

Depth of necrosis using different ablation techniques in healthy cervical tissue

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Disclosures

- Merck Speakers Bureau
- Employee of Basic Health International
- No financial relationship with WISAP or CryoPen®



Background: Global Cervical Cancer Burden

- Fourth most common cancer affecting women worldwide
- >528,000 new cases diagnosed every year
- >265,000 cervical cancer deaths in 2012
- 90% of deaths occur in low- resource settings
- Cervical pre-cancer can be detected and treated



Cryotherapy Challenges in the Field

- Typically performed using 50-70 kg CO₂ or NO₂ gas tanks
- A 5ft. tank may only treat 10-20 patients
- Procuring and transporting gas is expensive and potentially dangerous



Potential Solutions in LMICs

- **CryoPen® Cryosurgical System**
overcomes the cost, gas procurement, portability, and efficacy issues of traditional cryotherapy
- **Thermocoagulation (WISAP)**
Inexpensive, runs on electricity, can be used by both high-and mid-level healthcare providers



New Thermoablation Devices: Liger and WiSAP



WiSAP Thermoablator



Liger Thermoablator



Depth of Necrosis Study

- The goal of the clinical efficacy study is to describe the depth of tissue necrosis in women without cervical pathology
- Women undergoing hysterectomy for indications other than cervical pathology were recruited for the study
- Post-hysterectomy the depth of tissue necrosis was measured
- What is the goal of depth of necrosis?



Depth of Necrosis Tissue Example



Five-Arm Study (n=125 women)

- Single application of CO₂-based cryotherapy (5 minute freeze)
- Double application of CO₂-based cryotherapy (3 minute freeze, 5 minute thaw, 3 minute freeze)
- Single application of CryoPen® (5 minute freeze)
- Double application of CryoPen® (3 minute freeze, 5 minute thaw, 3 minute freeze)
- Single application of thermocoagulation at 120° C for 40 seconds



