A Single Center Pilot Study of Circumferential Anal Canal Radiofrequency Ablation to Treat Anal High-Grade Dysplasia

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Background

- HIV+ individuals are at high risk for anal high-grade squamous intraepithelial lesions (HSIL) at the squamocolumnar junction (SCJ), which can lead to cancer.
- Targeted HSIL ablation can decrease progression to cancer but current ablation methods are inadequate and recurrence remains high.
- Circumferential radiofrequency ablation (RFA) for esophageal dysplasia is safe, decreasing recurrence compared to targeted ablation. We endeavored to determine if this is true in the anus.

Methods

- This was a prospective trial on the efficacy of circumferential anal RFA using Barrx™ 60 focal catheters (Medtronic).
- HIV+ or HIV- subjects with one or more anal SCJ HSIL were eligible.
- Procedures were performed with sedation and local anesthesia.
- The entire SCJ was ablated (3 pulses of 12 J/cm2 per site) to treat baseline and occult HSIL(s).
- A post-RFA biopsy was taken.
- Subjects were assessed with high-resolution anoscopy at 3, 6, 9, and 12 months.
- Mandatory lesion site biopsies occurred at month 12. Recurrence was retreated with focal RFA.

RFA Treatment and Results

RFA catheter and application. The catheter was positioned at non-overlapping sites of the SCJ. Successive sites were treated until the entire SCJ was ablated circumferentially.

Post-RFA tissue and biopsy images. (A) Post-RFA tissue showing white eschar, much of which has sloughed off. (B) Biopsy taken immediately after RFA shows sloughed mucosa (red arrow) and possible viable HSIL (black arrow). Post-RFA biopsies showed possibly viable dysplasia in 5 (50%) patients, of whom two had HSIL at a follow-up visit (both at 3 months; 1 with a persistent HSIL and 1 with a metachronous HSIL).

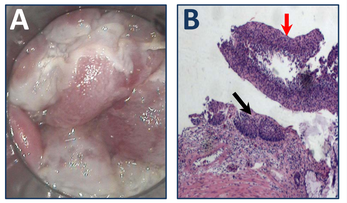

Table 1. Subject demographics

Parameter	Subjects (N=10)
Age at consent (years)	52 (29 – 70)
Gender = Male	10 (100%)
BMI (kg/m^2)	24 (22 – 26)
Ethnicity	
Caucasian	9 (90%)
Hispanic	1 (10%)
Smoking (yes)	0 (0%)
HIV status at baseline	
HIV-positive	9 (90%)
Years with HIV (n=9)	24.5 (1 – 29)
T-cell count (cells/mL; n=9)	730 (357 – 1167)
Viral load (particles/mL; n=8)	38 (0 – 377)

Data are expressed as n (%), or median (range)

Table 2. Treatment characteristics

Parameter	Subjects (N=10)
HSIL lesions treated initially	
Total HSIL lesions treated initially	29
HSIL lesions per subject	2 (2 – 8)
Quadrants with HSIL per subject	2 (1 – 4)
Procedure characteristics	
Duration of initial HRA (minutes)	13 (11 – 19)
Duration of initial RFA (minutes)	6.5 (5 – 13)

Data are expressed as N or median (range)

Adverse Events (AE)

No device-related serious AE

Mild device-related AE's: Thrombosed external hemorrhoid and soft anal stricture*

*easily dilated in-office at 3 months; resolved completely

Table 3. HSIL Persistence and Recurrence

Subjects (N=10)	3 Months	6 Months	9 Months	12 Months	Within 1 Year
Persistent HSIL	3 (30%)	1 (10%)	0 (0%)	0 (0%)	4 (40%)
Metachronous HSIL	1 (10%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)
Index Lesion (N=29)					
Index HSIL persistence	7 (24%)	1 (3.4%)	0 (0%)	0 (0%)	8 (28%)

Data are expressed as n (%)

Discussion

- Immediate post-RFA biopsy of a treated lesion showed dysplasia in 50% of subjects, but only two of these subjects recurred at follow-up.
- No lesion persisted after retreatment.
- All subjects were healed by 9 months, and all were dysplasia-free at 12 months.
- Circumferential anal canal RFA is quick and yielded total HSIL eradication with two or fewer treatments.
- Depth of destruction might be inadequate with one treatment; however a second targeted focal ablation resulted in no further dysplasia.
- Metachronous recurrence is rare.
- No treatment-related serious adverse events occurred. Two device-related mild AE's occurred
- Circumferential RFA appears more effective with less recurrence than targeted ablation especially in HIV+ subjects and obviates the need to identify all lesions.

Disclosures

- Clinicaltrials.gov registry ID: NCT02189161
- This study was sponsored by Medtronic (Sunnyvale, CA); medical writing support was provided by Medtronic