Consensus statement

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Sacral nerve stimulation for faecal incontinence and constipation: a European consensus statement

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Abstract

Aim In Europe during the last decade sacral nerve stimulation (SNS) or sacral neuromodulation (SNM) has been used to treat faecal incontinence (FI) and constipation. Despite this, there is little consensus on baseline investigations, patient selection and operative technique. A modified Delphi process was conducted to seek consensus on the current practice of SNS/SNM for FI and constipation.

Method A systematic literature search of SNS for FI and constipation was conducted using PubMed. A set of questions derived from the search and expert opinion were answered on-line on two occasions by an international panel of specialists from Europe. A 1-day face-to-face meeting of the experts finalized the discussion.

Results Three hundred and ninety-three articles were identified from the literature search, of which 147 fulfilled the inclusion criteria. Twenty-two specialists in FI and constipation from Europe participated. Agreement was achieved on 43 (86%) of 50 domains including the set-up of service, patient selection, baseline investigations, operative technique and programming of the device. The median of agreement was 95% (35–100%).

Conclusion Consensus was achieved on the majority of domains of SNS/SNM for FI and constipation. This should serve as a benchmark for safe and quality practice of SNS/SNM in Europe.

Keywords Faecal incontinence, constipation, sacral nerve stimulation, sacral neuromodulation, consensus, Delphi process

Introduction

Sacral nerve stimulation (SNS) or sacral neuromodulation (SNM), hereafter referred to as SNS, is a treatment option for faecal incontinence (FI) and constipation. Stimulation of the anterior ramus of the sacral spinal nerves S3 or S4 improves symptoms, thought to be due to a combination of local neuromodulation and modification of central nervous activity via afferent stimulation [1–3]. Many studies have demonstrated short- and medium-term success [4–15] and a double-blind cross-over study has shown that this is not due to a placebo effect [16]. SNS improves quality of life [17–22], with high levels of satisfaction [23,24].

Current practice is based on clinical trials of SNS for FI initiated in the 1990s [25], and there is now information on the longer-term outcome [26–29]. Late complications not encountered in the early assessments have been reported [30–32] and their management has largely been based on trial and error. There have been many studies on the initial selection criteria for SNS for FI, such as excluding patients with a sphincter defect. The sensitivity of the currently existing assessment procedure, such as the period of peripheral nerve evaluation (PNE), incontinence scores and bowel diaries, has been questioned.

There is little information on the long-term outcome of SNS for constipation and evacuation difficulties [33–40] despite initial success [41–44]. This group of patients may have psychological difficulties which will influence the results [45]. Several case reports have suggested that SNS offers improvement in patients with

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irritable bowel syndrome [46,47], anal pain [48,49], systemic sclerosis [50], muscular dystrophy [51], inflammatory bowel disease [52], congenital anomalies [53] and after rectal surgery with or without chemoradiotherapy [54–61], ileopouch anal anastomosis [62,63] or prolapse repair [64,65].

Despite the increased use of SNS there is little consensus on baseline investigations, patient selection and operative techniques. Since this is now the most prevalent invasive treatment for FI and constipation, it is essential that more information on current practice becomes available. For this reason, a modified Delphi process was initiated to determine practice and consensus among a large group of experts in Europe practicing SNS for FI and constipation.

Method

Literature search

PubMed was searched using the keywords 'sacral nerve stimulation' and 'sacral neuromodulation' for English-language articles published between January 1980 and October 2013. A search using each keyword was performed followed by combining this with the secondary keywords of 'constipation' and 'faecal incontinence'. A manual search for relevant articles and references that may have been missed by the search was also performed, and a final literature update was carried out in March 2014.

Inclusion criteria

Studies of SNS or SNM using the InterStim™ (Medtronic, Minneapolis, Minnesota, USA) device fulfilling the following criteria were included: prospective, retrospective and controlled trials reporting the outcome, specific complications and adverse events, technical aspects or cost-effectiveness and case reports specifically outlining new indications and adverse events of SNS or SNM.

