Sokol E. Management of fecal incontinence – focus on a vaginal insert for bowel control. 


Subjects

• This article looks at a series of studies that were conducted looking at the effectiveness of a vaginal insert for bowel control in women with fecal incontinence (LIFE clinical trial will be focused on for journal club).
  o 110 women were considered eligible who experienced an average of 11.66 FI episodes in two week bowel diary.
  o Inclusion criteria: 19-75 years old, history of FI for at least six months, minimum of 4 episodes of FI in bowel diary
  o Exclusion criteria: chronic watery diarrhea unmanageable by medication or diet, urinary or colorectal infections, presence of fistula, tumor of genitourinary or colorectal origin, IBD, chronic pelvic pain, vaginal prolapse beyond hymen, significant urogenital atrophy
  o Past management of FI: 18% reported previous management with biofeedback, 54% managed with dietary changes, 47% managed with fiber supplements.

• No randomization or control groups in any studies conducted.

Study design / method

• Main study of article (LIFE clinical trial) looked at safety and efficacy of the Eclipse device in 110 women who were fitted and then given opportunity to wear for at least one month and up to three months if fitted successfully.

• Oxford Centre for Evidence grading scale: 2c “outcomes research”
  o Single clinical trial with no randomization, blinding, or control groups involved.

• Control group: none.

• Experimental group
  o Patients completed bowel diary for two weeks before trial with average of 11.66 FI episodes
Fit with device and continued wearing if no discomfort in first week. 49 women did not complete study due to unsuccessful fitting.

Followed up in one month with 2-week diary completed during the second half. Patients had the option of continuing for additional two months if desired.

- Outcome measures
  - 2 week bowel diary
    - Success defined as >50% reduction in FI episodes at end of first month
  - Fecal Incontinence Quality of Life (Rockwood 2000)
    - Measures QoL with FI
    - Good reliability and validity
  - Modified Manchester Health Questionnaire (Kwon 2005)
    - Measures severity of FI and QoL
    - Good reliability and validity

- No blinding used in this study

Assessing the outcome

- 110 women were entered into the trial, 54 did not continue due to discomfort in first week of being fit with device or lost to follow-up
- 49.1% dropout rate is very high, main reason for dropouts was unable to fit successfully in four attempts.
- Intention to treat used with those who did not complete at least one month (but were successfully fit) as treatment failures.

Results

- At end of one month, 78.7% were considered treatment success (>50% reduction in FI)
- Mean FI episode decreased from 11.66 to 2.1 at end of one month
- Significant improvement in Fecal Incontinence Quality of Life and Modified Manchester scores after one month.
- Even higher rate of success (86.4%) with additional two months, but smaller sample size. Possibly due to the patients who experienced success in first month being more likely to continue for additional two months.
Conclusion

- Patients who were successfully fitted were able to achieve significant reduction in FI episodes.
- High rate of patients reported discomfort with fitting (45.5% vs 25-37% with pessary).
- Refer to Figure 4 for current FI treatments in regards to invasiveness (Diet modification, behavioral training, and PFM exercises have lower levels of invasiveness).

Limitation

- High dropout rate
- No blinding, randomization, or control groups
- Short length of device use

Discussion questions

- Has anyone treated a patient that has been fit for an Eclipse? What were the results? Does anyone know of any physicians in their areas that are fitting the Eclipse?
- Do you think the Eclipse device could be beneficial for patients with FI in addition to PT? Which patients would be most appropriate?
- Eclipse system fixes the FI symptoms but does not fix the underlying problem. It does not appear that any PFM assessment was done before fitting in order to determine strength or endurance of the muscles. Could physicians be educated on need for assessment before fitting to determine need for PT?

Additional references:

