AUTHORS: Bruce B. Allan, PhD, MD, FRCS(C), Kathryn Husarek, PhD

EARLY FEASIBILITY STUDY OF NON-ABLATIVE CRYOGEN-COOLED MONOPOLAR RADIOFREQUENCY TREATMENT FOR STRESS URINARY INCONTINENCE (SUI): 12-MONTH RESULTS

Introduction:
Stress urinary incontinence (SUI) is the most common type of urinary incontinence and affects millions of women worldwide. Current treatment options are limited and vary depending severity of incontinence and the impact on quality of life. Pelvic floor exercises offer some relief for women, but long-term compliance and sustainability is difficult. Surgery is often a last resort and has a multitude of complications and/or risks associated. This large gap in treatment options for SUI presents an opportunity to meet an unmet need in healthcare for women. This study aimed to investigate the safety and efficacy of a non-surgical cryogen-cooled monopolar radiofrequency (CMRF) treatment for SUI.
Methods:
This was a prospective study designed to demonstrate that the study treatment meets primary efficacy and safety endpoints. This study received Health Canada ITA clearance and approval from the Health Research Ethics Board of Alberta. Thirty-five (35) subjects meeting all the I/E criteria were enrolled and treated. Subjects were randomized into two groups; Group 1 received a single treatment and Group 2 received two treatments approximately six (6) weeks apart. Follow-up visits occurred at 1, 4, 6, and 12 months post-treatment. At the Screening Visit, and at each follow up visit, subjects were asked to perform a 1-hour pad weight test and to complete a 7-day bladder voiding diary and UDI-6, IIQ-7, and ICIQ-UI-SF questionnaires.
Results: Twenty-five (25) subjects completed the trial. The data indicate an improvement in SUI symptoms for subjects, as determined by the objective 1-hour pad weight test and the UDI-6, IIQ-7 and ICIQ-UI-SF questionnaires, with a greater than 50% reduction in pad weight for 52% of the subjects at 12 months. The overall response rate (improvement from baseline) is between 68-78% with all measures considered. In addition to efficacy, the CMRF system was well tolerated and safe.
Conclusions:
The outcome measures indicate a significant improvement in SUI symptoms as evaluated by the standardized objective 1-hour pad weight test and several subjective patient-reported outcome measures. The sustained benefit of the CMRF vaginal treatment suggests its potential for use as a non-surgical approach to treat SUI.