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ORIGINAL ARTICLE

Ageing with sacral nerve modulation for fecal incontinence: how many patients get benefit after more than 10 years?

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Abstract

Sacral nerve modulation (SNM) has represented a major advancement in the minimally invasive management of patients with fecal incontinence (FI). Although the success rate in the short–medium term has widely been demonstrated, the very long-term outcomes are poorly investigated. This study aims to assess the effectiveness of SNM in a cohort of patients with a follow-up longer than 10 years. Clinical records of patients submitted to SNM for FI in our tertiary referral colorectal Unit between 1998 and 2010 were retrospectively reviewed looking for status of the implantable pulse generator (IPG), follow-up duration, severity of FI by the St Marks' score and quality of life. 58 patients fulfilled the entry criteria and 36 (58%, median follow-up, 12 years) accepted to take part to the telephone interview, while 22 (38%) were lost to the follow-up. Nineteen patients had their IPG removed (Group A) while 17 (27%) had the SNM still active after a median follow-up of 13 years (Group B). In the group A, the median baseline St Marks' score was 13 and did not change after the IPG removal. In group B, the median baseline St Marks' score was 14, at last IPG substitution, it was of 7 and at the last follow-up dropped to 4. In the group A, the median SF-12 physical and mental scores did not change significantly while they improved significantly in group B. A progressive deterioration of the success rate of SNM with the time has been documented after a very long-term follow-up.

Keywords Sacral nerve modulation · Long-term outcome · Fecal incontinence

Background

Fecal incontinence can affect patients' quality of life severely [1]; nevertheless, it is just a functional disease and despite its ability to deteriorate the quality of life, it has no impact on the life duration; therefore, patients with fecal incontinence should have a life expectancy correspondent to the general population according to the age and comorbidities. Thus, the effectiveness of any surgical treatment for bowel dysfunction is expected to last for the entire duration of the life and then, the evaluation of the outcome of this procedure needs a very long follow-up. Furthermore, when the use of expensive and highly technological devices such as implantable pulse generators is required, the long-term reliability of the producer company must be considered.

In the last 20 years, sacral nerve modulation (SNM) has gained great appreciation among colorectal surgeons and incontinent patients because of its minimal invasiveness, and the reassuring efficacy in the medium–long term [2–7].

In fact, several studies, have shown that the effectiveness of SNM in treating fecal incontinence ranges between 45 and 90% [8, 9] of the patients according to the follow-up duration, sex and type of incontinence, but little is known on the very long-term outcome of these patients. In the common clinical practice, the percentage of incontinent patients with SNM implant undergoing surgical replacement of exhaust IPG (implantable pulse generator) after more than 5 years from the implant is often lower than expected and no studies have specifically addressed this issue.

The aim of this study is to follow-up patients who had the SNM implant more than 10 years before, to ascertain the percentage of battery changes, and long-term functional outcome and quality of life.

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Patients and methods

Clinical records of patients submitted to SNM for fecal incontinence in our tertiary referral colorectal Unit between 1998 and 2010 were retrospectively reviewed using a prospectively maintained database (FileMaker Pro 18- Filemaker Inc. Santa Clara CA 95054, USA) and completed by a telephone interview or outpatient visit.

After the study approval by the Institutional Review board, the patients were informed about the finality of the study and an oral informed consent was obtained.

Inclusion criteria were patients aged between 18 and 75 years old, both genders, affected by fecal incontinence who underwent permanent implant of an IPG after a positive clinical response to temporary SNM which was defined by > 50% improvements of the St Marks' score and/or > 50% decrease of number of episodes of fecal incontinence per week, and a follow-up of 10 years or longer.

Patents treated with SNM for chronic refractory constipation (6) and chronic pelvic pain (2) during the same time frame were excluded from the study.

Patients who did not undergo permanent SNM despite positive outcome during the temporary test were excluded from the study.

Telephone interviews were conducted to obtain long-term follow-up information including actual SNM state (ON/OFF), date of the last follow-up, evaluation of fecal incontinence using the St Marks' score [10] and quality of life using the 12-item Short Form Survey (SF-12) [11].

