Sacral nerve modulation for faecal incontinence influence of age on outcomes and complications. A multicentre study

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Sacral nerve modulation for faecal incontinence: influence of age on outcomes and complications. A multicentre study

SHORT RUNNING TITLE: Sacral nerve modulation in the elderly

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Paul Lehur is a consultant for Medtronic SA.

ABSTRACT

Aim: Faecal incontinence is frequent in the elderly. Little is currently known about the efficacy of sacral nerve modulation in the elderly. The present study aimed to assess the impact of age on the outcome of sacral nerve modulation and on the surgical revision and explantation rates by comparing the results of a large dataset of patients.

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Method: Prospectively collected data from patients who underwent an implant procedure between January 2010 and December 2015 in seven French centres were retrospectively evaluated. Three hundred fifty-two patients (321 females, median age 63 years [24-86]) were included. Clinically favourable and unfavourable outcomes and surgical revision and explantation rates were compared according to the age of the patients.

Results: A similar outcome was observed when comparing patients <70 years and ≥70 years (79.2% and 76.2% favourable outcome, respectively (p=0.89)). The probability of a successful treatment as a function of time was similar for the two age groups (i.e., <70 years and ≥70 years) (p=0.54). The explantation and revision rates were not influenced by age (<70 years vs. ≥70 years: 17 and 14%, respectively, p=0.89, and 42% and 40%, respectively, p=0.89). The probability of explantation as a function of time was similar for the two age groups (p=0.82).

Limitations: Retrospective study, rate of loss at follow-up, and different durations of patient follow-up.

Conclusions: Our results suggest that patients ≥70 years suffering from faecal incontinence benefit from sacral nerve modulation with a similar risk as a younger population.

What does this paper add to the literature?

Patients ≥70 years suffering from faecal incontinence can expect a similar benefit with a similar risk as a younger population when treated with sacral nerve modulation.

INTRODUCTION

Faecal incontinence (FI), which is defined as a recurrent chronic loss of ability to control anal sphincter and bowel movements resulting in the leakage of faeces, is a frequent condition that increases with age [1]. It is experienced by 2-17% of the general population and almost half of

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nursing home residents [2]. FI has a significant personal impact on the elderly and may be the main reason for their institutionalization [3]. It is also a major economic burden on health care systems [4].

It is thus of the utmost importance to appropriately manage FI in elderly patients, including dietary adjustments, symptomatic treatment of transit disorders, and behavioural therapy, including biofeedback [4]. If these conservative approaches fail, sacral nerve modulation (SNM) may be used to alleviate the symptoms of patients with FI [5]. SNM involves implanting a device that stimulates the sacral roots and that modulates colorectal motility and perception [6]. A successful SNM treatment, which is defined as a 50% reduction in FI symptoms, has been reported in 61-100% of trials [7]. Although many studies have reported that SNM is effective for treating FI, little is known about the influence of age on the outcome of the procedure. Most of these studies included age as a potential predictive factor of outcome but failed to establish a correlation between age and SNM results [8-10].

The present study aimed to determine whether age, associated with comorbidities, influences the efficacy of SNM, especially the success of permanent implantation and the need for surgical revision and/or explantation.

METHODS

Patients and data collection

Data prospectively collected from patients who underwent an SNM implant procedure for FI in seven French tertiary referral centres (Grenoble, Lyon, Marseille, Nantes, Rennes, Rouen, and Paris) from January 2010 to December 2015 were reviewed retrospectively.

Inclusion and exclusion criteria

Inclusion and exclusion criteria were those usually used to propose SNM. Inclusion criteria were at least one episode of FI and/or urgency per week for more than six months, no response to

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conservative therapies such as anti-diarrheal medications and biofeedback, a successful temporary test stimulation, and aged 18 years or over. Exclusion criteria were anatomic limitations preventing surgery, existing rectal prolapse, chronic constipation and/or diarrhoea resistant to medical treatment, chronic inflammatory bowel disease, active anal abscesses, fistulae, and pregnancy. No upper age limit was set on the selection of patients who consulted for FI, had no degenerative disease, did not have a high anaesthesia risk, and were not bedridden.

