-HSIL in both HIV+ and HIV- women. Lack of association between AS hypermethylation and A-HSIL may reflect characteristics of the anal milieu and warrants further investigation.

Basic Science

Isothermal HPV mRNA amplification for cervical cancer screening in resource-limited settings

Kathryn Kundrod[1], Chelsey Smith[1], Philip Castle[2], Kathleen Schmeler[3], Rebecca Richards-Kortum[1]. [1]Rice University [2]Albert Einstein College of Medicine[3], MD Anderson Cancer Center

Background: This study presents work towards the development of an HPV mRNA test for cervical cancer screening in resource-limited settings. Detection of E7 mRNA overexpression aims to achieve comparable sensitivity to DNA testing and specificity to oncoprotein testing for enhanced detection of cervical pre-cancer. Here, proof-of-concept work toward an isothermal, point-of-care HPV 16 E7 mRNA test is presented.

Methods: Synthetic DNA was used as a standard, and mRNA was extracted from SiHa cells and reverse transcribed. Quantification was performed by qPCR; isothermal amplification was performed with recombinase polymerase amplification (RPA). RPA reactions were peformed at 37 degrees C for 30 minutes, and amplicons were detected by gel electrophoresis.

Results: Using synthetic HPV 16 DNA for initial experiments, amplification down to concentrations of 100 copies/uL was demonstrated. Proof-of-concept amplification of E7 cDNA from SiHa cells was also shown. The RPA assay showed variability within conditions and requires further optimization.

Conclusions: In its current form, this assay relies on standard laboratory equipment. To translate this test to resource-limited settings, test components will be incorporated into a paper and plastic device, which has previously been demonstrated with RPA for HIV detection [1]. Next steps will include assay optimization to reduce variability and testing with clinical samples. With a fully integrated HPV mRNA paper-based test, more specific cervical pre-cancer screening could be achieved at a lower cost than with currently available commercial tests.

[1] BA Rohrman and RR Richards-Kortum. Lab Chip. 2012; 12(17):3082-8.

Colposcopy

ASCCP guideline change and management of the abnormal pap smear—accurately targeting intervention

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Background: To examine how changes to the American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines impact distribution of high-grade dysplasia and cancer as well as rates of intervention among patients with abnormal cervical cancer screening.

Methods: A prospective registry of 6,455 patients treated between January 2007 and December 2017 at a specialized center for evaluation of abnormal pap smear screening was queried to examine trends in patient characteristics, cytology results, histologic diagnoses, and interventions.

Results: Results: Mean patient age was significantly higher in 2017 compared to 2007 (38.0 years vs. 27.0 years; p<0.0001) and fewer pregnant patients were served (2.9% vs. 9.8%; p<0.0001). Rates of completed human papilloma virus (HPV) vaccination were lower in 2017 compared to 2007 (82.6% vs. 91.5%; p<0.0001). High-grade cytology represented a higher proportion of the referral base in 2017 than in 2007 (17.8% vs. 9.7%; p=0.007), as did patients testing positive for HPV (23.7% vs. 12.6%; p<0.0001). Patients diagnosed with high-risk histologies like cancer, adenocarcinoma in situ, or high-grade squamous intraepithelial lesion represented a larger proportion of the referral base in 2017 compared to 2007 (38.2% vs. 28.8%; p<0.0002). There was no statistical increase in cervical cancers diagnosed during this time interval (1.3% in 2017 vs. 0.2% in 2007; p=0.12). There was, however, a decrease in the percent of visits involving colposcopy in 2017 compared to 2007 (45.4% vs. 77.1%; p<0.0001).

Conclusions: Findings from this large prospective registry suggest that the ASCCP guidelines have functioned as intended in identifying high-grade dysplastic changes, minimizing unnecessary intervention, and optimizing excisional treatment decisions, especially in younger patients.

Other

Registered Nurse Management of HPV and Pap Results

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Background: The nursing program was designed to offer timely management of Pap and HPV results with intensive patient education while decreasing provider result management work.