The scores were calculated before SNM, after the last substitution of the IPG and at the last follow-up.

Further information (indication for SNM, patients' demographics, date of permanent implant, date and cause of eventual substitution and/or IPG removal, number of IPG substitutions, duration of implantation) was retrieved by the electronic database.

Etiology of fecal incontinence was classified in idiopathic, iatrogenic, obstetric, spinal trauma, miscellaneous, anterior resection syndrome, and chronic neurological disease.

Patients were called by telephone on working days between 8.00 and 20.00 by the same operators. For unresponsive patients, 3 telephone attempts were made in 3 different days, at different times.

Clinical information about patients unresponsive to the telephone call was obtained from the electronic database, when available.

Electrode and pacemaker implantation

Techniques of temporary and permanent sacral nerve modulation are described elsewhere [12]. Briefly, until 2000, the temporary test was carried out by a unipolar peripheral nerve percutaneous electrode evaluation (model 3057; Medtronic, Minneapolis, Minnesota, USA) (percutaneous nerve evaluation or PNE test), and the implantation procedure requiring the exposure of the sacral foramen throughout the incision of the pre-sacral skin, the insertion of the definitive electrode (model 3080, Medtronic, Minneapolis, MN, USA) into the sacral foramen, securing it to the sacral periosteum, was performed under general anesthesia; Since 2001, a quadripolar tined lead electrode (mod. 3889-28, Medtronic, Minneapolis, MN, USA) was inserted in the third sacral foramen percutaneously under local anesthesia using fluoroscopy and Seldinger's technique [13]; the electrode was tunnelized into the subcutaneous tissue and connected to a temporary external stimulator (Verify model 353101) when a two-stage implant had been planned. All patients responding positively to the temporary test had a permanent IPG (Interstim™ II Medtronic, Minneapolis, MN, USA) positioned subcutaneously in the gluteus area under local anaesthesia.

Statistical analysis

The results were reported in terms of median (interquartile range) and number of patients (percentage). A Wilcoxon rank-sum test for paired samples was used to evaluate changes in questionnaire and scores over the time. The categorical variables were analyzed using the two-sided Fisher's exact test. Data were analyzed using R Studio (Version 1.1.419–©2009–2018 RStudio, Inc).

Results

Ninety patients (74 females; median age, 58, range, 25–79 year; IQR 51.2–65) affected by faecal incontinence were admitted to our tertiary centre of coloproctology and underwent temporary SNM in the period between November 1998 and December 2010.

Fifty-eight patients (64.4%), (51 females; median age, 58 years old, range, 25–75 year; IQR 50.7–64.5) reported a good clinical response during temporary SNM and underwent definitive IPG implantation. The median follow-up period was 13 years (IQR 12–17).

Twenty-two of them (6 males; median age 60 years old, range 25–75, IQR 50–68) did not respond to the telephone call and were considered lost to the follow-up. This large

percentage of lost to follow-up could be justified considering the very long term of the follow-up in this study. Since some of the patients were treated about 20 years before, during which some of them could have been died, others moved far away from our city, some more changed the telephone number. Furthermore, most of them had no e-mail address at the time of the operation.

Thirty-six patients (62%) accepted to take part in the telephone interview (91.8% females with median age 58, IQR 51–63 years). The median follow-up period was 12 years (IQR 10.5–16). The etiology of the FI was idiopathic in 65.2% of the patients, iatrogenic in 27.9% (obstetric in 48.12%, spinal trauma in 32.88% and anterior resection syndrome in 19%), and miscellaneous in 6.9%

The difference between patients lost at follow-up and the remaining 36 patients included into the study was statistically significant for the gender, with the number of males, respectively, of 8 (30%) and 3 (8%) ($p=0.04$), but not for the age (median age: 60, IQR 50–68.2 and 58.5, IQR 52.2–63) ($p=0.71$).

Nineteen patients out of 36 had their IPG removed after a median period of 16 years (IQR 14–20) (Group A) while 17 patients had the SNM still active after a median follow-up of 13 years (IQR range 12–18) (Group B) ($p=0.26$) (Fig. 1). The baseline incontinence scores were comparable between the two groups ($p=0.46$).

