On Starting an Anal Dysplasia Clinic

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Last Updated: February 2, 2014
Madison Anal Dysplasia Clinic

- Clinic started in February 2012, limited to 2 clinics a month, increased to 3 in March 2013, and 4 in July 2013.
- Referrals focused on those patients already diagnosed with AIN, or previously diagnosed and treated for anal cancer (not including those treated with abdominoperineal resection).
- In June 2013, we decided to also emphasize HRA screening for women with known CIN.
- Infrared coagulation treatment began in September 2013.
Colposcope Parts

- Video Camera
- Eye Piece
- Camera Lens
- Light Source
- Objective lens
- Diopter Scale
- Interpupillary Dial
- Beam Splitter
- Magnification Dial
16x Magnification

25x Magnification
Essential Equipment for Procedures

- Cytology fixative, formalin
- Anoscopes (disposable or metal)
- 5% Acetic acid, Lugol’s & Monsel’s solutions
- K-Y Jelly, 1-5% lidocaine gel
- Non-sterile scopettes, Q-tips, gauze
- Forceps: Baby or Mini-baby Tischlers, flexible endoscope forceps, ENT forceps
- 1% injectable lidocaine, 30 gauge needles, 1cc syringes
Part II: Procedures

Cytology Collection  Digital Anorectal Exam
High Resolution Anoscopy  Biopsy
How to Perform an Anal Pap Smear

1. Insert moistened Dracon swab until it bypasses the internal sphincter and abuts the distal wall of the rectum.
2. Rotate swab in a circular fashion as it is withdrawn in order to sample cells from all aspects of anal canal.
6. Insert Q-tip wrapped in gauze soaked in acetic acid through anoscope.
7. Remove anoscope leaving the gauze & Q-tip inside. Soak for 1-2 minutes.
8. Remove gauze and re-insert anoscope.

9. Observe through colposcope slowly withdrawing the anoscope until the SCJ comes into focus.
HRA: Examination

- Thorough exam with biopsies, 15-20 minutes
- Areas to be examined:
  - SCJ
  - AnTZ
  - Anal Canal
  - Anal Verge
  - Perianal Skin

Satisfactory exam = ALL aspects viewed completely
Squamocolumnar Junction (SCJ)
11. Apply Lugol’s solution after identifying all aspects of AnTZ with acetic acid.
13. Observe the distal anal canal and verge as you withdraw the anoscope.

14. Wipe off lube, apply vinegar to perinatal region and examine on lower power.
Anal Biopsy Forceps
Biopsy

- Insert with forceps closed.

- Open forceps when lesion is viewed and can be placed within forceps mouth and biopsied.
Post-Biopsy Care

• Complications are rare

• Expect slight bleeding with bowel movements for several days

• Nothing per anus until comfortable and no bleeding

• Infection rare – explain signs and symptoms
Squamous Metaplasia
HGAIN (AIN 3) with CP & CM
Documentation of Lesions

- COLOR: AWE – flat, shiny, grey, red
- MARGINS: Distinct or indistinct
- CONTOUR: Flat or raised, MP
- VESSELS: CP, CM, Striated, WV
- LUOGOL’s: Negative, partial, positive
- OTHER: Epithelial honeycombing, ACG
From Novice to Expert

• Long learning curve

• *Not* – observe one, do one, teach one

• Observe 25, do 100, work 5 years, then teach

• Lesions can be subtle, don’t settle for the obvious especially in high-risk populations

• Biggest pitfall for novices is missing some lesions; or extent of disease – causes inadequate diagnosis and treatment
85% Trichloroacetic Acid (TCA)

• Useful for small internal warts and small areas of LSIL or HSIL
• Small amount is put into cup
• Wooden end of cotton tipped swab wicks up TCA
• Excess is shaken off
• Directly applied to lesion until it turns white, avoid dripping and treatment of normal tissue
• Usually at 2 to 3 week intervals for up to 4 treatments
Treatment with infrared coagulation

- Since 2002 the UCSF Anal Neoplasia Clinic has been using IRC to treat AIN 2-3 and condyloma
- Well tolerated with substantially less pain compared with surgical treatment, minor bleeding for a few days to weeks, very low incidence of significant problems in over 400 procedures
- Efficacy is good, some patients recur

IRC 2100 Infrared Coagulator
Redfield Corporation
Rochelle Park, NJ
Using Infrared Coagulation

- 5% anorectal lidocaine cream is placed in the anus for 10 to 15 minutes.
- Lesions visualized during HRA and small amounts of 1% lidocaine with epinephrine buffered with sodium bicarbonate are infiltrated beneath the lesions (10 cc control syringe with 25 gauge spinal needle).
- For peri-anal lesions a 30 gauge needle is used.
Using Infrared Coagulation

- Patients are advised to expect mild to moderate discomfort that usually lasts a few days to a week mostly with BMs.

- Bleeding can occur for several days or weeks, but rarely is severe.

- Refrain from receptive anal sex for 6 to 8 weeks or at a minimum, until the pain and bleeding stops.

- Return for follow-up in 2 to 4 months.
Precancerous lesion AIN 3...too large for TCA, IRC, OK
Case 1

HIV-positive MSM with a history of perianal HGAIN treated surgically for 5 years ago

Treated with IRC and debrided
The Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions: background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology.

- The final, approved recommendations standardize biologically relevant histopathologic terminology for HPV-associated squamous intraepithelial lesions and superficially invasive squamous carcinomas across all lower anogenital tract sites and detail the appropriate use of specific biomarkers to clarify histologic interpretations and enhance diagnostic accuracy. A plan for disseminating and monitoring recommendation implementation in the practicing community was also developed. The implemented recommendations will facilitate communication between pathologists and their clinical colleagues and improve accuracy of histologic diagnosis with the ultimate goal of providing optimal patient care.

Major Logistical Challenges

- Training.
- Procurement of equipment and space.
- No show rate was high, so we held sessions to inform referring providers so patients would know what to expect. Also created an HRA brochure for patients.
- Working with cytologists and pathologists to understand procedure and standardize diagnosis with LAST recommendations. (Including P16 and Ki67 staining for intermediate lesions.)
- Establishing a relationship with surgeon for referral of cases that need surgical evaluation and/or treatment.
- Preparing for the inevitable lack of capacity once the word gets out.
Major Unresolved Issues

- Level A evidence that treatment reduces risk of invasive anal cancer.
- Relatively high reported spontaneous resolution rates and recurrence rates post treatment.\(^1,2,3\)
- Identification of all disease and role of blind biopsies.\(^4\)
- Standardized lesion description terminology.
- Reimbursement.

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2 Tong WW, Jin F, McHugh LC, et al. Progression to and spontaneous regression of high-grade anal squamous intraepithelial lesions in HIV-infected and uninfected men. AIDS. 2013 Sep 10;27(14):2233-43
The AIDS Malignancy Consortium received funding in 2013 from the NCI to proceed with the definitive study to compare treatment versus observation for people with anal HSIL.

Proposed treatment options will include IRC/excision/electrocautery, topical 5-FU and imiquimod.

Proposed sample size is ~5,000 HIV-infected men and women age >35 y/o.

Primary outcome is invasive anal cancer.

Estimated anal cancer incidence of ~200/100,000 among study participants in the observation arm (HIV-infected with HGAIN and no prior therapy).

Projected 3-year accrual period and minimum follow-up period of 5 years.