Before and After CryoPen® Single Freeze

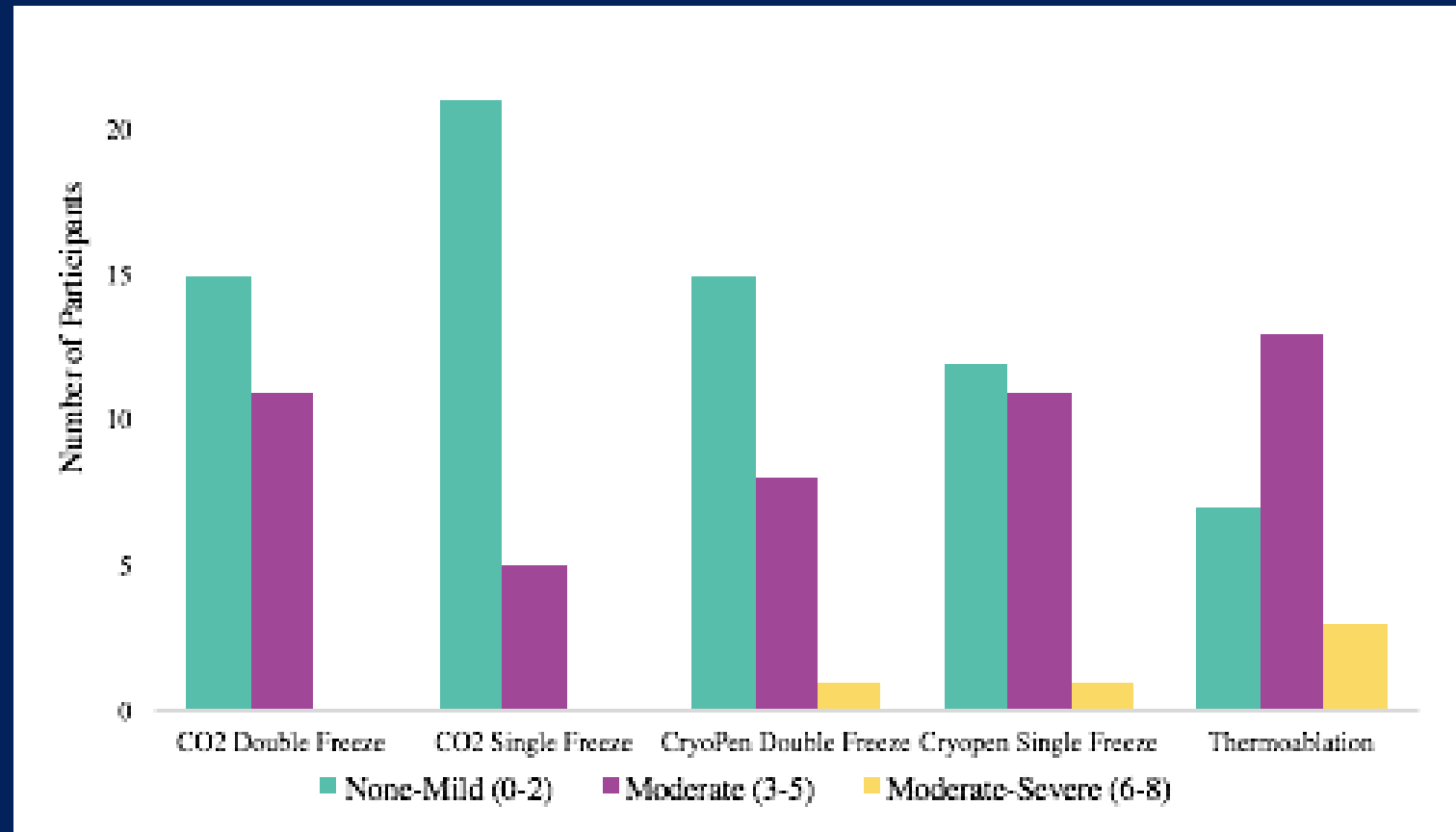


Selected characteristics of participants by treatment arm

	n	Range	Mean (SD)
Age			
CO2 double	26	30-64	45.5 (7.5)
CO2 single	26	32-58	45.5 (7.0)
CryoPen double	24	31-56	44.8 (5.9)
CryoPen single	26	38-62	44.7 (5.7)
Thermocoagulation	23	27-57	45.3 (6.7)
Parity			
CO2 double	25	0-7	1.6 (2.0)
CO2 single	26	0-7	2.0 (1.7)
CryoPen double	24	0-6	2.3 (1.5)
CryoPen single	24	0-4	1.6 (1.5)
Thermocoagulation	23	0-5	1.4 (1.4)
Pain			
CO2 double	26	0-4	2.2 (1.0)
CO2 single	26	0-3	1.8 (0.8)
CryoPen double	24	1-8	2.6 (1.4)
CryoPen single	26	0-6	2.5 (1.4)
Thermocoagulation	23	1-8	3.3 (1.8)