Group A

Nineteen patients (3 males, median age 59 years) underwent IPG removal after a median period of 16 years (IQR 14–20). Fifteen of them reported no benefit after an initial improvement of the incontinence symptoms, 3 patients had the IPG removed because of the onset of pain after a median period of 16 years and one further patient because of IPG displacement after 18 years. These 4 patients underwent IPG substitution at least once. All these patients did not ask for new SNM procedures because the advanced age and/or important comorbidities occurred, made incontinence symptoms more acceptable.

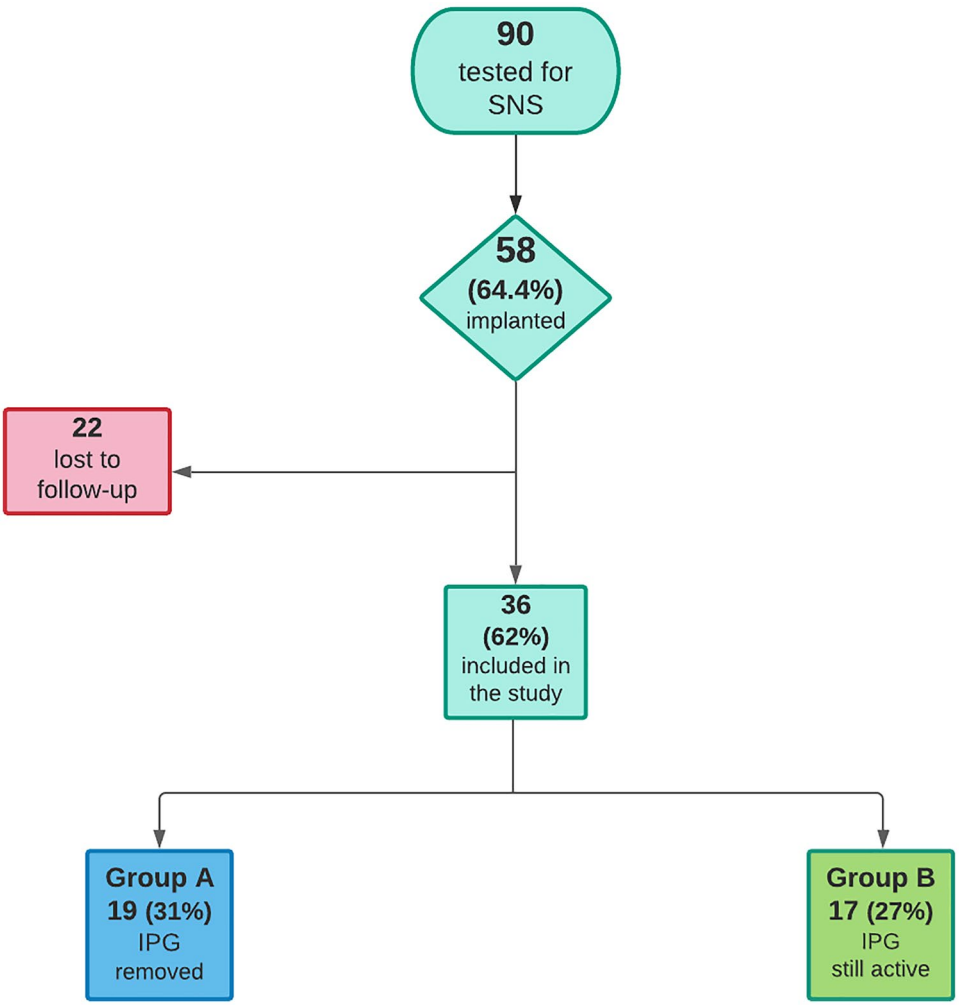

Fig. 1 Summary of patients included in the study (Color figure online)