Methods: After acquiring laboratory volumes for Pap and HPV testing over a year for the health group (IM,FP,Ped, OB GYN providers), RN FTEs were allocated to the program. With the assistance and approval of a medical director (OB GYN), a nursing protocol and operational workflow were designed based on the ASCCP guidelines for screening and follow up. Provisions were made for the patient specific documentation of the managing provider. RNs underwent a specialized education curriculum and competency was tested. Laboratory results were routed via the Electronic medical record to the program nurses. Nurses called each abnormal result, provided education to the patient and scheduled the follow up testing required. Standardized mail / email educational materials and information was sent reinforcing the conversation. Patients with abnormal results were tracked by the program to insure timely follow up testing is completed. The nurses managing the work were located in a centralized location and telecommuting positions. Quality evaluation was conducted monthly on each nurse to evaluate productivity, adherence to protocol and guidelines. In the implementation phases providers received FYI encounters on all abnormal results after nurse management.

Results: In 2016 the nurses managed 73,531 Pap results ordered by primary care providers and OBGYNs. Additionally nurses managed 11,000 HPV results and added on 8659 HPV tests. Nurse average quality for 2016 was 96% on all encounters evaluated when results were applied to the ASCCP algorithms. Time from result to patient contact was decreased from 251.69 hours to 10 Hours (normal results) and 3 hours (abnormal results). Patient education was enhanced. Patients were provided with standardized educational materials (not previously sent by providers providing test results). Providers in the system were "given back" 19,619 Hours to provide care with the nurse management of the results.

Conclusions: RN management of pap and HPV testing resulted in decreased time from lab result to patient outreach and communication, increased provider access by decreasing electronic work, and provided more robust individualized patient education.

Vulvodynia and Vulvar Pain

Prevalence of vulvodynia in transgender men

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Background: The prevalence of vulvodynia, defined as idiopathic vulvar pain of at least 3 months' duration, has not been studied in the transgender male population. The goal of this study is to determine the prevalence of vulvodynia

and its' relationship to hormone therapy in transgender men.

Methods: Transgender men ages 18-64 participated in an online survey that included demographics, medical history, and perceptions of the healthcare system. They were also asked about their reproductive history, hormone usage, and vulvodynia symptoms. Descriptive statistics were used to analyze the data.

Results: 268 transgender men completed the survey. Mean age was 25.3 (SD 8.6). 232 (87%) identified as white, 165 (62%) had private health insurance, and 95 (35%) graduated from college. 160 (60%) were currently on systemic testosterone. 52 (25%) have undergone gender related surgery. 133 (51%) were sexually active. 17 (7%) have experienced itching, burning or knife-like pain in the vulvo-vaginal area for more than 3 months. Of those, 7 (5%) were on systemic testosterone.

Conclusions: The prevalence of vulvodynia has not been determined in the transgender male population. It does not appear that testosterone increases the risk of vulvodynia. Further research is warranted to clarify the impact of vulvodynia in transgender men.

Poster Presentations

Anal/Perianal

Poster # 063

Serological Measures of Sex Hormones Are Associated with Anal Histological HSIL Risk Among MSM

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Background: Higher serum free testosterone (FT) is associated with increased prevalence of anal HPV16/18 infection in MSM. However, sex hormone associations with anal histological high-grade squamous intraepithelial lesions (hHSIL) have not been assessed.

Methods: 214 HIV+ and HIV- MSM from the Multicenter AIDS Cohort were seen for 336 High-Resolution Anoscopy (HRA) exams. Serum collected 24(+9) months prior was tested for albumin, SHBG (radioimmunoassay), and Total Testosterone and Estradiol (TE2) (LC/MS); serum FT (pg/mL) was estimated. Anal swabs were tested for 37 HPVs (PCR). High-risk (hr) HPV positivity was grouped as HPV16/18+, other Group 1+, and Group 2+; remaining HPVs were low-risk (lrHPV+). HRA biopsies were classified as hHSIL vs. <hHSIL. Self-reported sociodemographic/behavioral characteristics were collected. Multivariable adjusted GEE logistic regression models assessed relationships between log-transformed FT, TE2, and hHSIL.

