

CHRONIC FECAL INCONTINENCE (FI)

Clinical Evidence



DISEASE PREVALENCE

Prevalence



Patient Impact



Resources



CONSERVATIVE THERAPIES

Behavioral Therapy



ADVANCED THERAPIES

Sacral
Neuromodulation



Injectable
Bulking Agent



Sphincteroplasty



Medtronic

FECAL INCONTINENCE: A HIGHLY PREVALENT AND UNDERTREATED DISEASE

Adult population in Europe
>400 million^{1,2}

Adults with fecal incontinence
>19.2 million (4.8%³, range 0.8-8.3%^{3b})

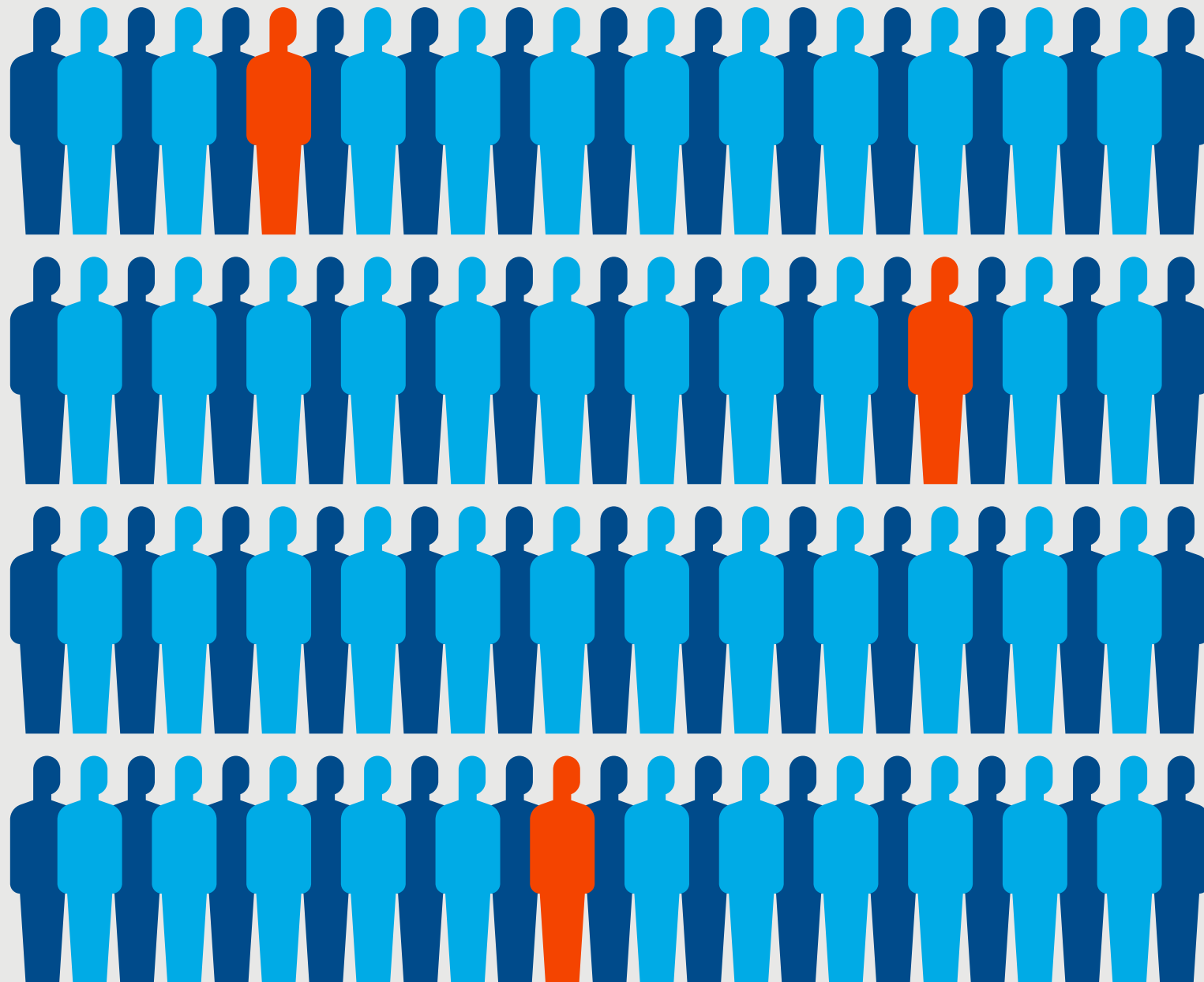
Bothersome enough to seek care
>5.2 million (27%, range 8-27%⁴)

Therapy goal not met with conservative therapies
>1.5 million (range 28-51%^{5,5b})

Potential candidate for SNM based on etiology
>1.3 million (≥85%⁶)



FI CAN HAVE A SEVERE IMPACT ON QUALITY OF LIFE^{7b}

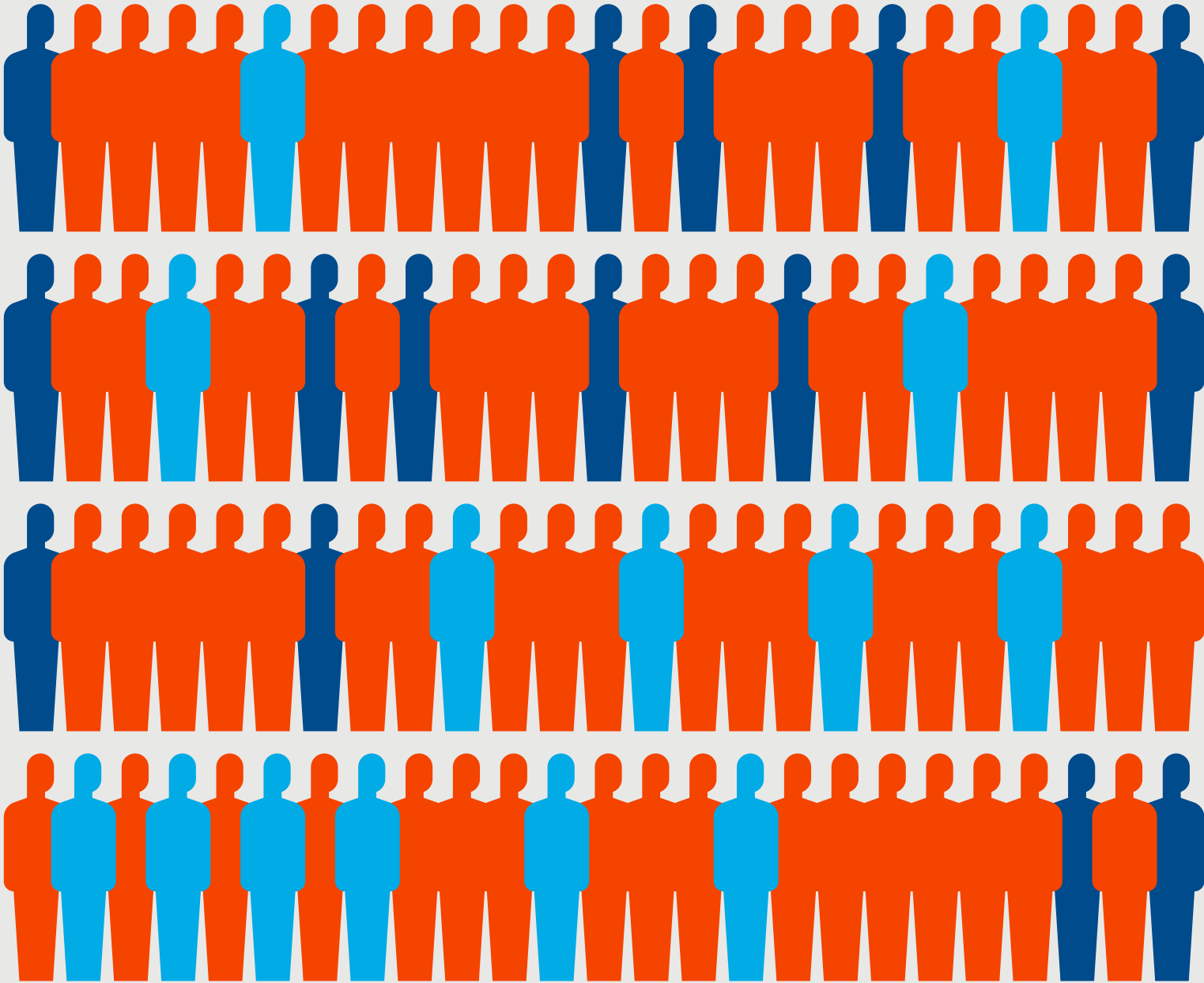


97%

of patients express
'bother' about this
condition⁷



PATIENTS SUFFERING IN SILENCE



Only
29%
speak to their
physician⁷

IF WE DON'T ASK, THEY WON'T TELL³⁶

HOW TO IMPROVE PATIENT ACCESS FOR FI

There is a need to improve patient access

Among 154 Primary Care Providers (PCP's), **the screening rate** for fecal incontinence was **only 35%**³⁶.