Reported Pain Severity by Treatment Method



Depth of necrosis (mm) by treatment arm, stratified by lip

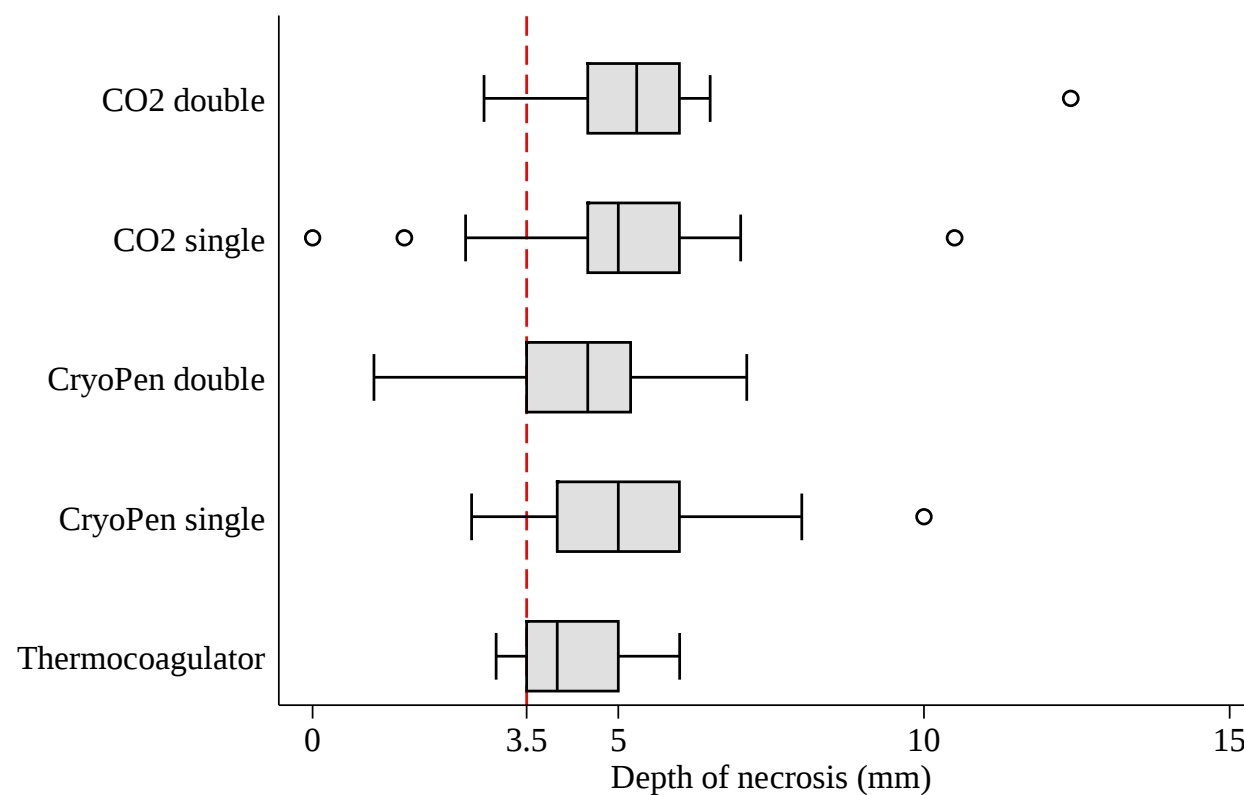
	n	range	Mean (SD)	Mean difference (95% CI)	Fail to meet 3.5mm benchmark (%)
Anterior Lip					
CO2 double	26	2.8-12.4	5.3 (1.7)	Ref.	2 (7.7)
CO2 single	25	0-10.5	4.9 (2.0)	0.44 (-0.62, 1.50)	5 (19.2)
CryoPen double	24	1-7.1	4.4 (1.3)	0.94 (0.56, 1.83)	5 (20.8)
CryoPen single	26	2.6-10	5.0 (1.6)	0.34 (-0.60, 1.28)	4 (15.4)
Thermocoagulation	23	3.0-6.0	4.2 (0.8)	1.06 (0.27, 1.86)	2 (8.7)
Posterior Lip					
CO2 double	26	3.5-8.5	5.6 (1.3)	Ref.	0 (0.0)
CO2 single	25	1.8-10	4.8 (1.8)	0.82 (-0.07, 1.72)	6 (23.1)
CryoPen double	24	2.1-7.5	4.5 (1.2)	1.03 (0.31, 1.76)	4 (17.0)
CryoPen single	26	2.2-7	4.8 (1.2)	0.81 (0.11, 1.52)	2 (7.7)
Thermocoagulation	23	3.0-6	3.9 (0.8)	1.63 (1.00, 2.27)	6(26.1)

Non-inferiority was considered if the 95% CI for the mean difference did not cross the non-inferiority margin of 0.8 mm.



