2009 Annual Evidence Update on Surgical Management of Faecal Incontinence

Introduction

Annual Evidence Updates (AEU) are produced by NHS Evidence and aim to draw together recently published, high quality evidence – focusing particularly on systematic reviews and published guidelines - which it is hoped will inform and enhance the decision making and planning of clinicians, commissioners and others involved in the process of health care.

This AEU on the surgical management of faecal incontinence updates the 2008 findings and reviews evidence published between July 2008 and August 2009 focusing specifically on surgical management, including biofeedback and implants. For more information on conservative management of faecal incontinence, please refer to the relevant pages on the gastroenterology & liver diseases specialist collection.

A detailed literature review was undertaken to retrieve systematic reviews, randomised controlled trials and other quality studies relevant to the surgical management of faecal incontinence including sacral nerve modulation, biofeedback and implants. A total of 27 articles were selected for review and appraised by a team of general and colorectal surgeons led by the specialist collection's external reference panel member for The Association of Coloproctology of Great Britain and Ireland, Mr Paul Hainsworth.

It is imperative that those involved in commissioning and delivering care are apprised of the best available evidence and guidelines against which to review their service. We hope that the AEU on the surgical management of faecal incontinence will provide a prime source of such evidence.

Evidence report and methodology:

- Evidence on the surgical management of faecal incontinence - including including sacral nerve modulation, biofeedback and implants
- Methods for retrieving and evaluating the evidence

With thanks to the Annual Evidence Update reviewers:

Mr Paul J Hainsworth MD FRCS - Consultant Colorectal Surgeon, Freeman Hospital, Newcastle upon Tyne and External Reference Panel Member for NHS Evidence - surgery, anaesthesia, perioperative and critical care

Mr Edward Kiff FRCS – Consultant Surgeon, University Hospital of South Manchester

Mr Peter Lunniss FRCS - Senior Lecturer – Centre for Academic Surgery, Institute of Cell and Molecular Science, The Royal London Hospital

Ms Lalitha Mahadavan MRCS - Colorectal Research Fellow, Royal Devon & Exeter NHS Foundation Trust and Topic Advisor for the Specialist Library

Ms Karen Nugent FRCS - Senior Lecturer, Southampton University Hospital

Mr Olagunju A Ogunbiyi MD FRCS - Senior Lecturer/Consultant Colorectal Surgeon, Royal Free & University College Medical School, London

Mr Anil Reddy - Freeman Hospital, Newcastle

2009 Annual Evidence Update on Surgical Management of Faecal Incontinence - Reviews

Evidence on the surgical management of faecal incontinence - including sacral nerve stimulation, biofeedback and implants.

Articles selected on the surgical management of faecal incontinence:

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<tr>
<th>Title</th>
<th>Author(s)</th>
<th>Clinical Reviewers’ Commentary</th>
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<tr>
<td>Immediate or delayed repair of obstetric anal</td>
<td>Nordenstam, J et al</td>
<td>First and second reviewers' comments: Debate around delay in suturing has occurred and this study presents randomised data of 165 patients with 3rd and 4th degree tears. In contrast with general UK practice, this</td>
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sphincter tears - a randomised controlled trial

The study adopted end-to-end sphincter repair as the standard surgical method. Although there was no difference in functional outcome at one year between the two groups, the study presents good long term data on incontinence rates after tears. Patients who delayed up to 12 hours for their repair of an obstetric tear did not suffer any worsening of outcome. This means that if an adequately trained surgeon is not available the patient can wait although in normal circumstances this should not occur.

A cost-effectiveness analysis of delayed sphincteroplasty for anal sphincter injury

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<td>Does magnetic stimulation of sacral nerve roots modify colonic motility? Results of a randomized double-blind sham-controlled study</td>
<td>Gallas, S et al</td>
<td>First reviewer's comments: A well designed good quality study assessing the effects of non-invasive magnetic sacral nerve stimulation on colonic and rectal motor activity. Though small, it provides further information on the mechanism of action of sacral nerve stimulation. In addition, it may prove to be a safe and non-invasive method of assessing patients for suitability for sacral nerve stimulation. Second reviewer's comments: This paper provides insight into the mechanism of action of SNS on colonic and rectal activity. It is elegant and involves a non invasive way of stimulating the bowel. All the subjects were symptom free and it will be interesting to see the effects of this sort of stimulation on constipated and incontinent patients. The paper supports the idea that colonic contractions can be inhibited by magnetic stimulation of sacral roots and the process may be developed to look at assessing patients for permanent SNS.</td>
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Articles selected on sacral nerve stimulation:

