

Statement from the Regional HTA Centre of Region Västra Götaland, Sweden

Sacral nerve stimulation (SNS) for fecal incontinence

Question at issue:

Is sacral nerve stimulation (SNS) an efficacious treatment for fecal incontinence, compared to antipropulsive medication, physiotherapy, or no treatment regarding symptoms, ability to work, health-related quality of life and cost-effectiveness?

PICO (Patient, Intervention, Comparison, Outcome)

- P = Adults with fecal incontinence or double incontinence, regardless of etiology.
- I = SNS
- C = Antipropulsive medication and/or physiotherapy, or no treatment.
- O = Validated patient-reported symptoms or symptom scores, ability to work, health-related quality of life, cost-effectiveness.

Summary of the health technology assessment:

Method and patient category:

The target population is adults with fecal incontinence. The prevalence of fecal incontinence is reported to 0.4-13.13% among adults. The treatment is determined by the cause of the incontinence, symptoms, age, co-morbidity, and generally includes medication and physiotherapy in outpatient settings. In advanced cases (colo)stomy may be considered. SNS treatment implies electrical sacral nerve stimulation, usually at the S3-S4 level of the spinal column, which initially temporarily, is provided transcutaneously, to study if the patient responds positively to the treatment. If the patient reports >50% improvement in the number of incontinence episodes, or urgencies, usually during one or two weeks test stimulation, a permanent electrode implantation is performed.

Level of evidence:

Wexner score (a validated symptom score for fecal incontinence) was in one of the studies reported to improve from 16 to 1.2 in the SNS group, whereas no difference was seen in the control group. The number of incontinence episodes was reduced from 9.5 to 2.9 (Tjandra et al). In the other study, the frequency of incontinence episodes was reduced by 90% when the stimulator was switched on, and by 75% when the stimulation was disconnected.

Among the patents that chose to have the stimulator ON after a crossover, an absolute reduction of incontinence episodes of 1.0 (1.7 with the stimulator ON vs. 0.7 with the stimulator OFF) per week was seen.

The systematic literature search resulted in two randomized controlled trials, and four case-series reporting adverse effects and risks, as well as health economical evaluations. One out of the two RCTs, reporting improvement in fecal incontinence with SNS therapy, was considered to be of moderate quality, whereas the other was judged to be of low quality.

The scientific support for a positive effect of SNS on fecal incontinence is insufficient.

Adverse effects and risks

21-48% had some kind of complication. In 2.7-8% of the cases the electrode was dislocated, necessitating reoperation. 2.7-4% of the patients had an infection necessitating removal of the entire system. Pain requiring surgical revision was reported in 5.4%, 10%, and 28%, in three different case series, respectively.

Ethical aspects:

It is ethically questionable to use a very expensive treatment, associated with risks of serious complications, in routine care when the scientific support for a patient benefit is insufficient.

Economical aspects

Total average cost for treatment of one patient with SNS for fecal incontinence is 117,438 SEK/patient. Regarding the published health economic studies, it must first be noted that the effectiveness of the therapy has insufficient scientific support. Four of the reviewed articles have evaluated SNS with health economic methodologies, and reported a cost per QALY for SNS therapy for fecal incontinence of approximately 250,000 SEK.

Concluding remarks

Two RCTs, one of moderate and one of low quality, as well as case series, reported positive effects of SNS on improved fecal incontinence that had previously failed to respond to other treatments. However, the scientific support for the treatment is insufficient and large adequately designed RCTs are needed. The SNS treatment is costly.

On behalf of the Regional HTA Centre of Region Västra Götaland, Sweden.

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