coloproctology 2016 · 38:8–21
DOI 10.1007/s00053-015-0079-7
Published online: 8 February 2016

V. Kahlke[1] · A. Fürst[2] · D. Leder[3] · M. Löhnert[4] · O. Schwandner[5] · T. Schwandner[6] · D. Weimann[7] · K. E. Matzel[8]

[1] Proktologische Praxis and Park-Klinik Kiel, Kiel, Deutschland
[2] Klinik für Allgemein- und Viszeralchirurgie, Caritas-Krankenhaus St. Josef, Regensburg, Deutschland
[3] Viszera Medizinzentrum, München, Deutschland
[4] Klinik für Allgemeinchirurgie und Koloproktologie, Klinikum Bielefeld Rosenhöhe, Bielefeld, Deutschland
[5] Abteilung für Proktologie, Krankenhaus Barmherzige Brüder, Regensburg, Deutschland
[6] Klinik für Allgemein- und Viszeralchirurgie, Asklepios Klinik Lich GmbH, Lich, Deutschland
[7] Chirurgische Gemeinschaftspraxis Marbach, Marbach am Neckar, Deutschland
[8] Sektion Koloproktologie, Chirurgische Universitätsklinik Erlangen, Erlangen, Deutschland

Sacral nerve stimulation as a therapy for fecal incontinence

Current patient-centered care in Germany

In the past 20 years, sacral nerve stimulation (SNS) has evolved into an essential element of fecal incontinence therapy. The therapeutic outcome of SNS is both reproducible and long-lasting. This method is therefore widely accepted and increasingly used. Based on the data currently available – several retrospective studies, observational studies, as well as prospective studies – there is no doubt about its effectiveness [1]. Sacral nerve stimulation was also found to be effective by an analysis of the Cochrane Collaboration [2].

Although there is no guideline for fecal incontinence therapy in Germany, it is recommended – also based on the British and American guidelines – to consider SNS as a therapeutic option for patients with fecal incontinence persisting despite adequate conservative therapy (constipating medication, pelvic floor exercises, and biofeedback therapy when indicated). Other possible causes for fecal incontinence, such as rectal prolapse, malignant tumors, or congenital diseases have to be excluded in advance.

Currently, 152 centers are performing SNS as a therapy for fecal incontinence in Germany. Their outcomes vary, thus being in accordance with the results published in literature. Although many publications and precise recommendations of the manufacturer do exist, questions about the method's practical application remained. The aim of this study was to gain insight into the reality of supply and to identify areas of incomplete knowledge or diverging proceedings.

The German version of this article can be found under doi:10.1007/s00053-015-0067-y

Material and Methods

All 152 centers performing SNS as a therapy for fecal incontinence were questioned in written form about the application of SNS and experiences related to this method.

In two meetings, a board of experts has defined 82 items regarding

- indication,
- inclusion criteria,
- contraindications,
- combined indications,
- criteria for implantation,
- preoperative diagnostics,
- conservative therapy,
- operation technique, and
- follow-up of SNS as a therapy for fecal incontinence (and constipation).

These items were composed in a questionnaire containing the following preformulated answers

- 1: complete disagreement,
- 2: disagreement,
- 3: neutral,
- 4: agreement,
- 5: complete agreement,
- 6: not relevant.

Only single answers were allowed: it was only possible to select one response per line in the questionnaire in the pdf format. Apart from this, there was a question about personal experience concerning practical application of SNS (number of performed implantations < 5, 5–24, ≥ 25), as well as a question asking for an estimation about frequency of deteriorations of the clinical outcome in the long run (six categories).

In the period between 06/2015 and 08/2015 the questionnaire was emailed five times to all known active centers (n = 152) having an appropriate contact person. 125 centers were reached in the first attempt. After contacting the still outstanding 27 centers in written form, the contact persons of further 18 centers were identified. Thus, 143 centers were contacted at least two times.

The questionnaire was sent back in an entirely analyzable form by n = 70 users (48,9 %). Acquisition of data was realized by direct emailing of the questionnaire to an e-mail address provided by *The Cloud Agency, Germany*. The senders were removed from the headers of the emails, providing complete anonymization. Thus, the board of experts was not able to relate an answer with the person giving the answer at any time. Raw

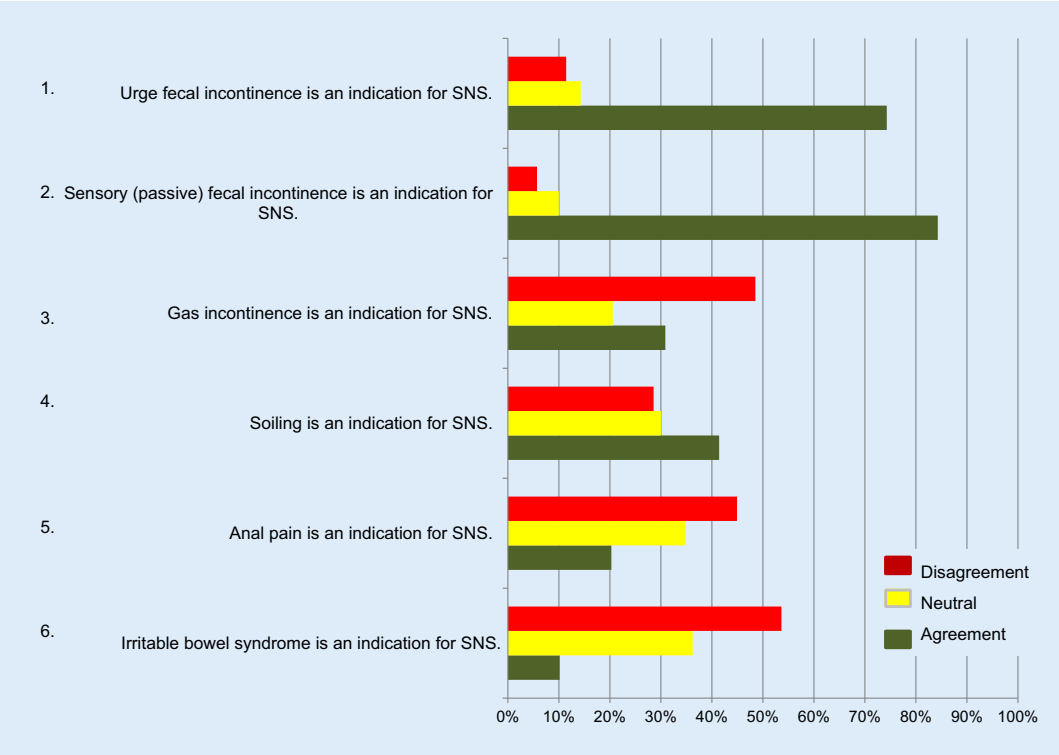


Fig. 1 ◀ Distribution of answers to items 1–6 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

data were processed and both absolute and relative distributions of the answers were depicted in an Excel file by *The Cloud Agency, Germany*.

The distribution of the answers to the respective questions is presented as a "traffic light principle", i. e. red meaning disagreement (= 1. complete disagreement + 2. disagreement), yellow meaning neutral (= 3. neutral), and green meaning agreement (= 4. agreement + 5. complete agreement). The answers will not be commented upon (or only briefly) if ≥ 2/3 of the respondents agree or disagree, and their responses are in agreement with the opinion of the board of experts. In all other cases, the members of the board of experts will try to elaborate with a detailed comment, providing a clarification regarding the content of the question and presentation of current literature. Centers will be classified as experienced centers (≥ 25 implantations) or less experienced centers (< 25 implantations). By doing so, big discrepancies in responses of those boards can be commented on where necessary or helpful.

Only items 7–10 have been classified as irrelevant by more than two respondents:

- There has to be at least one episode of incontinence of solid or liquid feces per week (n = 3).
- The patient has to be at least 18 years old (n = 3).
- The patient may not be older than 75 years (n = 4).
- There may be no anal sphincter dysfunction (n = 3).

The comments presented below are recommendations of a board under the direction of Prof. K. E. Matzel, University of Erlangen, that frequently applies this (board of experts) method. In the early stages, the manufacturing company (Medtronic, Meerbusch) initiated and supported this project. Later, both the survey as well as the preparation of this article, were completed under the patronage of the German Society of Coloproctology.

Results

Indications

Item 1. A clear majority of nearly 75 % defined urge incontinence as indication for SNS. The board of experts thoroughly supports this statement (**Fig. 1**).

Item 2. The board of experts as well as more than 84 % of the respondents considered sensory (passive) incontinence an indication for SNS (**Fig. 1**).

Item 3. Flatal incontinence is considered differently: Nearly 50 % of the respondents deny it as an indication, whereas 30 % consider it an indication, and about 20 % adopt a neutral position (**Fig. 1**). 37.5 % of the centers performing > 25 implantations per year consider flatal incontinence an indication, whereas only 21.4 % of the centers performing < 25 implantations per year share this view. Moreover, only one third of the board of experts considers it an indication. When it comes to the indication "flatal incontinence", a "trial and error approach" is used: only after having exploited all conservative treatment options, and lacking alternative treatment options, SNS might be considered as a potential treatment.

Item 4. Soiling is seen in a similar way to flatal incontinence: only about 40 % con-

Abstract · Zusammenfassung

coloproctology 2016 · 38:8–21 DOI 10.1007/s00053-015-0079-7

V. Kahlke · A. Fürst · D. Leder · M. Löhnert · O. Schwandner · T. Schwandner · D. Weimann · K. E. Matzel

Sacral nerve stimulation as a therapy for fecal incontinence. Current patient-centered care in Germany

Abstract

Sacral nerve stimulation (SNS) has developed into the standard procedure in the management of fecal incontinence in the past 20 years. The clinical benefit is reproducible and the patients achieve permanent satisfaction. The method has received high acceptance and continues to spread. This article highlights SNS use in practice in Germany in terms of the recommendations in the literature and guidelines from the manufacturer.

