



2.01.58 - Transanal Radiofrequency Treatment of Fecal Incontinence

Review Date: November 2018

Related Policies:

ID	Title	Status
2.01.64	Biofeedback as a Treatment of Fecal Incontinence or Constipation	Active

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With fecal incontinence 	Interventions of interest are: <ul style="list-style-type: none"> Transanal radiofrequency treatment 	Comparators of interest are: <ul style="list-style-type: none"> Medical management Biofeedback Sphincteroplasty 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Quality of life Treatment-related morbidity

Summary

Radiofrequency energy has been investigated as a minimally invasive treatment of fecal incontinence, in a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, radiofrequency energy is delivered to the sphincteric complex of the anal canal to create discrete thermal lesions. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue and improving continence.

For individuals who have fecal incontinence who receive transanal radiofrequency treatment, the evidence includes 8 nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Studies include a small number of patients, and estimates of treatment differences are very imprecise. Study follow-up periods vary and need to be considerably longer and involve larger numbers of patients to evaluate long-term outcomes properly. Three-year follow-up of a small cohort showed decrement in response over time. Multicenter randomized controlled trials with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions, physical therapies, or as an adjunctive treatment option for fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Objective

The objective of this evidence review is to determine whether transanal radiofrequency treatment for fecal incontinence improves the net health outcome compared with alternatives.

Policy

Transanal radiofrequency therapy is considered investigational as a treatment of fecal incontinence.

Policy Guidelines

The Secca procedure may be performed on an outpatient basis using conscious sedation and a local anesthetic.

CODING

Effective in 2017, there is no specific CPT code for this procedure. It would be reported with the unlisted code 46999.

Benefit Application

BlueCard/National Account Issues

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration-approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

Background

Fecal Incontinence

Fecal incontinence is the involuntary leakage of stool from the rectum and anal canal. Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. Etiologies vary and include injury from vaginal

delivery, anal surgery, neurologic disease, and the normal aging process. Estimated prevalence is 8% of the adult population.

Treatment

Medical management includes dietary measures, such as the addition of bulk-producing agents to the diet and elimination of foods associated with diarrhea; antidiarrheal drugs for mild incontinence; bowel management programs, commonly used in patients with spinal cord injuries; and biofeedback. Surgical approaches primarily include sphincteroplasty, although more novel approaches, such as sacral neuromodulation or creation of an artificial anal sphincter, may be attempted in patients whose only other treatment option is the creation of a stoma. Radiofrequency (RF) energy also has been investigated as a minimally invasive treatment of fecal incontinence, a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, RF energy is delivered to the sphincteric complex of the anal canal to create discrete thermal lesions. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue and potentially improving continence.

RF energy is a surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, RF energy has been investigated as a treatment for gastroesophageal reflux disease (ie, the Stretta procedure), in which RF lesions are designed to alter the biomechanics of the lower esophageal sphincter; in orthopedic procedures to remodel the joint capsule; or in an intradiscal electrothermal annuloplasty procedure, in which the treatment is intended in part to modify and strengthen the disc annulus. In all of these procedures, nonablative levels of RF thermal energy are used to alter collagen fibrils, which results in a healing response characterized by fibrosis. Recently, RF energy has been explored as a minimally invasive treatment option for fecal incontinence.

Regulatory Status

In 2002, the Secca™ System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for “general use in the electrosurgical coagulation of tissue and is intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.”¹ Food and Drug Administration product code: GEI.

Rationale

This evidence review was created in July 2003 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 4, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific

outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of transanal radiofrequency (RF) in patients who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of transanal RF improve the net health outcome in individuals with fecal incontinence?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with fecal incontinence who have failed conservative treatment.

Interventions

The therapy being considered is transanal RF.

Comparators

The following therapies are currently being used to treat fecal incontinence: medical management, biofeedback, and sphincteroplasty.

Outcomes

The general outcomes of interest are the frequency of incontinent episodes and the impact on quality of life.

A beneficial outcome would be elimination of incontinence, reductions in the frequency of incontinence, and improvements in quality of life.

A harmful outcome would be damage to the anal sphincter and an increase in incontinence frequency.

Timing

Procedural morbidity would be assessed within 30 days after the procedure. The impact of the treatment on incontinence would be assessed after 3 months to allow for remodeling, and after 3 to 5 years to assess durability.

