



## Sacral Nerve Stimulation for the Treatment of Pelvic Floor Diseases: A Bibliometric Analysis of Reported Randomized Controlled Trials

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### Abstract

**Objective:** The aim of this study was to analyze the quality of Randomized, Controlled Trials (RCT) focused on clinical benefits of Sacral Nerve stimulation (SNS) as a treatment of pelvic floor diseases. Secondarily, the changes of quality in reporting through the recent years were also studied.

**Summary Background Data:** Several studies reported results of clinical application of SNS as treatment of pelvic floor diseases. However, these studies are scarce and with a heterogeneous quality on its design and reporting forms.

**Methods:** An electronic search for all RCTs on SNS was undertaken by using the MEDLINE database via PubMed. The data collected were divided into general data, characteristics of reporting, methodology quality assessment using the Jadad scale and a validated methodology quality score (MINCIR score), and the journal impact factor. Reports were divided into two groups: Published articles from 2010 to 2014 (Group 1), and from 2015 to 2019 (Group 2).

**Results:** Twenty-four trials fulfilled the inclusion criteria of the study (Group 1, n=12; and Group 2, n=12). There were no significant differences in general characteristics of randomized, controlled trials between the two groups a part from the higher number of patients completed trials in group 2 ( $p=0.017$ ). In relation to the quality of reporting, we found a statistically significant higher MINCIR score in the published studies in Group 2 ( $p=0.012$ ).

**Conclusion:** In conclusion, in the last ten years there were a slightly increase of quality of reported randomized controlled trials focused in sacral nerve stimulation.

**Keywords:** Sacral Nerve Stimulation; Randomized controlled trial; Quality

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### Introduction

During the last fifteen years, Sacral Nerve Stimulation (SNS) has been established as a new therapy to effectively treat pelvic floor disorders, including gastrointestinal dysfunctions [1,2]. This treatment has been used specially for fecal and urinary incontinence but it has also an important role in the management of other gastrointestinal disorders such as chronic constipation [3], irritable bowel syndrome [4], or chronic pelvic pain and urinary symptoms.

SNS consists on the surgical placement of an electrode near the nerves of the sacral plexus to maintain the so called “neuromodulation of sacral roots” [5]. The technique was first applied by Tanagho and Schmidt, in the University of California in San Francisco, for patients affected by voiding urinary dysfunction or incontinence because of bladder instability [6]. Interestingly, the mechanism of action it is yet not fully understood. However, some of published series demonstrated that SNS, has an afferent effect through changes in brain activity and also some effect on afferent projections of the vagus nerve [7]. Thus, the medical community assumes that these changes may contribute to the restoration of functionality in all clinical disorders where therapy has been proven to achieve clinical benefits [8-10].

Several studies reported scientific evidence regarding clinical application of SNS as treatment of pelvic floor diseases [11]. However, these studies are scarce and with a heterogeneous quality on its design and reporting forms.

Therefore, our aim was to analyze the quality of Randomized, Controlled Trials (RCT)

published in the last ten years focused on clinical benefits of SNS as a treatment of pelvic floor diseases. Secondarily, the changes of quality in reporting through the recent years, were also studied.

## Methods

### Identification criteria

An electronic search for all Randomized, Controlled Trials (RCTs) on the use of SNS for pelvic floor diseases, including gastrointestinal and urinary clinical disorders, was undertaken by using the MEDLINE database *via* PubMed. The term “sacral nerve stimulation” was searched as the main text item. Additional search strategies included: The selection of “randomized controlled trial” as a type of article and publication on a ten-year period: from January 1<sup>st</sup>, 2010 to December 31<sup>st</sup>, 2019. Three researchers (JC, DP, CG) independently evaluated the studies that were eligible according to the identification criteria.

### Inclusion and exclusion criteria

All studies found by the identification criteria, which focused on adult patients, were included. Nonrandomized trials, duplicated articles, or articles that presented data from a previously published RCT, were excluded from the analysis. Articles in which the main outcome was not related to SNS but were identified by the search also were excluded from the study (e.g., treatment with tibial or pudendal nerve stimulation).