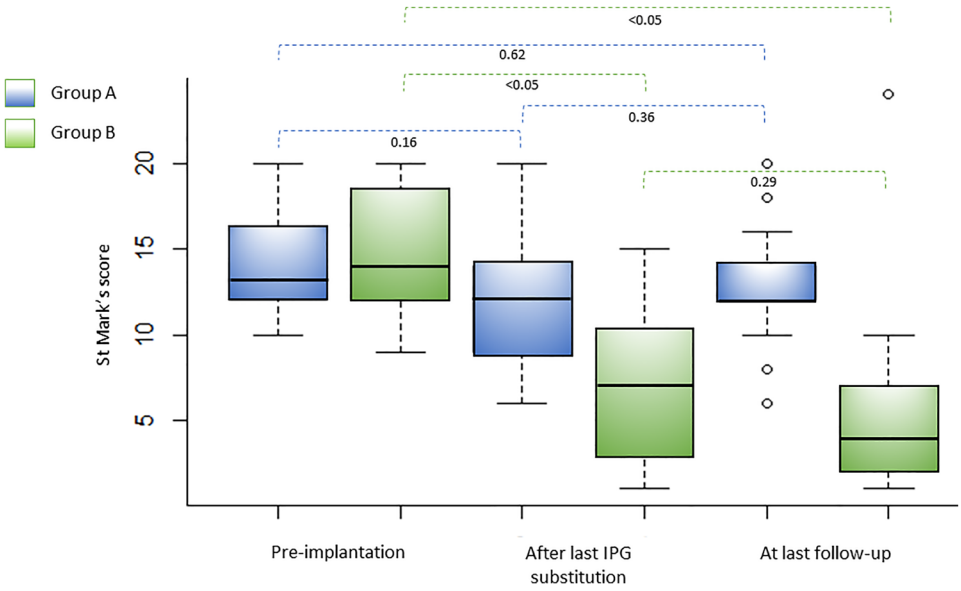

Fig. 2 Box plots of St Mark's score before the implantation, after the last IPG substitution and at last follow-up (Color figure online)

Median value of St Marks' score before the implantation was 13 (IQR 12–16); after a median period of 7 years (IQR 7–10) became 12 (IQR 8–14) and after the IPG removal remained at the same value of 12 (IQR 12–14). In eleven patients, St Marks' score did not change for the whole period of implantation, despite the initial improvement registered after the temporary SNM test (Fig. 2).

Seven patients, on the other hand, reported an improvement of the fecal continence at a median follow-up of 7 years, with a reduction of the score from a median value of 12 (IQR 10–16) to a median value of 6 (IQR 6–10) while 5 patients from this group, reported a worsening of fecal continence, with an increase of the score from a median value of 6 (IQR 6–9) to a median value of 12 (IQR 11–14) at last follow-up, when they had the device removed. Nevertheless, despite the deterioration of continence, they were unwilling to undergo further surgical procedures.

The median SF-12 physical domain score was 45.3 (IQR, 44.2–47.5) at baseline, 44.8 (IQR, 43.7–47.0) at last IPG substitution and 44.8 (IQR, 43.5–46, 7) at last follow-up.

The median SF-12 mental domain score was 44.4 (IQR, 41.1–45.9) at baseline, 44.9 (IQR, 43.0–47.3) at last IPG substitution and 45, 7 (IQR, 42.0–48.8) at last follow-up (Fig. 3a, b).

Group B

Seventeen patients (all females, median age 56 years) out of 36 underwent regular replacement (median 2, IQR1-3) of the implanted pulse generator after the expiry date of the battery and still have the SNM active. For these patients, the St Marks' score before implantation had a median value of 14 (IQR 11.5–18.5), at last IPG substitution it was of 7

