Cover Page:

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The use of an "Anal-Tape" in patients with fecal incontinence

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Introduction:

Fecal incontinence (FI), defined as the involuntary passage of stool for more than 3 months[1] and is a devastating disease. The negative impact on quality of life has been consistently demonstrated[2-4]. Moreover many patients with FI avoid leaving their homes do to fear of being exposed episodes of FI in public and thus restrict their social life[1]. In the elderly FI may be associated with institutionalization and mortality[5, 6].

The prevalence of FI is probably underestimated in most studies duo to unawareness of physicians and patients reluctance to report it to the associated social stigma[7]. Nevertheless the estimated prevalence vary depending on the population studied and the definition of FI [7-11]. In community settings the prevalence of FI increases with age an varies between 2.2 and 25%[12, 13]. In hospitals the prevalence is 18 to 33% and in nursing homes it rises up to 50 to 70%[1]

FI may be secondary to intestinal diseases, pelvic floor disorders, anal weakness, neurological and psychiatric diseases. Often the etiology of FI is multifactorial[1, 13]:

- Anal sphincter weakness
    - Traumatic: obstetric, surgical, others.
        - Obstetric anal sphincter injury can cause immediate FI, but more typically begins 2–3 decades after the injury.
    - Nontraumatic: scleroderma, internal sphincter degeneration of unknown etiology
    - Neuropathy: peripheral (e.g., pudendal) or generalized (e.g., diabetes mellitus)
- Disturbances of pelvic floor: rectal prolapse, descending perineum syndrome
- Disorders affecting rectal capacity or sensation:
    - Inflammatory conditions: IBD, post radiation
    - Rectal surgery: Pouch, low anterior resection
- Central nervous system disorders: dementia, stroke, brain tumors, multiple sclerosis, spinal cord lesions
- Psychiatric diseases, behavioral disorders
- Bowel Disturbances:
    - Diarrhea: irritable bowel syndrome, post-cholecystectomy diarrhea
    - Constipation and fecal retention with overflow.

The management of FI start with reassurance, explaining patients that the disorder is not uncommon. Dietary modifications, skin care, and medications to improve stool consistency and delivery to the rectum may suffice. Anti-diarrheal drugs should provided if diarrhea is present. Pelvic floor training and biofeedback training have been found effective as well[13].

Scheduled defecations (e.g. every morning) with or without water enemas to clean the left colon can benefit some patients.

Minimally invasive procedures such as injection of bulking agents to the anal sphincter and muscle augmentation with radiofrequency ablation (SECCA) as well as surgical interventions and sacral nerve stimulation may be of use to some patients but are complex, expensive and associated with adverse effects.

Consequently local mechanical devices, that can be applied externally are very attractive, some of them are already commercially available.

We developed an "anal tape" using a commercially available elastic band with a special adhesive that is approved for use in the skin. This adhesive band is available worldwide and is used by numerous people, especially athletes. The band can be fashioned in any form and taped to any area of the body with a healthy skin and is for single use. Thus a square of the band with a small opening in the center can be applied to the skin surrounding the anus providing support and additional pressure forces to the anal sphincter.

This study will explore the efficacy and safety of this device in patients with FI, importantly the tape is commercially available; thus we have no commercial interest in the success of the device.

Aims of study:

To determine the efficacy and safety of the "anal tape" device in patients with fecal insentience that match with the inclusion and exclusion criteria of this study.

Study design:

This is a 4 week open-label, non-blinded, non randomized study in patients with fecal incontinence.

The study will consist of two periods of two weeks:

- First two weeks - control period: Patients will be asked to continue his / her normal life and to answer to validated questionnaires of fecal incontinence, quality of life and to fill a stool diary.
    - The first week will be considered as the baseline period
    - The second week as the control period.

- Second two weeks - treatment period: Patients will be provided with the device, and ask to answer to the same questionnaires, stool diary and an additional usability questionnaire.

Study population

Male and female patients above the age of 18 suffering from fecal incontinence of any etiology and that match the inclusion and exclusion criteria.