The present study focused on patients who were implanted at least two years previously in order to have a minimally sufficient time lapse between implantation and assessment to properly evaluate the effectiveness of SNM. The study protocol was approved by each institution's human research committee (E2018-63) and complied with the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008).

All patients underwent a pre-implantation assessment that included recording their age at the time of the SNM procedure, gender, body mass index (BMI), comorbidities (i.e., diabetes, obesity, cardiovascular disease including high blood pressure, neurological disease including cerebrovascular disease, multiple sclerosis, epilepsy meningioma, psychiatric disorders including depression), type of FI (urge and/or passive incontinence), duration of symptoms, and FI severity as assessed by the Cleveland Clinical FI score [11]. All patients underwent a preoperative evaluation, including anorectal manometry and endoanal ultrasonography, to help determine the main cause of their FI.

Sacral nerve modulation procedure

A standard two-stage SNM procedure was performed [12]. A percutaneous test was used to assess the response of the patients to the treatment, i.e., an improvement of more than 50% in the number of FI episodes per week and/or FI days per week. A quadripolar electrode was placed in the right or left S3 or S4 foramen to assess motor responses, i.e., pelvic floor contraction associated with flexion of the ipsilateral hallux. The electrode was then placed in the location that gave the best motor response and was connected to an external pulse generator (Interstim Model 3625; Medtronic, Minneapolis, MO,

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USA) that delivered a continuous stimulation (pulse width 210 μsec, frequency 15 Hz). When a satisfactory response was obtained, an internal pulse generator (IPG) was subcutaneously implanted and was activated by remote control after the procedure, following which the amplitude was adapted to the patient's perception.

Outcome measures

As in a previous study [13], the primary treatment outcome was defined as favourable if the patient reported a therapeutic benefit from SNM, had no new complaints or interventions at the regular follow-ups, and did not consider discontinuing the treatment. The treatment outcome was defined as unfavourable if the patient was not satisfied with SNM and required an alternative treatment (medical treatment excluded) such as stoma formation or if the patient had switched off the IPG or had had it surgically removed [13]. Secondary outcomes were defined as improvements in the FI severity scores and the rate of surgical revisions or explantations.

Explantation was defined as the definitive removal of the device. Revision was defined as any surgical intervention, except explantation, including the replacement or relocation of any component of the device. In the event of multiple indications for revision, loss of efficacy of the device was deemed to be the cause solely in the absence of trauma, pain, or battery replacement. Patients were considered lost at follow-up if they were not seen in the outpatient unit in the year prior to the data collection (December 2017).

Data analysis and statistics

Patients were stratified into two groups according to their age (<70 years and ≥70 years). Data were reported as means±standard deviations or medians and ranges for continuous variables and percentages for categorical variables. For quantitative endpoints, the Mann-Whitney test or Wilcoxon test, as appropriate, was used to compare groups. For dichotomous endpoints, Pearson's chi-square

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test or Fisher's exact test, as appropriate, was used. For the treatment outcome, patients who were lost at follow-up were not included in the analysis. **Explantation-free rates were compared using Kaplan–Meier curves and the log-rank test.** Survival time was defined as the period between the implantation and the discontinuation of the therapy or the choice of another therapy. To provide more accurate comparisons of the surgical revision date according to age when the follow-up time was different, the rate of revisions per patient-month was calculated. All tests were two-sided. The significance level was set at $p<0.05$. Statistical analyses were performed using Statview version 5.0.

RESULTS

Patient characteristics

Four hundred sixty-nine patients (409 females, median age 63 years [24-86]) underwent a percutaneous test for FI during the study period. Of these, 352 (75%) (321 females, median age 63 years [24-86]) had a positive test result and were permanently implanted. The median age of patients with a positive or a negative test result was similar (median age 63 years [24-86] vs. 65 years [25-82], $p=0.88$).

Of the 352 implanted patients, 253 (72%) and 99 (28%) were respectively aged <70 years (median 59 years [26-69]) and ≥70 years (median 74 years [70-86]). Cohort demographics, characteristics, and main causes of FI according to age stratification are given in Table 1. There was no significant difference between the two age groups in terms of gender, duration of symptoms, type and cause of FI, or baseline FI severity scores (Table 1). In terms of comorbidity, obesity was significantly more frequent in the younger group ($p=0.003$) (Table 1) while a cardiovascular history was significantly more frequent in the older group ($p=0.02$) (Table 1).