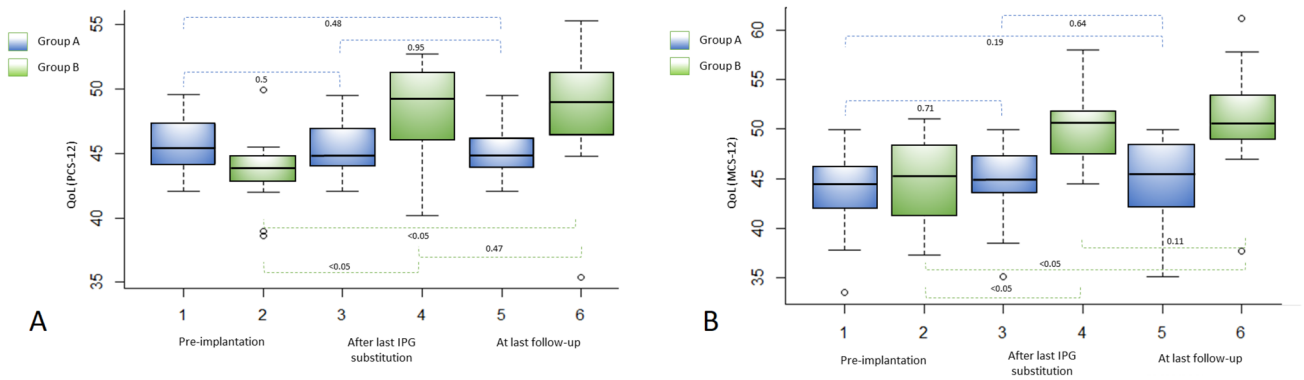

Fig. 3 Box plots of quality of life according to 12-item Short Form Survey 12 before the implantation, after the last IPG substitution and at last follow-up. **a** Physical domain score, **b** Mental domain score (Color figure online)

(IQR 2.5–10) and at the last follow-up dropped to 4 (IQR 2–8) (Fig. 2).

One patient reported a marked improvement of St Marks' score with a decrease from 20 (baseline) to 10 (after last IPG substitution) and then, at last follow-up, a considerable worsening (from 10 to 24). This patient, currently 78 years, is unwilling to have either outpatient visit or further surgical procedures because of the fear of contract the COVID-19 disease during the in-hospital period.

In this subgroup of patient quality-of-life analysis demonstrated a significant improvement in both SF-12 physical and mental domains. The median SF-12 physical domain score was 44 (IQR, 42.5–44.9) at baseline, 49.2 (IQR, 45.9–51.4) at last IPG substitution and 49.0 (IQR, 46.0–51.9) at last follow-up.

The median SF-12 mental domain score was 45.2 (IQR, 41.2–48.2) at baseline, 50.6 (IQR, 47.3–52.2) at last IPG substitution and 50.4 (IQR, 48.3–53.5) at last follow-up (Fig. 3a, b).

Discussion

SNM has revolutionized the therapeutic approach to fecal and urinary incontinence with great appreciation by both patients and surgeons; however, few studies have explored the very long-term outcome of this treatment. Actually, the true percentage of the success rate, is hardly presumed from the literature, considering the different length of the follow-up, the non-univocal definition of success outcome, and whether a per-protocol (PP) (only patients implanted) or intention to treat (ITT) (all the patients considered for the procedure) analysis was considered.

Acknowledgement of the very long-term outcome of any procedure for functional diseases, particularly those involving the use of expensive devices like IPGs, is of pivotal importance for patients and the national health system.

Our study was performed on a group of patients with at least 10 years of follow-up (median duration of 13 years) during which a minimum of 2 substitutions of the IPG should have occurred. Our review indicated that a relevant proportion of these patients (38%) is lost to the follow-up. This point is food for thoughts considering that, the mean age of these patients was not too high to suppose their death linked to the physiologic effects of ageing and not significantly different from the patients finally included into the study.

Neither, these patients were treated in other centers, because our tertiary referral center is the only one in Southern Italy and all the patients lived in our region (Apulia). Possible explanations include the change of the telephone number with the increasing use of mobile phone instead of home telephone which made impossible their contact. However, the loss of relevance of the fecal incontinence to these patients for the onset of other comorbidities or because of the potential curative effect of the fecal incontinence by long-term SNM, could have played a role. This last event, although rarely reported in other studies, is observed occasionally by several investigators (personal communications) and carefully described in a previous study from our group [14].

Nineteen out of the 36 patients who participated to the review had the IPG removed after a median period of 16 years due to different causes, but for the majority of them, the most important reason was the occurrence of other comorbidities and consequent loss of the impact of fecal incontinence on their quality of life. This statement reinforces the hypothesis above mentioned for patients lost to the follow-up.