We began with a written survey of all German centers active in the therapy for fecal incontinence (152), with 143 being contacted at least twice (143/152; 94,1 %), including 82 items regarding indication, inclusion criteria, contraindication, combined indication, indication for permanent implantation, preoperative diagnostic procedures, nonoperative therapy, operative technique and follow-up of the SNS system and continence. A complete survey was sent back by 70 colorectal surgeons (48.9 %). In terms of classical indications or contraindications for SNS, clear results of 60–97 % were found. Nonuniform replies were found in the secondary indications for SNS, such as anal pain, bloating or irritable bowel syndrome. Interestingly, 37 % of the colorectal surgeons would test patients with a complete spinal injury, although SNS requires residual function of the distal spinal nerves. Nonuniform replies were collected in terms of rare conditions such as anal atresia, cauda equina syndrome and spina bifida. The need of repeated MRI investigations (MRI of the head was not included) was considered to be a contraindication by 55 % of the respondents only, despite the fact that body MRI is contraindicated by the manufacturer. Rather uniform were all items of diagnostic procedures and timing of the operations (70–80 % consensus). Additional uniformity was found in terms of the operative strategy and the steps of follow-up.

This German national survey found a strong consensus in the use of sacral nerve stimulation for the management of fecal incontinence.

Keywords

Fecal incontinence · Sacral nerve stimulation/modulation · Anal canal · Electric stimulation therapy

Sakrale Nervenstimulation bei Stuhlinkontinenz. Versorgungsrealität in Deutschland

Zusammenfassung

Die sakrale Neurostimulation (SNS) ist in den vergangenen 20 Jahren ein fester Bestandteil in der Therapie der Stuhlinkontinenz geworden. Die reproduzierbaren und lang anhaltenden Behandlungserfolge der Stuhlinkontinenz führen zu einer hohen Akzeptanz und einer zunehmenden Verbreitung der SNS. Daher stellt sich die Frage der praktischen Anwendung dieser Methode in Deutschland im Vergleich zur Literatur und der durch den Hersteller gegebenen Empfehlungen. Es erfolgte eine schriftliche Befragung aller in der SNS-Therapie der Stuhlinkontinenz aktiven deutschen Zentren (152), von denen 143 mindestens zweimal kontaktiert wurden (143/152; 94,1 %) mit insgesamt 82 Aussagen zu Indikation, Einschlusskriterien, Kontraindikationen, Mischindikationen, Implantationskriterien, präoperativer Diagnostik, konservativer Therapie, Operationstechnik und Follow-up der SNS bei Stuhlinkontinenz. Der Fragebogen wurde von 70 Anwendern (48,9 %) vollständig auswertbar beantwortet und zurückgesandt. Bei den Aussagen zu Indikationen der SNS zeigte sich eine klare Einschätzung der befragten Zentren mit Zustimmungs- bzw. Ablehnungsraten zwischen 60–97 % zu den klassischen Indikationen. Uneinheitliche Antworten ergaben die Aussagen nach nicht genuinen Indikationen der SNS, wie analer Schmerz, Flatus und Reizdarm. Interessant war, dass 37 % der Befragten den kompletten Querschnitt als Indikation sahen, obwohl der Wirkungsmechanismus der SNS von einer – zumindest residualen – Funktion der kortikospinalen Achse abhängt. Weiterhin ergab sich eine hohe Übereinstimmung in der Einschätzung der wesentlichen Kontraindikationen (KI). Uneinheitliche Beurteilungen wurden insbesondere bei seltenen Entitäten wie z. B. Analatresie, Cauda equina und Spina bifida gegeben. Auffällig war, dass nur 55 % der Befragten in der Notwendigkeit zur Durchführung von regelmäßigen magnetresonanztomographischen Untersuchungen (außer Schädel) eine KI sahen, obwohl dieses seitens der Herstellerfirma explizit als KI gesehen wird. Erfreulich klar wurden die Abläufe zur Diagnostik und zu den Implantationskriterien mit Zustimmungsraten zwischen 70–80 % eingeschätzt. Auch bei den Aussagen nach dem intraoperativen Vorgehen und dem Follow-up zeigte sich ein einheitliches Bild bei den Befragten.

Die vorgelegte Befragung belegt eindrücklich, dass die Anwendung der SNS nicht nur im Hinblick auf technisch-operative Aspekte, sondern auch in Bezug auf die präoperative Diagnostik, die Patientenselektion (Indikationen und KI) und die Nachsorge/Nachbehandlung in der Breite weitgehend einheitlich gehandhabt wird.

Schlüsselwörter

Stuhlinkontinenz · Sakralnervstimulation · Analkanal · Elektrostimulationstherapie

sider it an indication, whereas about 30 % do not, and 30 % adopt a neutral position (Fig. 1). The board of experts does not consider it a genuine indication. The "trial and error approach" might be used in this case: only after having exploited all conservative treatment options, after having treated other causes which might lead to soiling (e. g. hemorrhoids, prolapse of the rectal mucosa, intussusception), and lacking alternative treatment options, SNS might be – with caution – considered a treatment option.

Item 5. Anal pain is also considered heterogeneously: a slim majority of 45 % do not consider it an indication, whereas 20 % consider it an indication, and 35 % adopt a neutral position (Fig. 1). Of note, only 7 % of the less experienced consider it an indication, whereas 30 % of the experienced centers consider it an indication. The board of experts does not consider it a genuine indication, es-

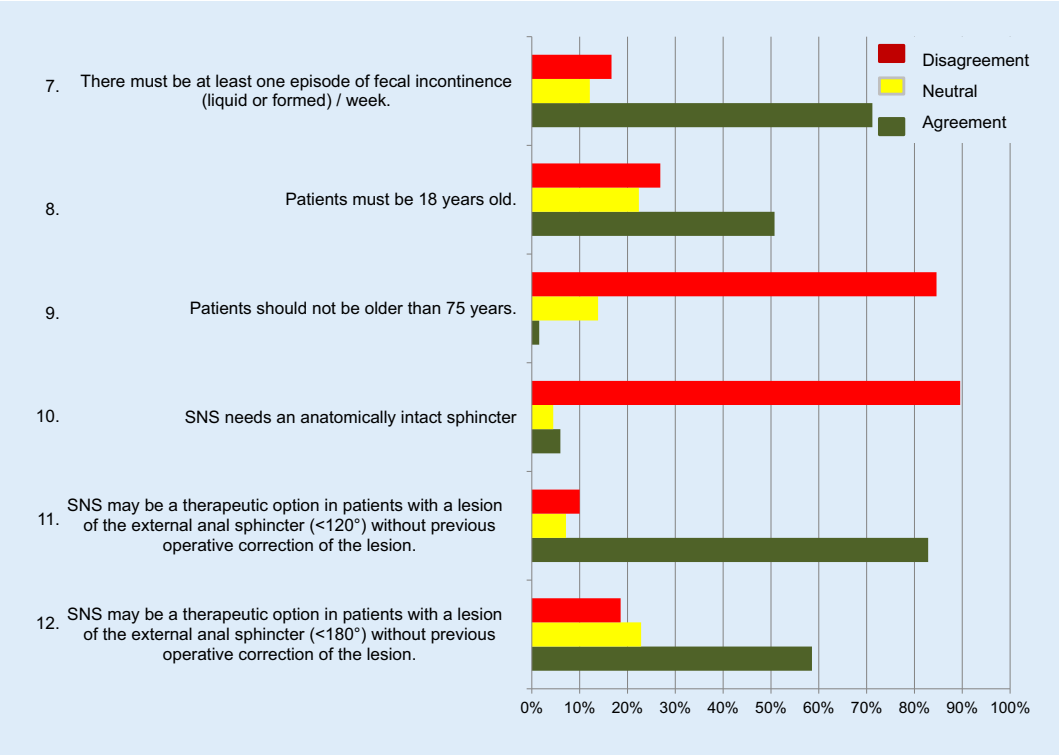


Fig. 2 ◀ Distribution of answers to items 7–12 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

pecially because of a lack of homogeneous data concerning this topic, and a small body of evidence. This might also be due to the fact that definitions of "pelvic/anal pain" vary greatly. Therefore, this indication is considered "experimental".

Item 6. When it comes to the indication concerning the irritable bowel syndrome, opinions are clearer: 53 % of the respondents refuse it, 36 % adopt a neutral position, and only 10 % consider it an indication. This is in line with the opinion of the board of experts, which does not see an indication and considers it "experimental". Moreover, SNS is not mentioned as a treatment option in the German S3-guidelines for irritable bowel syndrome [3]. But on the other hand, a positive effect of SNS for diarrhea-intended form of the irritable bowel syndrome has been shown [4].

Inclusion criteria

Item 7. A general consensus has been reached: there has to be at least one episode of fecal incontinence per week (**Fig. 2**).

Item 8. 50 % of the respondents agreed on a minimum age of 18 years. In contrast, the board of experts does not support a regular age restriction. Restriction is due to growth potentially leading to dislocation of the electrode. Therefore, the growth of children and adolescents shall be taken into consideration when thinking about the indication (e. g. after pull-through procedures).

Item 9. Correspondingly, there is no maximum age restriction. More than 80 % of the respondents as well as the board of experts share this view (**Fig. 2**).

