Development of a novel natural orifice thermoregulatory device for the treatment of chronic pelvic pain

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Thermal cycling using our intraluminal probe was found to be safe in porcine models and demonstrated no evidence of thermal injury.

Background

- Chronic Pelvic Pain (CPP) is a challenging disease process that significantly impacts sexual health, quality of life (QoL), and can result in potential self-harm.
- It burdens patients, families, and caregivers, accounting for 20% of the \$635 billion chronic pain expenses.
- In the United States, 15% of women of childbearing age (nearly 10 million women) are affected by CPP.
- Globally, CPP affects 1 in 5 women and 1 in 12 men.
- Cryoanalgesia has been previously described as a modality for management of perineal pain for patients with chronic perineal pain.
- Our objective is to create a device that can help in the alleviation of pelvic pain through natural orifice temperature cycling.

Methods

Device

 Natural orifice intraluminal thermal sensor equipped with diagnostic probes to measure depth of perfused/innervated tissues (Image 1).

Procedure

- 5 porcine models were anesthetized and a midline laparotomy incision was made (Image 2).
- Temperature sensing catheter probes were placed posterior to the rectum, posterior to the vagina, posterior to the bladder and anterior to the bladder. A cystotomy was made and a foley catheter and intravesical temperature probe were placed (Image 3). The thermoregulatory probe was inserted vaginally (Image 1).
- Following temperature cycling, pelvic exenteration was completed for pathologic evaluation.

Analysis

- Hot and cold cycling were completed over the course of 4 hours with tissue temperature monitoring (Graph 1).
- Thermal imaging documented the area around the probe following completion of the procedure (Image 4).
- Pathologic specimens were preserved in formalin for 48 hours and evaluated for signs for signs of thermal injury.

What We Learned

Image 1. Thermoregulatory device with specimen



Image 2. Incision and catheter placement





Image 3. Catheter probe locations





- the device.

Images and Graphs

Image 4. Temperature probe with thermal reading following procedure

Graph 1. Temperature variability during active and inactive phases of thermoregulatory probe



Results

Studies were completed on 5 porcine models and showed tissue perfusion with a depth of penetration of approximately 30 mm.

Maximum tissue temperatures reached 42C, while minimum temperatures reached 21C with vaginal and rectal tissue showing the largest temperature range.

Thermal imaging taken at the completion of the procedure showed cooling of tissues immediately adjacent to the probe.

Pathologic specimens were obtained following the conclusion of each procedure. Pathologic reports showed no evidence of thermal injury from use of

- surrounding tissues.
- tissues.
- efficacy in human subjects.

2) Ahangari A. Prevalence of chronic pelvic pain among women: an updated review. Pain Physician. 2014;17(2):E141-E147.



Conclusions

Thermal cycling using a natural orifice intraluminal probe was safe on five porcine models.

Significant cold and hot penetration was noted around the

Histologic evaluation of pathologic specimens showed no evidence of thermal damage on any of the examined

Further research is warranted to evaluate safety and

References

1) Evans PJ, Lloyd JW, Jack TM. Cryoanalgesia for intractable perineal pain. J R Soc Med. 1981;74(11):804-809. doi:10.1177/014107688107401106