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Sacral nerve modulation outcomes

Of the implanted patients, 47 (13.3%) were lost to follow-up at the time of data cut-off for this article. Three hundred and five patients were thus available for the outcome assessment. The mean length of follow-up was 3.4±1.9 years. Two hundred thirty-nine patients (78.4%) reported a favourable outcome and 66 (21.6%) reported an unfavourable outcome (Fig. 1). No differences in favourable/unfavourable outcomes were observed across age groups (p=0.85) with a similar mean length of follow-up (<70 years: 3.3±1.8 years vs. ≥70 years: 3.2±1.8 years, p=0.64) (Fig. 1). The rate of loss to follow-up was also similar between the two groups (p=0.65) (Fig. 1).

Kaplan-Meier estimates showed that patients in the <70 year group had the same probability of a successful treatment as patients in the ≥70 year group (p=0.54) (Fig. 2).

Excluding patients lost to follow-up, the overall FI severity score improved significantly over the course of the study, with a mean of 14.2±3 at baseline and a mean of 8.4±4.9 at the last follow-up visit (p<0.0001). There was no difference in the scores of the two groups of patients (i.e., <70 years and ≥70 years at baseline: 14.2±3 and 14.2±2.9, respectively, p=0.92, and at the last follow-up visit: 8.1±4.9 and 9±4.9, respectively, p=0.15). There was a significant difference between incontinence scores at baseline and at the last follow-up visit for each age group (<70 years: 14.2±3.0 at baseline vs. 8.1±4.9 at the last visit, p<0.0001; ≥70 years: 14.2±2.9 at baseline vs. 9.0±4.9 at the last visit, p<0.0001). The rates of improvement in the severity scores of the two age groups were not significantly different (Fig. 3).

Association between sacral nerve modulation success and predictive factors at baseline

A number of factors were examined that may predict outcomes (Table 2). Only a neurological disease identified as a comorbidity was related to the outcome of SNM. Patients with a neurological disease were more likely to experience treatment failure (p=0.003) (Table 2).

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Adverse events

A total of 169 surgical revisions were performed in 146 patients. Indications for revision were battery depletion in 82 cases (49.7%), loss of efficacy in 19 (11.5%), pain in 17 (10.3%), infection in 15 (9.1%), dysfunction in 18 (11%), lead migration in 7 (4.2), and other in 7 (4.2%). For 4 patients, the indications for revision were unknown. Because the length of follow-up was not identical for all patients, the revision rates per patient-month were calculated. These rates did not change according to the age of the patients (p=0.75) (Table 3). In addition, indications for revision did not differ significantly between the two age groups (Table 3).

There was no significant difference in the definitive explantation rates, and indications for explantation did not differ significantly with age (Table 3). Kaplan-Meier estimates showed that older patients had the same risk for explantation as the younger ones (p=0.82) (Fig. 4). The rate of reoperations (i.e., revisions and/or explantations) did not differ significantly with obesity (50% in obese patients vs. 47.2% in non-obese patients, p=0.78).

DISCUSSION

To the best of our knowledge, the present study is the largest to compare the outcomes and revision and explanation rates of patients in two age groups who underwent SNM for the treatment of refractory FI. Our results showed that 76% of patients aged ≥70 years who were implanted with a permanent device reported a successful SNM outcome, which was similar to the success rate reported by the younger group of patients. The revision and explantation rates were not influenced by the age of the patients.