Setting

Transanal RF is administered in an outpatient care setting by a gastroenterologist.

Systematic Reviews

An Agency for Healthcare Research and Quality Comparative Effectiveness Review, conducted by Forte et al (2016), assessed surgical treatments for fecal incontinence, including transanal RF treatment.² Reviewers identified only case series, which they addressed only under a key question related to adverse effects, not a key question related to comparative effectiveness. Reviewers concluded that the evidence for transanal RF treatment was insufficient to support its use for fecal incontinence.

Noncomparative Studies

Abbas et al (2012) retrospectively reviewed 27 patients who underwent the Secca procedure during a 6-year period (2004-2010) at a single medical center.³ Thirty-one procedures were performed for moderate-to-severe fecal incontinence. Most patients were women (mean age, 64 years), and the most common cause of incontinence was obstetrical injury. The median length of symptoms was 3 years. Biofeedback had failed in more than half of patients, and more than 20% of patients had previous surgical intervention to treat incontinence. No major complications occurred after the Secca procedure, and minor complications were observed in 5 (19%) patients (anal bleeding in four, vulvar swelling in one). A treatment response was noted in 21 (78%); mean Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score was 16 at baseline and 10.9 at 3 months postoperatively. Studies have suggested that a CCF-FI score greater than 9 indicates a significant impairment of quality of life.⁴ However, in the Abbas study, only 6 (22%) patients had a sustained long-term response without any additional intervention, and 14 (52%) patients underwent or were awaiting additional intervention for persistent or recurrent incontinence over a mean follow-up period of 40 months.

Ruiz et al (2010) reported on 1-year quality of life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence between 2003 and 2004.⁵ Twelve-month results were available for 16 (67%) patients. Mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months ($p=0.035$). Mean Fecal Incontinence Quality of Life (FIQL) score improved in all subsets except for the depression subscore. Authors' conclusions on the actual clinical significance of this improvement were uncertain.

Felt-Bersma et al (2007) published results of an uncontrolled study on the Secca procedure in 11 women with fecal incontinence who underwent baseline and posttreatment testing.⁶ Six (55%) patients reported improvement; Vaizey Incontinence Questionnaire scores improved 13%, but no changes were observed in anal manometry, rectal compliance measurement, or 3-dimensional anal ultrasound. Postoperative pain was reported to be slight in 8 (73%) patients, moderate in 2, and severe in 1. Lam et al (2014) reported 3-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence.⁷ Of the total cohort of 31 patients, 5 (16%) maintained a clinically significant response (defined as $\geq 50\%$ reduction in Vaizey Incontinence Questionnaire score) for 6 months, 3 (10%) maintained response for 1 year, and 2 (6%) maintained response for 3 years. Improvements from baseline in anal manometry (increased anorectal pressures or enhanced rectal compliance) were not observed.

Efron et al (2003) published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and was followed for 6 months.⁸ Patients served as their own controls. The study assessed change in fecal incontinence symptom scores and quality of life between baseline and follow-up. Fecal incontinence was assessed with CCF-FI score, and quality of life was assessed with the FIQL score. Both the CCF-FI and FIQL scores improved in a steady, gradual manner over a 6-month period, from 14.6 to 11.1 for the CCF-FI and from 2.5 to 3.1 for the FIQL. Of 44 patients who had an initial baseline CCF-FI score greater than 9, a total of 15 (34%) achieved CCF-FI score less than 10 at 6 months. Improvement also was assessed using the Medical Outcomes Study 36-Item Short-Form Health Survey, focusing on mental and social parameters. Mean social function subscore improved from 64.3 to 34.4, and mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all 9 parameters (eg, days with any fecal incontinence dropped from 10 in a 14-day period to 7). In contrast, there were no differences in objective measures of anal sphincter function (ie, there were no differences in manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects), as noted on endoanal ultrasound. Authors noted that determining the mechanism of action for the procedure was not a study objective. Three significant procedure-related complications occurred during the trial. Two patients developed anal ulceration, and one developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in 5 patients, transient worsening of incontinence in 4 patients, and anal pain in 5 patients.