Active screening by PCP's could shorten the delay in patient access, since the duration of symptoms before specialized treatments has been reported to be about **5 years**^{18,36,37}.

PCP's welcome educational materials on treatment algorithms³⁶.

Screening outcomes may be affected by the terminology: patients prefer terms such as "accidental bowel leakage" or "bowel control issues" instead of fecal incontinence^{7,36}.

72% of patients who had not sought care believed that doctors need to speak directly to patients³⁸.



CONSERVATIVE TREATMENTS ARE LIMITED⁵

Non-invasive measures to control symptoms:

- Pads
- Dietary modifications
- Medications
- Physical therapy
(including Biofeedback)

PADS

MEDICATIONS

DIET
MODIFICATIONS

PHYSICAL
THERAPY



FI TREATMENT ALGORITHM AND CLINICAL GUIDELINES

“Sacral neuromodulation has become the first line surgical treatment for fecal incontinence in people failing conservative therapies.”⁸

ICI



ASCRS



Medical History

Loose stools, anorectal surgeries, obstetric history

Conservative Treatments

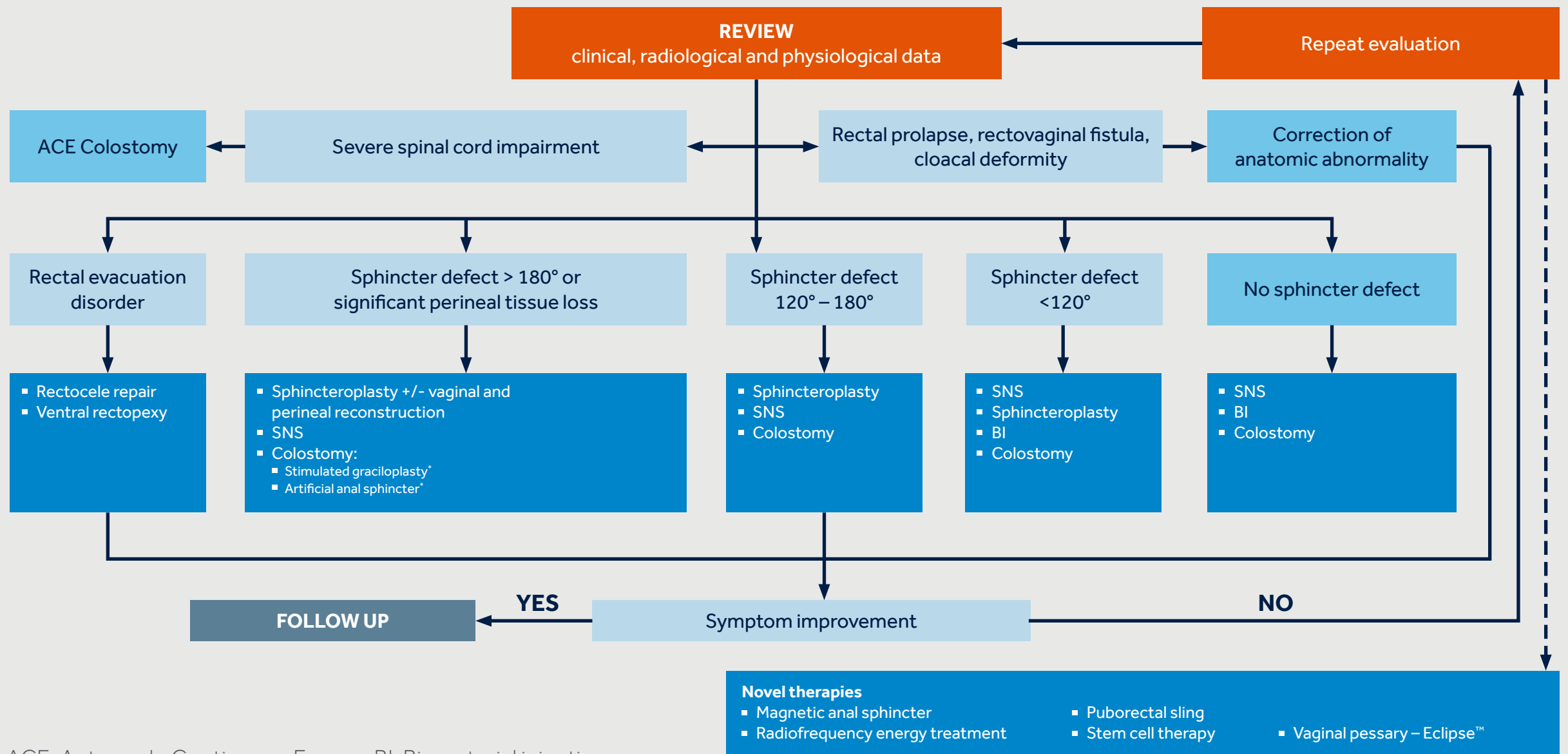


Medications

Evaluate for specialized therapies

ICI 2017

SURGICAL MANAGEMENT OF FECAL INCONTINENCE



ACE: Antegrade Continence Enema, BI: Biomaterial injection

SNS: Sacral Nerve Stimulation,

*Not widely available.

[Herold A. Lehur P.A., Matzel K.E, O'Connell P.R.(eds.). Coloproctology, Springer 2017, DOI 10.1007/978-3-662-53210-2_9.]



ICI GUIDELINES 2017¹⁶

ADVANCED THERAPIES

Sacral Neuromodulation

Sacral neuromodulation is an effective treatment in patients with severe incontinence unresponsive to conservative treatment. It may be effective as a first line treatment in patients with an anal sphincter defect. The therapeutic benefits are sustained in the medium to long term. The mechanism of action is uncertain however effects on sensory afferents appear most probable.

Grade of Recommendation: B

Anal Sphincteroplasty

Anal sphincteroplasty should be considered in symptomatic patients with a defined defect in the external anal sphincter. Overlapping EAS repair is usually performed. Results appear to deteriorate with time. Redo sphincter repair may be feasible in patients with a poor continence outcome.

Grade of Recommendation: C

Grade A: Recommendation usually depends on consistent level 1 evidence

Grade B: Recommendation usually depends on consistent level 2 and or 3 studies, or 'majority evidence' from RCTs

Grade C: Recommendation usually depends on level 4 studies or 'majority evidence' from level 2/3 studies or Delphi processed expert opinion

Grade D: "No recommendation possible" would be used where the evidence is inadequate or conflicting

SNM has the highest Grade of Recommendation of all advanced therapies for the treatment of fecal incontinence ¹⁶



ICI GUIDELINES 2017¹⁶

ADVANCED THERAPIES

Injectable Biomaterials

The role of injectable biomaterials in treatment of faecal incontinence remains to be established but may be of value in the treatment of passive incontinence. The optimum bulking agent and technique of application remains to be determined.

Grade of Recommendation: D

Artificial Bowel Sphincter

Artificial bowel sphincter is a treatment for patients who have failed other modalities of treatment. Obstructed defecation and device erosion have been problematic. Currently the device is not commercially available.

Grade of Recommendation: C

In the ICI guidelines 2017 both Gatekeeper™ and Sphinkeeper™ have been categorized as injectable biomaterials¹⁶.