Items 10–12. An intact sphincter is not considered a precondition for SNS. In fact, a majority (> 80 %) considers defects of up to 120° an indication (**Fig. 2**). This is supported by good data records (**Fig. 2**; [5]). Only 60 % consider defects of > 120° and ≤ 180° an indication. Among those, experienced centers rather consider it an indication (69 % vs. 45 %). The board of experts also considers the latter an indication, despite still sparse data [6].

Items 13–16. The respondents agreed (85–98.5 %) that SNS might be useful in the case of fecal incontinence following anterior rectal resection, after low anterior rectal resection and chemoradiotherapy, following anorectal surgery, and status post pelvic irradiation. The board of experts unanimously shares this view ([7, 8]; **Fig. 3**).

Item 17. SNS can also be used as treatment for fecal incontinence consequent to multiple sclerosis = encephalitis disseminata (MS/ED). Although the respondents (74 %, **Fig. 4**) as well as the board of experts clearly agreed with this point, it has to be mentioned that there are no clear studies on long-term outcome, especially none taking into account the course of disease. Of note, when SNS is used in patients with multiple sclerosis, MRI checkups have to be performed. The manufacturer only considers MRI head coil (1.5 Tesla (T), horizontal closed) as safe for the actual stimulation system. Uncomplicated MRI has been increasingly reported. Nevertheless, according to the manufacturer, MRI bears unforeseeable risks (see item 30) [9–11].

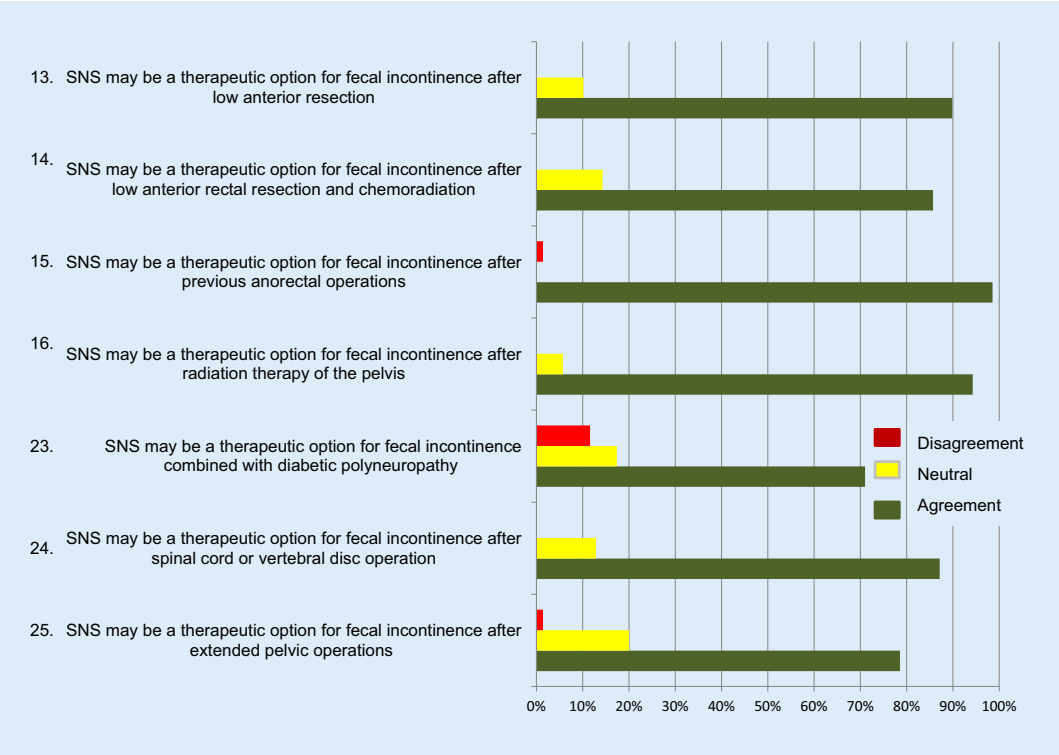


Fig. 3 ◀ Distribution of answers to items 13–16 and 23–25 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

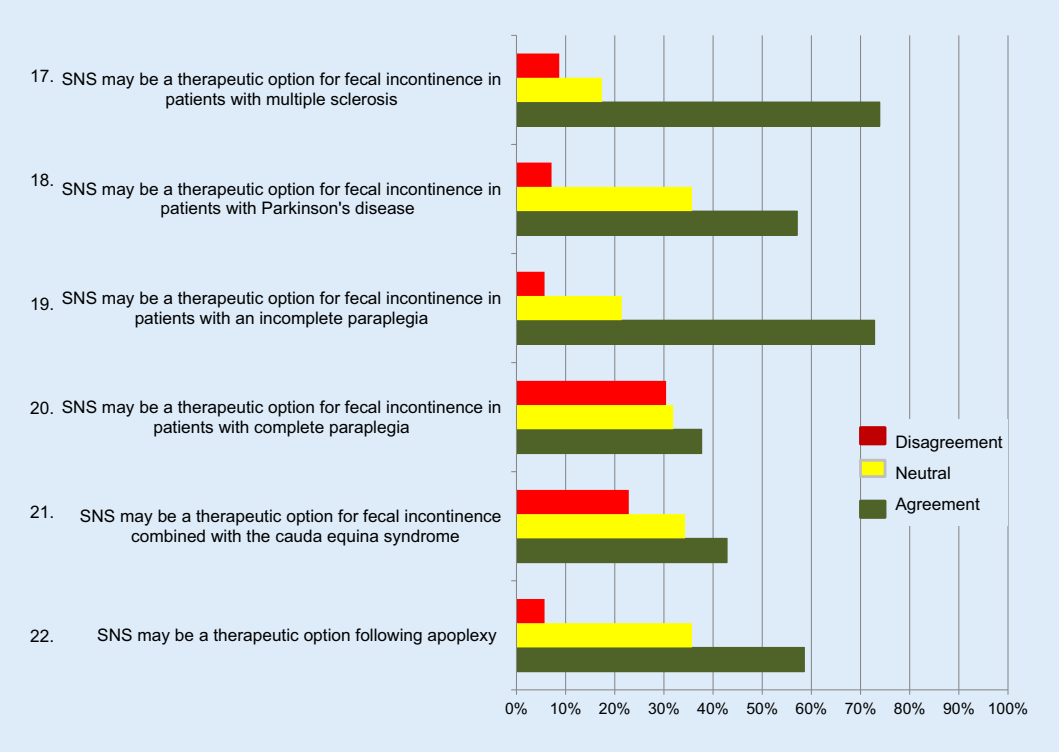


Fig. 4 ◀ Distribution of answers to items 17–22 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

Item 18. 57 % of the respondents consider fecal incontinence in patients with Parkinson's disease an indication for SNS. 35 % adopt a neutral position and 8 % refuse this indication (**Fig. 4**). The board of experts agreed that SNS might be used as a potential treatment for fecal incontinence in patients with Parkinson's disease. There are no explicit studies about this topic. Handling of the patient's programmer might be impaired in patients with Parkinson's disease.

Item 19. The board of experts as well as the respondents agree on using SNS

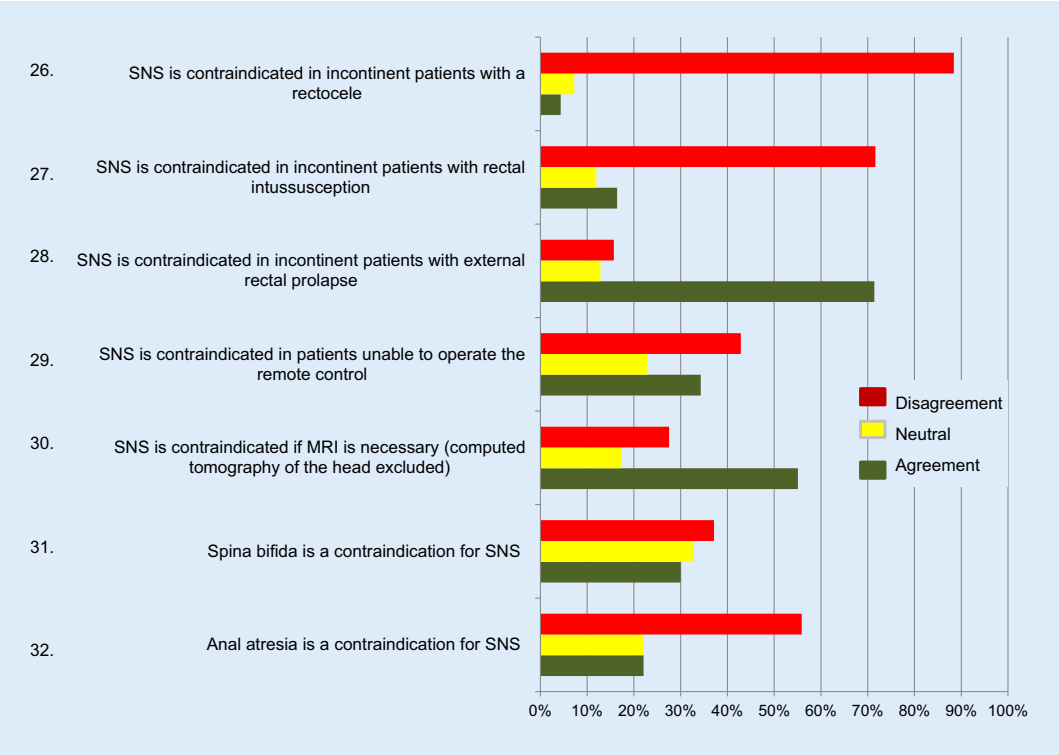


Fig. 5 ◀ Distribution of answers to items 26–32 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement, *MRI* magnetic resonance imaging)

in patients with fecal incontinence and incomplete paralysis (agreement 73 % vs. 21 % neutral vs. 5 % disagreement).