An analysis of the data from a large multicentre cohort of patients suffering from FI and who underwent an SNM treatment is particularly important for older patients given that significant alterations in the anorectum may occur with aging, including changes in enteric neural structure and function [14], which may affect continence and may have a differential impact on neuromodulation

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treatment modalities. There are relatively few reports of SNM outcomes in older adults, and the results are inconclusive. Only one preliminary study of 23 patients aged >65 years led the investigators to suggest that older patients perceive a similar benefit as younger patients [15]. However, the study was limited to a cohort of only 13 patients >70 years and did not compare them to a cohort of younger patients. Of all the studies that assessed age as a predictor of treatment outcome [8-10,13], only one reported that age was negatively related to successful outcomes 5 years after implantation [13]. Maeda et al. reported that with every 1-year increase in age, the odds of a successful outcome decreased by 4.3% [13]. Although we used the same definition of favourable outcome as Maeda et al., it might not be possible to compare their results with ours due to different population structures. The median age of the population studied by Maeda et al. (60 years [28-88]) was slightly lower than ours [13]. Some of the data required to evaluate the impact of age on SNM results were missing, including comorbidities that can affect SNM outcomes, particularly in the elderly. In the present study, patients with a neurological disease listed as a comorbidity had reduced odds of a successful outcome after SNM implantation. However, we cannot exclude the possibility that our definition of a favourable outcome may have influenced our results. Younger patients might more aggressively seek symptom resolution by other therapies while older patients may give up, keep the SNM device turned on, and not ask for alternative treatments. Such influences involving patient motivation to continue therapy were not captured in our analysis, but the fact that the FI severity scores improved in both the older and younger groups following SNM argues against this hypothesis.

The second aim of the present study was to evaluate the influence of age on revision and explantation rates. We expected that the elderly patients might suffer more complications, especially because of the higher prevalence of cardiovascular disease in this group. However, this was not the case. The present study, as well as others [15-17], did not find any association between advanced age and definitive explantation or revision rates. In addition, an examination of the distribution of the reasons for revision or explantation did not reveal any variation with respect to age. Aside from patient-reported outcomes, previous studies showed that comorbidities such as obesity can be associated with reoperations [17]. However, the present study revealed no influence of obesity on revision or

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explantation rates. This point is important to mention because of the higher obesity rate in the younger group of patients that could bias our results with respect to the influence of age on revisions or explantations.

Our total explantation rate was higher than those previously reported in other large series of patients followed on a long-term basis after implantation [10,18,19]. In the present study, 14% of the patients, regardless of age, were definitively explanted compared with 3-5% in other studies [10,18,19]. This difference could be due to different practices in the surgical centres involved. In the present study, most of the explantations were due to a loss of efficacy. In such cases, explantation is not compulsory and depends on the patient and/or the surgeon. A standardization of surgical practices may thus be in order if we wish to reduce the costs associated with SNM [20]. However, the 40% revision rate observed in the present study is consistent with long-term revision rates reported by others [10,13].

The limitations of the present study included its retrospective design, which prevented us from prospectively analysing data from at least three balanced age groups (i.e., young, middle-aged, and old) with a power analysis that takes the rate of loss at follow-up into account. Our population was similar to those of previous studies reporting a median age between 55 and 65 years, with most under 75 years [21]. We could not exclude the possibility that older patients might refuse implantation more often than younger patients. As the data came from patients who underwent an SNM procedure from 2010 to 2015, the duration of follow-up differed. Nonetheless, the mean duration of the follow-up was similar for the two groups, and the analyses of successful outcomes and explantation and revision rates were related to the duration of the follow-up. Although the age limit to define the elderly often refers to individuals between 60 and 75 years of age, the Word Report on Ageing and Health states that there is no precise age cut-off [22]. Consequently, the choice of 70 years as the cut-off in the present study was arbitrarily based on the need to identify a balanced sub-group of the most elderly patients. In addition, the present study involved elderly patients who were physically and mentally fit. The efficacy of SNM for elderly patients who live in institutions and who have a severe motor impairment and/or a mental disability was not investigated.

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CONCLUSION

FI is problematic for many older adults. As the population ages, the need for effective and safe management strategies will only increase. It is thus important to conduct ongoing assessments of currently available treatments for elderly patients. Our data suggest that older patients exhibit significant improvement with a similar reoperation rate as younger patients after neuromodulation for FI. Age alone should not be considered as a limiting factor in SNM therapy.

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Table 1: Cohort demographics, characteristics, and main causes of faecal incontinence according to age stratification in 352 patients who underwent definitive SNM battery implantation.