Inclusion criteria:

- ≥18 years old
- Fecal incontinence for more than 6 months
- Willing to participate
- Understand the study procedures
- Is able to apply and remove the "anal tape" without significant assistance of others.
- Have done sigmoidsocopy or colonoscopy and anal manometry within five year of screening visit
    - If there is clinical suspicion of proctitis a new sigmoidoscopy will be required as part of the regular clinical evaluation of patient with suspected proctitis.

Exclusion criteria:

- Advanced full thickness rectal prolapse.
- Injured, inflamed or any significant disease in the peri-anal skin.
- Allergy to any component of the device, either known of developed during testing in the screening visit (see below).
- Moderate to severe proctitis of any etiology.

Outcome variables:

Primary outcomes:

- Any improvement in any of the domain explored by the Fecal Incontinence quality of life questionnaire[14].

Secondary outcomes:

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- A 50% reduction in the number of episodes of FI or days per week, evaluated with the bowel diary and the weekly Wexner questionnaire.
- Any improvement in Wexner score, both total score and any of its components.
- Any improvement in quality of life score, and in any of its component.
- Usability score
- General satisfaction using a VAS score.
- Willingness of the patient to continue using the anal tape after the study.

Safety outcome:

- Any adverse effect that can be related to the device.

Number of patients:

In this study each patient will be his own control before and after the intervention. We expected minimal change (if any) during the control period. We calculated that 20 patients in each group are required to have a 80% chance of detecting, (with a significant 5% level), an increase in 5 points in the quality of life questionnaire from 20% in the control period to 60% in the treatment period.

Study procedures:

The study includes 3 office visits:

- Screening day 0:
    - Obtain informed consent for participation.
    - Personal information and demography: Age, medications, medical history, obstetric history (e.g. number of vaginal deliveries, obstetric anal sphincter injury) etc.
    - Obtain detailed FI related history:
        - Possible etiology
        - Review sigmoidoscopy and manometric data.
        - Type of FI:
            - Stool consistency
                - Gas
                - Liquid
                - Solid
            - Urge incontinence
            - Passive incontinence
    - Physical examination including digital rectal examination.
    - Overview of inclusion and exclusion criteria.
    - Obtain informed consent
    - Explain the use of the "anal tape"

    - Apply the "anal tape" to the arm or leg for 30 minutes in order to examine unexpected skin reaction to the device.
    - Provide the patient with the questionnaires:
        - To fill immediately:
            - Quality of life
            - Wexner
        - To fill in day 7 of study
            - Quality of life
            - Wexner
        - Bowel / stool diary
    - Insert all data into the database.

- Follow up day 14:
    - Retrieve questionnaires from day 7 and stool diary.
    - Explain again the use of the "Anal Tape"
    - Provide the patient with 28 (two for every day of the intervention period) single use "Anal Tapes".
    - Provide the patient with additional questionnaires:
        - To fill immediately:
            - Quality of life
            - Wexner
        - To fill in day 21 of study
            - Quality of life
            - Wexner
        - Bowel / stool diary
    - Insert all data into the database.

- Follow up day 28 and end of study:
    - Retrieve questionnaires from day 21 and stool diary.
    - Provide the patient with additional questionnaires:
        - To fill immediately:
            - Quality of life
            - Wexner
            - Usability score
    - Ask the patient about general satisfaction using a VAS score.
    - Ask the patient about willingness to continue using the anal tape after the study (yes or no answer).
    - Insert all data into the database.

Anorectal manometry:

- If there is clinical indication to perform anorectal manometry (according to one of the investigators), a new anorectal manometry will be required as part of the regular clinical evaluation, but in these cases we will measure anal pressure with and without the "anal tape" in situ.
    - We expect that up to 10 patients will require this additional evaluation.

Statistical Analysis Plan (SAP):

Descriptive statistics will be used to define baseline demographic characteristics of patients. Patients' data and clinical parameters will be given as means with standard deviation (SD), for normally distributed variables; and as median with range or interquartile range (IQR) in parenthesis as indicated, for non-normally distributed variables. Differences between the continuous variables during the control and the intervention period will be analyzed by t-test or the Mann-Whitney U test for normally or non-normally distributed variables respectively. Paired, Two-tailed tests with a significance level of 5% will be used in all analyses. All calculations will be performed using IBM statistics SPSS v25.

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