SACRAL NERVE STIMULATION WITH INTERSTIM® FOR THE TREATMENT OF FAECAL INCONTINENCE REFRACTORY TO CONSERVATIVE TREATMENT: A COST-UTILITY ANALYSIS

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Abbreviations

COL	Colostomy	**ICUR**	Incremental Cost-Utility Ratio
CT	Conservative Treatment	**PTNS**	Percutaneous Tibial Nerve Stimulation
CUR	Cost-Utility Ratio	**SR**	Sphincter Repair
FI	Faecal Incontinence	**SNS**	Sacral Nerve Stimulation
IBA	Injectable Bulking Agents		

Aim

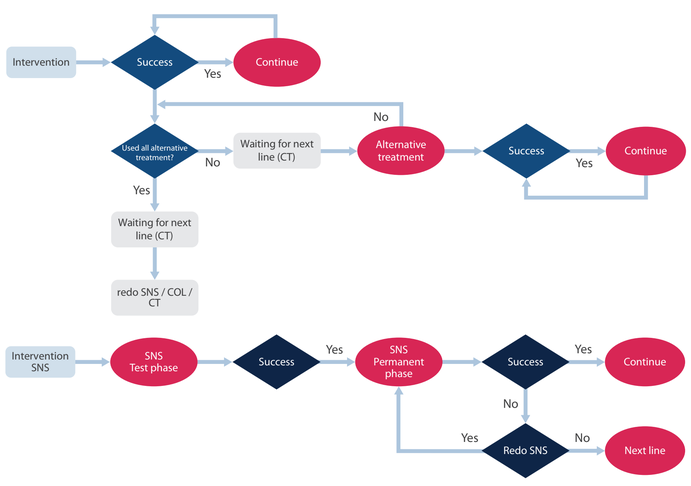
To estimate the cost-effectiveness of sacral nerve stimulation (SNS) using InterStim® therapy compared to alternative treatments for patients with faecal incontinence (FI) refractory to conservative treatments (CT).

Method

A patient-level simulation model with a lifetime horizon was developed. Two sub-populations, differentiated by the presence or absence of a surgically repairable sphincter defect, were analyzed. The isolated, sequential and summative clinical and economic effects of InterStim therapy against alternative treatments were modelled. Alternative treatments were anal sphincter repair (SR), injectable Dextranomer in stabilized hyaluronic acid (NASHA/Dx) and percutaneous tibial nerve stimulation (PTNS).

The effectiveness (including quality of life) and safety data for most of the interventions were based on a systematic literature review performed ad hoc [1] and assessed as the proportion of patients with treatment success at set time-points. Depending on the response to a treatment, subjects either could continue with the current therapy or progress to the next line of treatment (Figure 1). When all therapeutic options had been exhausted, continued conservative treatment and colostomy were deemed to be last-line therapies.

Figure 1. Model structure



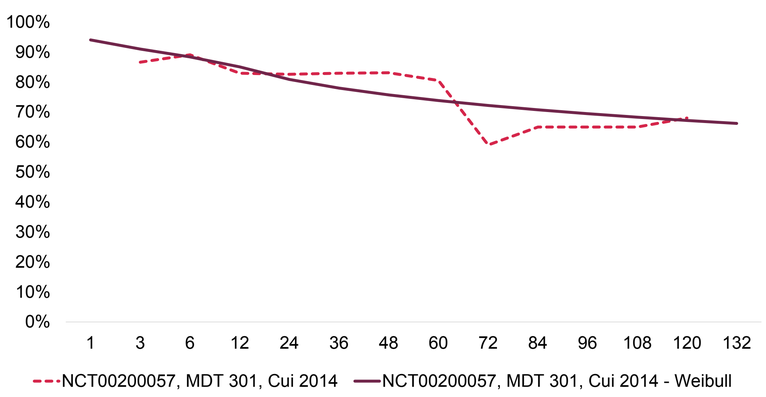
A cost utility analysis was performed from the perspective of the UK national health service (NHS). Direct medical costs derived from the 2015/16 UK National Tariff and National Institute of Clinical Excellence costing report 2007 were considered. Sensitivity analysis and discounting at 3.5% for cost and outcome were included.