	Aged <70 years N=253	Aged ≥70 years N=99	P-value
Demographic characteristics:			
Age (years)	59 [24-69]	74 [70-86]	--
Female (%)	230 (90.9)	91 (91.9)	0.93
Male (%)	23 (9.1)	8 (8.1)	
BMI (Kg/m^2)	N=244 26.7±5.2	N=95 24.8±4.1	0.003
Medical comorbidities:			
Mean number per patient	1.1±1.2	1.2±1.1	0.29
*Type of comorbidity**			
-Diabetes	24 (9.5)	10 (10.1)	0.99
-Cardiovascular disease	69 (27.3)	40 (40.8)	0.02
-Neurologic disease	22 (8.7)	10 (10.1)	0.84
-Epilepsy	3 (1.2)	0	--
-Multiple sclerosis, spinal cord injury	5 (2)	0	--
-Stroke	7 (2.8)	6 (6)	0.25
-Neuropathy	2 (0.8)	2 (2)	0.67
-Others (Parkinson's, Chiari, sciatica)	5 (2)	2 (2)	0.99
-Psychiatric disease	34 (13.4)	11 (11.1)	0.01
-Obesity	58 (22.9)	10 (10.1)	0.25
-Other	55 (21.7)	28 (28.3)	

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Faecal incontinence			0.11
Type:	N=244	N=98	
-Urge	98 (40.2)	28 (28.6)	
-Passive	75 (30.7)	39 (39.8)	
-Mixed	71 (29.1)	31 (31.6)	
Duration (months)	N=242 84.3±88.1	N=90 92.4±92.6	0.60
*Main cause**:	N=222	N=89	0.99
-Sphincter trauma	120 (54)	48 (53.9)	0.99
-Pudendal neuropathy	73 (32.9)	29 (32.5)	--
-Neurological disease (cauda equina syndrome, spinal cord disorder, stroke)	6 (2.7)	0	0.27
-Idiopathic	25 (11.3)	15 (16.8)	0.15
-Post-surgery and/or radiotherapy	11 (4.9)	9 (10.1)	--
-Other	6 (2.7)	0	
Baseline severity score	N=242 14.2±3	N=99 14±3.4	0.77

Results are expressed as a number (percentage), a mean±standard deviation, or a median (range). The number of patients is given when different from the total population. BMI: body mass index.

*One patient could have more than one comorbidity or cause of faecal incontinence.

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Table 2: Comparison of background variables, baseline demographics, comorbidities, and faecal incontinence characteristics of the favourable and unfavourable outcome groups after permanent implantation. Patients lost to follow-up were excluded from this analysis.

	Favourable outcome N=239	Unfavourable outcome N=66	P-value
Demographic characteristics:			
Age (years)	63 [26-86]	63.5 [24-85]	0.85
Female (%)	223 (93.3)	58 (88)	0.23
Male (%)	16 (6.7)	8 (12)	
	N=234	N=65	
BMI (Kg/m^2)	26.3±5	26.1±5.5	0.60
Medical comorbidities:			
Mean number per patient	1.1±1.1	1.4±1.4	0.12
*Type of comorbidity**			
-Diabetes	22 (14.5)	8 (17.8)	0.76
-Cardiovascular disease	70 (46)	26 (57.8)	0.22
-Neurologic disease	16 (10.5)	13 (28.9)	0.003
-Psychiatric disease	33 (21.7)	9 (20)	0.97
-Obesity	47 (30.9)	15 (33.3)	0.90
-Other	60 (39.5)	17 (37.8)	0.95
Faecal incontinence:			
Type:	N=244	N=66	0.43
-Urge	98 (40.2)	22 (33.3)	
-Passive	75 (30.7)	27 (40.9)	
-Mixed	71 (29.1)	17 (25.8)	

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Duration (months)	N=225	N=64	
	85.8±83.3	88.1±94.8	0.99
*Main cause**:	N=213	N=64	
-Sphincter trauma	120 (56.3)	34 (53.1)	0.76
-Pudendal neuropathy	63 (29.6)	26 (40.6)	0.13
-Neurological disease	3 (1.4)	2 (3.1)	--
-Idiopathic	28 (13.1)	7 (10.9)	0.80
-Post-surgery and/or radiotherapy	13 (6.1)	7 (10.9)	0.30
-Other	6 (2.7)	2 (3.1)	--
	N=228	N=64	
Baseline severity score	14.2±2.9	14.1±3.3	0.92

Results are expressed as a number (percentage), a mean±standard deviation, or a median (range). The number of patients is given when different from the total population. BMI: body mass index. *One patient could have more than one comorbidity or cause of faecal incontinence.