Only 17 (27%) out the 58 patients in our series are still using the SNM successfully after a median follow-up of 13 years. These findings suggest that the very long-term outcome further deteriorates with time compared with the 60–70% success rate reported at 5 years.

The long-term outcome of SNM has been investigated by several Authors in the last decade, however, very few studies report a follow-up of at least 5 years and only 2 have investigated the results after a minimum of 10 years of follow-up. As far as long-term outcome for SNM is concerned, these 5 years of time limits should be considered more reliable than shorter follow-ups, since, according to the Customer Care Medtronic DIRECTO, it covers the mean time duration of the live battery in the implanted IPG in the vast majority of the cases. Therefore, only patients who reported true benefits from this therapy are expected to return to their referral center to replace the exhausted pacemaker. Looking to the outcome reported by these papers, including multi-center European and USA surveys, about 55–89% of the implanted incontinent patients report a prolonged benefit from SNM (corresponding to at least more than 50% improvement of the incontinence scores or episodes of fecal incontinence per month) (Table 1).

In the survey from the St Mark's Hospital, 185 incontinent patients from a total cohort of 256, had a median follow-up longer than 5 years (median 132, range 60–276) [15]. This paper shows that the median incontinence score was 10/24 compared to the baseline median score of 19/24, but it is impossible to understand how many patients met the criteria for a successful outcome. In a Danish study from Maeda and co-workers [16], 101 patients with minimum 5 years of follow-up were reviewed reporting a 55.6% success rate in a PP analysis and 42.6% in an ITT analysis. The multi-center American survey [17] also describes the long-term (minimum 5 years) outcome of 76 successfully treated incontinent patients among 120 originally implanted (63%) showing that 64 of them (89%) still have benefit (> 50% improvement

Table 1 Outcome of SNM with a mean follow-up longer than 5 years (60 months)

First author	Year/country	N. of patients	Follow-up duration in months (mean, range)	Success rate (≥ 50% improvement in FI score)
Altomare DF	2015 Europe multicenter	228	84 (70–113)	71% (PP) 45% (ITT)
Maeda Y	2014 Denmark	101	60	55.6% (PP) 42.6% (ITT)
Hull T	2013 USA Multicenter	76	60 (60–96)	89%
Leo CA	2020 (UK single center)	185	132 (60–276)	62%
Desprez	2020 France Multicenter	360	120	45% (PP) 27%(ITT)
Janssen [20]	2017	278	85.1 (3–183)	71%
Present study	2021 Italy (single center)	58	156* (IQR 144–204)	27%

*Median

of the incontinence scores). Furthermore, when a stronger criterion for the definition of success is applied (> 70% improvement of the incontinence scores) the success rate drops to only 36%.

The multi-center European survey from Altomare and co-workers [18], reports the long-term outcome (minimum 60 months) of 265 implanted patients out of 466 patients tested showing that 71% of them in a PP analysis and 47.7% in an ITT analysis, reported some benefit (minimum 50% improvement of the incontinence scores) while 50% achieved full continence after a median follow-up of 84 months. This group of patients did not include French and Danish patients and UK patients treated in one of the most important colorectal referral English center (the St Marks Hospital) and, therefore there is no overlapping with the results of other European papers focusing on the same topic. On the other hand, the German patients included by Matzel and co-workers in another study on the long-term outcome of SNM, was not considered since they were included into the multi-center European survey.

Finally, a very recent paper [19] reports the 10 years evaluation of a cohort of 360 French incontinent patients from a multi-center retrospective study, claiming a 45% success rate in PP evaluation and 27% in ITT analysis. This paper matches the inclusion criteria with our study very well, but the success rate is more favorable than our 27%. The reasons for this are unclear. Nevertheless, it contributes to document a progressive deterioration of the outcome of SNM with the time. In fact, in this paper the success rate, in the PP evaluation, clearly deteriorated from 87.5% after 1–3 years, to 71.7% after 5 years and to 45% after 10 years.

Limitations of this study are the retrospective nature, the single-center experience, and the small sample size which can limit the reliability of the results.