### Data collection

The available studies were read in detail, analyzed, and data were extracted. The data collected were divided into general data, characteristics of reporting, and quality methodology assessment.

### General data

In this section we included: The country of authors (or main author), the name of the journal and type of pelvic floor disorder (fecal incontinence, chronic constipation, urinary disorder, and irritable bowel syndrome or IBS). Clinical disorder was divided according to authors criteria in Gastrointestinal symptoms (Fecal incontinence, Constipation and IBS) and the remaining as a urinary symptom. Finally, the specific RCT design that was used (multicenter, double-blinded, cross-over, or placebo-controlled trial).

### Characteristics of reporting

The following variables were recruited: Description of method of randomization, total number of patients randomly assigned in the study, total number of patients followed during the study, presence of a flow diagram, comments on ethical approval, on written informed consent, and finally any reference to the type of support or sponsorship for the study (e.g., financial source for study such us grant or industry). These items were selected, based on the description of the CONSORT guidelines for reporting RCT adequately [12].

### Quality methodology assessment and journal impact factor

All included articles were assessed by using two systems: The Jadad scale [13] and MINCIR score [14], a validated methodology quality score used in previous studies.

Jadad scale is a five-point scoring system that includes three items to assess the methods used to generate random assignments, methods of double-blind assessment, and a description of dropouts and withdrawals by intervention group [13]. A score that represents the sum of the three items is generated, with a final score that can vary

from 0 to 5 points: 0 points are for the worst methods used, and 5 points are for the best. This scale was first described for assessment of pain studies, but because it incorporates components that are directly related to the control of bias, it has been used recently in other topics.

MINCIR score was described some years ago and used for several bibliometric analysis [14]. This scale is composed of three items: The first is related to the study design, the second to the population sample size in the study (adjusted according to the presence or absence of a sample size justification), and finally the third part is related to the methodology used in the reporting paper (objective, design, eligibility criteria, and their justification). According to this, a score which represents the sum of the three items that is generated, with a final score that can vary between 6 and 36 points, with 6 points being the worst methodologic quality study and 36 points being the best (Table 1).

### Journal impact factor

Finally, we analyzed the journal impact factor using the Science Citation Index (SCI) database for every journal that published each RCT on SNS. The journal impact factor was extracted from the 2019 updated SCI version.

Two investigators (JC and DP) completed the quality assessment independently and blinded to each other's result. Discrepancy between evaluations was solved by discussion and, if there was a lack of agreement, by the final decision of the senior author (DP). The study was presented at the IRB of our institution.

### Statistical analysis

Data were entered into a database and were analyzed by using SPSS for Mac v. 10 statistical packages (SPSS™, Inc., Chicago, IL). To test the effect of time of publication on the quality of reporting of RCT data, reports were divided into two groups: Published articles from January 1<sup>st</sup>, 2010 to December 31<sup>st</sup>, 2014 (Group 1), and published articles from January 1<sup>st</sup>, 20015 to December 31<sup>st</sup>, 2019 (Group 2).

Continuous data were presented as a median and range in parentheses and categorical as absolute numbers or percentages. Categorical data were compared by using the Pearson chi-squared test if at least 80 percent of the cells had an expected count of five or more and all cells had an expected count of more than one. If this assumption did not hold, Fisher's exact test was used. The continuous data were analyzed using nonparametric tests (Mann-Whitney U test). Finally, the correlation between scoring systems and journal impact factor were explored by Spearman's correlation test. A bilateral p value <0.05 was considered statistically significant.

