National Institute for Health and Clinical Excellence

878 – Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence
Consultation Comments table

IPAC date: Thursday 10 March 2011

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1	Consultee 1 Private Sector Professional (USA)	**1**	The wealth of data which is either published or presented is very convincing regarding the efficacy of this procedure. Â This site lists several well-known studies that clearly demonstrate safety and efficacy. It is certainly reasonable to state that "complete understanding of which subsets of disease respond more maximally has not yet been fully elucidated (obstetrical injury responds the best) but it would be misleading to inform patients that there is "uncertainty about the procedures efficacy." Â I find most of my patients very educated and when presented with actual data, they can see what works and what is uncertain. Â I also believe that a more balanced approach to counseling is in order, especially as the more invasive approaches such as graciloplasty, artificial sphincter implants or implanted electrical stimulation devices have horrendous success rate and concomitant complication rates even in the best of hands. Â Therefore a measured presentation of any and all techniques with rates of success and complication will provide for a more informed consent process.	Thank you for your comment. Section 1.1 points out that this uncertainty in efficacy is because it is limited to the short-term in the published evidence and in small numbers of patients. Section 2.2.1 states that this procedure is intended to be less invasive than alternative surgical treatments. Section 1.2 of the guidance is intended to ensure patients are correctly informed about the procedure at consent.

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2	Consultee 2 CEO Mederi Therapeutics USA	**1**	Regarding the statement that further definition of suitable patients is necessary, the current clinical pathway (minus Secca) is to refer patients for conservative therapies such as diet modification, anti-diarrhea drugs, and then to pelvic exercises such as biofeedback. If these measures fail the next step in the current path involves invasive options such as overlapping sphincteroplasty, artificial sphincter implantation, or sacral nerve stimulator implant. Clinical studies demonstrate that these options have variable (45%-80%)results and relatively high complication rates (22%-49%). As Secca has a very low reported complications (.002)and equivalent results (50-84%), is significantly less invasive than any of the second line treatments,and is substantially less expensive than any of these options, it is proposed that in well selected (mild to moderate CCF Wexner score of 9-17) patients, Secca would be the second line of treatment for patients who have failed conservative treatments (first line) and prior to invasive and expensive options (third line). Secca therapy, if not successful, does not preclude application of any of the third line treatments.	Thank you for your comment. The Committee did not feel that the evidence was sufficient to recommend which patients would benefit from this procedure. The Interventional Procedures Advisory Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.

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3	Consultee 1 Private Sector Professional (USA)	**2.1**	There is a terrible prejudice in the presentation in this section. Where is the mention of the Secca procedure as a second line of therapy, intermediate to first line and final option. Â It is a bit unreasonable to go from biofeedback and antidiarrheal agents directly to colostomy. The Secca procedure needs to inserted here as an intermediate choice to be fair-handed in the process. Â The Secca procedure is not new, and has been used worldwide for nearly a decade! Â I suggest that that qualifies it as a "current treatment." No?	Thank you for your comment. NICE Interventional Procedures guidance does not report trade names or names of individual devices.
4	Consultee 2 CEO Mederi Therapeutics USA	**2.1**	As in many treatments, such as sacral nerve stimulationthe precise method of action is not fully understood. However, as the temperature of Secca cannot exceed 90C there is limitedif any, and very temporary scarring. Known tissue effects of other RF energy applications would indicate the method of action is collagen deposition resulting in decreased tissue compliance. Such decreases have been documented in several studies. There are no treatments below the dentate. Treatment level 1 is at the dentate and moves deeper into the anal canal in 5mm increments. The treatment protocol is for 5 levels in each quadrant.	Thank you for your comment. Section 2.2.1 and 2.2.2 of the guidance will be changed.

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5	Consultee 1 Private Sector Professional (USA)	**2.2**	The treatments are all at or above the dentate line and NEVER below the dentate line. The aim of the procedure has NEVER been to specifically cause a degree of scarring. Known tissue effects of other RF energy applications would indicate the method of action is collagen deposition resulting in decreased tissue compliance. Such decreases have been documented in several studies. Â The aim of the procedure is to cause muscle thickening, elongation of the anal canal and to alter sphincter reflexes to allow the patient to recover and control potential incontinence events. Â There are no studies that demonstrate scarring occurs.	Thank you for your comment. Section 2.2.1 and 2.2.2 of the guidance will be changed.
6	Consultee 1 Private Sector Professional (USA)	**2.3**	In my personal experience, all patients report benefits in the form of fewer episodes of incontinence, decreased embarrassment, and improved control of potential incontinent events. Regarding 2.3.4, this must be the only study that demonstrates no improvement and should be therefore discounted, until an explanation for total lack of efficacy is better explained, in that patient subset.	Thank you for your comment. Section 2.5.1 of the guidance states that the Committee noted the serious impact of faecal incontinence on patients' quality of life. Section 2.3.1 reports significant improvements in Fecal Incontinence Quality of Life questionnaire (FIQL) in this study. A discrepancy between significant clinical results and non-significant anometric manometric results was reported in a number of studies in table 2 (ex. Felt-Bergsma 2007; Lefebure 2008 only reported significant resting pressure changes).
7	Consultee 1 Private Sector Professional (USA)	**2.4**	It should be made clear, that in all of these reports the side effects reported are minor, short-lived, and temporary and fall well below the rates of more invasive procedures. There has never been a published report or regulatory compliant of anal stenosis with this procedure.	Thank you for your comment. In section 1.1, the Committee considered that there were no major safety concerns. Anal stenosis was listed as an anecdotal adverse event by one of the Specialist Advisers who is about to use this procedure in the UK..
8	Consultee 2 CEO Mederi Therapeutics USA	**2.4**	There have been no reported incidents of anal stenosis in any reporting database.	Thank you for your comment. Please see response to comment 7.