Item 20. In contrast, SNS is not suited as a treatment for patients with complete paralysis, as the mode of action of SNS depends on at least residual function of the corticospinal tract. Partial lesion of the corticospinal tract is no contraindication (see 21) [12–14].

Item 21. SNS is suited as a treatment for patients with cauda equina syndrome (see 20). Electrode placement under local anesthesia might be considered, as the residual muscular activity may be diminished in patients with cauda equina syndrome. Moreover, prolongation of the evaluation period might be considered. A cauda equina syndrome may cause alterations in both the typical motor and sensory reaction patterns after stimulation of the sacral spinal nerves. Stimulation of S2 may possibly show a therapeutic effect.

Item 22. Both the majority of the respondents (59 %) as well as the board of experts do not consider cerebrovascular insult (stroke) a contraindication for SNS (**Fig. 4**). Localization and dimension of the cerebrovascular insult may influence the indication. Apart from that, the patient's general condition and cognitive skills shall be considered.

Item 23. There was general consensus that SNS might be suited as treatment for patients with fecal incontinence and diabetic polyneuropathy (**Fig. 3**).

Item 24. Surgery of the vertebral column might result in fecal incontinence. In these cases, there can be a good therapeutic effect of SNS therapy. Because of potential lesions in the efferent pathways, the motor response might be reduced during acute testing. Testing should be the same as in cauda equina syndrome. In this survey, 87 % of the participants have agreed on this indication. With 93 % of agreement this result was even more pronounced among the experienced surgeons. The board of experts also supported this indication.

Item 25. Fecal incontinence as a consequence of radical surgery of the lesser pelvis is clearly considered an indication both by the participants of the survey (79 %) and by the board of experts (**Fig. 3**).

Contraindications

Item 26. There is general consent among the participating centers (nearly 90 %) as well as the board of experts that a rectocele is no contraindication for SNS (**Fig. 5**).

Item 27. Likewise, rectal intussusception is no contraindication for SNS. Again, there was general consent among the respondents (over 70 %). Of note, there was a greater support among the more experienced centers compared to less experienced centers (79 % vs. 62 %) (**Fig. 5**). The board of experts also shares this view, but refers to a study by Prapasrivorakul et al. [15]. In this study it was shown that patients with rectal intussusception (Oxford grade 3,4) exhibit a worse therapeutic outcome than patients without intussusception.

Item 28. The majority of participants (71 %) consider external rectal prolapse a contraindication for SNS (**Fig. 5**). As a higher rate of agreement concerning

this question was expected, the board of experts underlines that this question refers to a *manifest* external rectal prolapse. SNS may be a good therapeutic option for persistent fecal incontinence after surgical correction of a rectal prolapse [16, 17].

Item 29. The respondents were divided on the question whether a patient's inability to handle the remote control shall be considered as contraindication for SNS: 43 % disagreement, 23 % neutral, 34 % agreement (**Fig. 5**). The board of experts agreed that either the patient himself or a companion should be able to turn the stimulator off if necessary (e. g. pain, before surgeries, potential adverse effects).

Item 30. Only 55 % of the involved centers consider the planned regular necessity of MRI (except for MRI of the head) a contraindication for SNS (**Fig. 5**). 17 % adopt a neutral opinion, 27 % do not consider it a contraindication. In this context, it has to be mentioned that according to the guidelines of the manufacturer, Medtronic Inc., MRI (except for MRI Head coil (1.5 Tesla (T), horizontal closed)) is contraindicated for patients with an implanted neurostimulator for SNS. This recommendation is based on technical/physical considerations, as there might be high electrical current flow at the tip of the electrode, resulting in burns and nerve injuries. See also item 17.

Item 31. Spina bifida per se is no contraindication for the use of SNS. Placement of the electrode close to the nerves is an essential element of SNS therapy. In case of patients with spina bifida, pretherapeutic imaging of both anatomic bone and nerve structures is needed. As there are several forms of manifestation of spina bifida, no conclusions on operational reliability and their functional relevance for symptom relief can be drawn from the topography of the nerves. Therefore, testing of multiple nerves and atypical localizations (e. g. S2) shall be considered [18, 19].

Item 32. As the effect of SNS is not restricted to the anus and its motor and the sensory functions, the majority of the participants as well as the board of experts consider fecal incontinence in patients with status post anal atresia an indication for SNS therapy. Nevertheless, positioning of the electrode might be complicated, as its placement orients itself on motor and sensory responses. Depending on the degree of these, motor and sensory transformations, local anesthesia or general anesthesia might be considered for the intervention [20, 21].

Item 33. Fecal incontinence in patients with Crohn's disease is not seen as a categorical contraindication for SNS by 70 % of the respondents [22].

Item 34. 25 % of the respondents categorically consider fecal incontinence in patients with chronic diarrhea a contraindication for SNS. It has to be mentioned that the therapeutic outcome of SNS is diminished in patients with chronic diarrhea. Only one publication indicates a better therapeutic effect in patients with loose stool consistency [23].

Prior to more invasive measures and after considering differential diagnoses, SNS might be considered as a therapeutic option for the treatment of fecal incontinence in patients with diarrhea, if conservative treatment does not show a therapeutic effect.

Item 35. Resecting rectal surgeries (including STARR, Trans-STARR, resection rectopexy) within the previous 12 months do not represent a general contraindication for SNS. Of note, the board of experts agreed on waiting at least 6 months post-surgery, as a satisfying improvement of symptoms can be achieved by conservative therapy in this timespan. SNS represents a promising therapy for persistent fecal incontinence.

Item 36. Resection for rectal cancer in the last 12 months does not represent a general contraindication for SNS (**Fig. 6**). Of note, the board of experts agreed on waiting at least 12 months post-surgery, as a satisfying improvement of symptoms can be achieved by conservative therapy in this timespan. SNS represents a promising therapy for persistent fecal incontinence. Especially in cases of ileostomy or colostomy reversal/closure, this waiting period should be respected. In cases of uncontrollable symptoms, SNS represents a successful therapeutic option [7]. Additionally, oncological follow-up care should be complete.

Item 37. Existence of a chronic presacral cavity following rectal or anal anastomosis/anastomotic leak does not constitute a general contraindication. However, incorrect insertion of the electrodes into the cavity leading to secondary infections is possible in cases of big cavities located posterior in the presacral space.

Item 38. Indication for implantation of a system of permanent stimulation is based on documented decline of symptoms (frequency of episodes of fecal incontinence) during test stimulation. This is not possible in cases of a protecting stoma. Until today, there is no testing system able to provide a valid prediction for the function of the anal sphincter and degree of continence after restoration of the intestinal track. Basically, there exists no contraindication in patients with a stoma, but the board of experts agreed that an evaluation of testing success is not possible with standard methods, such as documentation of bowel movement. This is reflected in the answers of the study participants, which heterogeneously trend towards an indifferent recommendation. A possible approach to this condition is the PNE testing procedure combined with enemas while the stoma is in place, followed by a tined-lead test following ileostomy or colostomy reversal/closure.

Item 39. A planned pregnancy is no contraindication for an implantation, but the patients have to be educated about Medtronic's recommendation of suspending the stimulation during pregnancy. There are no data about the influence of the stimulation on the course of a pregnancy or on the fetus. Among the users of SNS in Germany,

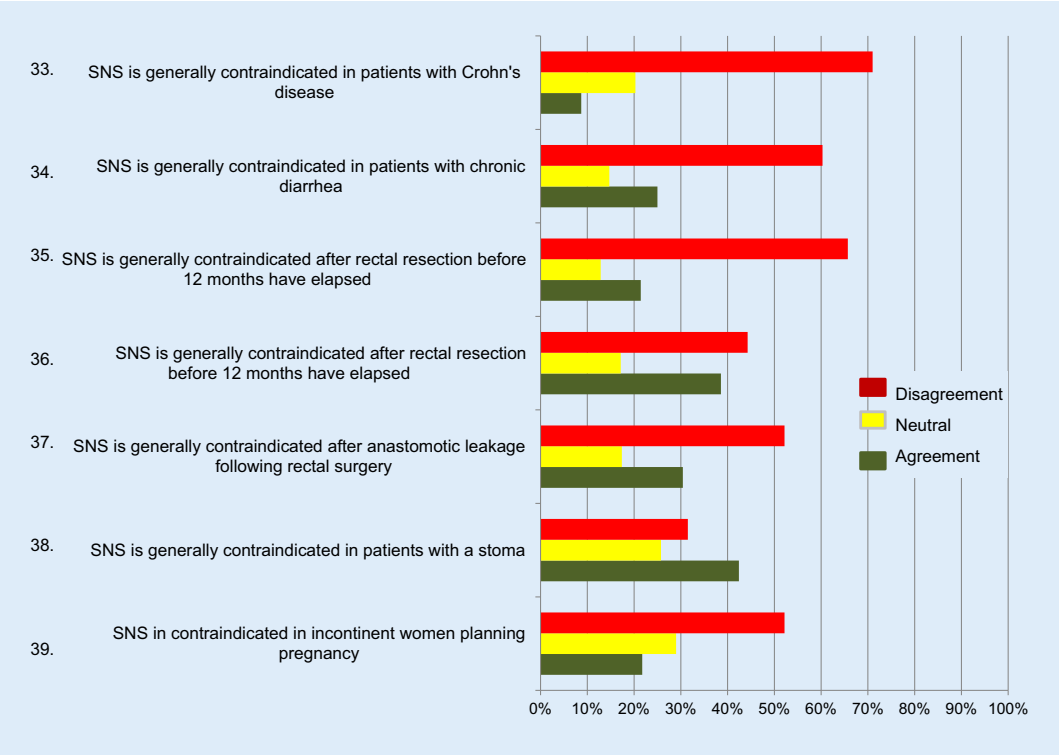


Fig. 6 ◀ Distribution of answers to items 33–39 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