Grade A: Recommendation usually depends on consistent level 1 evidence

Grade B: Recommendation usually depends on consistent level 2 and or 3 studies, or 'majority evidence' from RCTs

Grade C: Recommendation usually depends on level 4 studies or 'majority evidence' from level 2/3 studies or Delphi processed expert opinion


Grade D: "No recommendation possible" would be used where the evidence is inadequate or conflicting



FI: ASCRS GUIDELINES

Sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects⁹

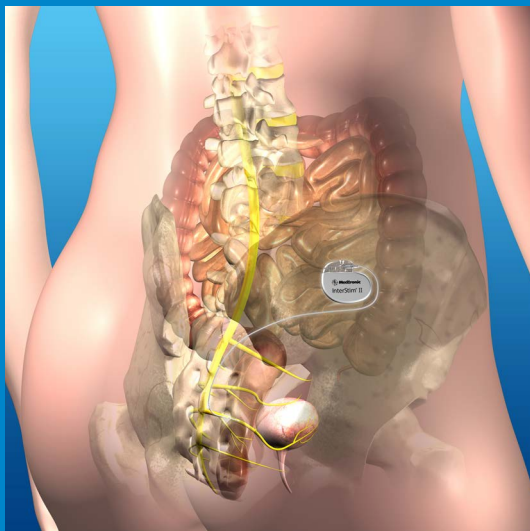
Sphincteroplasty, with its irreversible nature as a direct surgery on sphincter muscles and its poor long-term outcomes, may be unappealing for a benign condition such as fecal incontinence. In contrast, SNM is a less invasive, reversible surgical option.^{8,10}

Conservative treatments	
Patients who do not respond	
	
Strong recommendation: Moderate evidence (1B)	SNM and Sphincteroplasty
Strong recommendation: Low evidence (1C)	Repeat anal sphincter reconstruction Artificial sphincter Colostomy Correction of anatomical pathologies
Weak recommendation: Moderate evidence (2B)	Injection of bulking agents Radiofrequency energy delivery

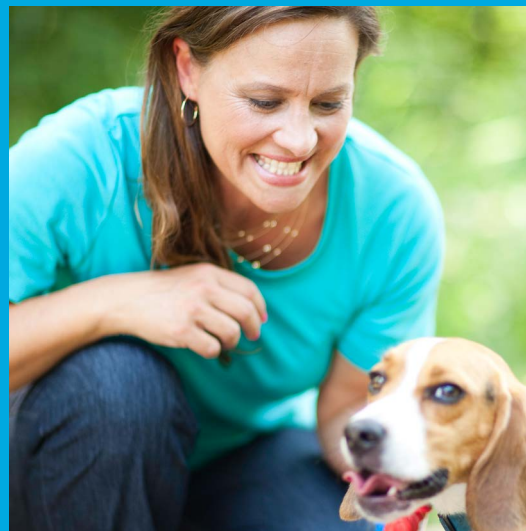


SACRAL NEUROMODULATION (SNM)

Mechanism
of Action



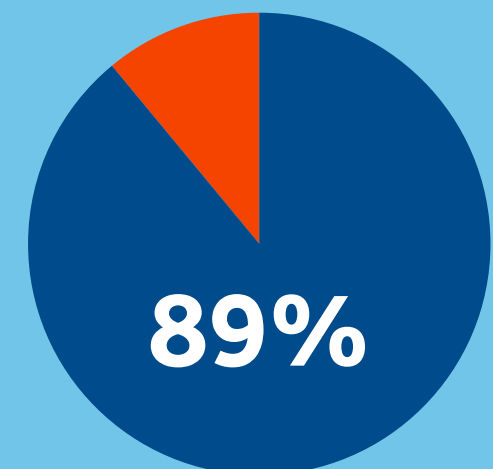
Patient
Selection



Efficacy



Quality of life



89% therapeutic success in patients with fecal incontinence, defined as an improvement in incontinent bowel episodes per week of $\geq 50\%$ at 5 years (completer analysis)



LEADING THEORIES IN MECHANISM OF ACTION

Neural pathways in the brain, spinal cord and sacral nerves together regulate urine as well as stool storage and elimination through coordination of bladder / bowel, it's sphincters and the pelvic floor muscles^{12,13}.

Whereas, in the early days of SNM, research has focused on end-organ effects, there is now a move away from the assumption that a defective sphincter has primacy in patients with fecal incontinence¹⁴.

InterStim™ influences neural communication to establish function.

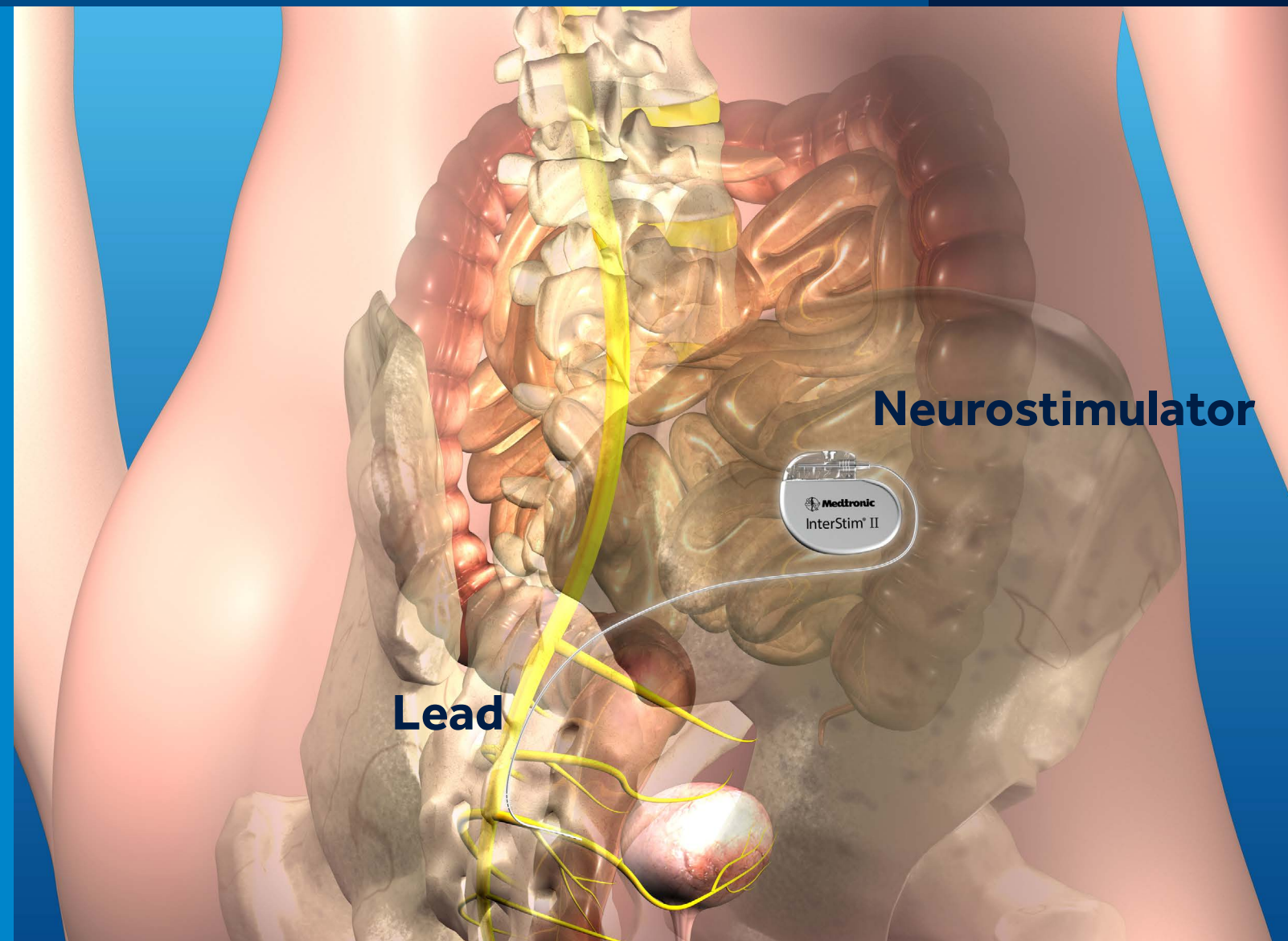


MEDTRONIC SACRAL NEUROMODULATION

INFLUENCES NERVE ACTIVITY

Medtronic SNM delivers electrical stimulation to a sacral nerve via an implanted neurostimulator.

SNM is thought to modulate rectal sensation by stimulating the afferent pathway and changing brain activity relevant to the continence mechanism⁹.