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Table 3: Number and reason for revision and explantation procedures according to age in patients implanted for faecal incontinence.

	Aged <70 years N=253	Aged ≥70 years N=99	P-value
Implant revision:			
Number of patients having a revision procedure	106 (41.9)	40 (40.4)	0.89
Number of revisions/100 patient-month	0.003±0.001	0.002±0.009	0.75
Causes of revision procedure(relative to the total number of revisions)*			
-Battery depletion	57 (46.7)	25 (58.1)	0.27
-Loss of efficacy	16 (13.1)	3 (7)	0.42
-Pain	13 (10.7)	4 (9.3)	0.99
-Infection	11 (9)	4 (9.3)	0.99
-Dysfunction	13 (10.7)	5 (11.7)	0.99
-Lead migration	6 (4.9)	1 (2.3)	--
-Other	6 (4.9)	1 (2.3)	--
Explantation:			
Number of patients having a definitive explantation	43 (17)	14 (14.1)	0.89
Causes of explantation (relative to the total number of explantations)*			
-Loss of efficacy	21 (48.8)	7 (50)	0.99
-Pain	7 (16.3)	3 (21.4)	0.97
-Infection	14 (32.5)	2 (14.3)	0.32
-Dysfunction	5 (11.6)	2 (14.3)	--
-Other	5 (11.6)	0	--

Results are expressed as numbers (percentages) or means±standard deviations. * One patient could have more than one cause for a revision or explantation procedure.

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Figure 1: Study flowchart.