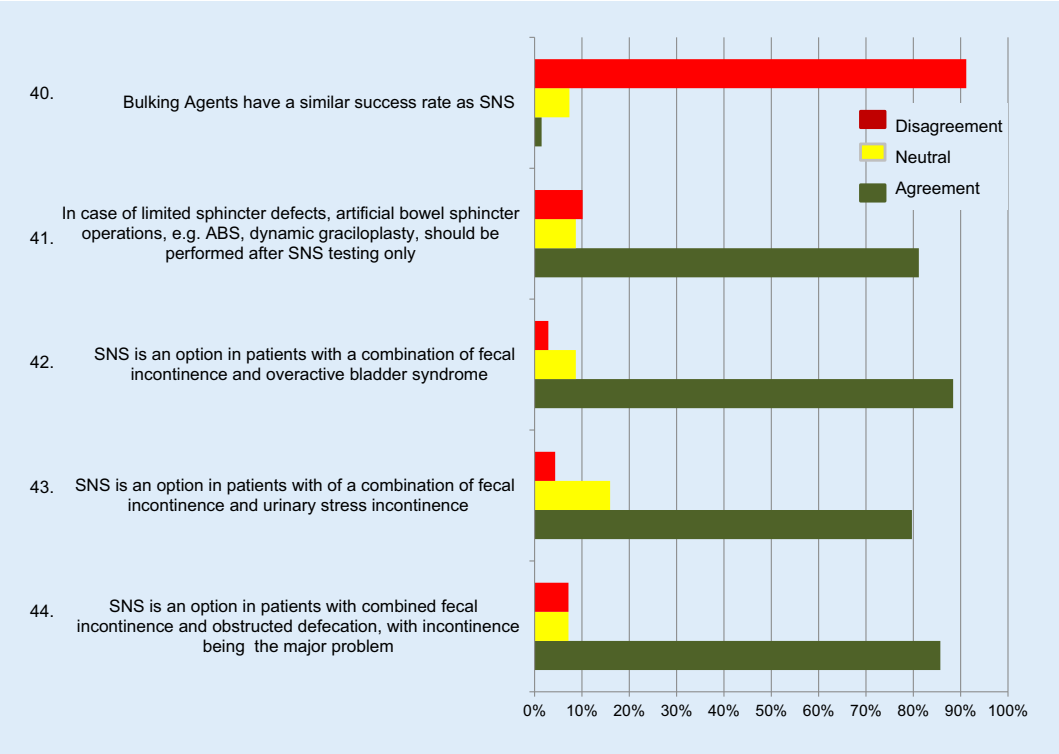


Fig. 7 ◀ Distribution of answers to items 40–44 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement, *ABS* artificial bowel sphincter)

22 % consider a planned pregnancy a contraindication, 52 % would perform an implantation (Fig. 6). Taking into account Medtronic's recommendation, the board of experts does not consider planned pregnancies a contraindication.

Item 40. Both the study participants and the board of experts do not consider bulking agents to be equivalent to SNS for the treatment of fecal incontinence therapy (Fig. 7).

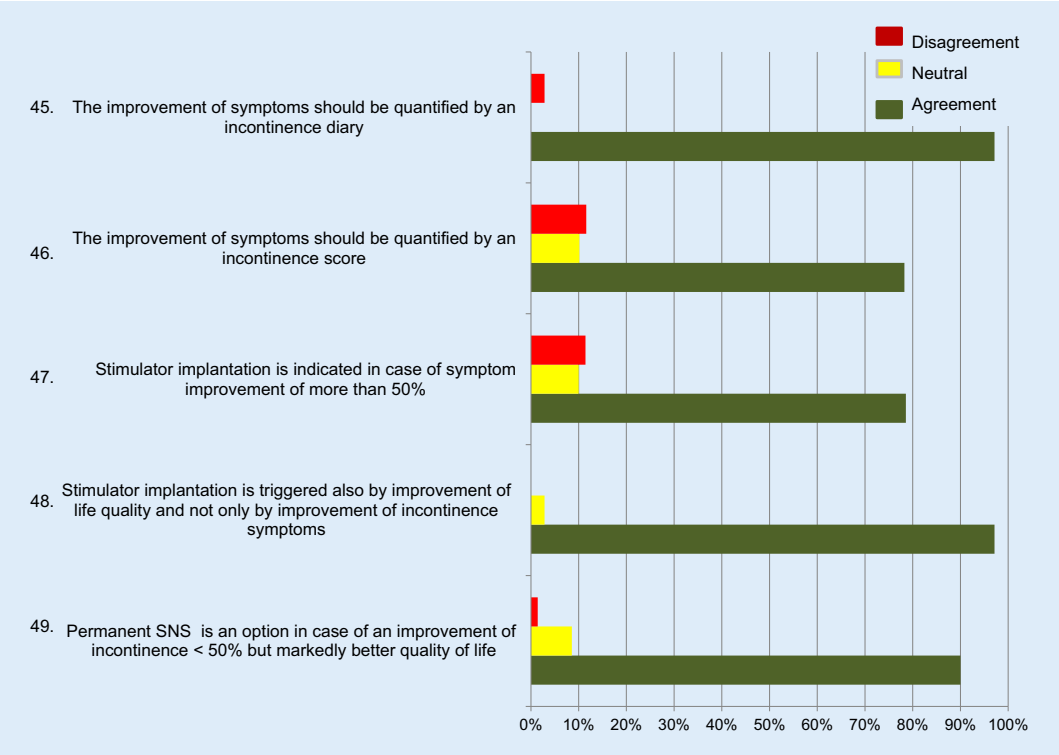


Fig. 8 ◀ Distribution of answers to items 45–49 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

Item 41. Sphincter replacement (artificial anal sphincter or graciloplasty) should be performed after failure of less invasive therapies exclusively. This is clearly reflected in the results of this survey, and is also supported by the actual guidelines ([24]; ◘ **Fig. 7**, see also the comment on items 12/13).

Combined indications

Items 42/43. In general, neither stress urinary incontinence nor urge incontinence is a contraindication for the use of SNS as a therapy for fecal incontinence. However, from a urological point of view stress urinary incontinence is not considered an indication for SNS. An amelioration of symptoms is not expected if stress urinary incontinence coincides with fecal incontinence [25]. Surprisingly, it was not possible to find a difference in the responsive behavior of proctologic users of SNS considering stress urinary incontinence or urge incontinence. In both cases there is a high degree of agreement (88 % for urge incontinence and 79 % for stress urinary incontinence, ◘ **Fig. 7**). In case of patients with fecal incontinence and urinary retention, caution is advised and a urological assessment shall be conducted before SNS.

Item 44. An obstructed defecation syndrome is not a contraindication for SNS. In patients with fecal incontinence and obstructed defecation syndrome, SNS is a good therapeutic option. Potential restrictions have been illustrated in question 27 [15].

Criteria for implantation

Item 45. 97 % of the participants were in favor of documenting changes of symptoms by a bowel habit diary. This was also supported by the board of experts (◘ **Fig. 8**).

Item 46. There was consensus that changes of symptoms shall be additionally documented with an incontinence score.

Item 47. As recommended in most publications, definitive implantation of a stimulator should be performed after improvement of symptoms of at least 50 %.

Item 48. Apart from improvement of symptoms, most of the respondents (nearly 100 %) also consider improvement of quality of life as essential for decision-making for an implantation.

Item 49. 90 % of the participants consider an improvement of symptoms of less than 50 % combined with an improvement of quality of life an indication for implantation (◘ **Fig. 8**). The board also supports this view. However, this opinion is not based on valid study data, as almost all authors use a cut-off value of ≥ 50 %, although there is no validation for this value. According to expert opinion, an improvement of less than 50 % shall result in an extended testing period. An improvement of symptoms of at least 30 % combined with an improved quality of life may be considered an indication for implantation [26, 27].