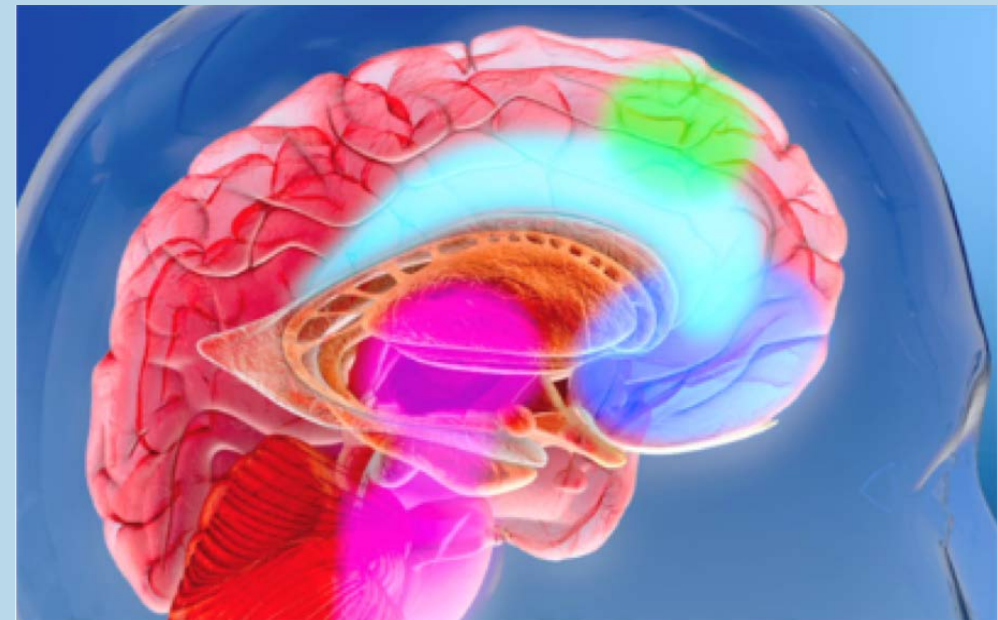


MEDTRONIC SACRAL NEUROMODULATION

INFLUENCES NERVE ACTIVITY

SNM induces effects on the central nervous system (CNS) such as changes in the contralateral frontal cortex, reflecting focus attention and changes in the ipsilateral caudate nucleus, an area related to learning¹⁶.

A joint mechanism of action of SNM for bladder and bowel dysfunctions reflects expert opinion¹⁵.



SELECTING APPROPRIATE PATIENTS

INDICATIONS

- Urinary Urge Incontinence (OAB wet)
- Urgency Frequency Syndrome (OAB dry)
- Non-obstructive Urinary Retention
- Chronic Fecal Incontinence
- Mixed incontinence where urge incontinence is the primary complaint

For patients who have failed or were not able to benefit from more conservative treatments



PATIENT SELECTION

FECAL INCONTINENCE

PASSIVE
INCONTINENCE

URGE
INCONTINENCE

SNM improves symptoms for both patients with **urge and passive fecal incontinence**.
The frequency of incontinent episodes per week fell from a mean of 16.4 to 2.0 at 24 months¹⁸.

Because of the highly predictive value of the test stimulation, **a pragmatic, trial-and-error approach** to patient selection evolved over time¹⁶.



GENERAL RECOMMENDATIONS^{*10,16,18,19}

FOR INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

- Chronic FI of a duration greater than 6 months
- Defined as involuntary passage of solid or liquid faeces at least once a week
- Failed or not candidates for more conservative treatments
- >18 years

Exclusion criteria

- Anatomic limitations preventing the successful placement of an electrode
- Previous rectal surgery
 - Such as rectopexy, rectal resection, or anal sphincteroplasty, if performed within the last 12 months or 24 months in case of cancer
- Defects of the external anal sphincter over 120°**
- Chronic inflammatory bowel disease
- Complete spinal-cord injury
- Stoma in situ
- Pregnancy
- Limited cognitive function

* List is not exhaustive

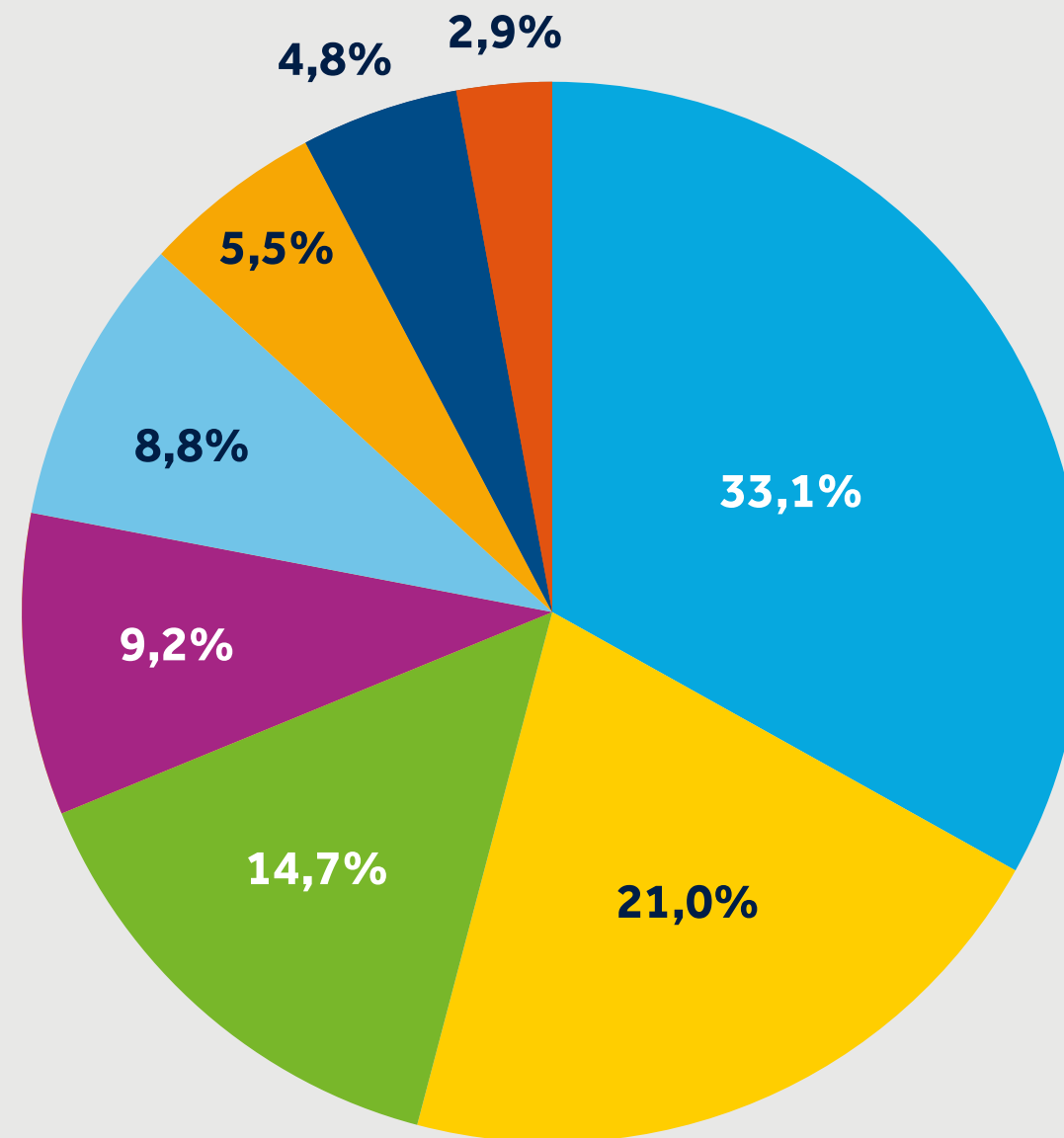
** Exclusion criteria not rigorous



FECAL INCONTINENCE HAS MANY ETIOLOGIES

Etiologies of FI (%)¹⁷

- Idiopathic
- Iatrogenic
- Obstetric trauma
- Neurological disease
- Pelvic surgery
- Post ARR
- Spinal trauma / lesion
- Other