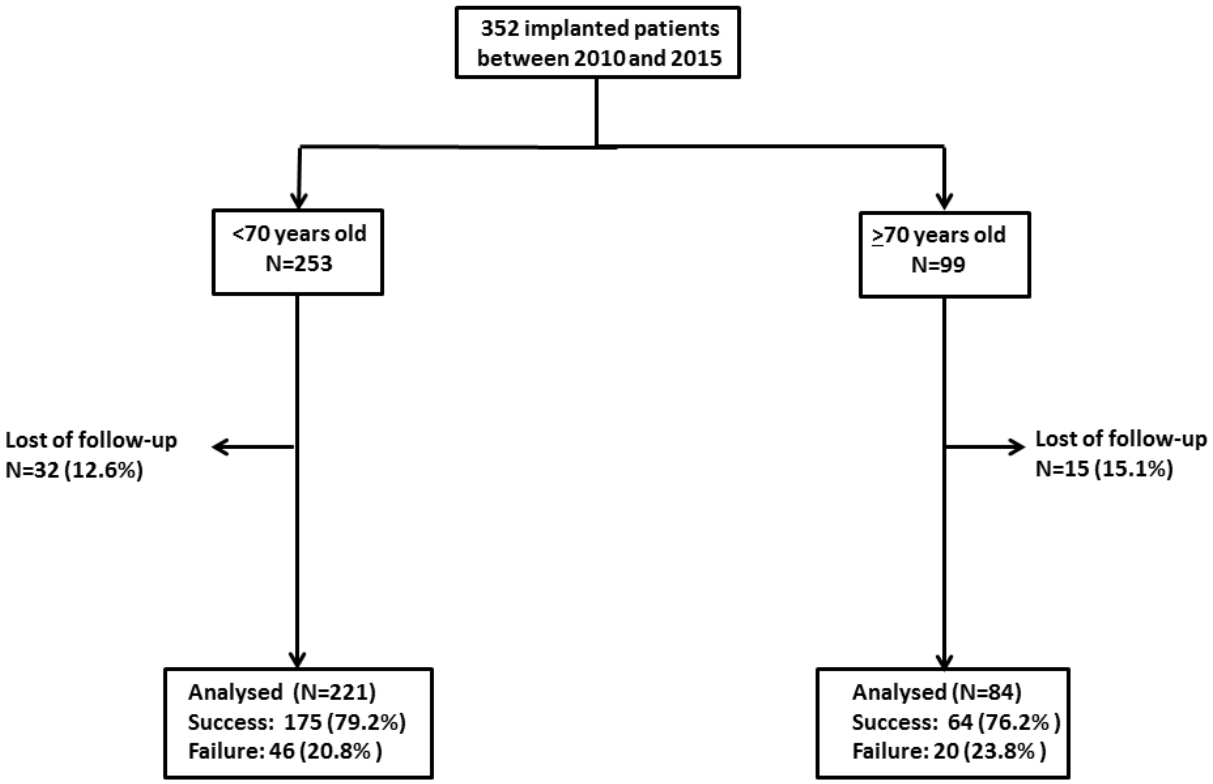

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Figure 2: Kaplan-Meier survival analysis for favourable outcomes after sacral nerve modulation implantation in the two groups of patients (<70 years vs. ≥70 years).

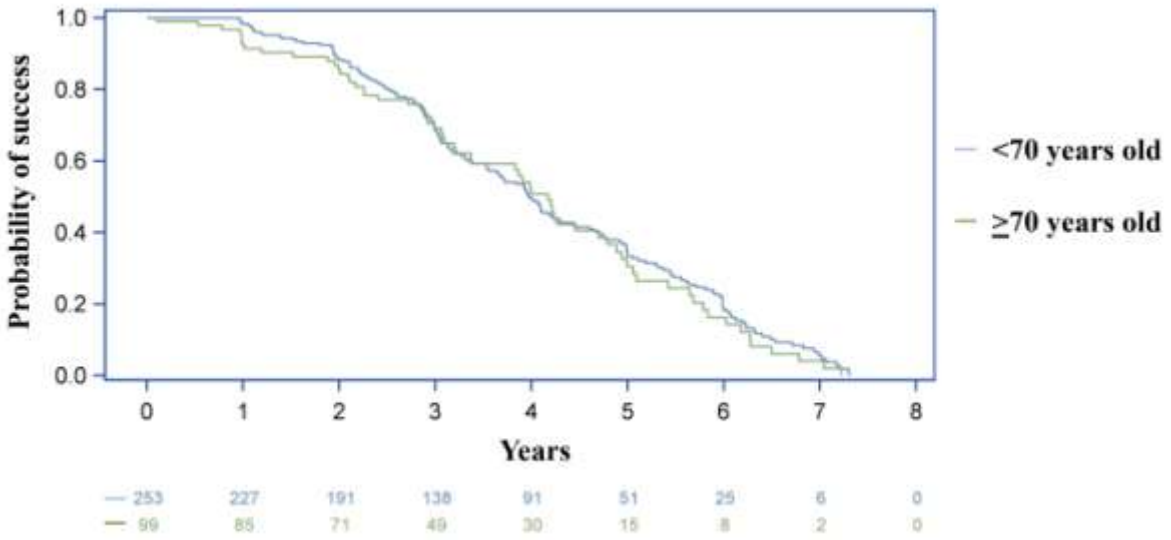

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Figure 3: Comparison of the different rates of improvement in faecal incontinence severity scores before and at the last follow-up visit after sacral nerve modulation battery implantation in the two groups of patients (<70 years vs. ≥70 years).

