Cost of pelvic floor repair for faecal incontinence
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two methods of pelvic floor repair for faecal incontinence were compared. These were post-anal repair (PAR) and total pelvic floor repair (TPFR). TPFR was PAR combined with anterior levatorplasty.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with faecal incontinence due to definite obstetric trauma, injury after prior anal surgery, sexual trauma, incontinence complicating post-obstetric straining, diabetic neuropathy, or obstetric factors. Patients were excluded from the study if they had rectal prolapse, co-existing anorectal malignancy, inflammatory bowel disease, diverticular disease, megacolon, megarectum, co-existing rectovaginal fistula, congenital abnormalities, or prior colorectal operations.

Setting
The setting was secondary care. The economic study was carried out in Birmingham, UK.

Dates to which data relate
The effectiveness and resource use evidence was gathered during 1980 to 1992. The price year was 1999.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
No power calculations to determine the sample size were carried out. The method used to select the sample was not reported. In addition, there was no information as to how the patients were allocated between the two groups. An overall sample of 79 patients was included in the analysis. This comprised 69 female and 10 male patients with a mean age of 51 years (range: 21 - 81). There were 47 patients in the PAR group and 32 in the TPFR group.
Study design
This was a case-control study, carried out in a single centre (the University Department of Surgery at the Queen Elizabeth Hospital in Birmingham). All patients were investigated in the physiology laboratory by anal manometry and ultrasonography. The mean follow-up was 6.6 years for TPFR and 9.7 years for PAR. The loss to follow-up was unclear.

Analysis of effectiveness
All patients included in the sample were accounted for in the analysis. The main outcome measure was represented by the overall functional outcome of the interventions. This was measured in terms of the following:

full continence, where the patients did not need to wear pads and only had minor episodes of flatus or liquid stool incontinence;

improved continence, where patients had some persistent incontinence which did not have a major impact on their lifestyle; and

unimproved incontinence or requiring end stoma, that is, patients with persistent incontinence with a major impact on their lifestyle and requiring another operation.

The secondary health outcomes assessed in the analysis were the number of admissions, operations, hospital stay, outpatient preoperative and postoperative visits, and operation time. The authors stated that the study groups were not comparable at baseline. Hence, the outcomes assessed were merely descriptive in terms of the type of pelvic floor repair used.

Effectiveness results
The number of patients who reached full continence was 13 (28%) in the PAR group and 17 (53%) in the TPFR group.

The number of patients who improved but who were still incontinent was 13 (28%) in the PAR group and 13 (41%) in the TPFR group.

The number of patients with unimproved incontinence or requiring end stoma was 21 (45%) in the PAR group and 2 (6%) in the TPFR group.

The total number of admissions was 114 (2.42 per patient) in the PAR group and 38 (1.18 per patient) in the TPFR group.

The total number of operations was 104 (2.12 per patient) in the PAR group and 37 (1.15 per patient) in the TPFR group.

The total length of hospital stay was 994 days (21.1 per patient) in the PAR group and 637 days (19.9 per patient) in the TPFR group.

The total number of outpatient preoperative visits was 98 (2 per patient) in the PAR group and 64 (2 per patient) in the TPFR group.

The total number of outpatient postoperative visits was 395 (8.40 per patient) in the PAR group and 149 (4.65 per patient) in the TPFR group.

The total length of operation time was 7,910 minutes in the PAR group and 3,390 minutes in the TPFR group.

Clinical conclusions
The authors did not draw any clear conclusions about the two surgical procedures. They acknowledged that it was difficult to draw firm conclusions, as the follow-up periods were different for the two procedures. The authors also
pointed out that the low success rate of PAR meant that they would find it difficult to recommend this procedure.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore carried out.

**Direct costs**
The costs were measured for the days in hospital, number of preoperative outpatient visits, number of postoperative outpatient visits, amount of time spent by surgeon, and the operating theatre. The quantities were generally reported separately from the prices, with the exception of the operating theatre (quantity not given).

Discounting was not carried out, even though the costs were incurred over a long period due to re-operations. The quantities were estimated using actual data from the hospital. The prices were taken from 1999 NHS figures.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
The indirect costs were not calculated.

**Currency**
Euros.

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The average total cost was Euro 4,043 for a patient in the PAR group, and Euro 3,254 for a patient in the TPFR group.

The average duration was 9.7 years for the PAR group, and 6.6 years for the TPFR group.

The costs of adverse effects were taken into account.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
The two interventions could not be compared since the length of follow-up for total pelvic floor repair (TPFR) was too short to establish whether it could be recommended, and the study groups were not comparable. However, the authors pointed out that the success rate was greater for patients treated with TPFR and the overall costs were smaller, mainly due to the higher number of re-operations in the post-anal repair (PAR) group.
CRD COMMENTARY - Selection of comparators
The choice of the treatments compared was valid, as they consisted of two surgical treatments that have been accepted for faecal incontinence for several years. You should assess whether they represent widely used health interventions in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a case-control study. However, there were certain drawbacks in the study design. First, the patient groups were not shown to have been comparable at analysis. Second, it was unclear how the patients were allocated to the different treatment groups. It might be inferred from the article that the hospital changed its method of treating faecal incontinence over time, and so the treatment a patient received depended on the date at which they were admitted. If the latter were true, it would explain why the authors were able to have a longer follow-up for one treatment than for the other. However, it does not explain why the authors did not curtail the time of the PAR follow-up, in order to have an identical follow-up time for both patient groups. Finally, due to the lack of randomisation, potential confounding and bias may have occurred. These issues limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was estimated in the effectiveness analysis. Thus, a cost-consequences analysis was carried out. It might have been useful if the benefit had been analysed from the patients' perspective, in order to see what value the patients put on a successful operation. Also, to see how much they put a negative value on an unsuccessful operation, and how these outcomes compare with the consequences of doing nothing.

Validity of estimate of costs
The study was conducted from the perspective of the NHS. All the relevant categories of costs were included in the analysis. The indirect costs were not included, but could have been important as patients and their families have to face the cost of faecal incontinence. A complete breakdown of the costs was reported. In addition, the unit costs were given separately from the quantities of resources. However, the direct costs do not appear to have been correctly calculated, as discounting did not take place. The costs were treated deterministically and sensitivity analyses were not performed. Surprisingly, the authors presented the costs in Euros, yet at the time of the study (the price year was 1999) the original prices must have been in UK pounds sterling and the authors did not state what exchange rate was used.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies. However, they did not address the issue of generalisability to other settings. The authors did not present their results selectively, but their conclusions did not appropriately reflect the scope of the analysis. It was unclear whether some patients would be worse off with unsuccessful surgery than with no surgery. The authors regarded the high rate of unsuccessful surgery as a waste of resources. However, without a valuation of the successful operations it is not possible to draw that conclusion.

Implications of the study
The authors state that any new surgical interventions for faecal incontinence should be carefully evaluated in terms of the costs, continence and quality of life.

Source of funding
None stated.

Bibliographic details