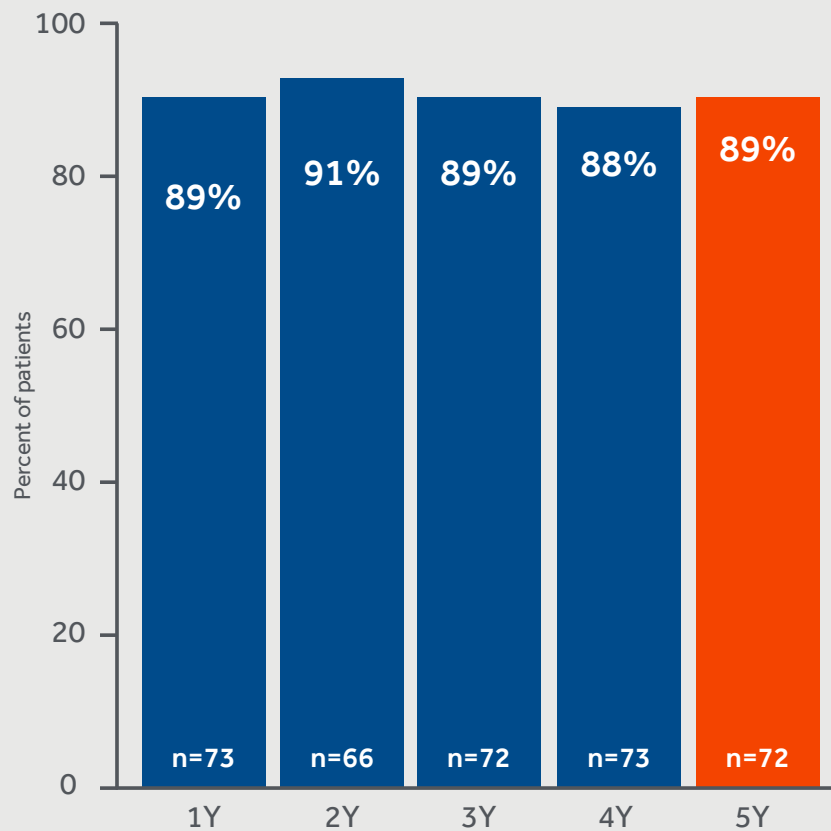
ARR: anterior rectal resection



PROVEN LONG-TERM CONTROL

5 year outcomes

Sustained clinical success rates¹¹



89%
clinical success rate
at 5 years

Numbers reflect completers analysis ($p < 0.0001$), defined as patients who had complete data at baseline and annual visits

Success in patients with fecal incontinence, defined as an improvement in incontinent bowel episodes per week of $\geq 50\%$

5 year outcomes

SNM vs. OMT



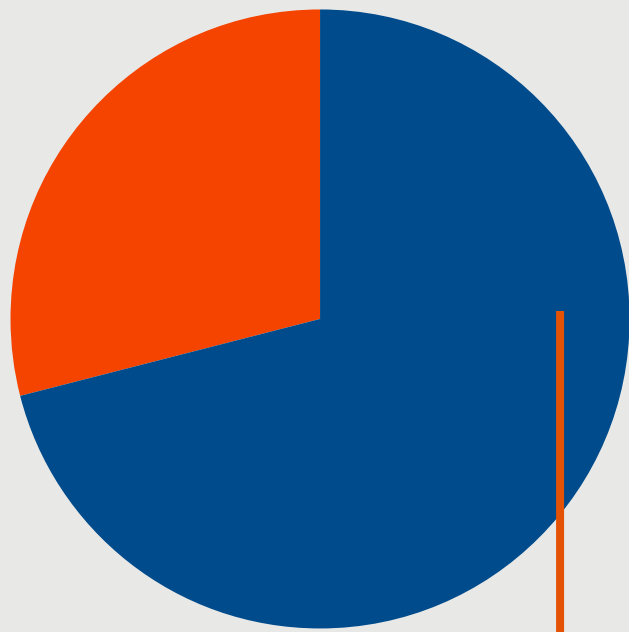
Sphincter defect



Adverse events



SNM OUTPERFORMS OPTIMAL MEDICAL THERAPY (OMT)



71%

of SNM patients achieved $\geq 50\%$ improvement in FI episodes / week at 12 months²⁰

47%

of patients in the SNM group achieved complete continence at 12 months²⁰

The OMT group showed no significant improvements in FI symptoms, Wexner scores, FIQOL Index and SF-12 scale. Optimal medical therapy consists of bulking agents, pelvic floor exercises and dietary management²⁰.

5 year outcomes



SNM vs. OMT

Sphincter defect



Adverse events

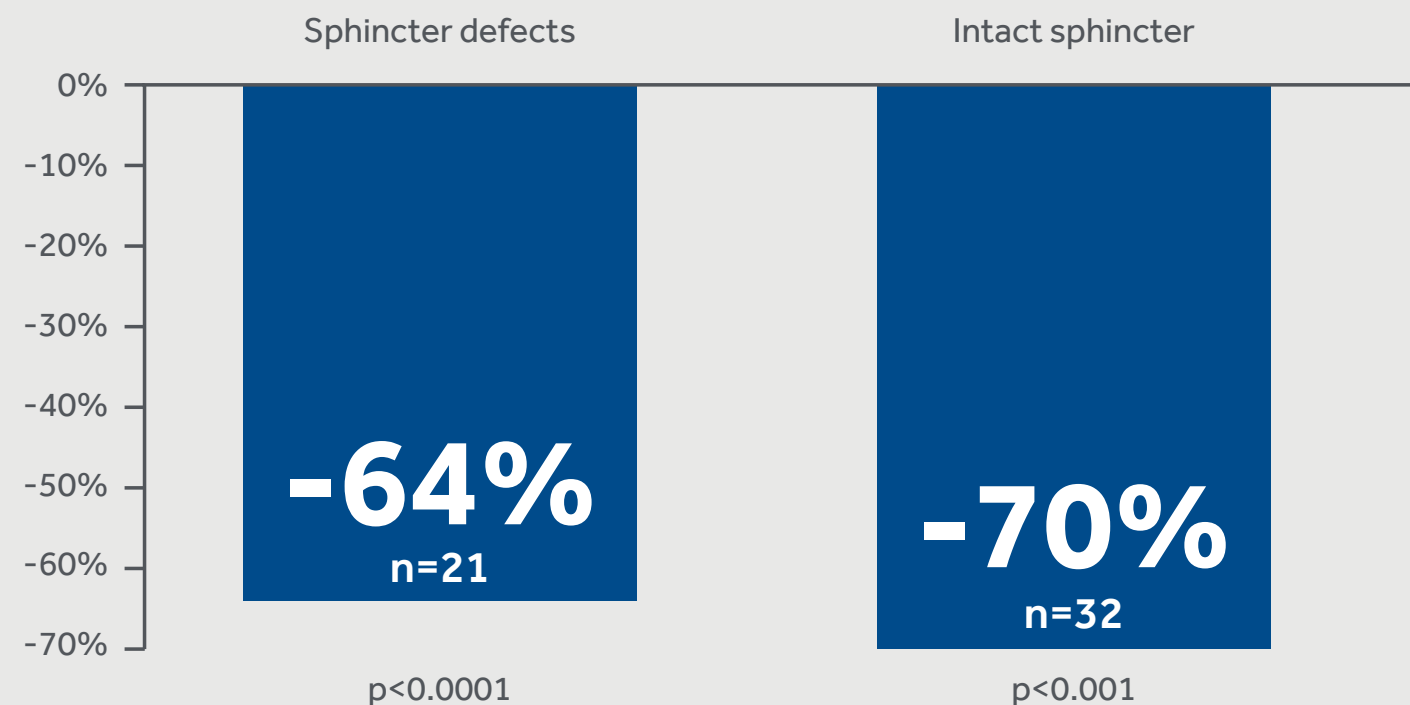


SNM BENEFITS PATIENTS WITH AND WITHOUT EXTERNAL ANAL SPHINCTER DEFECTS

All patients

with and without defects showed significant improvements in fecal continence ($p < 0.001$) and quality of life following implant, and at 12 months ($p < 0.0125$).¹⁹

Decrease in weekly incontinent episodes¹⁹



This study excluded patients with sphincter defects > 120 degrees.

