A Single Center Pilot Study Accessing Subject Tolerability and Quality Of Life After Circumferential Anal Canal Radiofrequency Ablation of High-Grade Dysplasia

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Background

- HIV-positive (HIV+) patients are at high risk for anal high-grade squamous intraepithelial lesions (HSIL), which can progress to cancer.
- Most dysplasia occurs at the squamocolumnar junction (SCJ).
- Radiofrequency ablation (RFA) effectively treats SCJ esophageal and anal dysplasia to hopefully decrease progression to cancer.
- Circumferential esophageal SCJ ablation is safe and well tolerated. We endeavored to determine if this was true in the anus.

Methods

- This was a prospective study to investigate safety and tolerability of circumferential anal RFA using Barrx™ 60 RFA focal catheters (Medtronic) in subjects with ≥ 1 anal SCJ HSIL.
- HIV+ or negative subjects were eligible.
- The entire SCJ was ablated to treat baseline and occult HSIL(s).
- Subject symptoms and quality of life were assessed with non-validated surveys prior to ablation, for 28 days post-ablation, and at 3, 6, 9, and 12 months after treatment.
- Subjects reported their experiences on a visual scale ranging from 0 to 10.

Results

Table 1. 28 day post-RFA subject-reported symptoms

Subject-reported symptoms after circumferential RFA	Maximum level[a]	Resolution time[b]
Anal pain[c]	7 (2 – 11)	15 (0 – 29)
Bowel movement (BM) pain	6 (4 – 10)	19 (0 – 29)
Difficulty with BM	4 (0 – 9)	13 (0 – 21)
	Subjects[d]	
Anal bleeding[e]	7	1 (0 – 4)
Bowel movement bleeding	10	4 (0 – 16)
Incontinence (any anal discharge)[e]	7	2 (1 – 4)

Data are expressed as n or median (range); N=10

a. On a scale of 0-10 (0 = no experience; 10 = severe experience)
b. Days until subjects report only "none", "minimal", or a score = 0 or 1
c. One subject reported pain = 11 on day 26 but reported pain as 1-4 for all other days
d. Number of subjects reporting mild, moderate, or severe
e. No subjects reported "severe" level of symptom

Table 2. Pain relief medication usage

	Subjects (N=10)	Days of usage
Non-narcotic	10	13 (3 – 22)
Narcotic	3	8 (4 – 14)

Data represented as n or median (range)

Table 3. Adverse events (AEs)

Variable	Subjects (N=10)	Device Relationship?
Total AE	4	---
Anal stricture	1	Definite
Asthma attack	1	No
External thrombosed hemorrhoids	1	Probable
Fluid in ear	1	No
Serious adverse events (SAE)	0	---

Data are expressed as n or n (%)

Table 4. Subject quality of life survey results

Subject QOL diaries	Initial visit	3 month visit	12 month visit
Over the last 3 months indicate the:			
Degree of worry about your anal canal condition[a]	4.5 (2.42)	2.9 (1.81)	1.2 (1.69)
Amount of stress due to your anal canal condition[a]	3 (2.71)	1.9 (1.66)	0.8 (1.03)
Do you worry about development of anal cancer? (answer: yes)	7 (70%)	1 (11.1%) (N=9)	5 (50.0%)
In the last month did you experience:			
Anal pain? (answer: yes[b])	3 (30%)	0 (0%)	0 (0%)
Difficulty with bowel movement? (answer: yes[b])	2 (20%)	1 (10%)	0 (0%)
Did you try to have anal sex but could not? (answer: yes)	0 (0%) (N=9)	0 (0%) (N=7)	0 (0%) (N=9)

Data are expressed as mean (SD) or n (%); percentage is based on total subjects enrolled (N=10) except cases of non-responsiveness where noted

a. On a scale of 0-10 (0 = no experience; 10 = severe experience)
b. Yes = score ≥ 2 on a scale of 0-10

Discussion

- Two device-related mild AE occurred in one subject each (externally thrombosed hemorrhoid and soft anal stricture). Both resolved conservatively (stricture was dilated in office with an anoscope).
  - No serious AE occurred.
- All subjects who tried receptive anal sex post-RFA succeeded, including the subject with the dilated stricture.
- Narcotics usage for pain relief was minimal.
- Participants reported less pain and worry at 3 and 12 months following the treatment.
- Circumferential RFA of anal canal HSIL in HIV+ subjects was well-tolerated with easily controlled pain, minimal bleeding and minimal adverse events.

Disclosures

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