Preoperative diagnostics

The participants of the survey are in agreement with the process of diagnostic procedures (◘ **Fig. 9**). Before diagnostic SNS, a standard medical history and clinical investigation (including proctoscopy

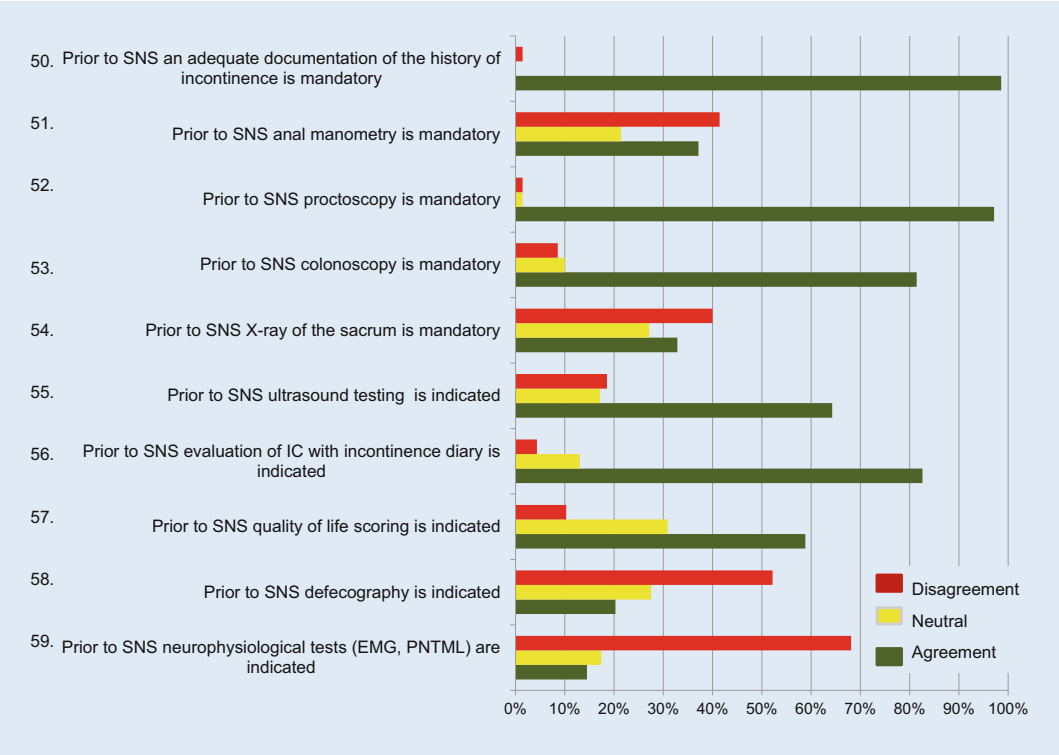


Fig. 9 ◀ Distribution of answers to items 50–59 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement, *IC* incontinence, *EMG* electromyography, *PNTML* pudendal nerve terminal motor latency)

and colonoscopy) of fecal incontinence shall always be conducted. Special importance is attributed to a detailed proctologic history and to the analysis of the bowel habit diary.

Item 50. There is consensus that medical history must be part of the diagnostic procedure.

Item 51. There are different views on the necessity of anal manometry (**Fig. 9**). Nearly 40 % disagree on the necessity of anal manometry, 35 % agree with it. Because of its high intra- and inter-individual variation of measuring results, the significance of anal manometry for indication of SNS is limited. Therefore, it is not mandatory, but it might give an option in selected cases [28]. In the context of a diagnostic evaluation of rectal hyposensitivity, anorectal manometry might produce impact in the decision-making for considering SNS.

Items 52/53. The participants of this survey decided that a proctoscopy or colonoscopy (nearly 100 % and over 80 %, respectively) is mandatory before every SNS (**Fig. 9**). The board of experts also supports this view.

Item 54. There is disagreement about the necessity of a radiological imaging of the sacrum among the participants of the survey: 40 % would perform SNS without this imaging, 32 % would not apply SNS without it. According to the board of experts, radiological imaging of the sacrum is not obligatory, but might be helpful for identification and prevention of electrode placement difficulties due to anatomic complexities in some groups of patients (e. g. patients with congenital anomalies, spina bifida).

Item 55. About two thirds of the respondents think that anal endosonography should be a part of the diagnostic procedure before SNS (**Fig. 9**). The board of experts does not consider anal endosonography as mandatory, but should always be considered as a part of the diagnostic work up for fecal incontinence if defects of the sphincter (e. g. postpartum, after anal fistula surgery) are expected or do exist [29]. Moreover, anal endosonography should be part of diagnostics if therapeutic alternatives are considered (e. g. SNS vs. anal sphincter repair) [28, 29].

Item 56. The board of experts, as well as 82 % of the participants of this survey, considers the use of a bowel habit diary mandatory before SNS (**Fig. 9**).

Item 57. Documentation of quality of life before SNS is considered mandatory in 60 % of the respondents (**Fig. 9**). Preoperative documentation of quality of life is not mandatory, but might be helpful both for deciding on the definitive implantation of the stimulator after test stimulation and for assessing of the therapeutic outcome. The documentation is difficult as there is no valid German quality of life questionnaire. See also item 49.

Item 58. The board of experts as well as nearly 52 % of the participants of this survey do not consider dynamic imaging (defecography, dynamic MRI of the pelvic floor) mandatory before treatment with SNS. However, diagnostics should always include dynamic imaging if symptoms of both fecal incontinence and defecation disorder (obstructed defecation syndrome) interact simultaneously [30,

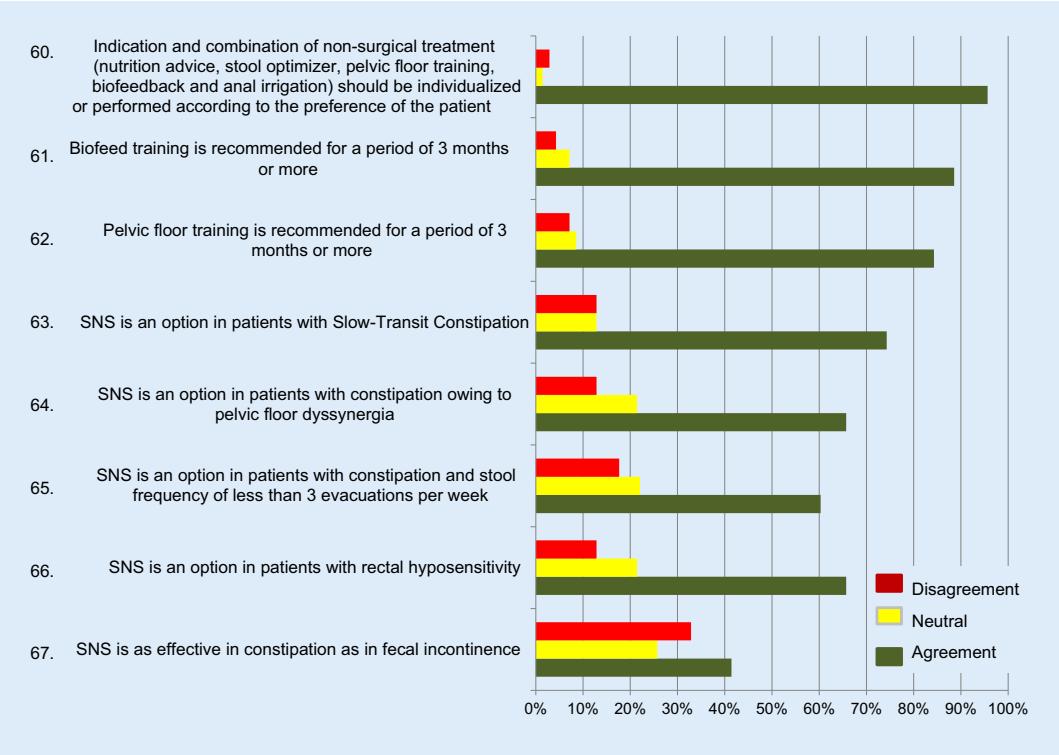


Fig. 10 ◀ Distribution of answers to items 60–67 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

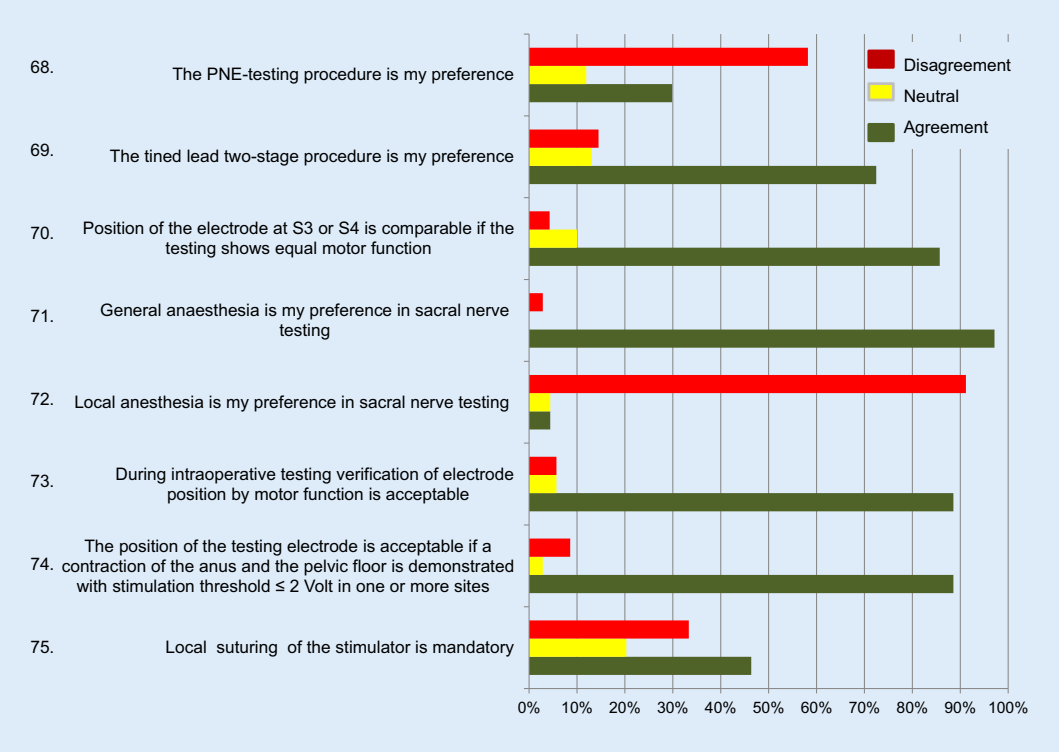


Fig. 11 ◀ Distribution of answers to items 68–75 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement, *PNE* percutaneous nerve evaluation)

31]. Since combined disorders of fecal incontinence and defecation disorders were reported [28–31], dynamic imaging might be helpful for identification of findings leading to morphologic obstruction (e. g. rectal intussusception) and findings resulting in functionally disadvantageous outcomes after SNS [15].