Results: Men were 59 (IQR: 53-64) years old, White non-Hispanic (80%), ever-smokers (80%) and HIV+ (61%); 51% had hHSIL. Men with hHSIL reported more recent anoreceptive partners than those with <hHSIL: (25 vs. 13 partners, p=0.03). Higher FT was not associated with hHSIL (OR=0.9 (0.7, 1.3)). Each log (2.7-fold) higher TE2 was associated with reduced odds of hHSIL (OR=0.5 (0.3, 0.9)). Compared to men without HPVs or only lrHPV+, HPV16/18+ men had more hHSIL (OR=4.3 (1.7, 10.7)); other HPV+ groups did not (p>0.05).

Conclusions: FT was not associated with hHSIL prevalence; however, higher TE2 was associated with lower hHSIL. FT may influence hHSIL indirectly. More research is needed to examine the influence of testosterone on estradiol bioavailability.

Cervical Cancer

Poster # 064

Implementation of a Clinical Decision Support System for Cervical Cancer Screening and Surveillance

Kathy MacLaughlin[1], Ravikumar Komandur Elayavilli[1], Maya Kessler[1], Walter Kremers[1], Kavishwar Wagholikar[1], Branden Hickey[1], Marianne Scheitel[1], Darrell Schroeder[1], Hongfang Liu[1], Rajeev Chaudhry[1]. [1] Mayo Clinic

Background: Evaluate the impact of implementing a clinical decision support system (CDSS) with real time CDSS-generated alerts to clinicians on cervical cancer screening and surveillance rates.

Methods: We previously developed a complex CDSS based on national guidelines for cervical cancer screening and management with 13 screening pathways and 41 pathways for surveillance, defined as high-risk patient screening or follow-up of abnormal Pap, HPV or colposcopy. Big data infrastructure was utilized to process and then incorporate the CDSS into electronic health records to provide a screening or surveillance recommendation to the clinician.

Results: 1307 patients with a visit in which the clinician received CDSS recommendation had Pap or Pap/HPV co-test completion rates of 60.8%, compared with 32.6% of 1150 historical control patients with no clinician CDSS alert ($p < 0.001$). However, significant gains were seen in the screening population only.

Conclusions: CDSS-generated alerts for clinicians were associated with improvement in cervical cancer screening rates but no impact was seen in the patient population overdue for surveillance testing. Clinicians may not have understood or trusted the more complex recommendations. A study of targeted patient reminders to high risk women identified by CDSS was completed just prior to implementation of real time alerts for clinicians. This may have limited our ability to study the effectiveness of this intervention for surveillance. Further study targeting the high risk population is warranted.

Poster # 065

Concordance of Pap Tests in Patients with Two Cervices, a Case Series

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Background: Uterine developmental abnormalities are relatively common and often underdiagnosed. The resultant complete or partial failure of fusion of müllerian ducts can lead to a duplicated cervix with or without a transverse vaginal septum. One might expect equal risk of HPV infection, cervical dysplasia, and cancer in both cervices due to shared stroma, equal exposures, and immune responses. However, a number of case reports demonstrate discordant pathology in this population. We present the first case series of patients with two cervices to characterize the incidence of discordant findings on paired pap smears and discuss influencing characteristics.

Methods: Patients with cervical duplication were identified by querying the laboratory information system and details regarding anatomy and interventions investigated via chart review of the electronic medical record.

Results: One hundred and thirteen samples were identified and reviewed from sixteen patients with two cervices. Eight of the sixteen patients had multiple unoriented and/or unilateral pap tests. Diagnoses included twelve ASCUS, six LSIL, and nighty-four NILM. Seven instances of Pap test discordance were noted involving five patients, with varying anatomic configurations.

Conclusions: A number of patients received pap tests of a single cervix with laterality not specified. Highlighting the importance of sampling and documentation, patients with poorly visualized or difficult to access cervices may not have adequate testing and potential misdiagnoses. In cases of discordant results with one side reported as negative, the question of whether both sides are sent for reflex HPV testing needs to be addressed.