In conclusion, our study focuses on the important issue of the long-lasting duration of the effectiveness of the SNM for fecal incontinence suggesting that, while a selected group of incontinent patients will maintain benefits from SNM in the very long-term (more than 10 years), the percentage of these patients is around 1/3 of those originally implanted. This information should be taken into consideration and correctly reported to the patients and the health national services.

Author contributions AP: conception and design of the study, acquisition analysis and interpretation of data, writing the paper, final approval of the version to be published. MR: acquisition analysis and interpretation of the data, writing the paper, final approval of the version to be published. RD: acquisition analysis and interpretation of the data, interpretation of the results, writing the paper, final approval of the version to be published. GT: acquisition analysis and interpretation of the data, interpretation of the results, writing the paper, final approval of the version to be published. GT: acquisition analysis and interpretation of the data, final approval of the version to be published GL: acquisition analysis and interpretation of the data, final approval of the version to be published Prof MDF: acquisition analysis and interpretation of the data, interpretation of the results, final approval of the version to be published.

Declarations

Conflict of interest The authors declare no conflicts of interest.

Human and animal rights All procededures involving human participants were in accordance with ethical standards of the institutional ethic committee and with the 1964 Helsinki declaration and its later amendments.

Informed consent Informed consent was obtained from patients included in this study.

References

1. Sailer M et al (1998) Quality of life of patients with fecal incontinence. Langenbecks Arch Chir Suppl Kongressbd 115:973–975
2. Simillis C et al (2019) A systematic review and network meta-analysis comparing treatments for faecal incontinence. Int J Surg 66:37–47
3. Mege D et al (2019) Sacral nerve modulation for faecal incontinence: influence of age on outcomes and complications. A multicentre study. Colorectal Dis 21(9):1058–1066

4. El-Gazzaz G et al (2009) Sacral neuromodulation for the treatment of fecal incontinence and urinary incontinence in female patients: long-term follow-up. Int J Colorectal Dis 24(12):1377–1381
5. Hollingshead JR, Dudding TC, Vaizey CJ (2011) Sacral nerve stimulation for faecal incontinence: results from a single centre over a 10-year period. Colorectal Dis 13(9):1030–1034
6. Altomare DF et al (2009) Long-term outcome of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 52(1):11–17
7. Matzel KE (2011) Sacral nerve stimulation for faecal incontinence: its role in the treatment algorithm. Colorectal Dis 13(Suppl 2):10–14
8. Brochard C et al (2019) Is Sacral nerve modulation a good option for fecal incontinence in men? Neuromodulation 22(6):745–750
9. Matzel KE et al (2009) Sacral nerve stimulation for faecal incontinence: long-term outcome. Colorectal Dis 11(6):636–641
10. Vaizey CJ et al (1999) Prospective comparison of faecal incontinence grading systems. Gut 44(1):77–80
11. Ware J Jr, Kosinski M, Keller SD (1996) A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care 34(3):220–233
12. Matzel KE et al (2017) Sacral neuromodulation: standardized electrode placement technique. Neuromodulation 20(8):816–824
13. Spinelli M et al (2005) A new minimally invasive procedure for pudendal nerve stimulation to treat neurogenic bladder: description of the method and preliminary data. Neurourol Urodyn 24(4):305–309
14. Altomare DF et al (2013) The effects of sacral nerve stimulation on continence are temporarily maintained after turning the stimulator off. Colorectal Dis 15(12):e741–e748
15. Leo CA et al (2020) Long-term outcome of sacral nerve stimulation for faecal incontinence. Colorectal Dis 22:2191
16. Maeda Y et al (2014) Outcome of sacral nerve stimulation for fecal incontinence at 5 years. Ann Surg 259(6):1126–1131
17. Hull T et al (2013) Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. Dis Colon Rectum 56(2):234–245
18. Altomare DF et al (2015) Long-term outcomes of sacral nerve stimulation for faecal incontinence. Br J Surg 102(4):407–415
19. Desprez C, et al (2020) Ten-year evaluation of a large retrospective cohort treated by sacral nerve modulation for fecal incontinence: results of a French multicenter study. Ann Surg
20. Janssen PT et al (2017) Fecal incontinence treated by sacral neuromodulation: Long-term follow-up of 325 patients. Surgery 161(4):1040–1048

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