Item 59. There is general consensus that neurophysiological examinations (e. g. EMG, PNTML) are not obligatory before SNS, as they do not influence the decision-making.

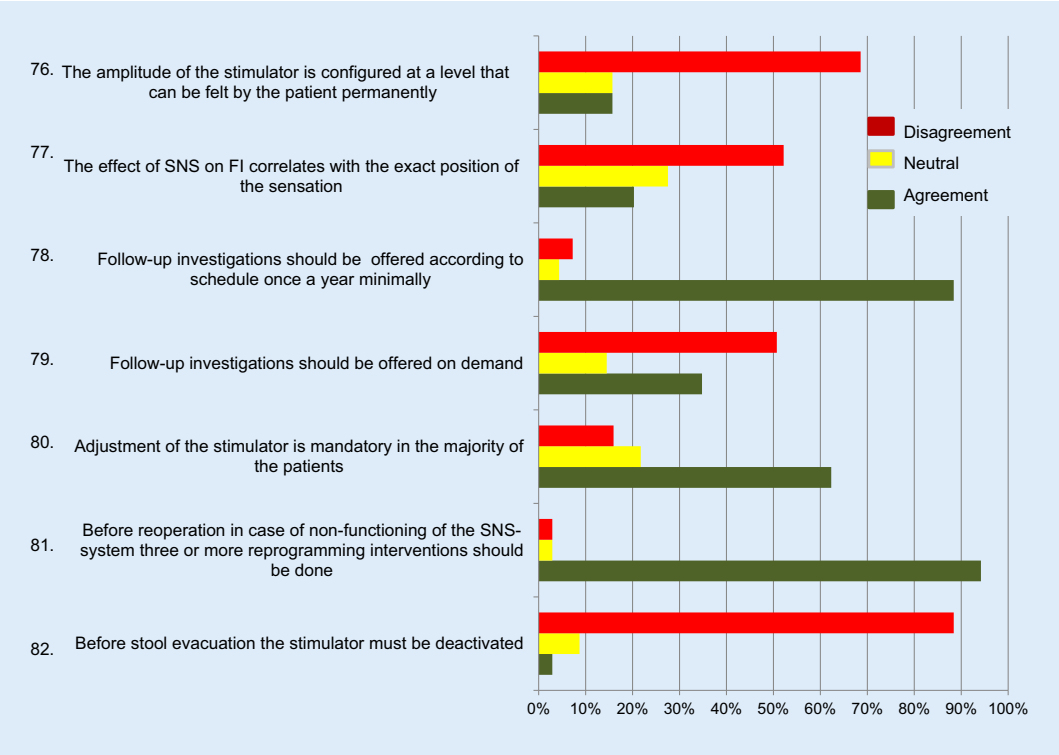


Fig. 12 ◀ Distribution of answers to items 76–82 of the questionnaire given by n = 70 surgeons using sacral nerve stimulation (SNS). Data are % of n = 70 in traffic light system (*red* disagreement, *yellow* neutral, *green* agreement)

Conservative therapy

Items 60–62. There is broad consensus that conservative therapeutic measurements for fecal incontinence shall be adapted to each individual patient. They should be conducted for a certain timespan before indicating SNS (**Fig. 10**). According to the board of experts, this timespan usually comprises three months for pelvic floor exercises and for biofeedback.

Obstipation

Item 63. 74 % of the respondents agree on considering slow transit constipation (STC) as indication for SNS. There is uncertainty among the centers that have performed fewer than 25 implantations at the time of the survey. 58 % of them consider STC an indication for SNS, while 85 % of the more experienced centers consider STC an indication for SNS (**Fig. 10**). In the literature, varying results have been published. The board of experts considers SNS an appropriate treatment for STC. In contrast to other therapeutic options (e. g. colectomy), it is a reversible and a minimally invasive treatment, thus justifying the implantation despite the lack of long-term data and despite the often observed reduction in the effectiveness during the course.

Item 64. Pelvic floor dyssynergia was considered an optional indication for SNS by 65 % of the responding centers. The board of experts shares this view. As there are no large studies on this subject, there is sparse evidence for this kind of treatment.

Item 65. As the definition of constipation also includes infrequent defecation, 60 % consider this an indication.

Item 66. Rectal hyposensitivity may be seen as a cause for constipation. Knowles et al. [32] have reported that 9 out of 13 patients have benefited from stimulation even after a follow-up of 19 months. This disease is considered an indication by 66 % of the users of SNS in Germany. The authors of this article consider these patients may be appropriate for SNS.

Item 67. The effectiveness of SNS in patients with constipation was estimated to be similar to the typical indication "incontinence" by more than one third (41 %) of the users of SNS in Germany (**Fig. 10**). On one hand, there is no great difference in the affirmative response of experienced (44 %) and less experienced surgeons (38 %). On the other hand, both indications are not considered equivalent by more of the less experienced (41 %) than the experienced (27 %) operators. The data on implantation in patients with constipation is not as clear as in fecal incontinence. There are no long-term studies, and there is a reduction in the effectiveness during the course [2]. The board of experts agreed that SNS is appropriate for patients with refractory constipation (see comment on item 63).

Operation technique

Items 68/69. Approximately 70 % of the users prefer the two-stage method with the tined-lead electrode, whereas about 30 % prefer the PNE method (**Fig. 11**). Preference of the two-stage method has increased continuously in recent years. The decision to use either the PNE or the two-stage test depends on several factors. In the case of nonresponsiveness of the electrodes, an advantage of

the PNE test is that the electrodes can be removed noninvasively, whereas the tined-lead probe needs to be explanted under anesthesia. An advantage of a testing phase with a tined-lead electrode is that it can remain in place in case of a successful testing.

Item 70. There is consensus that the S3 and S4 electrode positions are considered equivalent.

Items 71/72. The majority of study participants (96 %) undertake the interventions under general anesthesia. Surgery with local anesthesia is performed only rarely (4 %), but remains reserved for certain cases.

Items 73/74. There is consensus that one motor response during intraoperative placement of the electrode is appropriate, although a motor response on several poles is desirable. Moreover, only one active pole is no indication for stopping the therapy.

Item 75. There is disagreement regarding the necessity of local fixation of the stimulator. Preparation of the subcutaneous cavity should prevent the stimulator from shifting and displacement. Movement of the stimulator might lead to pain at the implantation site and restricted availability of the stimulator. Even though the stimulator does not need to be fixed with sutures, it might be useful in selected cases.

Follow-up

Item 76. There is consensus among the respondents that the amplitude can be adjusted in a way that the patient does not feel the stimulation at any time (**Fig. 12**; [33]).

Item 77. The exact position of the sensation is irrelevant for the clinical effectiveness.

Items 78–80. Follow-up checks should be conducted regularly. In the context of necessary reprogramming and nonresponsiveness of some patients within the first 3–12 months, checks should be conducted more than once a year in the beginning.

Item 81. There is agreement regarding reduction in the effectiveness. Reprogramming should be attempted at least three times before revision or explantation of the device (**Fig. 12**). A systematic proceeding comprising X-ray imaging, "stimulation holiday", and reprogramming appears reasonable [34].

Item 82. Deactivating of the stimulator before defecation is not mandatory (see question 29).

Discussion

The objective of this study was to survey German colorectal surgeons experienced in the clinical practice of SNS for the treatment of fecal incontinence. The responses were then reviewed and commented upon by a board of experts (i. e., frequent users of the technique) to highlight consensus and clarify divergent views. The respondents' knowledge of the literature and manufacturer's guidelines was of particular interest.

Up-to-date uniform recommendations from other European countries are available in Italy and France [35–37], and an exchange of knowledge in this highly standardized procedure may be of great value. Evidence-based classifications of treatment options for fecal incontinence exist [2, 38–40] and will be updated shortly.

The intention of this survey was to describe the reality of SNS in Germany. As our response rate was 48 %, its representativeness should be viewed critically. Nevertheless, it shows a rather high consensus, also supported by the board of experts, regarding patient selection, technical aspects, and follow-up care. Moreover, there is little variation between the replies of high- and low-volume users. Of concern was the fact that questions with little consensus underscore the need for further practitioner education: e. g., almost 40 % of respondents stated that SNS can be a therapeutic option in patients with complete paralysis.

Conclusion

In summary, SNS seems to be performed quite homogeneously regarding technical aspects as well as preoperative diagnostics, patients' selection (indications and contraindications), and follow-up.

Corresponding address

V. Kahlke
Proktologische Praxis and Park-Klinik Kiel
Beselerallee 67, 24105 Kiel, Deutschland
info@proktologie-kiel.de

Acknowledgement. We thank Mr. Markus Noll for his support in translating this manuscript.

Compliance with ethical guidelines

Conflict of interest. A. Fürst: travel costs, fee for consulting activities, company Medtronic. V. Kahlke: consultant, company Medtronic, fee for lectures, company KADE, fee for lectures, company Falk. D. Leder: Global advisory board member Coloplast A/S Humlebaek, DK, Wellspekt Healthcare Goethenburg, S, consulting activities, company Medtronic. M. Löhnert: travel costs, fee consultant Ethicon Germany, Tyco Germany, Falk Foundation, Aesculap, Medtronic. K.E. Matzel: consultant company Medtronic, proctoring: Covidien, Cook. O. Schwandner: travel costs, fee for consulting activities, company Medtronic. T. Schwandner: travel costs, fee for consulting activities, company Medtronic. D. Weimann: travel costs, fee for consulting activities, company Medtronic.