Colposcopy

Poster # 066

Using a New Hand-Held Colposcope in Combination with Cryotherapy and LEEP in a See-And-Treat Screening Program

Ameila Goldstein[1], Prachi Godiwala[2], Tierney O'Keefe[3], Lena Goldstein[1], Karen O'Keefe[4], Casey O'Keefe[5], Andrew Goldstein[1]. [1]Center for Vulvovaginal Disease [2]George Washington University [3]Squalitum High School 4 Bellingham Bay Family Medicine [5]Pacific Northwest Urology Specialists

Background: Logistical and economic issues make traditional cytology-based cervical cancer screening challenging in developing countries. As such, see-and-treat programs using VIA have been developed. However, there are several limitations to VIA. VIA can be affected by poor visual acuity of the examiner, a dim light source, and inadequate training. In addition, it produces no permanent image for documentation or quality control. However, advances in optical technology have the potential to alleviate these deficiencies.

Methods: 250 Peruvian women living in the Amazon basin were screened using a hand-held digital colposcope based on smartphone technology (EVAtm system, MobileODT, Israel). All women who were positive during screening had biopsies. Women suspected of having low-grade lesions were treated with cryotherapy. Women suspected of having high-grade lesions were treated with LEEP.

Results: 26 women screened positive during colposcopy. Of the 20 women who were suspected of having low-grade dysplasia, 15 had CIN 1 and 5 were negative for dysplasia. Of the 6 women suspected of having high-grade dysplasia, 1 had cervicitis, 2 had CIN2, and 3 had CIN3. Of the 4 women suspected of having invasive carcinoma, 3 had invasive cancer and one had severe cervicitis.

Conclusions: Digital colposcopy with EVAtm has many benefits and eliminates many of the deficiencies of VIA. It takes extremely high-quality digital cervicographs that can be used for documentation and quality control. The digital cervicographs are uploaded to a cloud-based portal to facilitate consultation with expert colposcopists. Lastly, it can help to distinguish between high-grade and low-grade lesions.

Poster # 067

The Effect of Cervical Transformation Zone on the Colposcopic Diagnosis of Cervical Intraepithelial Neoplasia

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Background: To analyze the effects of cervical transformation zone (TZ) on the colposcopic diagnosis of cervical intraepithelial neoplasia (CIN).

Methods: We retrospectively evaluated 482 patients who underwent conizaion between September 2012 and September 2016. The cytology, colposcopic impressions, and histological diagnoses from biopsy and cone specimens were compared.

Results: An agreement of 88.1% was observed between high-grade cytology and final histological diagnoses among the three TZ types. Significant differences between the colposcopic impressions and final histological diagnoses were observed for TZ type 1 and 2 versus type 3. The overall agreement was 89.1% regarding the histology findings on colposcopically directed biopsy (CDB) and cone specimens, which correlated significantly with TZ (p=0.004) and the number of cervical biopsies (p=0.032). The agreement between histology results on endocervical curettage (ECC) and the final histology results was 28.24% in the patients with TZ type 3.

Conclusions: Cervical TZ types variably influence colposcopically diagnostic accuracy for CIN, and TZ type 3 was associated with the lowest accuracy.

Poster # 068

Pregnancy After Cervical Conization or Loop Electrosurgical Excisional Procedures: How Many Is Too Many?

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[1]Brigham and Women's Hospital [2]Massachusetts General Hospital

Background: Pregnancy after cervical conization or loop electrosurgical excisional procedures: how many is too many?

Methods: This was a retrospective cohort of women who underwent at least one cervical conization and had documentation for the next pregnancy recorded at an affiliated tertiary care institution between January 1, 2000 and June 1, 2014. Only women with singleton gestations and documentation of cervical length after 16-20 weeks were included. Cone and loop electrosurgical excision procedure (LEEP) characteristics were taken from pathology reports. Hazard ratios were obtained from Cox regression models.