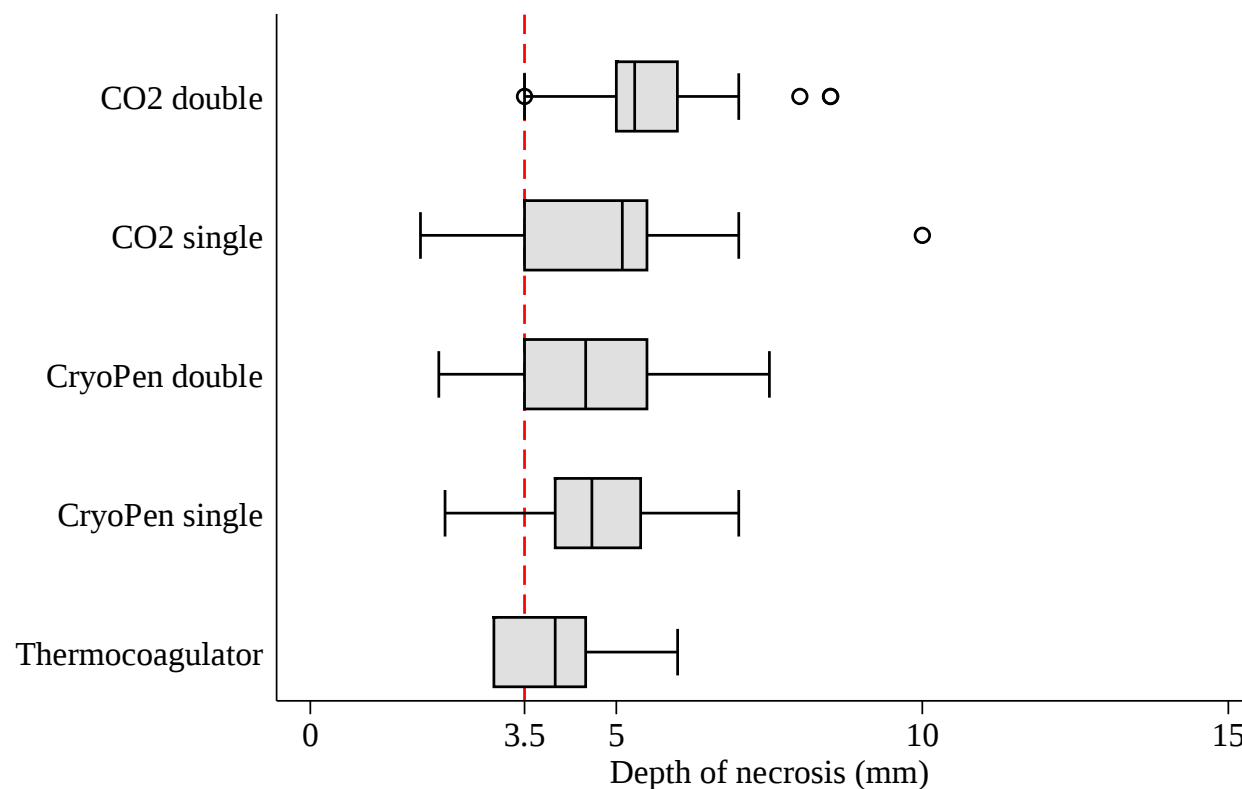
Depth (mm) of the anterior lip by different ablation techniques

Depth (mm) of the anterior lip by different ablation techniques



Depth (mm) of the posterior lip by different ablation techniques

Depth (mm) of the posterior lip by different ablation techniques



Tangible Benefits of LMIC-adapted CryoPen®

“Usually for a period of 2 months we use 3 tanks of N20 for \$280 (USD) each. Since we started using CryoPen® at Manitané in June 2015, we keep one tank full just in case. So that means from June 2015 to April 2016 (11 months) we have saved \$4620 (USD).”

-Dr. Marc Augustin, Medical Director of Fondation St. Luc, Haiti



Conclusion

- Alternative treatment to gas-based cryotherapy are being developed and are commercially available for purchase
- Bench testing and depth of necrosis show that these are not inferior to standard cryotherapy
- Moderate pain is higher with thermoablation but remains tolerable to patients
- A randomized trial comparing CryoPen® to WiSAP thermoablation and CO₂ cryotherapy is currently underway
- Cost effectiveness of these methods are also being investigated



Thank You!

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Questions?