Four health states with different utilities were evaluated:
- no FI symptoms state where utility value was assumed as in general popultion, equal 0.86,
- FI with reduction in symptoms, with utility 0.71,
- FI without response to treatment, with utility 0.64,
- Colostomy, with utility 0.68.

SNS

Temporary evaluation of SNS can be performed using basic evaluation (monopolar lead) or advanced evaluation (bipolar tined lead). Outcome, morbidity and overall cost differs based on the approach used. Therefore, both types of evaluation were considered. The percentage of patients responding to treatment after basic evaluation is 69% versus 83% for advanced evaluation. [1] For patients progressing to chronic SNS, Weibull regression analysis of the percentage of patients with >50% reduction of incontinent episodes at fixed time points was performed [2-7]. It was assumed that 45.7% of patients who respond to treatment are fully continent.

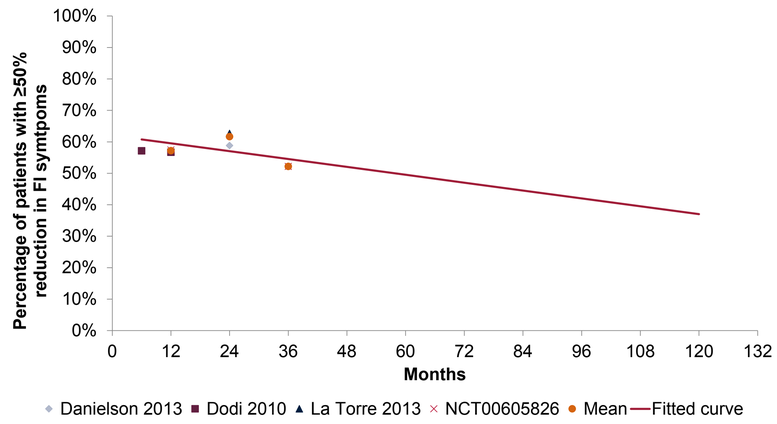
Figure 2 SNS long-term effectiveness summary (≥50% reduction in FI episodes)



NASHA/DX

Linear regression analysis of the percentage of patients with >50% reduction of incontinent episodes at fixed time points was performed. [1] It was assumed that 22.23% of patients who respond to NASHA/DX are fully continent [8] and 53% of patients required an additional injection in the short term.

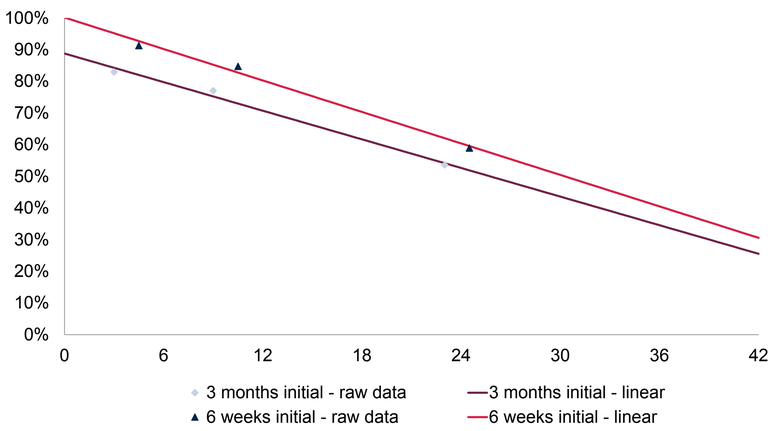
Figure 3. NASHA/DX long-term effectiveness – ≥50% reduction in FI episodes



PTNS

Linear regression analysis of the percentage of patients with >50% reduction of incontinent episodes at fixed time points was performed. [1] It was assumed that an initial response is achieved by 76.7% [1] and 54.6% of patients who respond to treatment are fully continent [9].

Figure 4. PTNS long-term efficacy summary (≥50% reduction in incontinence episodes)



SR

There is no published data regarding >50% reduction of incontinence episodes following sphincter repair. Therefore, response was determined using Weibull regression analysis of data reporting improvement of Park's continence scale to grade II or less. [10] Those data were consistent with data from other publications concerning variously defined response. [1] A statistical curve fitted to clinical data was used in calculations concerning the number of patients completely continent after surgery.