Results: Fifty-three women met inclusion criteria. Of these, 27 women had one cold knife or loop cervical conization and 26 had at least one cone plus additional cervical procedures prior to pregnancy. All median cervical lengths were normal. For women with one prior cone, the median cervical length at the 16-20 week survey was 3.9 cm; for women with two or more prior procedures, the median cervical length was also 3.9 cm (p=0.81, Table 1). In a survival analysis, women with two or more procedures had over a two-fold increase hazard for early delivery early than those who had one after controlling for cerclage and BMI (hazard ratio (HR) 2.0, 95% CI 1.07-3.89). Total depth excised in all procedures was also associated with preterm birth (OR 2.6, 95% CI 1.3-5.2).

Conclusions: Women with multiple cervical procedures can remain at increased risk of preterm birth despite having a normal cervical length.

HPV Screening and Management

Poster # 069

Characteristics of Cervical LEEP and Association with Cervical Length and Delivery Outcomes in the Subsequent Pregnancy

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Background: To establish median cervical length in the pregnancy after LEEP and to identify any characteristics of LEEP or resultant pathology associated with adverse pregnancy outcome.

Methods: This is a retrospective cohort analysis of women who underwent one cervical LEEP and had subsequent prenatal care and delivery at the same institution between July 1, 1994 and July 1, 2015. Women with multiple gestations, multiple LEEPs, or incomplete records were excluded. Size of specimen excised and pathology were abstracted from pathology reports. Cervical lengths were taken from the radiologic record. Obstetric outcomes were abstracted from the delivery record.

Results: A total of 92 women met inclusion criteria. The most common pathological diagnosis was CINII/III (67.4%). Median cervical length was 3.6cm (interquartile range (IQR) 3.3-4.0cm). Median gestational age at delivery was 39.0 weeks (IQR 37.9-39.9 weeks) and 11 (12%) women had a preterm delivery (<37 weeks). When stratified by low grade (benign or CIN I) versus high grade dysplasia (CIN II/III or ACIS), there was no difference in cervical length at 16-20 week ultrasound (3.6cm vs 3.6cm, p=0.8) or preterm delivery (13.8% vs 11.1%, p=0.70). The median depth of LEEP specimen was 0.7cm (IQR 0.5-1.0cm). Depth of excision of LEEP or calculated volume of tissue removed did not affect the risk for preterm delivery (p=0.16 and p=0.28, respectively).

Conclusions: In this cohort, median cervical length was normal and preterm birth rate was within the expected range among the general population. Midtrimester cervical length, LEEP characteristics, and pathologic diagnosis were not associated with increased risk of preterm birth, adding to literature questioning the association of LEEP with preterm birth.

Poster # 070

Expression Profile of CK7 and p16ink4a in Cervical Intraepithelial Neoplasia and Correlation with Clinical Outcome

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Background: This immunohistochemical study aimed to evaluate the p16 and CK7 expression profile in different degrees of cervical squamous intraepithelial neoplasia (CIN), and non-neoplastic cervical tissue.

Methods: Formalin-fixed paraffin-embedded (FFPE) tissue samples included 100 cervical biopsies of precursor lesions distributed into CIN 1, CIN 2, CIN 3 groups and 47 samples in the non-neoplastic group. Immunohistochemistry assay was performed in tissue microarray and the 4 µm tissue section with antibody clone G175-405 for p16ink4a at a dilution of 1:50 (Zeta Corporation) and the pre-diluted FLEX antibody clone OV-TL 12/30 for CK7 (Dako). Quantitative variables and clinical outcome were analyzed by Kruskal-Wallis and Chi-square or exact Fisher tests, respectively ($P < 0.05$).

Results: CIN 1 and CIN 2 groups' clinical follow-up showed that most patients had a favorable outcome. CIN 1 group showed the p16ink4a or CK7 isolate immunoexpression had a greater sensitivity and negative predictive value as well as relevant specificity estimate. p16ink4a positive predictive value was greater than CK7. Combined expression profile of p16ink4a and CK7 showed that the sensitivity, specificity and positive and negative predictive values had the maximum index in CIN 1 group. Combined expression of p16ink4a and CK7 showed that 85.7% of patients presented unfavorable clinical outcome with the positive expression for both markers in CIN 2.

