Placement of artificial bowel sphincters in the management of faecal incontinence

Medicare Services Advisory Committee

Authors' objectives
To examine the effectiveness of artificial sphincters, compared with stimulated syngeneic muscle transfers, in the control of intractable faecal incontinence that has not responded to treatment using more conservative approaches.

Searching
The authors searched seven databases for articles published in any language.

1. The Cochrane Library (Issue 3, 1999) was searched using the terms 'fecal incontinence', 'anal incontinence', 'artificial bowel sphincter', 'artificial anal sphincter', 'anus', 'prostheses' and 'implants'.

2. MEDLINE, Biological Abstracts and CINAHL were searched from 1966 to September 5, 1999 using the terms 'artificial bowel sphincter', 'artificial anal sphincter', 'fecal incontinence', 'anal incontinence', 'anus (surgery)', 'prostheses' and 'implants'.

3. Best Evidence was searched from 1991 to 1999 using the terms 'fecal incontinence', 'anal incontinence' and 'sphincter'.

4. HealthSTAR and PubMed (September, week 5, 1999) were searched using the terms 'artificial bowel sphincter', 'artificial anal sphincter', 'fecal incontinence', 'anal incontinence', 'anus (surgery)', 'prostheses' and 'implants'.

The authors also searched the reference lists of retrieved studies, and contacted experts in the field and the manufacturer of the device for additional information or studies.

Study selection
Study designs of evaluations included in the review
Any study designs appear to have been eligible for inclusion. Those included in the review were descriptive case series. The duration of follow-up ranged from 1 month to 10 years. Studies that did not include primary data, e.g. reviews, letters to editors and editorials, were excluded. In addition, studies that included data published in another study, or were not published in English, were excluded.

Specific interventions included in the review
Artificial bowel sphincters (ABS) or artificial urinary sphincter (AUS), compared with dynamic graciloplasty (a stimulated syngeneic muscle transfer). The authors did not find any direct comparisons of ABS or AUS with dynamic graciloplasty.

Participants included in the review
Patients with intractable faecal incontinence that has not responded to treatment using more conservative approaches. The included participants were predominantly female. Forty per cent of incontinence was due to a neurological disorder (including idiopathic sphincter weakness). The reasons for incontinence were: sacral agenesis, obstetric injury, major trauma, neurological disorder, imperforate anus, failure of previous treatment, or idiopathic sphincter weakness.

Outcomes assessed in the review
No a priori outcome measures were reported. In the review, the authors assessed the degree of faecal control, and immediate post-operative and secondary adverse events. Quality of life was also assessed.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.
Assessment of study quality
The authors do not state that they assessed validity. However, they classified the included studies according to the National Health and Medical Research Council-revised hierarchy of evidence (see Other Publications of Related Interest). A committee of six experts was involved in classifying the studies.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Data were extracted and presented in tables for the following categories: study identification, location (country of origin), year of publication, study and participant characteristics (age, number of males, causes of incontinence), outcomes, adverse events, follow-up, and comments.

Methods of synthesis
How were the studies combined?
The number of adverse events were summed and presented in a table, as were the functional outcomes of participants (degree of faecal control).

How were differences between studies investigated?
The authors do not report any means of assessing differences between the studies.

Results of the review
Seven descriptive case series involving a total of 60 patients were included; the sample sizes ranged from 1 to 17 patients. Five studies focused on the follow-up of patients implanted with the AUS, while one study looked into the implantation of the ABS. The remaining study with 13 participants looked at both ABS (4 participants) and AUS (9 participants).

Study quality.
The findings represented the experience of a limited number of centres and a select group of participants. In addition, there were no control groups, there was a high likelihood of selection bias, and there may be measurement bias due to the lack of controls. The authors stated that randomised controlled trials would be the ideal, however, none were found.

Faecal control.
Of the total 60 patients, only 36 participants (60%) had follow-up details. Of these 36 patients, approximately 23 (64%) were continent to solid faeces, 23 (64%) were continent to liquid stool, and 15 (42%) were able to control flatus. The intention to treat numbers for the proportion of patients able to control faeces, liquid stool and flatus were approximately 38% (23 out of 60), 38% (23 out of 60) and 25% (15 out of 60), respectively. The authors stated that the apparent continence to solid faeces may be an overestimate, as there were no data on how many of these patients were incontinent to solid faeces before undergoing implantation, and whether an improvement in their condition actually resulted.

Adverse events.
Surgical site infections were common (11 cases) and, although they were controlled by the use of appropriate antibiotics, some cases were serious enough to warrant removal of the device. Erosion of the adjacent skin or ulceration occurred in 4 instances (only 3 cases were listed in the results table), and faecal impaction occurred in 2 cases. There were no cases of the device eroding through the sphincter musculature and into the anal canal. There were 8 cases of post-operative device failure. In addition, 17 of the 60 implants required removal, 8 of which were immediate or early (up to 1 month post-implantation).
Quality of life.

Only 3 studies (n=29) looked at the impact of the procedure on the patients' quality of life. Overall, there were reports of improvements in the role-emotional, social and physical-functioning domains of the Short Form 36 questionnaire. The studies did not provide data about specific changes, although they made blanket statements attesting to the general improvement of quality of life in those participants in which devices were implanted.

Cost information

The authors state that because issues of clinical effectiveness and safety remain unresolved, it is not yet possible to perform an economic evaluation of the sphincters and their role in the management of faecal incontinence. The review quoted some costs (Australian dollars) for graciloplasty and ABS.

Authors' conclusions

The authors stated that the use of the artificial bowel sphincter has demonstrated some positive effects in the management of faecal incontinence, and in the quality of life of patients undergoing the procedure. However, it was difficult to quantify the degree of this benefit due to serious deficiencies in the design of the studies conducted to date. There was no strong evidence to determine whether the advantages of this procedure were significantly greater than those of other treatment alternatives (or no treatment) in individuals receiving the device. The supporting committee also noted that evidence in support of the comparator, dynamic graciloplasty, was also lacking.

The authors also state that it was impossible to make firm conclusions about the safety profile of the device. However, a number of adverse events were reported, including removal of the device due to failure or surgical site infection, which occurred in about 30% of cases in those studies assessed.

CRD commentary

The main drawback of this review was the quality of the included studies. The authors commented that their most serious concern was the lack of control groups with which to make comparisons. They were also worried about selection bias, since there was no a priori participant selection criteria before enrolment in the individual studies. The authors stated the research question, although it was worded differently in two places in the review, and also stated some of the inclusion and exclusion criteria. The literature search was comprehensive although it was limited to English language publications.

The quality of the included studies was classified using a hierarchy of evidence scheme, which revealed that the included studies were of insufficient quality to enable a valid determination of the effectiveness. Despite this, the validity of the included studies was not assessed, and this would have shown the difference between well- and badly-conducted case series. The authors did not report how the articles were selected, or who performed the selection and data extraction. The data extracted were reported in tables and discussed in the text of the review. The studies were only summed in the tables, and were not analysed further.

The authors' conclusions appear to follow from the results, but should be viewed with caution because of limitations in the quality of the included studies and in the review process.

Implications of the review for practice and research

Practice: The authors state that since there is currently insufficient evidence pertaining to the placement of ABS in the management of faecal incontinence, it is recommended that public funding should not be supported at this time.

Research: The authors imply that further high-quality research is needed to establish the safety and effectiveness of these procedures.

Bibliographic details

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Other publications of related interest

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.