Figure 5. SR long-term effectiveness – probability of treatment response

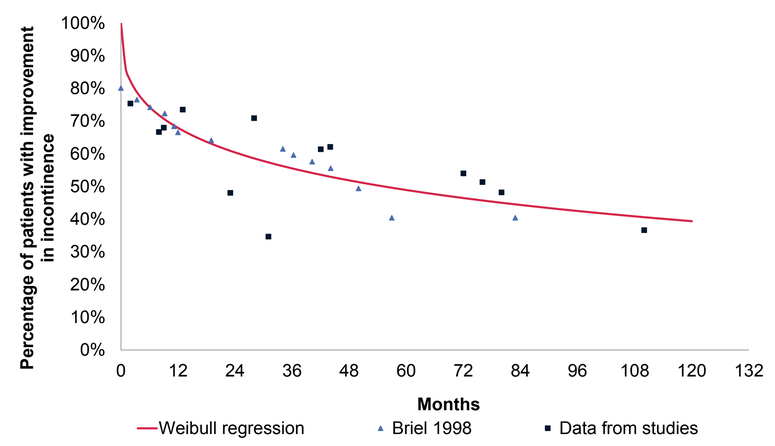


Table 1. Adverse events

Adverse event	Result
SNS	
Events connected with surgical revision	Surgery in 6.25% of the patients
Events connected with lead replacement	Surgery in 4.28% of the patients
Events connected with device replacement	Surgery in 1.76% of the patients
Events connected with device explantation	Surgery in 4.87% of the patients
SR	
Wound abscess, hematoma, fistula	Reoperation in 10% of the patients
NASHA Dx	
Pain or discomfort, bleeding (i.e anal bleeding), injection site bleeding, inflammation, abscess	Minor surgery in 5% of the patients
Colostomy	
Parastomal hernia, retraction, obstruction, bleeding, fistula, ischaemia/necrosis, stenosis, prolapse	Reoperation in 5% of the patients annually

Results

For every comparison, using SNS instead of one of the comparators or adding SNS to it, gave additional benefits (Table 2). Depending on the comparison the average weekly number of FI episodes was reduced by 0.77-2.37 after replacing the comparator with SNS and by 1.68-3.09 after adding SNS to the evaluated treatment. Corresponding differences in gained QALY were 0.32-0.69 and 0.48-0.92. In almost all comparisons incremental cost-utility ratio for SNS was within the £30,000 per QALY threshold recommended by the National Institute for Health and Clinical Excellence as an effective use of NHS resources (Table 3).

Table 2. Results of deterministic analysis

Treatment path	Total costs	QALY	Number of FI episodes per day
Patients with small or no sphincter disruption			
NASHA Dx -> SNS[a]	24 971 GBP	11.41	0.74
NASHA Dx[a]	21 728 GBP	10.86	1.01
SNS[a]	30 430 GBP	11.30	0.83
PTNS[a]	23 976 GBP	10.62	1.17
PTNS -> SNS[a]	27 879 GBP	11.36	0.80
COL / CT	25 268 GBP	10.38	1.27
Patients with surgically reparable disruption			
SNS -> SR[a]	26 428 GBP	11.61	0.67
SR -> SNS[a]	20 216 GBP	11.47	0.70
SR[a]	17 518 GBP	10.98	0.94
SNS[a]	30 444 GBP	11.31	0.83

a) at the end of each treatment path COL or continuation of CT are used

Table 3. Incremental results

Strategy of using SNS	Extreme value	ICUR[a]
Patients with small or no sphincter disruption		
Replacement by SNS	MIN	9 395
	MAX	19 700
Adding SNS	MIN	5 245
	MAX	5 928
Patients with surgically reparable disruption		
Replacement by SNS	-	40 255
Adding SNS	MIN	5 607
	MAX	14 357

a) incremental cost-utility ratio

Conclusions

SNS is a relevant treatment for faecal incontinence in patients who have failed conservative management. It brings additional benefits at an acceptable cost.

References

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