5 year outcomes



SNM vs. OMT



Sphincter defect

Adverse events



ADVERSE EVENTS

SNM vs. OMT

Adverse events with SNS included pain at implant site, seroma which resolved after percutaneous aspiration, and excessive tingling in the vaginal region. There was no septic complication requiring explantation.²⁰

SNM in patients with sphincter defects*

Study found no septic complications requiring explantation. Adverse events include seroma which resolved after percutaneous aspiration, mild pain at the implant site which resolved with analgesics, and excessive tingling in the vaginal region which subsided after device reprogramming.¹⁹

SNM: 5 year outcomes

Most adverse events were treated successfully with medication or device reprogramming. The most common adverse events ($\geq 5\%$ of patients, $n=120$) were implant site pain, paresthesia, change in sensation of stimulation, implant site infection, urinary incontinence, neurostimulator battery depletion, diarrhea, pain in extremity, undesirable change in stimulation, buttock pain.¹¹

*This study excluded patients with sphincter defects > 120 degrees.

5 year outcomes



SNM vs. OMT



Sphincter defect



Adverse events



ADVERSE EVENTS

FROM A META-ANALYSIS²¹

n=665
permanently
implanted patients

Complication rate:
15%

Explantation rate:
3%

Pain or local discomfort: 6%

Lead displacement / breakage: 4%

Infection: 3%

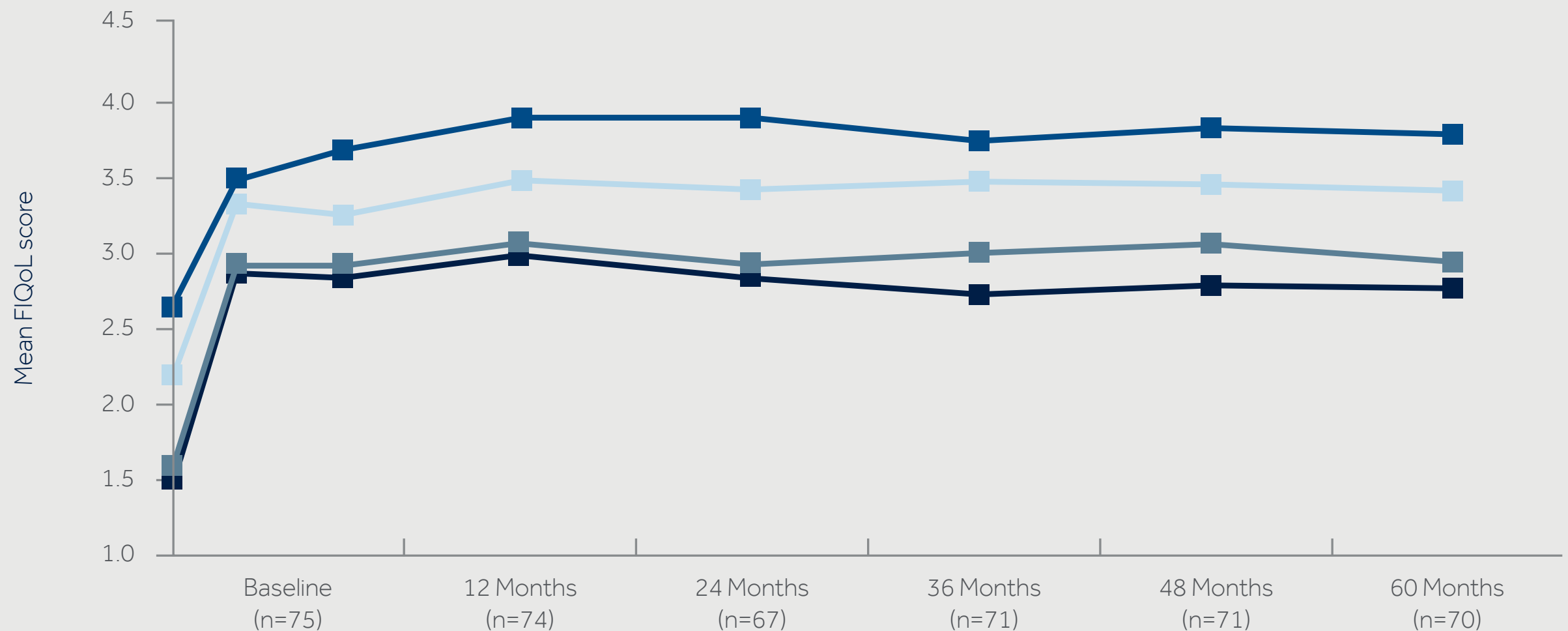
Seroma: 3%*

*About half of the cases could be resolved by antibiotics



SIGNIFICANT IMPROVEMENT IN QUALITY OF LIFE SUSTAINED AT 5 YEARS

Mean fecal incontinence quality of life (FIQOL) score¹¹

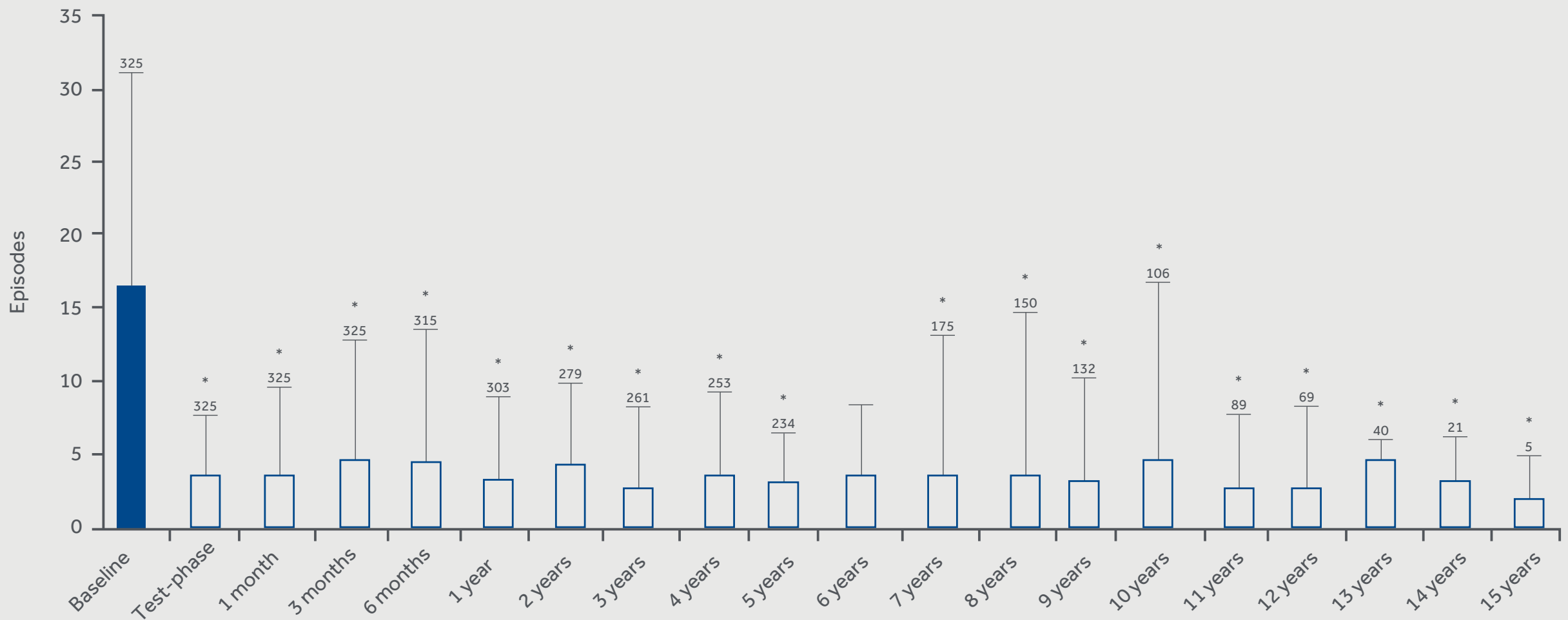


Key: ■ Depression/Self-Perception ■ Lifestyle ■ Coping/Behavior ■ Embarrassment



PROVEN EFFICACY

LONG-TERM RESULTS²⁴



Incontinence episodes per 3 weeks; values are represented as mean ± SD. Numbers represent number of patients at follow up. *Statistically different compared with baseline.

