Incidence, associated factors, genotypes and predictors for clearance HPV infection and abnormal cervical lesions in women in south western Uganda

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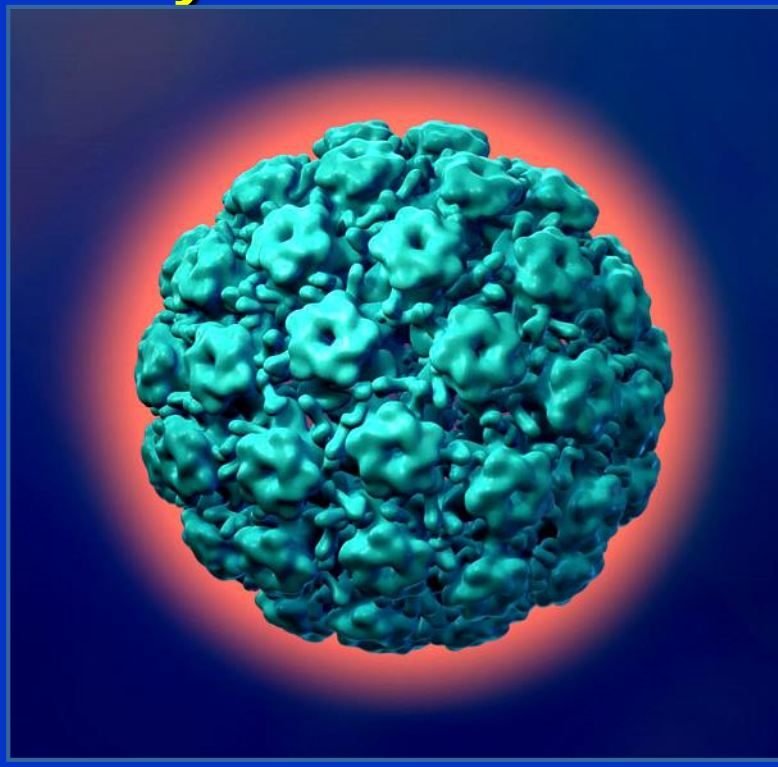
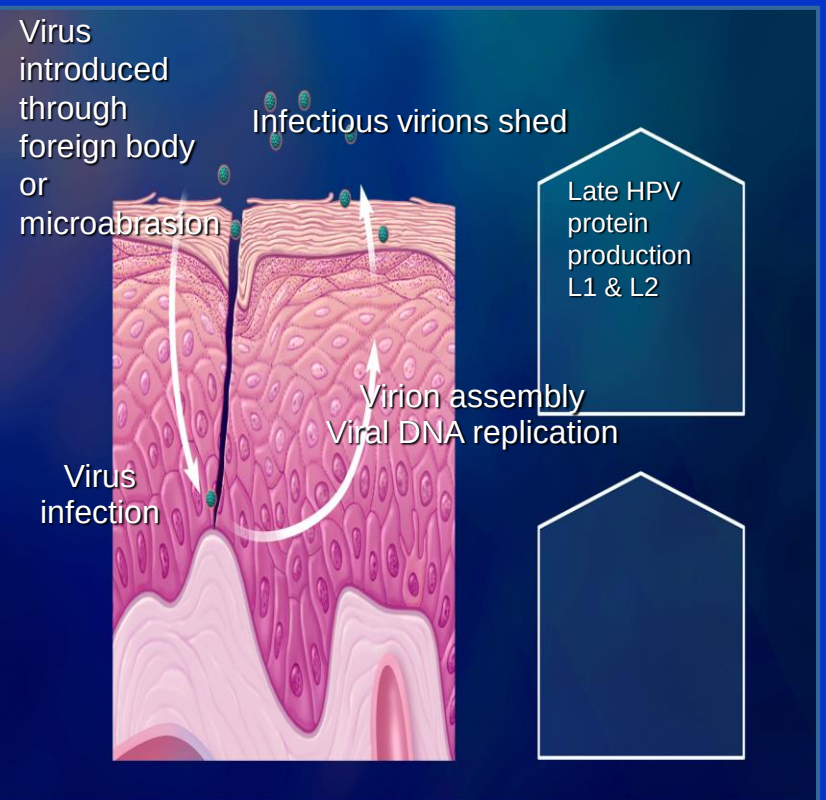
Background: HPV- A necessary cause for Cervical Cancer

- Bosch et al

Analysis of 932 specimens from women in 22 countries indicated prevalence of HPV DNA in cervical cancers worldwide = 99.7%.[2]





- >100 types identified
- ~30–40 anogenital
  - ~15–20 oncogenic

  Most common in ICC 16; 18; 33;31; 35;45;52;58;

Muñoz N, Bosch FX, de Sanjosé, et al. *N Engl J Med*. 2003;348:518–527. 2. Walboomers JM, Jacobs MV, Manos MM, et al. *J Pathol*. 1999;189:12–19.