The exclusion criteria included studies reporting SNS or SNM using implantable devices other than InterStim, nonimplantable devices, animal studies, letters and comments and articles not in English. Review articles were not included but were cross-checked for completeness of the literature search.

The consensus process

A steering group of experts was formed who had a common interest in improving the clinical practice of SNS. It cross-checked and validated the recent literature. The composition of the group of specialists involved in the present consensus statement was derived from literature review and recommendations of other experts. All had performed more than 50 SNS implants.

The consensus process was conducted by a modified Delphi method. The specialists in the study group were asked to complete a questionnaire constructed on a web-based electronic survey system (http://www.smartsurvey.co.uk). Each specialist completed the questionnaire independently to maintain anonymity. Each question, asking whether the expert agreed or not with the question, had to be answered on a scale of 0–10 scale. There was also space for each expert to make comments if necessary. The steering group analysed the outcome of the first round and modified the questionnaire for the second round, which was also conducted online using the same web-based survey with the outcome of the first round shown. Following the two rounds, both the steering committee and the study group participated in a face-to-face meeting. All the topics raised during the first two rounds were discussed and voted on using an interactive system which consisted of a handheld device with immediate transmission of the anonymized results to MobiTED Systems (IT-Service-Center, Universität zu Lübeck, Lübeck, Germany). The possible answers included: Scale 1 abstain, Scale 2 Strongly disagree to Scale 6 stongly agree. Achievement of consensus was defined as more than 80% agreement. The percentage was calculated by the number of participants who agreed or strongly agreed divided by the total number of votes, excluding abstentions. The Scottish Intercollegiate Guidelines Network (SIGN) grading system was used to quantify the quality of evidence and recommendations [66].

Results

Literature review

Three hundred and ninety-four articles were identified from the search. Of these 146 fulfilled the inclusion criteria. One article was added outside the literature search as a reference for evidence grading. The flow diagram is shown in Fig. 1.

Participants

Twenty-two specialists from European countries were invited by e-mail to take part. Three declined or did not respond, leaving 19 specialists. One of these dropped out after the first round, leaving 18 who completed both rounds. Another specialist dropped out before the face-to-face meeting, leaving 17. The steering committee consisted of five members who joined in

the voting, making a total of 22 individuals who took part in all phases of the study.

Consensus

Consensus was achieved in 43 (86%) out of 50 possible statements.

SNS for faecal incontinence

The unit using SNS

The experts felt that:

- SNS should be offered in a specialty pelvic floor centre where a range of other treatments, conservative or surgical are also available.

(Abstained 3, voted 19. Agree/strongly agree 19. Agreement 100%. Evidence grade 4. Recommendation D.)

Treatment before SNS

A small randomized controlled study had shown that SNS improved symptoms significantly more than medical therapy and advocated SNS as a potential first-line treatment [67].

However, in general,

- SNS should be offered after conservative treatments, such as dietary advice, medication to thicken the stool, laxatives, irrigation and biofeedback, have failed [68].

(Abstained 1, voted 21. Agree/strongly agree 19. Agreement 90%. Evidence grade 4. Recommendation D.)

Baseline investigation

There have been conflicting results regarding the effect of SNS on anal sphincter function with reports of no effect [69,70] or improvement [6,11,71–76]. SNS appears to increase the sensory threshold to rectal distension, although whether this is related to physical changes in rectal capacitance is uncertain [73,77–80].

- Pretreatment investigations that could be considered include anorectal physiology testing (manometry, rectal capacity/sensory measurement) and endoanal ultrasound. Endoanal ultrasound is relevant to select a subset of patients who may benefit from treatments other than SNS. The results are helpful for discussion with the patient and for research, but may be of little value in decision-taking and the prediction of outcome. (It was noted that in some countries these investigations are requirement for reimbursement.)

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 4. Recommendation D.)