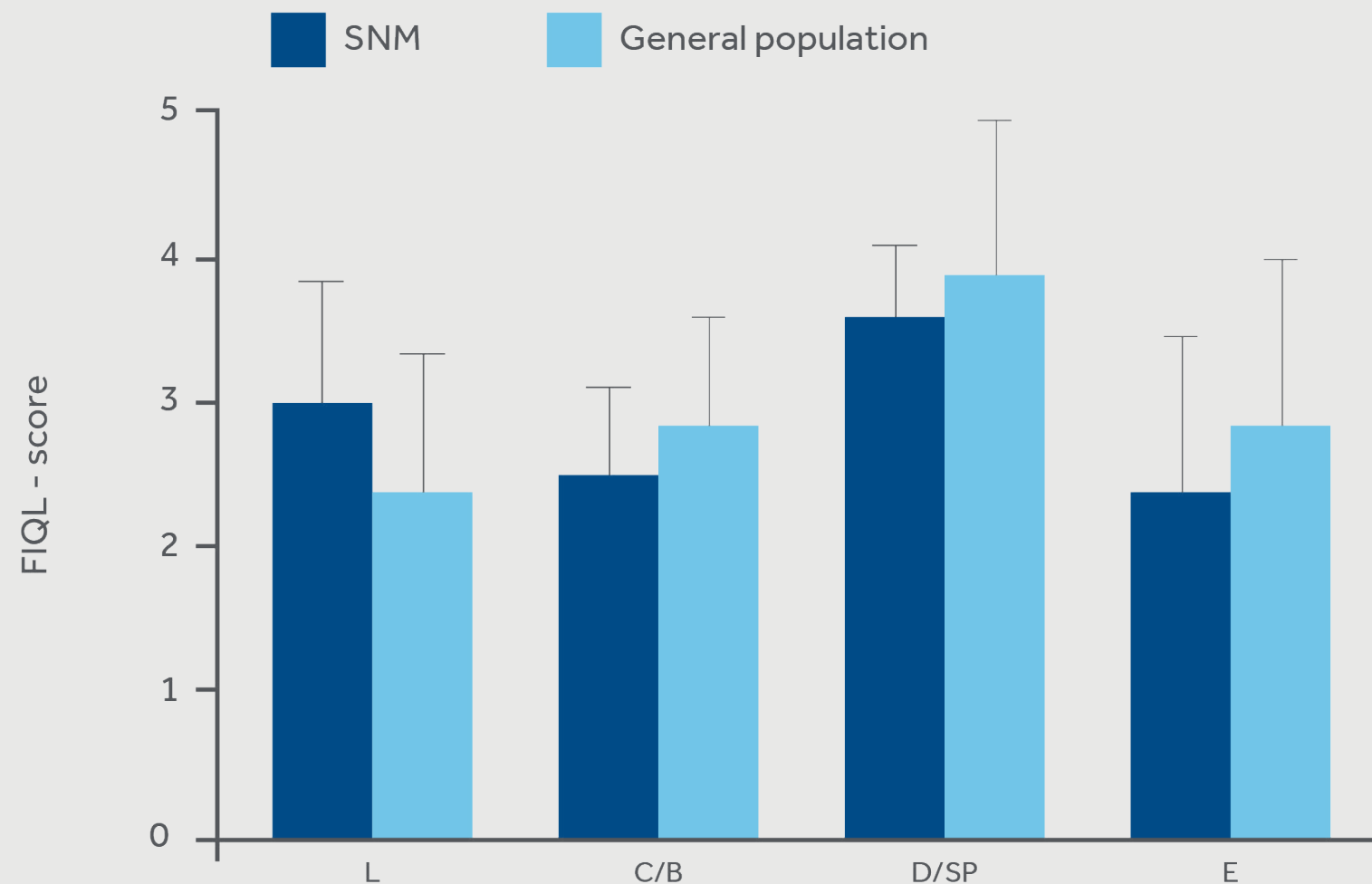
VALIDATED OUTCOME MEASURES^{23,23b}

A reduction of $\geq 50\%$ in fecal incontinence episodes has been suggested as a validated, standard measurement for defining clinical outcome in FI along with the measurement of quality of life^{23b}.

The 50% criterion has been evaluated as a meaningful and useful primary outcome measure.

QUALITY OF LIFE

SNM TREATED PATIENTS VS. GENERAL POPULATION²⁴



Results of the Fecal Incontinence Quality of Life questionnaire. values are presented as mean (SD). L, Lifestyle; CB, coping/behavior; DSP, depression/self perception; E, embarrassment.

Conclusions

Quality of life of patients with successful SNM for fecal incontinence did not differ significantly from the general population.