Background

- Consistent evidence of association btn HPV and pre-cancer and cancerous cervical lesions
- Attributable fraction of cervical cancers due to HPV-82% in developed countries versus 91% in low resource countries
- The immune system and HPV clearance in immune-competent versus HIV-positive subjects individuals

  -Probably due to the inability to control the expression and replication of HPV

Background

- HPV DNA-detected in up to 99.7% of cervical cancers worldwide
- Other factors: smoking, parity, education, diet, physical inactivity, sexual behavior
- Limited data are however, available on the distribution of HPV genotypes in the general population and in ICC in Uganda

Background

- 7.3% of Ugandans (ages 15-49)-HIV positive, prevalence is higher among women (8.3%) than among men (6.1%), prevalence in south Western Uganda is 8%.

- Gynocular studies:

  1. Gynocular versus stationary colposcope-significant agreement in assessing cervical lesions in HIV positive women

  2. Gynocular versus stationary colposcope, by the Swede score system in VIA positive women

  3. Cervical lesion detection by nurses versus doctors using Gynocular versus stationary colposcope

Background

- Cervical cancer-1st leading cause of cancer deaths in women aged 15 to 44 years in Uganda. Prevalence of CIN2 and 3 in HIV positive women at MRRH is 12.3% and cervical cancer is 2.4%

- Association btn HIV infection and cervical cancer is known but the effect of HIV on treatment outcomes and progression of lesions to cancer in S Western Uganda is unknown

- HPV genotypes, HPV clearance, incidence and factors associated with HPV infection in HIV positive women in Western Uganda are largely unknown

Rationale

- Prevalence of cervical cancer is high, preventive strategies include HPV vaccination but available vaccines are active against HPV 16, 18.

- **Important:**

  -to know the HPV genotypes

  -to evaluate the relationship of HPV positivity and Gynocular colposcopy SWEDE SCORE and correlation to cytology and histopathology diagnosis in women HIV infected women

  -The accuracy in detecting cervical lesions by nurses versus doctors using a stationary colposcope and Gynocular

Study Aims

- Determine prevalence + factors associated with genital HPV in women attending CCP clinic
- Determine the genital HPV genotypes in women attending CCP clinic
- To describe the effect of HIV infection on the accuracy of cervical cancer screening tests (LBC, VIA, VILI, HPV DNA)
- Determine the correlation btn VIA/VILI, LBC, HPV DNA diagnosis and Gynocular colposcopy

Study Aims

- Determine the predictors for clearance of genital HPV infections and abnormal cervical lesions among women attending CCP clinic
- Describe the relationship of HPV sero-positivity and Gynocular colposcopy SWEDE SCORE and correlation to cytology and histopathology diagosis in women HIV infected women attending CCP clinic
- Evaluate the accuracy in detecting cervical lesions by nurses/MW versus doctors using a stationary colposcope and Gynocular

Methodology

Study design*:* This will be an open prospective cohort study

Study Setting: MRRH, cervical cancer clinic

Study Population*:* Women attending cervical CCP clinic at MRRH, South Western Uganda

Sampling procedure*:* Consecutive sampling for all women attending the CCP clinic at MRRH

Sample size: 1000

Study Variables

1. Socio demographic variables
2. Sexual history variables
3. Obstetric/Gynecological variables
4. Medical history variables
5. Investigations
6. Treatment modalities

Study procedure

- Enrolment-completed after a woman has given consent
- The woman will then undergo an exam by inserting a vaginal speculum and using an Ayre spatula and endo-cervical brush
- The woman will undergo routine VIA/VILI procedure
- One specimen will be picked from every woman in the study and will undergo PCR for HPV DNA gene mapping

Statistical analysis

- Data will be analyzed by means of the continuity-corrected $\chi 2$ method or Fisher's exact test, as required, and the probability of a type I error (α) will be set at 0.05 (two-tailed)

- For risk factor analysis, the results of the hybrid capture II test will be used to define the presence of carcinogenic HPV, and a reference category will be designated for each variable

- The effect of age will be estimated using indicator variables for the different age categories using the oldest age group as the reference category

Statistical analysis

- Any variables that will be significantly associated in univariable analyses with the presence of carcinogenic HPV ($p < 0.10$) will be entered in a logistic regression model

- The rate of clearance of HPV after one year will be calculated on how many women had the HPV infection and will have now cleared the infection by the end of the one year

Ethical consideration

Ethical approval: Department of Obstetrics and Gynecology, MUST REC and UNCST

Quality control: The completed data abstraction forms will be checked by a second person on missing data or discrepancies

An independent Obstetrician/Gynecologist will check the forms to ensure completeness

All data will be double entered and cross-checked in SPSS Version 20