Imaging before peripheral nerve evaluation (PNE)

- A plain X-ray taken before PNE could be useful for identifying any skeletal abnormalities in patients with

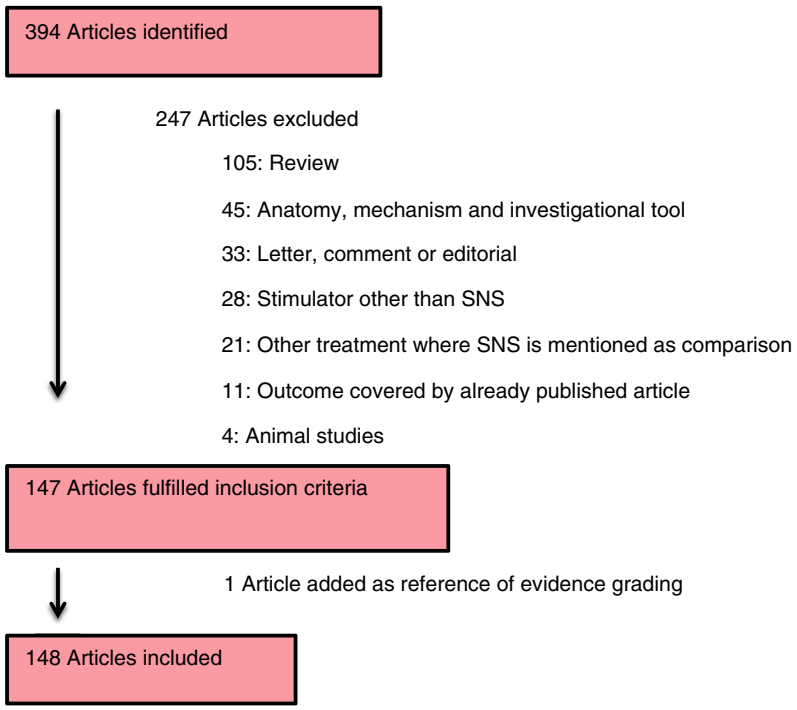

Figure 1 Flow diagram of the literature search.

imperforate anus, spina bifida, myelomeningocoele and previous spinal surgery.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

- MRI should be performed before SNS in patients with spina bifida owing to the potential anatomical skeletal deformity.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

Predictive factors

Age, stool consistency, improvement of urge incontinence, low threshold to obtain motor/sensory response and the use of a permanent lead for PNE have been reported by some authors to predict the outcome, whether good or bad. Others have, however, reported no correlation between preoperative manometry, age or duration of symptoms and the outcome [81–89].

- Any patient with FI should be considered for SNS unless it is contraindicated.

(Abstained 0, voted 22. Agree/strongly agree 19. Agreement 86%. Evidence grade 4. Recommendation D.)

SNS or sphincter repair

In the early years of SNS, an intact sphincter was a prerequisite for a patient to be considered, but there are many studies reporting a good outcome in the presence of a sphincter defect [90–97]. There is little information on whether the magnitude of the sphincter defect affects the outcome [93]. Thus there are data suggesting that SNS can be effective in patients with a defect of 120° [98] and other studies concluding that it is more effective for lesser degrees of displacement [91,92].

- A sphincter defect is no longer considered a contraindication to SNS, but careful consideration is needed when sphincter repair would also be an option.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

- In the absence of solid evidence, the following factors need to be considered in choosing between SNS and sphincter repair when both are potentially indicated: (i) age of the patient, (ii) timing of the onset of incontinence after sphincter injury, (iii) the size of the defect, (iv) the quality of the sphincter muscle, (v) the longitudinal length of the sphincter defect, (vi) isolated external anal sphincter (EAS) or combined with an internal anal sphincter (IAS) defect, (vii) a cloacal defect, (viii) pelvic floor weakness ± rectal intussusception.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

Bowel diary and incontinence score

During early experience with SNS a bowel diary was used as the main assessment tool to determine the effect of PNE. It is now recognized that this may be inaccurate owing to poor patient compliance or inaccurate data entry.