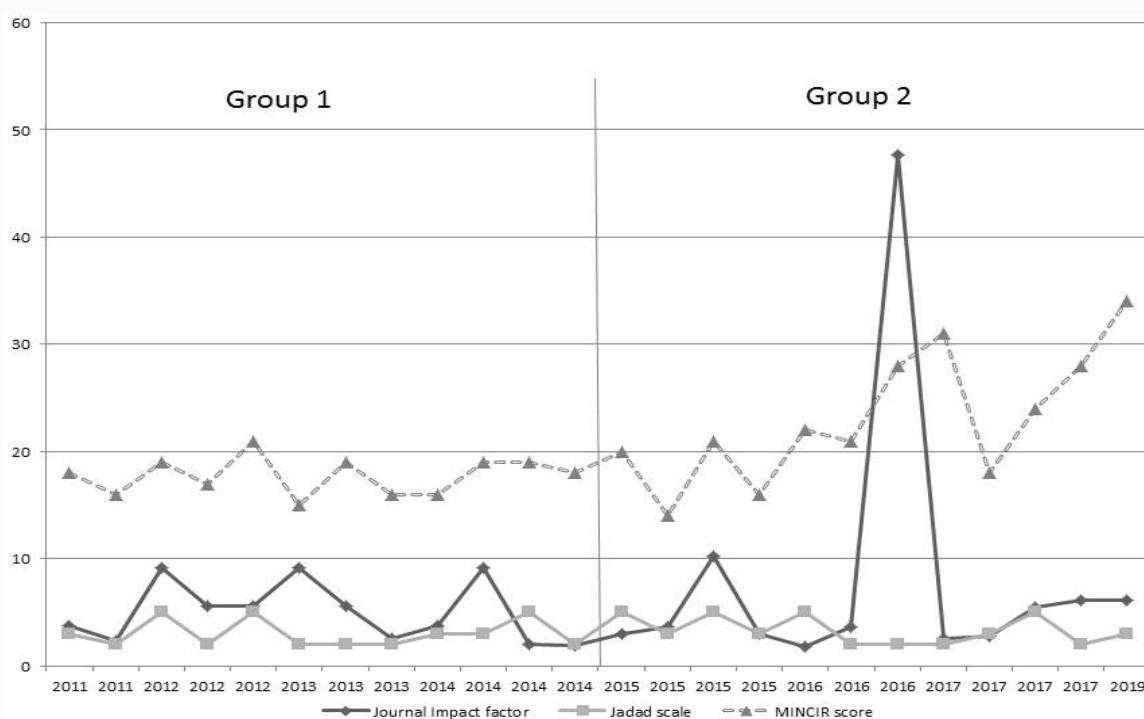
## Results

### Characteristics of analyzed studies

Between January 2010 and December 2019, 973 articles were found in PubMed using the search term “sacral nerve stimulation”. Of those, 48 were RCTs (4.9%).

Twenty-four trials fulfilled the inclusion criteria of the study (Group 1, n=12; and Group 2, n=12). The remaining articles were excluded because they were not focused on Sacral Nerve Stimulation (SNS) or they did not complete the aims of the study.

In Table 2 it is shown the characteristics of articles included according to its year of publication (Group 1, articles published from 2010 to 2014 and Group 2, from 2015 to 2019). The most reported clinical disorders where SNS was the selected therapy, were fecal



**Figure 1:** Evolution of quality metrics (Journal impact factor, Jadad scale and MINCIR score) of published RCTs on Sacral Nerve Stimulation for pelvic floor diseases.

**Table 1:** The Methodologic quality score or MINCIR score [14].

	Score
<b>1. Study design</b>	
Multicentre, clinical trial	12
Randomized, clinical trial (double-blind)*	9
Clinical trial (simple blind or non-blinded, non-randomized) <sup>†</sup>	6
Concurrent cohort studies	4
Case-control studies and historic cohort studies	3
Cross-sectional studies	3
Case series	1
<b>2. Studied population x justification factor<sup>‡</sup></b>	
≥ 201	6 or 12
151–200	5 or 10
101–150	4 or 8
61–100	3 or 6
31–60	2 or 4
≤ 30	1 or 2
<b>3. Methodology</b>	
<b>Objective</b>	
Precise and definite objectives are presented	3
Imprecise objectives are presented	2
No objectives are presented	1
<b>Design</b>	
The design used is mentioned and justified	3
The design used is only mentioned	2
The design used is neither mentioned nor justified	1
<b>Selection criteria</b>	

Inclusion and exclusion criteria are described	3
Inclusion or exclusion criteria are described	2
No selection criteria are described	1
<b>Sample size</b>	
Justified sample size	3
Non-Justified sample size	1
<b>Final score= ITEM 1 + ITEM 2 + ITEM 3</b>	Score 6 to 36

\*Includes clinical trials with restricted randomization and quasi-experimental studies

<sup>†</sup>Includes experimental studies (pre-post)

<sup>‡</sup>Justification factor is x 2 if the sample was justified and x 1 if it was a non-justified sample size

incontinence (33.3%) followed by chronic constipation and finally urinary symptoms (both 28.6%). Additionally, two studies focused on irritable bowel syndrome (9.5%).