Three other very small case series (n=15, 19, 8) were performed outside the United States.^{9, 10, 11} In two, no clear benefit was noted for the procedure.

Section Summary: Noncomparative Studies

A small body of observational studies or noncomparative, single-arm trials have reported on changes in incontinence symptoms after the Secca procedures. Given the small number of studies conducted and the limitations of those trials (ie, small number of patients, lack of control arm and randomization, inconsistencies with inclusion and exclusion criteria, short-term follow-up), the efficacy of RF therapy for fecal incontinence is not supported in the literature.

Summary of Evidence

For individuals who have fecal incontinence who receive transanal RF treatment, the evidence includes 8 nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Studies include a small number of patients, and estimates of treatment differences are very imprecise. Study follow-up periods vary and need to be considerably longer and involve larger numbers of patients to evaluate long-term outcomes properly. Three-year follow-up of a small cohort showed decrement in response over time. Multicenter randomized controlled trials with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions, physical therapies, or as an adjunctive treatment option for fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued guidance on radiofrequency treatment for fecal incontinence in 2011.¹² NICE concluded that “evidence on endoscopic radiofrequency therapy of the anal sphincter for fecal incontinence raises no major safety concerns. There is evidence of efficacy in the short term but in a limited number of patients.”

In 2016, NICE published a Medtech innovation briefing on the Secca system for fecal incontinence.¹³ These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, the relevant published evidence, and cost information. These briefings do not contain recommendations. The briefing noted that “Secca therapy is a minimally invasive treatment option available for people with incontinence of solid or liquid stool at least once a week, in whom conservative management options have not controlled symptoms.”

American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons, in its 2015 clinical practice guidelines, noted: “Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.”¹⁴ The guidelines also stated: “Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.”

American College of Gastroenterology

The American College of Gastroenterology published guidelines on the management of benign anorectal disorders in 2014.¹⁵ The guidelines indicated that there is insufficient evidence to

recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. The College also asserted that the biologic rationale for this type of treatment is unproven.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in October 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

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Codes

Codes	Number	Description
CPT	46999	Unlisted procedure, anus
HCPCS		
ICD-10-CM		Investigational for all diagnoses
	R15.0-R15.9	Fecal Incontinence
ICD-10-PCS		ICD-10-PCS codes are only for use on inpatient services. There is no specific ICD-10-PCS code for this procedure. One of the following codes might be used.
	0D5R3ZZ	Surgical, gastrointestinal system, destruction, anal sphincter, percutaneous
Type of service	Surgery	
Place of service	Inpatient, Outpatient	

Policy History

Date	Action	Description
07/17/03	Add policy to Medicine section	New policy
04/16/04	Replace policy	Policy updated with literature review; no change in policy statement
03/15/05	Replace policy	Policy updated with literature review; no change in policy statement
12/14/05	Replace policy	Policy updated with literature review; no change in policy statement
12/12/06	Replace Policy	Policy updated with literature review; no change in policy statement
02/14/08	Replace Policy	Policy updated with literature review; reference added; no change in policy statement
03/12/09	Replace policy	Policy updated with literature review; references added; no change in policy statement
03/11/10	Replace policy	Policy updated with literature review; no change in policy statement
12/09/10	Replace policy – coding update only	ICD-10 codes added to policy.
03/10/11	Replace policy	Policy updated with literature review through January 2011; reference added; no change in policy statement
11/10/11	Replace policy	Policy updated with literature review through August 2011; references reordered; no change in policy statement
11/08/12	Replace policy	Policy updated with literature review through September 2012; references 2 and 10-11 added; references reordered; no change in policy statement
09/12/13	Replace policy	Policy updated with literature review through August 1, 2013; no new references added; no change in policy statement
09/11/14	Replace policy	Policy updated with literature review through August 19, 2014; reference 6 added; no change in policy statement
12/10/15	Replace policy	Policy updated with literature review through November 10, 2015; reference 12 added. Policy statement unchanged.
11/10/16	Replace policy	Policy updated with literature review through November 2,

		2016; references 2, 13, and 15 added. Policy statement unchanged.
11/09/17	Replace policy	Policy updated with literature review through September 11, 2017; no references added. Policy statement unchanged.
11/08/18	Replace policy	Policy updated with literature review through September 4, 2018; no references added. Policy statement unchanged.

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