- A bowel diary is useful at baseline and in the short term for the assessment of symptoms.

(Abstained 1, voted 21. Agree/strongly agree 19. Agreement 90%. Evidence grade 4. Recommendation D.)

- Compliance with filling in a bowel diary in the long term is poor.

(Abstained 0, voted 22. Agree/strongly agree 15, neutral 4, disagree 3. Agreement 68%. Evidence grade 4. Recommendation none.)

- The incontinence score is useful when taken in conjunction with the bowel diary to monitor outcome compared with baseline values. The score is, however, usually computed over a longer period than PNE and may therefore not reflect the true efficacy of PNE.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

Criterion for successful PNE

- An improvement in symptoms of > 50% is the criterion of successful PNE. There are data to suggest that greater improvement may lead to better long-term outcome [85].

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

Criteria for successful SNS

- The same assessment tools cannot be used for PNE and during the follow-up of patients receiving implantation of a permanent device. Quality of life should also be considered in the long-term. In addition to bowel diaries, other tools such as objective symptom and quality of life scoring systems should be used.

(Abstained 1, voted 21. Agree/strongly agree 21. Agreement 100%. Evidence grade 4. Recommendation D.)

Counselling

SNS is a form of maintenance therapy. Reprogramming and/or revisional surgery may be required during the

course of treatment, including removal of the device as a result of complications [99–102].

- Patients should be informed that SNS may improve but not abolish incontinence symptoms in around 75% of patients [103] and the efficacy may not be maintained in the long term [31,104,105].

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 2+. Recommendation C.)

SNS in children

The use of SNS in children and adolescents has been limited [106–109].

- SNS should only be performed in highly selected cases in dedicated centres within a research programme.

(Abstained 1, voted 21. Agree/strongly agree 21. Agreement 100%. Evidence grade 2−. Recommendation D.)

SNS and pregnancy

There is no evidence of any detrimental effect of SNS during pregnancy [34,110,111] but for reasons of caution:

- It is recommended that any functioning SNS implanted pulse generator (IPG) should be switched off as soon as the patient is aware that she is pregnant.

(Abstained 0, voted 22. Agree/strongly agree 18. Agreement 82%. Evidence grade 3. Recommendation D.)

- SNS should not be started during pregnancy.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 3. Recommendation D.)

SNS in the elderly

- There is no upper age limit to the use of SNS [112] as long as the patient is deemed to be fit.

(Abstained 0, voted, 22. Agree/strongly agree 18. Agreement 82%. Evidence grade 3. Recommendation D.)

SNS for concomitant urinary symptoms

- SNS may be indicated for a patient with FI and urinary symptoms. Such patients should be discussed with a urologist [113–119].

(Abstained 0, voted 22. Agree/strongly agree 19. Agreement 86%. Evidence grade 2−. Recommendation D.)

SNS for spinal cord injury

- Patients with incomplete spinal cord injury, cauda equina, spina bifida or disc prolapse may benefit from SNS [49,120–123].

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 2−. Recommendation D.)

SNS for other functional bowel disorders

Efficacy of SNS for functional bowel disease and pelvic floor disorders including anal pain has not been demonstrated owing to limited data [46–48,124–127].

- SNS for functional bowel disease and pelvic floor disorders is currently not recommended as a standard treatment until further information is available.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 3. Recommendation D.)

Contraindications

- Contraindications of SNS include patients who require regular MRI of the abdomen and thorax. Patients with a sacral deformity, skin conditions at the site of implantation and bleeding diathesis should be informed of the risk of technical difficulties and complications. In the latter case a full clotting screen is indicated followed by appropriate advice on whether SNS should be performed.

(Abstained 1, voted 21. Agree/strongly agree 20. Agreement 95%. Evidence grade 4. Recommendation D.)

Definition of PNE

- PNE is defined as percutaneous nerve evaluation using a temporary electrode or a tined (quadrupolar) lead which would be definitive in the event of a > 50% improvement in symptoms.