Conclusions: CK7 and p16ink4a combined immunoexpression showed a better diagnosis of cervical lesions and the negative expression in CIN 1/2 groups had a greater negative predictive value for patients' clinical outcome.

Poster # 071

Efficacy of a Coriolus Versicolor-Based Vaginal Gel in High Risk HPV+ Women. Preliminary Results.

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Background: To evaluate the efficacy of Papilocare® -a Coriolus versicolor-based vaginal gel- to clear HPV and to normalize pap smear in high risk HPV+ women.

Methods: An exploratory, prospective, observational non-controlled study. High risk HPV+ vaccinated and unvaccinated women older than 24 years were included during routine follow-up visits and treated with Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months (except menstrual days). Primary endpoint: composite efficacy variable consists of percentage of patients with normal pap smear and/or HPV clearance at month 6 vs baseline. Secondary variable: percentage of patients clearing HPV 16-18 vs baseline.

Results: A total of 86 patients, mean age 42.1 years (24 to 81) were included. At 6 months, 53% of women negativized pap smear and/or cleared HPV and were classified as responders to treatment. A total of 25 patients were positive to HPV 16-18 at baseline (12 and 13 with positive and negative pap smear, respectively). Overall, at 6 months, 48% of these patients cleared HPV 16-18 (50% and 46% of patients with positive and negative pap smear, respectively).

Conclusions: In these preliminary analyses, Papilocare® shows positive trend to improve pap smear alterations and HPV clearance in women infected by high risk HPV, after 6 months; these findings need to be confirmed upon analyses completion

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Poster # 072

Analysis of 2318 Cases of Human Papillomavirus Genotyping and the Related Factors

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Background: To investigate the distribution of human papillomavirus genotypes which were screened in the gynecological out-patients of Nanjing Drum Tower Hospital, as well as its correlation with women's age and seasons, and to calculate the clearance time of the virus, in order to make a contribution to the theoretical basis of cervical disease prevention and treatment.

Methods: A retrospective study of the results of HPV genotyping out of cervical samples from 2318 volunteers were performed to work out the correlation between the distribution of the HPV genotypes and patients' age as well as seasons. Then We selected only the ones who were the first time to be found out HPV infection, and followed them up and redid HPV genotypes every 3 months until they became negative to calculate the HPV clearance time.

Results: The results of HPV genotyping of 2318 cases: 908 cases turned out negative, and 1410 positive (60.83%), the most common genotypes of high-risk HPVs were HPV16, 58, 52, 31, 53 and 33, while those of the low-risk HPVs were mainly HPV81 (CP8304), 11 and 6. The infection rates of High-risk HPV varied with age. 1) ≤ 53 years old group: 537 cases, 285 of which were high-risk HPV positive (53.07%). 2) 31-40 years old group: 791 cases, 431 of which were high-risk HPV positive (54.49%). 3) 41-50 years old group: 642 cases, 346 of which were high-risk HPV positive (53.89%). 4) 51-60 years old group: 272 cases, 121 of which were high-risk HPV positive (44.49%). 5) ≥ 76 years old group: 76 cases, 28 of which were high-risk HPV positive (36.84%). The difference of the infection rates among the groups was statistically significant (P <0.05). The infection rates of high-risk HPV also varied with seasons. The total number and the high-risk HPV positive number in each season were 766 and 442 (57.70%) in spring, 628 and 356 (56.69%) in summer, 413 and 228 (55.21%) in autumn, 511 and 254 (49.71%) in winter, respectively. The difference of the infection rates among the groups was statistically significant (P <0.05). There was a statistically significant difference between the infection rate in winter and that in spring or summer (P <0.05). There was no statistically significant difference (P> 0.05) besides. The distribution of HPV genotypes in four seasons: 1) The most common HPV types in spring were HPV16 (12.92%), HPV58 (12.14%), HPV52 (9.92%) and HPV31 (7.31%); 2) The most common HPV types in summer were HPV16 (16.88%), HPV58 (9.55%), HPV52 (9.39%) and HPV18 (6.69%); 3) The most common HPV types in autumn were HPV11 (16.22%), HPV58 (10.65%), HPV52 (10.65%), HPV33 (6.30%) and HPV18 (4.73%); 4) The most common HPV types in winter were HPV16 (10.57%), HPV58 (10.18%), HPV52 (8.81%), HPV31 (5.68%) and HPV53 (5.68%). A total of 99 women who were the first time found HPV positive, and routinely redid HPV genotypes every 3 months till negative. There were 72 cases of high-risk HPV infection, and the average clearance time of HPV among those cases was 268.53 days. Particularly the average clearance time of HPV16 among those cases was 272.23 days. There were 27 cases of first-found low-risk HPV infection, and the average clearance time was 219.19 days. The clearance time was contained within 3-12 months in 50% of all 99 high-risk HPV positive women while the median clearance time was 182 days.