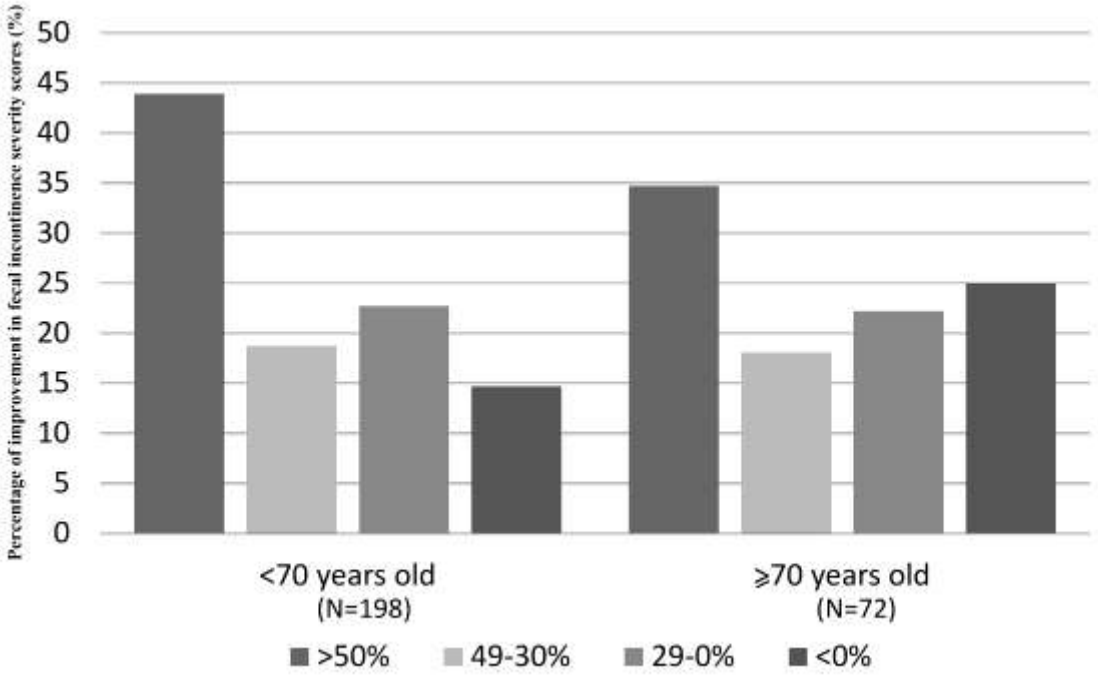

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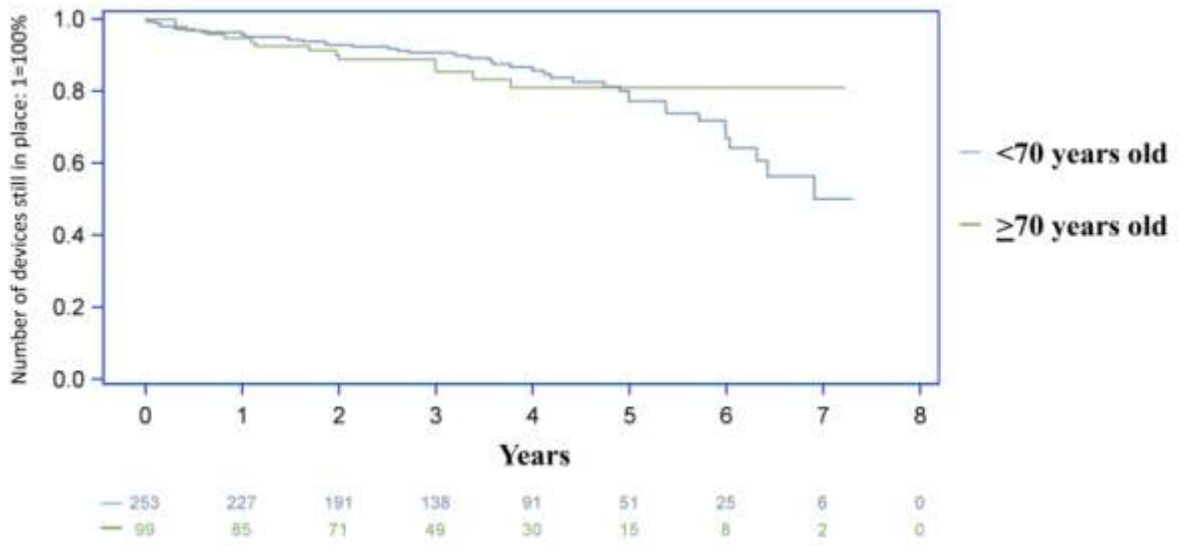
Figure 4: Comparative analyses of explantation-free rates in patients treated by sacral nerve modulation according to age.



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