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 3. Recommendation D.)

The duration of PNE

- The participants unanimously felt that the current manufacturer's recommendation of a 2-week period is not long enough to assess the efficacy of stimulation. It was suggested that PNE should be conducted for more than 2 weeks and up to 4 weeks.

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 4. Recommendation D.)

Type of lead and anaesthesia for PNE

Four of the 22 experts used a temporary electrode only for PNE and five used a temporary or a tined lead. Thirteen performed PNE with a tined lead only. There was a considerable discussion about whether

PNE should be performed under local or general anaesthesia.

- The outcome of PNE is not influenced by the type of lead nor the form of anaesthesia [128,129].

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 3. Recommendation D.)

Radiological guidance during insertion of a temporary electrode

There have been reports of radiologically guided temporary lead insertion for patients with a sacral abnormality [130].

- In general, it is sufficient to locate the optimal site for lead placement during PNE using anatomical markings including bony prominences.

(Abstained 4, voted 18. Agree/strongly agree 10, neutral 5, disagree/strongly disagree 3. Agreement 56%. Evidence grade 4. Recommendation none.)

Fluoroscopy for insertion of a permanent tined lead

- Fluoroscopy should be used for PNE using a permanent tined lead.

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 3. Recommendation D.)

Postoperative X-ray for temporary lead insertion

- For PNE using a temporary lead, a postoperative X-ray may be helpful to confirm the position of the temporary lead.

(Abstained 5, voted 17. Agree/strongly agree 6, neutral 6, disagree/strongly disagree 5. Agreement 35%. Evidence grade 4. Recommendation none.)

Temporary lead

- When positioning the temporary lead for PNE, it should be the aim to obtain sensory and motor response at the lowest amplitude of stimulation.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

Tined lead for PNE

- Using a tined quadrupolar lead for PNE should be the aim to achieve an anal sensory response around the anus in a patient under local anaesthesia and a contraction of the pelvic floor or anal sphincter with the patient under local or general anaesthesia with as many electrodes as possible.

(Abstained 1, voted 21. Agree/strongly agree 20. Agreement 95%. Evidence grade 4. Recommendation D.)

Infection during PNE

Some degree of bacterial contamination appears to occur on temporary lead insertion [131,132]. Infection following permanent electrode insertion is an uncommon but recognized complication [132,133]. No clinician who attended the consensus meeting had experienced any clinically relevant infection with a temporary lead insertion.

- In the absence of clinical trials, there was concern among the experts of a potential risk of infection in performing PNE using a tined lead.

(Abstained 0, voted 22. Agree/strongly agree 16. Agreement 73%. Evidence grade 4. Recommendation none.)

Failed PNE using a temporary lead

Some experts felt that lead displacement may be due to noncompliance of patients with the instructions and therefore a negative predictor for SNS which requires maintenance over long period of time.

- If PNE using a temporary lead failed due to lead displacement, it is not recommended to retest the patient with a new PNE.

(Abstained 1, voted 21. Agree/strongly agree 12, neutral 4, disagree/strongly disagree 5. Agreement 57%. Evidence grade 4. Recommendation none.)

Antibiotics

- One dose of prophylactic antibiotics should be given before the implantation of a tined lead and implantable pulse generator (IPG).

(Abstained 2, voted 20. Agree/strongly agree 20. Agreement 100%. Evidence grade 4. Recommendation D.)

- The use of an antibiotic-impregnated sheet [134] during implantation of the device is currently not recommended.

(Abstained 0, voted 22. Agree/strongly agree 16. Agreement 73%. Evidence grade 4. Recommendation none.)

- No routine antibiotics are needed postoperatively.

(Abstained 1, voted 21. Agree/strongly agree 18. Agreement 86%. Evidence grade 4. Recommendation D.)

Subcutaneous pocket for the implantable pulse generator (IPG)

- It is sufficient to make the pocket for the IPG as small as possible. Suture fixation is not needed, although this is a deviation from the manufacturer's recommendations.