OTHER ADVANCED THERAPIES

INJECTABLE
BULKING
AGENTS



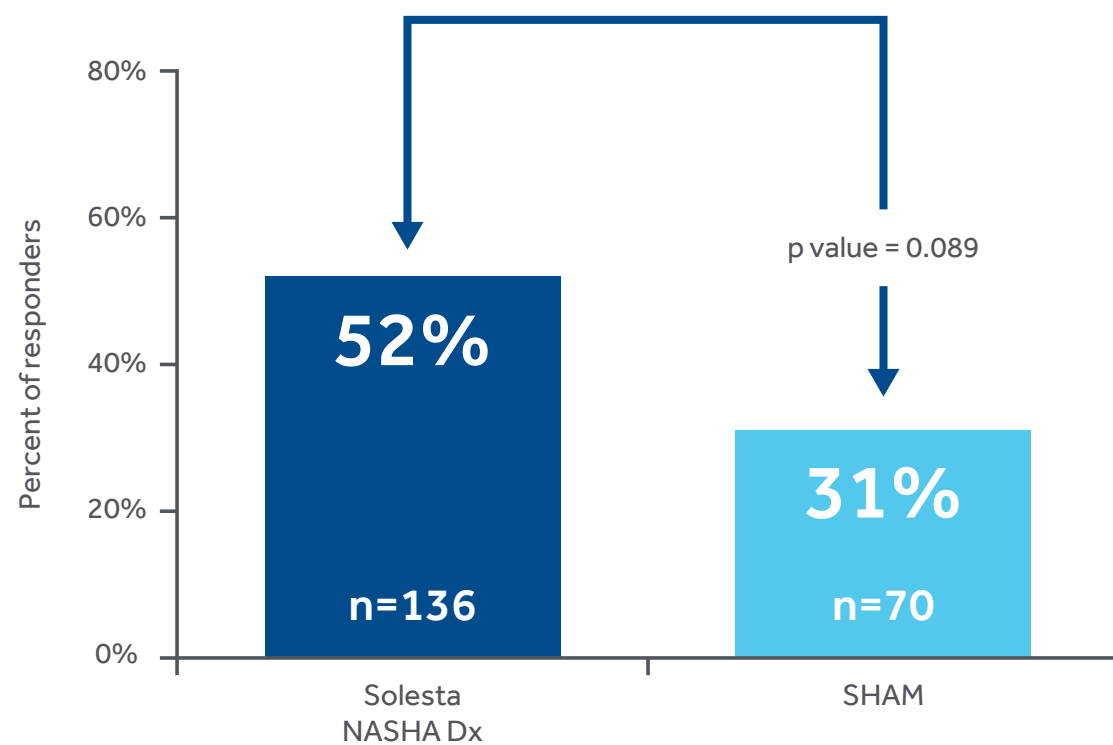
SPHINCTEROPLASTY



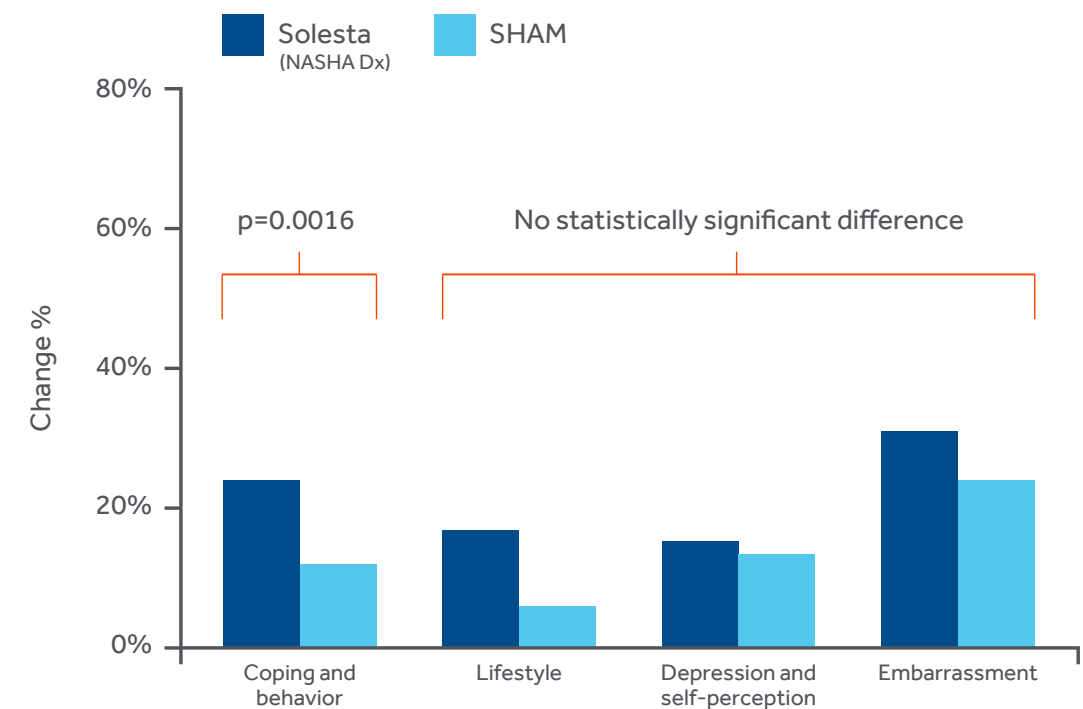
CLINICAL OUTCOME OF BULKING AGENTS²²

Bulking agent

Reduction in episodes >50%



Change in fecal incontinence quality of life (FIQL) score at 6 months²²



ADVERSE EVENTS AND RETREATMENTS WITH BULKING AGENTS^{16,22}

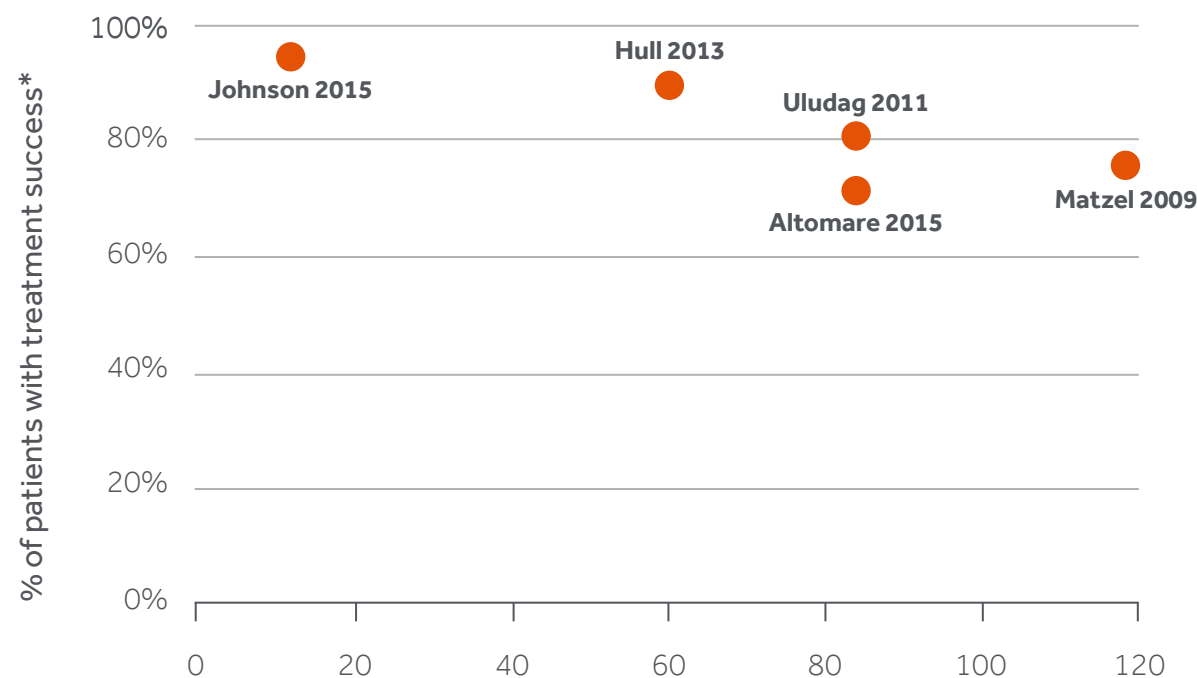
The NASHA Dx group had more adverse events, including proctalgia, rectal bleeding, pruritus, diarrhea, constipation, fever, and two serious complications of rectal abscess and prostatic abscess compared with the SHAM group.

82% of 136 patients in the NASHA Dx group received retreatment within 12 months.



LONG-TERM OUTCOME SNM AND SPHINCTEROPLASTY

Sacral Neuromodulation (SNM)^{25,26,27,28,29}

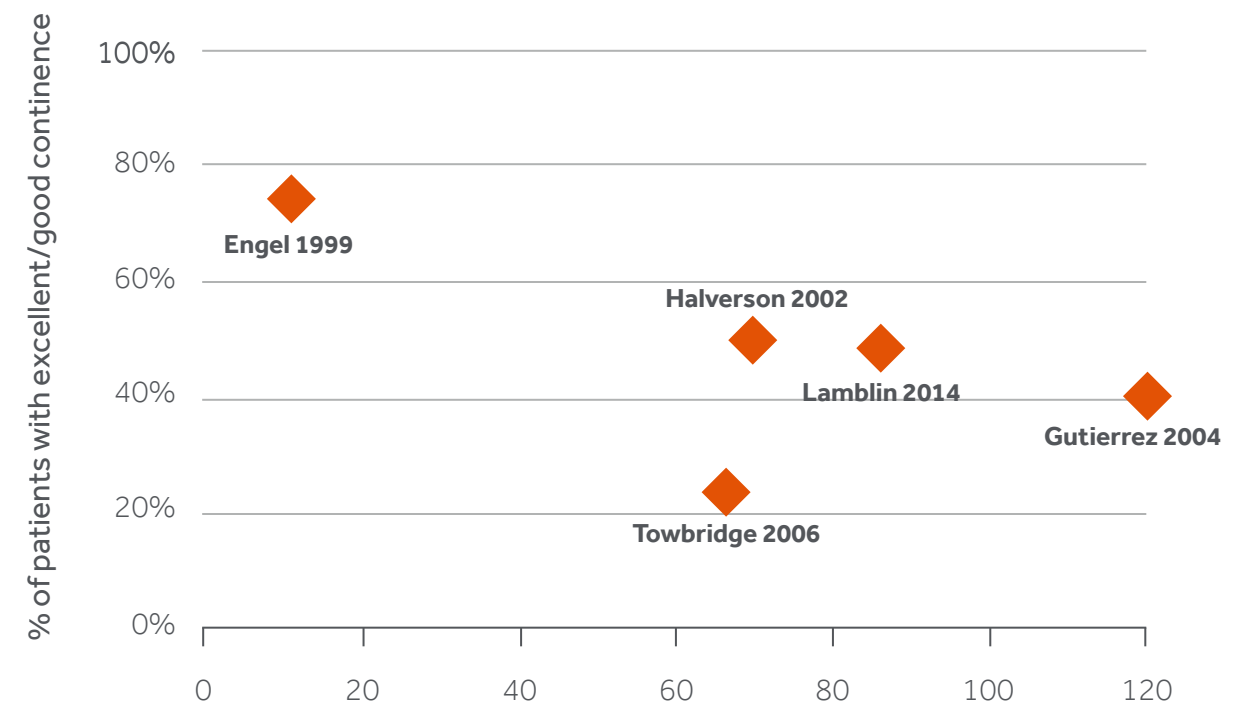


* defined as $\geq 50\%$ improvement of symptoms per protocol analysis

SNM: 'The findings of **sustained symptomatic improvement** with extended follow-up are in accordance with several other series focusing **on long-term outcome**.'

**Symptom improvement was measured by the reduction of weekly incontinence episodes; Johnson used the Wexner-Score.

Sphincteroplasty (SR)^{30,31,32,33,34}



Per protocol analysis. Success parameters may vary between different studies

SR: 'Most patients improve after sphincteroplasty, **but outcomes deteriorate over time**.'

'A mean of 66% reporting excellent or good results in the short term.'



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Sacral neuromodulation therapy provided by the InterStim™ system is indicated for the management of the following chronic intractable (functional) disorders of the pelvis and lower urinary or intestinal tract: overactive bladder, fecal incontinence, and nonobstructive urinary retention.

See the appropriate InterStim™ device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com



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