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<td>Results of biofeedback therapy together with electrical stimulation in faecal incontinence with myogenic lesions</td>
<td>Sun D et al</td>
<td>First reviewer's comments: This is a prospective study assessing the results of biofeedback therapy (BFT) and electrical stimulation (FS) in the treatment of faecal incontinence resulting from myogenic lesions in 126 patients from September 2002 - September 2005. The sample size is large for a study of this nature. There is a clear description of the methods and results of the study. Significant improvement is noted in the clinical scores of patients treated with this method and this is maintained at two year follow up. Significant improvement is also noted in the squeeze pressures and sphincter electromyography amplitudes. Eighteen patients (14%) have been lost to follow up in this study. However, this is a treatment regimen that requires continued patient cooperation and compliance as well as a skilled and motivated therapist. This study has demonstrated that this combination therapy has been successful in improving the quality of life of patients with this difficult problem. The study also illustrates the need for future research into availability and timing of a reinforcement programme using this treatment strategy. Conclusion: Biofeedback therapy (BFT) and electrical</td>
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stimulation (ES) is an effective method in the treatment of patients with faecal incontinence resulting from myogenic lesions.

Second reviewer's comments: This paper is interesting. The number of male patients seems high but also there was a high level of postoperative incontinence. The follow up is excellent - adding to the strength of the paper. In England and Europe we struggle to maintain this level of follow up and also patient motivation. As many other surgical interventions may have deleterious side effects, effective conservative treatment is an important direction of travel. This is a useful paper as the results are backed up by improvements in anorectal physiology and maintained over time.

Fecal Incontinence and Biofeedback Therapy

Norton C

This review has comprehensively reviewed all conservative modes of management of faecal incontinence (FI). Up to date and relevant references have been reviewed in this article and good evidence based discussion has been provided for the various treatment options.

Articles selected on implants:

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<td>Injectable silicone biomaterial (PTQ[trademark]) is more effective than carbon-coated beads (Durasphere) in treating passive faecal incontinence - A randomized trial</td>
<td>Tjandra JJ et al</td>
<td>First reviewer's comments: A randomized controlled trial of two commercially available sphincter bulking materials for the treatment of internal anal sphincter weakness. 10ml PTQ injected in the intersphincteric plane under ultrasound guidance was compared with 10ml Durasphere injected submucosally. The precise method is given in the paper. Both worked but Durasphere was associated with worrying complications. Efficacy was maintained at 12 months only in the PTQ group. Second reviewer's comments: The patients in the majority had a weak but intact internal anal sphincter. The results have not been stratified according to presence or absence of external anal sphincter defects.</td>
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| Transabdominal artificial bowel sphincter implantation for faecal incontinence | NICE                | First reviewer's comments: Limited current evidence based on single small case series. Only high faecal incontinence score/severe incontinence were included in the case series. Risks noted include significant risk of revision surgery. Long term efficacy not proven  
Second reviewer's comments: Although a small series, this procedure represents a new technique and new device for severe faecal incontinence. I think it should be included as it contributes by looking at a novel approach to neo sphincters. The device should only be used for those with high incontinence scores. |
| Intersphincteric injected silicone biomaterial implants: a treatment for faecal incontinence | Soerensen MM et al | First and second reviewers' comments: This is a case series which assesses the functional and physiological outcomes following intersphincteric injection of silicone biomaterial, in 33 patients with faecal incontinence of various aetiologies (and of whom 17 had no sphincter defects), with a limited mean follow up of one year. Although as a group, continence scores reduced significantly following treatment at both three months and which was sustained at end follow up, the degree of reduction was of marginal clinical significance, and was mainly reflected by improved control over liquid stool. However, six patients derived substantial symptomatic improvement. Outcome was unrelated to incontinence severity or aetiology. There were no complications associated with the injections. Anal manometry revealed no changes in pressures as a result of treatment, and migration of the implanted biomaterial, as evidenced by ultrasound, had no impact on treatment efficacy in this small cohort. There were no benefits to quality of life apart from scores in general mental health. The discussion offers a brief review of previous studies using injectable agents for the treatment of faecal incontinence, and their limitations. As this treatment is safe, and |
since it can have a marked effect in a minority of patients, it may be considered within the treatment armamentarium.