(Abstained 1, voted 21. Agree/strongly agree 19. Agreement 90%. Evidence grade 4. Recommendation D.)

Programming

- Change of voltage and/or electrode (pole/contact) configuration is a first step in reprogramming.

(Abstained 3, voted 19. Agree/strongly agree 18. Agreement 95%. Evidence grade 4. Recommendation D.)

- Measurement of impedance is helpful for identifying a circuit problem.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

- Data are limited on the effect of variations of programming such as cyclic mode [135], switch on/off [136], change of pulse width and frequency [137,138]. A few studies suggest that subsensory stimulation does not change the clinical efficacy [139,140]. Overall, the impact and benefit of these variations are unclear.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

Pain around the implantable pulse generator (IPG)

- When pain around the IPG site does not respond to changes in the programme settings or to other measures such as analgesia medication, topical ointments and local anaesthesia, re-siting in the ipsilateral buttock, contralateral buttock or abdomen should be considered.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

Management of loss or lack of efficacy

- In the event of loss of efficacy in the absence of a mechanical fault, reprogramming should be attempted on at least two occasions.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

- Re-implanting a permanent tined lead should be considered when there is no gross displacement of the lead as seen on X-ray, no abnormal impedance indicating a circuit problem and failure to respond to reprogramming.

(Abstained 0, voted 22. Agree/strongly agree 19. Agreement 86%. Evidence grade 4. Recommendation D.)

Follow-up

It was unanimously agreed that patients should been given access to advice when they experience problems, but there was no consensus on the timing and interval of follow-up.

- The first SNS follow-up appointment should be arranged at 1–3 months after implantation for stimulation programming/adjustments.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

- Regular follow-up should be arranged after 3 months.

(Abstained 0, voted 22. Agree/strongly agree 19. Agreement 86%. Evidence grade 4. Recommendation D.)

- *Ad-hoc* follow-up should be offered when a problem occurs during SNS.

(Abstained 0, voted 22. Agree/strongly agree 22. Agreement 100%. Evidence grade 4. Recommendation D.)

Cost-effectiveness

The literature suggests that SNS is cost-effective for severe refractory FI [141–147], but studies on cost-effectiveness have not taken into account the long-term loss of efficacy and the need for ongoing concurrent therapy.

- Cost-effectiveness beyond 5 years is unclear. There are different arrangements for reimbursement in European countries and thus it is difficult to ascertain cost-effectiveness from the limited data available.

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 3. Recommendation D.)

SNS for constipation

The indications of SNS for constipation

Despite studies that reported a good outcome of SNS for constipation [33–39,41–43,45,109,148] the treatment is not widely adopted when compared with it use for incontinence. SNS for constipation is not universally approved by the regulatory authorities in Europe.

- SNS for constipation could be considered for patients who have had symptoms for more than a year and after failed conservative treatment. The patient should have slow transit constipation and/or symptoms of outlet obstruction without a mechanically correctable cause.

(Abstained 0, voted 22. Agree/strongly agree 16. Agreement 73%. Evidence grade 4. Recommendation none.)

Investigations before PNE

- Baseline investigations should include estimation of colonic transit time and defaecography. Anorectal physiology testing may be useful. Hirschsprung's

disease must be excluded. A psychological assessment should be considered before deciding on SNS.

(Abstained 0, voted 22. Agree/strongly agree 21. Agreement 95%. Evidence grade 4. Recommendation D.)

General considerations

- SNS for constipation is less effective than when used in FI and further research is needed.

(Abstained 0, voted 22. Agree/strongly agree 20. Agreement 91%. Evidence grade 4. Recommendation D.)

Criterion for successful PNE

- The criterion for successful PNE for constipation should be 50% improvement in constipation symptoms as recorded in the bowel diary. Objective symptom scores for constipation and outlet obstructive symptoms and quality-of-life scales should be used together at baseline.