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9	Consultee 1 Private Sector Professional (USA)	**2.5**	The bottom line here (no pun intended) is that majority of properly selected patients who have failed first line therapy and then undergo the Secca procedure have less incontinence, fewer episodes of loss of control or embarrassment and can stop wearing diapers or nappies. The procedure represents the second line of treatment for patients who have failed conservative treatments (first line) and prior to invasive, less effective and expensive options (third line). Secca therapy, if not successful, does not preclude application of any of the third line treatments.	Thank you for your comment. The potential to significantly alter a patients' life has been highlighted in this section.

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10	Consultee 3 Private Sector Professional (USA)	**General**	I am a board-certified colorectal surgeon in southern California and have used the Secca procedure in the treatment of patients with anal incontinence who have failed conservative therapy and are not candidates for a surgical sphincterplasty. I have treated 22 patients with no adverse effects/complications. Transient worsening of symptoms for 72 hours or less was reported by several patients. I have noted subjective improvement in patient's symptoms (by report of decreased frequency of incontinence episodes, ability to defer defecation, or pad use) in 50% or greater and have had several patients report a complete response to therapy. The procedure is cost-effective compared to conventional sphincter repair which typically involves a 24-48 hour inpatient hospitalization following surgery and prolonged period of time off from work due to the relatively high rate of wound complications and infection. Even if patients do not report significant improvement in symptoms, most remain satisfied with the procedure because it causes minimal pain, does not necessitate time off from work, and most importantly, does not preclude further surgical therapy. Overall, I feel the procedure is an important and useful treatment option for anal incontinence. , MD, FACS, FASCRS	Thank you for your comment. Cost-effectiveness is not part of the remit of the IP Programme.

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11	Consultee 4 Private Sector Professional (USA)	**General**	I am a Colorectal surgeon in Port Charlotte, Florida. I have been been using the Secca procedure for 7 years. I have performed over 2 dozen procedures to date and have had tremendous results for my patients. I use Secca as a bridge in the gap between conservative treatments and surgery. Secca is a very safe alternative with a low complication rate as compared to other options such as the artificial sphincter. I am extremely happy with my results and would recommend Secca as a first line option for all surgeons.	Thank you for your comment.

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12	Consultee 5 Private Sector Professional (Netherlands)	**General**	I have now treated about 35 patients with SECCA. The method seems save and besides local bleeding we have not seen any serious complication. Recently we have submiited abstracts of the first 25 patients and follow up to two symposia witch weren accepted: The meeting of colorectal surgeons in Sorrento 2010 and in March 2011 for the Dutch Society of gastroenterology (NVGE). It seems a treatment witch can be valuable for patients who fail fibers and physiotherapy before going for other treatments like sacral nerve stimulation or gracilis plasty. We have now a success rate of around 60%, meaning that the patients have good or some improvement. Even after failure, other therapeutic surgical options are stille possible. Besides the medical / patients point of view the finances are also considerable less expensive then surgery. The dutch colorectal surgeons agree with this policy. The [redacted] publication about the SECCA cab be found on PUBMED looking for Felt-Bersma	Thank you for your comment. Conference abstracts are not eligible for presentation to the Committee. The publication referred to by this consultee was included in table 2 of the overview.

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13	Consultee 6 Private Sector Professional (Italy)	**General**	I'm a Secca Mederi user. I work in the Digestive Motility and Endoscopy Unit of the San Giovanni Battista Hospital, University of Torino, Italy. I've been informed by the Mederi european product manager that the device is under revision in UK. I've been invited to referr about my personal experience with the Secca System. Although the number of cases that we have done to treat fecal incontinence I should say that this procedure is feasible, safe and effective also on the out-patient basis. If more information would be useful please contact me.	Thank you for your comment.
14	Consultee 7 Private Sector Professional (Italy)	**general**	We are sending a note regarding the results of the SECCA in patients with anal incontinence. At Molinette's Hospital in Torino we have used the SECCA in few patients but we have very good results after a short follow up. We want to enfatize the efficacy, the good relation between cost effectivness of SECCA compared to other options and the ecxellent patients satisfation. At time we have only 5 cases at 6 months follow up. we are seriusly interested to continue this experience and to publish our study. best regards	Thank you for your comment.

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