Thermal ablation in LMICs

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Disclosures

President/Founder of non-profit BHI
Speaker bureau: Merck, Cooper Surgical
Advisory board: Mylan Pharmaceuticals

No conflict with any device company for diagnostics or treatment
## Treatments for cervical cancer endorsed by WHO

### Excision procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Details</th>
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<tbody>
<tr>
<td>LEEP</td>
<td>Gold standard in high-resource settings</td>
</tr>
<tr>
<td></td>
<td>Must be performed by trained clinicians</td>
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<tr>
<td></td>
<td>Can have serious complications</td>
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<tr>
<td>CKC</td>
<td>Must be performed by a surgeon under anesthesia</td>
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<td></td>
<td>Invasive</td>
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### Ablation procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Details</th>
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<tr>
<td>N₂O or CO₂</td>
<td>Standard treatment in LMICs</td>
</tr>
<tr>
<td>(Gas-Based Cryotherapy)</td>
<td>Little training required</td>
</tr>
<tr>
<td></td>
<td>No serious complications</td>
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<td></td>
<td>Cure rates for CIN2+ similar to LEEP (77-93%)</td>
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</table>
Thermal ablation (aka cold coagulation, thermoablation, thermocoagulation)

- Desktop device used since 1970s (new handheld devices recently available)
- Ablates tissue by using heat – superficial epithelium blisters, underlying stroma and glandular crypts are destroyed
- Meta-analysis shows cure rates around 95%
- Rigorous trials needed to determine true efficacy, safety, and recommendations for treatment details
- WHO endorsement forthcoming!
Thermal ablation devices on the market

Original desktop device

Cold coagulator (WiSAP, Brunnthal, Germany)

New handheld devices

C3 Cold coagulator (WiSAP, Brunnthal, Germany)

Thermocoagulator (Liger/Cure Medical, Lehi, UT)
Who should get thermal ablation?

- Patients with a positive screening test (HPV, HSIL, biopsy-confirmed CIN2/3)
- Patients with none of the following contraindications to ablation:
  - SCJ is not completely visible
  - Lesion larger than 75% of cervix
  - Lesion extending into cervical canal
  - Suspicion of cervical cancer
How should thermal ablation be performed?

• Conventional treatment:
  • Set temperature to 100°C - 120°C
  • Overlapping applications until entire SCJ is ablated
  • Each application lasts 20-40 seconds
• Currently, there is no standardized protocol for thermal ablation
Manufacturers offer a wide range of probe shapes and sizes.
Different probe tips are used at the clinician’s discretion.
Changes to new WiSAP handheld device

- Optimized visualization:
  - Longer handle (increased by 30mm)
  - Optimized visualization (LED lights moved from the top to the side to avoid obstructing vision)

- Detachable probes:
  - Designed to accommodate multiple-probe protocol and 1-probe protocol

- RCT to begin October 2019

New C3 Thermoablator prototype (WiSAP, Brunnthal, Germany)
Upcoming RCT

- Funding from NIH Academic-Industrial Partnership and Gateway for Cancer Research
- Goal: to develop a standardized thermal ablation protocol optimized for LMICs
- 3-arm randomized design:
  - Gas-based cryotherapy
  - Thermal ablation with single 17mm conical tip
  - Thermal ablation using 8mm endocervical tip followed by 10mm flat tip
Primary endpoint

Clearance of CIN2+ as determined by biopsy before entry into study and at 12 months post-treatment
Important information about about thermal ablation

• Can be performed by midwives/nurses
• Need to be able to visualize the ENTIRE SCJ
• An external battery will last for 60 applications (Liger) or 100 applications (WiSAP)
• No need for local anesthesia
• Device requires very little maintenance
• No high-quality evidence on HIV+ patients
• Liger can be autoclaved, WiSAP handheld no autoclave
• Auto-sterilization is not recommended
Summary

- Thermal ablation is an exciting opportunity for treatment of cervical precancer in LMIC
- New handheld devices are portable, low-cost and easy to maintain
- Trials on desktop device demonstrate high efficacy
- Likely similar efficacy in handheld devices
- Trials underway regarding efficacy in general population, HIV+ women, and streamlining of protocol
Thank you