Conclusions: The most common high-risk HPV genotypes that screened in the gynecological out-patients of Nanjing Drum Tower Hospital were HPV16, 58, 52, 31, 53 and 33, while the most common low-risk HPV genotypes were HPV81(CP8304), 11 and 6. The infection rate of high-risk HPV varied with age and the higher stage of age was ≤50 years old, while the rate declined after 51 years old. The infection rates of high-risk HPV also varied with seasons. The rate in spring or summer was higher than that in winter, and there was no statistically significant difference besides. The distribution of HPV types in four seasons are slightly different. HPV16/58/52 are most common in all seasons. In addition, HPV31 is common in spring, while HPV18 is common in summer, and HPV33 is common in autumn. 5. In our study, the clearance time was contained within 3-12 months in 50% of all 99 high-risk HPV positive women while the median clearance time was 182 days.

HPV Vaccination

Poster #073

Tablet-Based Patient Education Regarding Human Papilloma Virus (HPV) Vaccination

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Background: The aim of the study is to assess the efficacy of electronic tablet-based education regarding human papilloma virus infection and prophylactic vaccination among women presenting for their initial appointment in a specialized pap smear evaluation clinic.

Methods: A prospective study was conducted of all new patients presenting to the pap smear evaluation clinic. Each new patient was approached by a patient navigator and, if willing to participate, took a 4 question pre-test and then completed an education module on the electronic tablet followed by a 5 question post-test. The questions and module focused on the pathogenesis of cervical abnormalities and the connection between HPV and cervical cancer. All materials were available in both English and Spanish.

Results: Between June 2017 and December 2017 118 patients voluntarily participated in the tablet education. One-hundred and nine patients (92%) were English speaking. Following the tablet education, 108 (92%) of women identified cervical cancer as a problem that can be caused by HPV, as compared to 104 women (88%) in the pre-test. Knowledge of head and neck cancer as a problem that could be caused by HPV was also increased from 10% to 77%. Before the module, 76% of women answered that they would definitively recommend the HPV vaccine for a child in their family. In the post-test 83% of women answered "definitely would". Eighty-nine percent of patients rated the tablet module as "extremely" or "very" helpful.

Conclusions: Tablet –based education improves patient knowledge of HPV-associated cancers and is feasible in an outpatient clinic setting.

Other

Poster # 074

Preferences for Home-Based Self-Sampling Versus Clinic-Based Cytology Testing for Cervical Cancer Screening

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Background: To compare preferences (utilities) for home-based self-sampling (with mailed-in samples) and clinic-based cytology testing and to identify factors associated with a preference for home-based self-sampling.

Methods: We conducted a cross-sectional study of 262 women ages 21-65 at two clinics in San Francisco. Participants completed a questionnaire and computerized time trade-off assessments of cervical cancer screening scenarios. Mean utility scores were determined for two pairs of scenarios: normal home-based self-sampling results versus normal clinic-based testing results, in both the present year and in the past. We used multivariate outcome models that simultaneously modeled outcomes describing both paired scenarios and allowing for comparison of intra-pair utility means while adjusting for covariates.

