STANDARDIZED PROCEDURE
INFRARED COAGULATION THERAPY (Adults, Peds)

I. Definition

Infrared Coagulation (IRC) Therapy is a treatment for anogenital warts, low grade squamous intraepithelial neoplasia (LGAIN) or high grade squamous intraepithelial neoplasia (HGAIN). IRC is an ablative therapy which can effectively treat these lesions as an office procedure. As such it is akin to ablative therapies such as cryotherapy or TCA application which are already approved standardized protocols for Advanced Health Practitioners.

II. Background Information

A. Setting: The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision

1. The necessity of the procedure will be determined by the AHP in verbal collaboration with the attending physician or his/her designee. Direct supervision will not be necessary once competency is determined, as provided for in the procedure. At that time, general or indirect supervision is acceptable as needed for complicated presentations of disease.

   Designee is defined as another attending physician who has > 5 years HRA experience, and who works directly with the supervising physician and is authorized to supervise the NP.

C. Indications

IRC is indicated for patients diagnosed with anogenital warts, anal low-grade squamous intraepithelial neoplasia (LGAIN), or anal high-grade squamous intraepithelial neoplasia (HGAIN)

IRC can also be used to treat perineal, vaginal, or penile low-grade (LG) or high-grade (HG) intraepithelial neoplasias if limited in size and number, and that do not require larger ablative therapies such as laser.

D. Precautions/Contraindications

Patients with known neutropenia, platelet counts below 60,000, patients receiving anti-coagulant therapy or with coagulation disorders. The AHP will consult with the attending physician or designee, or the treating hematologist, to determine appropriate anti-coagulation therapy or short-term discontinuation of the anti-coagulation therapy before, during, or after treatment.

III. Materials

IRC Coagulator (mobile unit)

Related Materials:
STANDARDIZED PROCEDURE
INFRARED COAGULATION THERAPY (Adults, Peds)

1. Redfield IRC 2100 EO Sterilized Disposable Contact Tip/Sheath
2. Lidocaine 1% or 2% HCL with epinephrine 1:100,000 injectable. May be buffered with Sodium Bicarbonate in a ratio of 10 ml Lidocaine:2 ml Sodium Bicarbonate
3. Lidocaine 5% cream
4. 25 gauge spinal needle with 10 ml controlled syringe or 3 ml and/or 1 ml syringes with 1 inch, 30 gauge needle.

IV. Infrared Coagulation Therapy

A. Pre-treatment evaluation
   Patient will have received an HRA, gynecologic cervical, vulvar or anal colposcopy or penile exam using magnification with colposcope, per previously described protocols confirming the presence of either warts, LGAIN LG intraepithelial neoplasia or HGAIN HG intraepithelial neoplasia clinically or confirmed by histology.

B. Procedure
   1. The procedure and its risks will be explained and a consent to perform the procedure will be signed.
   2. A digital rectal anal exam will be performed to rule out the presence of abnormal masses.
   3. A colposcopy or HRA exam, or colposcopy for gynecologic or penile treatments will be performed to determine and verify the location of the lesion(s) to be treated.
   4. Lidocaine 5% cream will be inserted or applied to the area(s) and allowed to be absorbed for approximately 5-10 minutes.
   5. For anal-associated disease, the anoscope or speculum will be re-inserted; for gynecologic treatments the speculum will be left in place and will not require reinsertion, and 0.5-1 ml of lidocaine 1% or 2% with epinephrine buffered with Sodium Bicarbonate will be injected adjacent to each lesion to be treated. For penile lesions, the lidocaine will not contain epinephrine. Prior to the injection of the lidocaine, the syringe will be aspirated to be certain there is no intravascular infiltration.
   6. If both internal and external lesions are to be treated, the lidocaine is only inserted into lesions in the first area treated (usually internal). Insertion of lidocaine into the second area will be done prior to that treatment.
   7. A Redfield IRC 2100 EO sterilized Teflon disposable Contact Tip/Sheath is placed on the IRC Coagulator arm with attention to be certain that the tip of the sheath is in contact with the tip of the coagulator arm. The IRC Coagulator is set for 1.5 seconds.
   8. The tip of the IRC Coagulator is held to the lesion and heat is applied in the preset dose level of 1.5 seconds by depressing the Coagulator trigger. The application is repeated until the entire lesion is blanched white. Treatment continues until all lesions have been treated.
9. Lesions are debrided using a forceps or a small dry cotton-tipped swab, cotton swab, or wooden tip of Q-tip to the level of the submucosal vessels. If bleeding occurs during the debridement, the IRC is reapplied for an additional 1.5 seconds to control the bleeding and to be certain the lesion is completely ablated. All treated areas are carefully assessed to ensure that there is no active bleeding, then the procedure is complete.