The majority of all published RCT were carried out in Europe (54.16%). The British Journal of Surgery was the journal that published most RCTs on sacral nerve stimulation, followed by Annals of Surgery and Colorectal Disease journals.

Interestingly, and probably due to the type of treatment SNS consists of, there are 9 out 24, cross-over clinical trials. None of the characteristics of the trials had statistically significant differences according to the period of publication. Nineteen studies (79.1%) were classified as gastrointestinal symptoms and the remaining 5 (20.8%), as urinary symptoms.

#### Quality assessment of analyzed studies

The mean impact factor was higher in published trials of Group 1 but these differences have not achieved statistical significance ( $p=0.977$ ).

When comparing the different randomized trials between the

**Table 2:** General characteristics of included randomized controlled trials according to the date of publication.

	<b>Group 1</b> Published from 2010 to 2014 (n=12)	<b>Group 2</b> Published from 2015 to 2019 (n=12)	<b>p value*</b>
<b>Country of main author</b>			
Australia	2 (16.6)	1 (8.3)	0.120
China	1 (8.3)	0 (0)	
Denmark	6 (50)	1 (8.3)	
UK	1 (8.3)	5 (41.6)	
USA	1 (8.3)	4 (33.3)	
Other	1 (8.3)	1 (8.3)	
<b>Journal</b>			
Annals of Surgery	3 (25)	0 (0)	0.890
American Journal of Obstetrics & Gynecology	0 (0)	2 (16.6)	
British Journal of Surgery	3 (25)	1 (8.3)	
Colorectal Disease	0 (0)	3 (25)	
Diseases of the Colon and Rectum	0 (0)	2 (16.6)	
The Journal of Urology	1 (8.3)	1 (8.3)	
Neurogastroenterology and Motility	2 (16.6)	0 (0)	
Other	3 (25)	3 (25)	
<b>Type of RCT</b>			
Multicenter trial	0 (0)	5 (41.6)	0.410
Double-blinded trial	3 (25)	4 (33.3)	
Cross-over trial	7 (58.3)	2 (16.6)	
Placebo-controlled trial	2 (16.6)	1 (8.3)	
<b>Type of pelvic floor disorder</b>			
Gastrointestinal symptoms	9	10	
Urinary symptoms	3	2	1.0

Data are numbers with percentages in parentheses; \*Chi-square's test

two groups (Table 3), we found that the group 2 as a most recent published trials, have a higher MINCIR score ( $p=0.012$ ) and more included patients ( $p=0.013$ ) who completed the studies ( $p=0.017$ ). There was also a higher score in Jadad scale in the RCTs in Group 2 (2.5 in Group 1 vs. 3 in Group 2,  $p=0.51$ ). However, these differences were not statistically significant. In Figure 1 it is shown the evolution of quality indicators according to year of publication.

When the different RCT were analyzed in regard to clinical disorders (gastrointestinal symptoms vs. urinary symptoms, Table 4), a higher impact factor was observed in gastrointestinal indications (2.36 vs. 3.44,  $p=0.063$ , respectively). However, there were no differences regarding other variables; the MINCIR score (18 vs. 19,  $p=0.78$ ) and the Jadad scale (2 vs. 3,  $p=0.18$ ).

When we analyzed correlation between the two methods of quality evaluation: Journal impact factor with Jadad scale and MINCIR score, we found that they were not correlated with statistical significance ( $p=0.944$  and  $p=0.269$ ).