Results: Clinic-based testing had a higher mean utility than home-based self-sampling in the present year (0.965, 0.949) and in the past (0.972, 0.951), indicating a preference for clinic-based testing over self-sampling in the context of normal test results. Overall, model-predicted utilities adjusted for sociodemographic and clinical factors were significantly higher for clinic-based testing compared to home-based self-sampling in the present and past. Income had an interaction effect in scenarios describing the two methods in the present ($p=0.017$) and past ($p=0.0005$). At the highest income level, the mean utility for home-based self-sampling was higher than clinic-based testing (present: 0.983, 0.961; past: 0.984, 0.944); this pattern was reversed at the lowest income level (present: 0.957, 0.990; past: 0.939, 0.986).

Conclusions: On average, women preferred clinic-based testing to home-based testing. Preferences vary, however, with higher income women tending to prefer home testing.

Underserved Populations (Transgender, Homeless, Native American, etc.)

Poster # 075

Gynecologic Screening for Men in an OBGYN Resident Community Outreach Clinic: The Transgender Care Experience

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Background: To promote the importance of providing gynecologic screening for transgender men (TGM) who desire to keep their female organs while developing an educational program for OBGYN providers.

Methods: In June 2015, the Womens' Health Center (WHC) at Reading Hospital, the site for OBGYN resident ambulatory education, was approached to become a resource for transgender (TG) patients. This also presented the opportuntiy to develop an educational program for providers in TG healthcare. From June 2015 till August 2016, when we saw our 1st patient, allowed us time to educate ourselves, establish standards of care, collaborate with other services, and reach out to the community. We present our experience in developing our program and experiential data from 16 months of practice in caring for TGM.

Results: The primary outcome was the development of a comprehensive service for TG patients and an ongoing educational opportunity for providers and staff. We will present a development time line. The following table is some of our intial experiential data which has received IRB exempt designation and will be compared to total WHC data.

Total TG Patients	New TG Patients	TGM Patients	TGM PAP Smears	TGM STI Screen
70	20	23	5	14

Conclusions: Addressing the gynecologic needs of TG patients requires sensitivity, compassion, and education of patients and providers. Servicing the transgender community is an important aspect of care for OBGYN providers. TGM have similar gynecologic needs as other female patients.

Vaginal Intraepithelial Lesions and Neoplasia

Poster # 076

The Roles of Colposcopy and Vaginectomy in Early Diagnosis of Vaginal Cancer After Hysterectomy

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Background: To investigate the values of cytology, hrHPV, colposcopy, transvaginal sonography (TVS), magnetic resonance imaging (MRI) and vaginectomy in early diagnosis of vaginal cancer after hysterectomy.

Methods: A retrospective study was performed in Obstetrics and Gynecology Hospital of Fudan University. Patients diagnosed with high-grade vaginal intraepithelial lesions (HSIL) by colposcopy-directed biopsy after hysterectomy and underwent vaginectomy were included from 2008 to 2017.

Results: Eighty-six patients were diagnosed with vaginal HSIL by colposcopy-directed biopsy. Abnormal cytology and positive hrHPV accounts for 96.1% and 96.2%. A total of 18.6% (16/86) of patients were diagnosed with squamous cell cancer by vaginectomy, with the median interval between hysterectomy and vaginectomy 2.5 years. Among cancer, 93.7% occurred after hysterectomy for cervical precancer (31.2%) and cancer (62.5%); 6.3% for myoma. None of 86

patients showed an abnormal vaginal apex via TVS. Two of 6 abnormal vaginas and 7 of 14 normal vaginas on MRI were confirmed cancer. In colposcopy impression, cancer was diagnosed was in 30.2% (13/43) of patients with suspicious cancer and 9.7% (3/31) with insufficient inspection. Vaginal vaginectomy showed significantly less operation time and blood loss than laparoscopic vaginectomy (P=0.014, P=0.039). However, one patient diagnosed with vaginal HSIL by vaginal vaginectomy was found pelvic cancer recurrence 11 months after vaginal vaginectomy.

Conclusions: Colposcopy is pivotal in evaluation of abnormal cytology/hrHPV tests after hysterectomy and decision making of vaginectomy to detect early cancer. Laparoscopic vaginectomy can examine and remove both the pelvic and vaginal lesions more thoroughly, but with more surgical difficulty than vaginal vaginectomy.