C. Post-procedure
The patient is reminded there will be bleeding, generally minimal, with bowel movements for up to two weeks. The patient will be told that it is common for bleeding to stop within a few days, but may reoccur 10 days post-treatment and is not cause for alarm. Post-procedure pain is generally associated with bowel movements for up to a few days, but discomfort may persist for several weeks and is generally minimal. The patient will be given appropriate pain management instructions including soaking in warm water for at least 3x daily, and pain medication will be prescribed PRN.

Sloughing of tissue is expected and not cause for concern. If uncontrolled bleeding or infection develops the patient will be instructed to page the AHP, who will inform the supervising MD as needed. Sexual intercourse or insertion of anything per rectum other than prescribed medications, is to be deferred for 6-8 weeks.

A. Follow-up treatment
The patient will be seen for a follow up colposcopy or HRA examination 2-3 months post-treatment.

V. Documentation
A progress note will be dictated to the referring physician indicating the location, description and number of lesions treated, as well as amount of Lidocaine used.

A. Documentation is in the electronic medical record

1. Documentation of the pretreatment evaluation, and consent
2. Record the time out, procedure, EBL, the outcome, patient tolerance, medications given, and the plan in the note, as well as any teaching and discharge instructions.
3. Documentation of the location, description, number of lesions, clinical impression, and comparison to prior exam. Adequacy of the HRA will be documented.
4. Adequacy of treatment will be documented. If all lesions were not treated, untreated areas will be documented with documentation for the reason the treatment was not completed (e.g. rapid swelling or extensive disease precluding completion of treatment).

B. All abnormal or unexpected findings are reviewed with the supervising physician.
VI. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.

2. The Advanced Health Practitioner will demonstrate knowledge of the following:
   a. Medical indication and contraindications of Infrared Coagulation Therapy and Colposcopy
   b. Risks and benefits of the procedure
   c. Related anatomy and physiology
   d. Consent process (if applicable)
   e. Steps in performing the procedure
   f. Documentation of the procedure
   g. Ability to interpret results and implications in management.

3. The AHP who has demonstrated competency in performing HRA and has been approved for providing HRA at UCSF will be eligible to perform IRC.

4. Each AHP is to directly observe this procedure performed by experienced HRA providers approved by the supervising physician or designee. Designee is defined as another attending physician who has > 5 years HRA experience, and who works directly with the supervising physician and is authorized to supervise the NP. The observation period will be a minimum of five IRC ablation procedures or more if deemed necessary by the supervising physician or designee.

5. AHPs with no prior IRC experience will then complete a preceptorship, which involves a supervised performance of at least 10 IRC procedures. Supervision will be provided by the supervising or designee, and will be with an experienced attending with >5 years HRA experience. During the supervised preceptorship, the AHP will be given instruction on performing IRC procedures similar to a residency program. At the end of the preceptorship, the AHP will have gained the skills necessary to perform IRC ablation competently at a novice level.

6. AHPs with prior IRC ablation experience obtained prior to employment at UCSF will be evaluated per section 8 below.

7. Additional supervised preceptorship will be determined at the discretion of the supervising physician or designee.

8. At the end of the supervised preceptorship, the AHP will be evaluated for competency by an experienced HRA attending (more than 5 years experience). The AHP will be evaluated performing 6 IRC ablation procedures. This evaluation will determine whether the AHP is considered competent to provide IRC ablation independently at UCSF.
STANDARDIZED PROCEDURE
INFRARED COAGULATION THERAPY (Adults, Peds)

9. The Advanced Health Practitioner will ensure the completion of competency sign-off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.

2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least twenty-five procedures per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.

3. Demonstration of continued proficiency shall be monitored through the annual evaluation.

4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted. In addition, the AHP will provide an approximate number of total procedures performed per year.

VII. RESPONSIBILITY
Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

VIII. HISTORY OF PROCEDURE
Revised February 2012 by Subcommittee of the Committee for Interdisciplinary Practice
Reviewed February 2012 by the Committee on Interdisciplinary Practice
Prior revision Sept 2009
Approved February 2012 by the Executive Medical Board and the Governance Advisory Council.

This procedure is intended for use by UCSF Medical Center staff and personnel and no representations or warranties are made for outside use. Not for outside production or publication without permission. Direct inquiries to the Office of Origin or Medical Center Administration at (415) 353-2733.