The accompanying manuscript does not include studies on humans or animals.

References

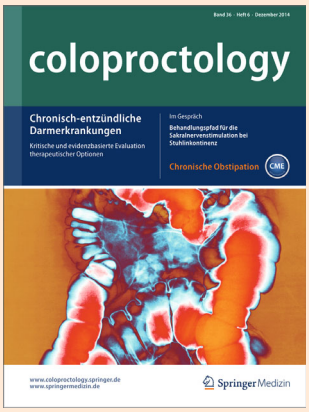
1. Matzel KE, Bittorf B (2015) Sakralnervenstimulation in der Koloproktologie. Coloproctology 1:17–25
2. Thaha MA, Abukar AA, Thin NN, Ramsanahie A, Knowles CH (2015) Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database Syst Rev 8:CD004464 doi:10.1002/14651858.CD004464.pub3
3. Layer P, Andresen V, Pehl C et al (2011) S3-Leitlinie Reizdarmsyndrom: Definition, Pathophysiologie, Diagnostik und Therapie. Gemeinmsame Leitlinie der Deutschen Gesellschaft für Verdauungserkrankungen (DGVS) und der Deutschen Gesellschaft für Neurogastroenterologie und Motilität (DGNM). AWMF Reg Nr: 021/016. http://www.awmf.org/leitlinien/detail/ll/021-016.html
4. Fassov JL, Lundby L, Laurberg S et al (2014) A randomized, controlled, crossover study of sacral nerve stimulation for irritable bowel syndrome. Ann Surg 260(1):31–36. doi:10.1097/SLA.0000000000000559
5. Chan MK, Tjandra JJ (2008) Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. Dis Colon Rectum 51(7):1015–1024

6. Boyle DJ, Knowles CH, Lunniss PJ et al (2009) Efficacy of sacral nerve stimulation for fecal incontinence in patients with anal sphincter defects. Dis Colon Rectum 52(7):1234–1239
7. Schwandner O (2013) Sacral neuromodulation for fecal incontinence and "low anterior resection syndrome" following neoadjuvant therapy for rectal cancer. Int J Colorectal Dis 28(5):665–669
8. Thomas GP, Bradshaw E, Vaizey CJ (2015) A review of sacral nerve stimulation for faecal incontinence following rectal surgery and radiotherapy. Colorectal Dis 17(11):939–942
9. Andretta E, Simeone C, Ostardo E et al (2014) Usefulness of sacral nerve modulation in a series of multiple sclerosis patients with bladder dysfunction. J Neurol Sci 15(347):257–261
10. Remmen F, Dindo D (2013) Fecal incontinence–a treatable problem! Ther Umsch 70:403–406
11. Holzer B, Rosen HR, Novi G et al (2007) Sacral nerve stimulation for neurogenic faecal incontinence. Br J Surg 94:749–753
12. Lombardi G, Del Popolo G (2009) Clinical outcome of sacral neuromodulation in incomplete spinal cord injured patients suffering from neurogenic lower urinary tract symptoms. Spinal Cord 47:486–491
13. Carrington EV, Evers J, Grossi U et al (2014) A systematic review of sacral nerve stimulation mechanisms in the treatment of fecal incontinence and constipation. Neurogastroenterol Motil 26:1222–1237
14. DuddingTC, Hollingshead JR, Nicholls RJ et al (2011) Sacral nerve stimulation for faecal incontinence: patient selection, service provision and operative technique. Colorectal Dis 13:e187–e195
15. Prapasrivorakul S, Gosselink MP, Gorissen KJ et al (2015) Sacral neuromodulation for faecal incontinence: is the outcome compromised in patients with high-grade internal rectal prolapse? Int J Colorectal Dis 30(2):229–234
16. Jarrett ME, Matzel KE, Stösser M et al (2005) Sacral nerve stimulation for fecal incontinence following surgery for rectal prolapse repair: a multicenter study. Dis Colon Rectum 48:1243–1248
17. Yap JR, Zufferey G, Rosen H et al (2010) Sacral nerve modulation in the treatment of fecal incontinence following repair of rectal prolapse. Dis Colon Rectum 53:428–431
18. Lansen-Koch SMP, Govaert B, Oerlemans D et al (2011) Sacral nerve modulation for defaecation and micturition disorders in patients with spina bifida. Colorectal Dis 14:508–514
19. Al Ghrebawi A (2013) Sakralnervenstimulation bei Spina bifida. coloproctology 35:141–143
20. Nicholls RJ, Vaizey CJ (2013) Sacral nerve stimulation for faecal incontinence secondary to congenital imperforate anus. Tech Coloproctol 17:227–229
21. Bloemendaal ALA, Gorissen K, Prapasrivorakul S et al (2015) Sacral nerve stimulation for faecal incontinence due to imperforate anus in VATER/VACTERL association. Int J Colorectal Dis. doi:10.1007/s00384-015-2282-y
22. Vitton V, Gigout J, Grimaud J-C et al (2008) Sacral Nerve Stimulation can improve continence in patients with Crohn's Disease with internal and external anal sphincter disruption. Dis Colon Rectum 51:924–927
23. Gallas S, Michot F, Faucheron JL et al (2011) Predictive factors for successful sacral nerve stimulation in the treatment of faecal incontinence: results of trial stimulation in 200 patients. Colorectal Dis 13:689–696
24. Madoff RB, Laurberg S, Lehur P et al (2012) Surgery for fecal incontinence. In: Abrams P, Cordozo L, Khoury S, Wein A (eds.) ICUD-EAU: 5th International Consultation on Incontinence. ICUD, Paris, pp 1488–1526
25. Lucas MG, Bosch RJ, Burkhard FC et al (2013) European Association of Urology. EAU guidelines on surgical treatment of urinary incontinence. Actas Urol Esp 37(8):459–472
26. Maeda Y, O'Connell PR, Lehur PA et al (2015) Sacral nerve stimulation for faecal incontinence and constipation: a European consensus statement. Colorectal Dis 17(4):O74–87
27. Carrington EV, Evers J, Grossi U et al (2014) A systematic review of sacral nerve stimulation mechanisms in the treatment of fecal incontinence and constipation. Neurogastroenterol Motil 26(9):1222–1237
28. Kim M, Isbert C (2013) Anorektale Funktionsdiagnostik. Therapiealgorithmus bei Obstruktion und Inkontinenz. Chirurg 84:7–14
29. Löhnert M (2015) Stuhlinkontinenz. In: Schwandner O (ed.) Proktologische Diagnostik. Springer, Heidelberg (in press)
30. Schwandner O, Bruch HP (2006) Entleerungsstörung bei klinisch nachgewiesener Intussuszeption und ventraler Rektozele. Bildmorphologische Relevanz mit spezieller Fokussierung auf die Sigmoidozele. Coloproctology 28:97–105
31. Schwandner O (2012) Indikationen und chirurgische Therapieoptionen beim obstruktiven Defäkationssyndrom. Viszeralmedizin 28:260–266
32. Knowles CH, Thin N, Gill K et al (2012) Prospective randomized double-blind study of temporary sacral nerve stimulation in patients with rectal evacuatory dysfunction and rectal hyposensitivity. Ann Surg 255(4):643–649
33. Duelund-Jakobsen J, Buntzen S et al (2013) Sacral nerve stimulation at subsensory threshold does not compromise treatment efficacy: results from a randomized, blinded crossover study. Ann Surg 257:219–223
34. Matzel KE, Bittorf B (2013) Treatment of sphincter insufficiency. Chirurg 84(1):39–45
35. Falletto E, Ganio E, Naldini G et al (2014) Sacral neuromodulation for bowel dysfunction: a consensus statement from the Italian group. Tech Coloproctol 18(1):53–64
36. Leroi AM, Damon H, Faucheron JL et al (2009) Club NEMO. Sacral nerve stimulation in faecal incontinence: position statement based on a collective experience. Colorectal Dis 11(6):572–583
37. Vitton V, Soudan D, Siproudhis L et al (2014) French National Society of Coloproctology. treatments of faecal incontinence: recommendations from the French National Society of Coloproctology. Colorectal Dis 16(3):159–166
38. National Institute for Health and Care Excellence (2007) Faecal incontinence: the management of faecal incontinence in adults. NICE guideline CG49. National Institute for Health and Care Excellence, London
39. Paquette IM, Varma MG, Kaiser AM et al (2015) The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. Dis Colon Rectum 58(7):623–636
40. Abrams P, Cardozo L, Khoury S, Wein A (eds.) (2012) 5th International Consultation on Incontinence Paris, February 2012. ICUD consultations, Paris. http://www.icud.info/incontinence.html

Für Autoren

Möchten Sie einen Beitrag für *coloproctology* einreichen?

Wir freuen uns, dass Sie unsere Zeitschrift *coloproctology* mitgestalten möchten.



Für folgende Rubriken können Manuskripte eingereicht werden:

- **Übersichten**
- **Originalien**
- **Kasuistiken**

Um Ihnen bei der Manuskripterstellung behilflich zu sein, haben wir für unsere Autoren ausführliche Autorenleitfäden und Musterbeiträge für die verschiedenen Rubriken zusammengestellt. Diese und weitere Hinweise zur Manuskripterstellung finden Sie online unter dem Menüpunkt „Hinweise für Autoren" unter www.coloproctology.springer.de

Die Einreichung Ihres Manuskripts erfolgt über die Redaktion, die Ihnen ebenfalls bei weiteren Fragen zur Manuskriptgestaltung zur Verfügung steht:

Christiane Jurek
christiane.jurek@springer.com

Wir freuen uns auf Ihre Beiträge!

Ihre Redaktion von *coloproctology*