(Abstained 1, voted 21. Agree/strongly agree 20. Agreement 95%. Evidence grade 4. Recommendation D.)

Discussion

Being based largely on expert opinion and sometimes conflicting published results, the above statements are not rules and should not be construed as establishing a legal standard of care or as encouraging or discouraging any particular treatment. They are intended to provide information that may assist clinicians in performing SNS for FI or constipation.

This study reports the first attempt to pool the opinions of European experts on SNS. In doing so it is noteworthy that the evidence base for almost all of the questions posed was poor. As a result the level of evidence and the recommendations were consistently no better than that which would result from expert opinion, which was in fact the mainstay of the pooled opinions.

Having evolved from an initial phase of observational trials this was nevertheless a timely opportunity to review the present position and consider important aspects such as the set up, indications, counselling and contraindications. The very high rate of consensus reflects general unanimity among practitioners in the field, but this was not surprising given the nature of the group and the general paucity of rigorous scientific data.

There was, however, a measure of disagreement, for example on the need for the baseline investigations of manometry and endoanal ultrasound in patients with incontinence. It is clear that such tests do not predict the outcome of treatment, and the only measure which does is PNE. Manometry and endoanal ultrasound may be useful for identifying patients who may be suitable for other treatments. Another important point is the use of the bowel diary. The experience of experts was variable regarding patients' compliance with filling in lengthy and detailed bowel diaries. Some felt this was the most sensitive assessment tool, and with instructions by clinicians there was no issue with compliance, whilst others felt this was too impractical to be imposed on all patients over many years. However, it is clear that scoring systems for incontinence are liable to many sources of error. (The subject has been reviewed in an Editorial by Vaizey who demonstrated the inaccuracy of this form of assessment of patient function [149].)

There was no agreement on the timing of follow-up assessments. While these must be arranged at a frequency convenient to the unit regarding the resources available, there should be general agreement on this important matter so that data from one unit can be compared with those from another.

The use of SNS for patients with a sphincter defect was debated in depth and the resulting statement does not offer a clear-cut answer. This is obviously due to the lack of prospective comparative studies. Any prospective trial can only be multicentric because the number of patients treated in any given unit is small. Such a study is greatly needed.

The opinions expressed by the members of the group included some deviations from the manufacturer's recommendations, including the duration of PNE and nonfixation of the IPG. Readers are advised that the present article is not imposing these practices nor should these statements be construed as a legal standard. The reasons for such deviations were explained to the manufacturer during the process and we hope that they will be reflected in future amendments of the manual.

There were many aspects of operative technique that could not be agreed upon. For example, some experts felt it was necessary to perform PNE under local anaesthesia in order to be able to elicit a sensory response. Others felt it that implantation under local anaesthesia would cause too much pain. Half of the experts used a tined lead only for PNE. Such variations in technique reflect diversity of practice for a relatively simple procedure.

There has been a marked increase in the number of publications on SNS over the last decade, but most are prospective case series and cohort studies and very few have been randomized controlled trials. The results of the current survey for consensus show dramatically that

large randomized trials are needed and, as stated above, they will have to be multicentric to obtain sufficient numbers in a reasonable period of time.

Acknowledgements

We would like to thank the urologists Professor Phillip van Kerrebroeck and Professor Emmanual Chartier Kastler for their participation as nonvoting observers in the consensus meeting. Thanks are also extended to Professor James Jones who gave a lecture on the mechanism of SNS using an animal model during the consensus meeting.

Author contributions

All authors contributed equally to the conception, design and drafting the work and revising it critically for important intellectual content. All authors gave final approval of the version to be published.

Conflicts of interest

YM, PROC, PAL, KM and SL received honoraria as speakers and PROC, PAL, KM and SL received research grant from Medtronic. Medtronic supported travel arrangement for the consensus meeting. The meeting was also partly supported by the Internationalization Grant from Aarhus University Hospital. Medtronic had no influence on the conception, design and conduct of the process except for providing the voting device used during the consensus meeting.

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Appendix 1:

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