Other studies of interest:

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<td>A prospective study assessing anal plug for containment of faecal soilage and incontinence</td>
<td>Chew MH et al</td>
<td>This case series of 30 patients from Singapore provides useful information on the use of the Peristeen Anal Fistula Plug. The series is unusual in that only 4 patients had obstetric injuries and 17 were male. Tolerance and efficacy, assessed over a three week period, were better than in European reports which the authors attribute to careful attention to plug placement in the lower rectum. There is a helpful literature review and the paper serves as a useful reminder for the plug.</td>
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<td>Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study</td>
<td>Lefebure B et al</td>
<td>First and second reviewers’ comments: This is a novel treatment for faecal incontinence which might work by causing scarring in the anal canal. Several studies have been performed with favourable results. This study demonstrated no real clinical benefit.</td>
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| Submucosal injection of stabilized nonanimal hyaluronic acid with dextranomer: a new treatment option for fecal incontinence | Danielson J et al  | First reviewer's comments: New option of management of faecal incontinence with minimal morbidity. Only short term follow up. Effective in less than 50% of patients.  
Second reviewer's comments: Several injectable bulking agents have been trialled for faecal incontinence. 'Stabilized nonanimal hyaluronic acid with dextranomer' is a novel agent borrowed from the field of urology with promising early results. Whereas patients with internal anal sphincter injuries have usually been targeted in such studies, the indication for treatment in this cohort of 35 patients was merely the absence of a complete sphincter defect (internal and external components) on ultrasound and/or clinical examination. The authors report clinical response (i.e. at least a 50% reduction in incontinence episodes over four-week serial periods) in 44% patients at 6 months and 56% at 12 months. Apart from some immediate inflammatory reactions, no long-term side effects or serious adverse events were reported. Further studies are required before recommending this treatment for routine clinical practice. |
| New options for the treatment of fecal incontinence                  | Margolin DA       | First and second reviewers’ comments: This is a well written review paper on the current surgical and non-surgical management options available for faecal incontinence. The hidden cost and burden of faecal incontinence has also been introduced well and discussed in the paper. All the different management techniques have been subdivided and the relevant articles for each subheading have been reviewed with the appropriate conclusions drawn on each. The data presented in this paper is relevant to the UK practice. As the authors have stated, long term outcomes are eagerly awaited on many of the newer techniques available for the management of faecal incontinence. |

References:


7. National Institute for Health and Clinical Excellence (NICE) Transabdominal artificial bowel sphincter implantation for faecal incontinence [full text]


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**2009 Annual Evidence Update on Surgical Management of Faecal Incontinence - Methods**

**Methods for retrieving and evaluating the evidence**

NICE issued guidance on the [management of faecal incontinence in adults](http://example.com) in June 2007 based on literature published prior to October 2006. In 2008 we published an update on the then available evidence. The current update aims to present evidence published between July 2008 and August 2009 focusing on the surgical management of faecal incontinence including sacral nerve modulation, biofeedback and implants (as advised by our surgical reviewers).

The search aimed to identify guidelines, systematic reviews, randomised controlled trials and other high quality studies published in English. Due to the paucity of evidence in this very focussed subject, the clinical reviewers included lower level evidence when they considered it to be of interest to the community of colorectal surgeons.

**Search strategies**

Searches were conducted in Medline and Embase (both Dialog and Ovid versions). The search strategies for Medline and Embase were based on those used in the NICE guideline, Faecal Incontinence. Please refer to Appendix C (pages 11 and 31-32) of the guideline appendices for full details.

**Search strategy for Medline**

1. Fecal Incontinence/
2. ((faecal or feca or faeces or feces or defecally or anal or anally or stool or stools or bowel or double or defecat$ or defaecat$) adj (incontinence or incontinent or urge$ or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).tw.
3. ((direct adj apposition adj sphincter adj repair) or (sphincter adj reconstruction) or (external adj anal adj sphincter adj placation) or (neoanal adj sphincter) or (colonic adj conduit) or (gracilis adj muscle adj augmentation)).tw.
4. ((gracilis adj neosphincter) or (perineal adj puborectalis adj sling adj operation) or (pelvic adj floor adj repair) or (SECCA adj procedure) or (SECCA adj device) or (radio adj frequency adj energy adj delivery) or bioinjectibles).tw.

5. (collagen or teflon or silicone or durasphere or macroplastique or PTP or bioplastique or colostomy or (stoma adj creation) or (temporary adj stoma) or (permanent adj stoma) or (perioperative adj management adj regimes) or (post adj surgical adj regimes)).tw.

6. or/1-4

The search was repeated in Embase with the appropriate adjustments.
We also searched DARE, HTA, NEED, the NLH Guidelines Finder, the Cochrane Library, NICE, and SIGN.
27 articles were considered for appraisal

**Inclusion criteria**
Publication types - guidelines, systematic reviews, health technology assessments, economic evaluations, meta-analyses, case reports or series
Publication dates - July 2008 - August 2009
Treatments considered – surgical procedures; sacral nerve modulation; biofeedback; injectible implants
Publication language - English only