## Discussion

In the last few years, many articles have been published on several series of patients about the clinical benefits of SNS as a therapy for pelvic floor diseases, especially for fecal incontinence. Different specialties manage this therapy, such as Urology or Gastrointestinal

**Table 3:** Quality indicators of reporting RCT included in the study.

	<b>Group 1</b> Published from 2010 to 2014 (n=12)	<b>Group 2</b> Published from 2015 to 2019 (n=12)	<b>p value</b>
<b>Method of random allocation sequence</b>			
Computer random	1 (8.3)	3 (25)	†0.530
Sealed envelopes only	4 (33.3)	2 (16.7)	
Table with random numbers	1 (8.3)	1 (8.3)	
Other	1 (8.3)	3 (25)	
No mention	5 (41.7)	3 (25)	
<b>No. of patients randomly assigned</b>	20 (7-240)	58.5 (11-386)	*0.012
<b>No. of patients completed the study</b>	19.5 (7-240)	55.5 (11-364)	*0.017
<b>Flow chart diagram</b>	7 (58.3)	7 (58.3)	†1
<b>Comments on ethical approval</b>	11 (91.7)	12 (100)	†0.307
<b>Written, informed consent</b>	11 (91.7)	12 (100)	†0.307
<b>Support</b>			
No support	6 (50)	7 (58.3)	†0.355
Grant	4 (33.3)	5 (41.7)	
Company	2 (16.7)	0 (0)	
No mention	0 (0)	0 (0)	
<b>Jadad scale (maximum 5)</b>	2.5 (2-5)	3 (2-5)	*0.514
<b>MINCIR score (maximum 36)</b>	18 (15-21)	21.5 (14-34)	*0.012
<b>Journal Impact factor</b>	4.69 (1.86-9.20)	3.61 (1.84-47.70)	*0.977

Data are numbers with percentages in parentheses or medians with ranges indicated

\*Nonparametric test (Mann-Whitney U test); † Chi-squared test

Surgery; and despite its costs and some unanswered questions about the exact mechanism of action, SNS has been established in daily practice and clinical guidelines [15].

Randomized Controlled Trials (RCT) are an essential source of scientific evidence. However, they are scarce, not always well designed and in some cases, they are not being reported adequately. Inadequate reporting makes the interpretation of RCT results difficult and borders on unethical practice when biased results receive false credibility [16].

This is why we decided to analyze in detail the quality of RCT on SNS for pelvic floor disorders. Surprisingly only 5% of all publications on SNS were RCT. Our group previously developed a bibliometric analysis of RCT in fecal incontinence [16]. Consequently, we agreed that it would be adequate to do the same study design and analysis focused on SNS.

When we analyzed the results, we found some interesting findings. We found similar quality of reporting RCT throughout a period of ten years, despite a significant number of patients were enrolled in clinical trials in recent years. This reflects the fact that in recent years and when some therapy is introduced in daily practice, more patients are needed to demonstrate with multicenter trials its value to be considered as a standard of care.

Otherwise, we found a small number of trials considering economic assessment of SNS. This type of cost-analysis on SNS is warranted as is other important consideration for the evaluation of new therapeutic alternatives. Especially recently when efficacy it is of paramount importance.

**Table 4:** Characteristics of reported RCT according to type of symptoms of clinical disorder where SNS was tested.

	<b>Urinary symptoms (n=5)</b>	<b>Gastrointestinal symptoms (n=19)</b>	<b>p value</b>
<b>Method of random allocation sequence</b>			†0.161
Computer random	2 (40)	2 (10.5)	
Sealed envelopes only	0 (0)	6 (31.6)	
Table with random numbers	0 (0)	2 (10.5)	
Other	0 (0)	4 (21.1)	
No mention	3 (60)	5 (26.39)	
<b>No. of patients randomly assigned</b>	20 (15-58)	81 (31-313)	*0.044
<b>No. of patients completed the study</b>	20 (15-55)	81 (30.5-302)	*0.036
<b>Flow chart diagram</b>	4 (80)	10 (52.6)	†0.269
<b>Comments on ethical approval</b>	4 (80)	19 (100)	†0.046
<b>Written, informed consent</b>	5 (100)	18 (94.7)	†0.600
<b>Support</b>			†0.327
No support	4 (80)	9 (47.4)	
Grant	1 (20)	8 (42.1)	
Company	0 (0)	2 (10.5)	
No mention	0 (0)	0 (0)	
<b>Jadad scale (maximum 5)</b>			
Median (range)	2 (2-5)	3 (2-5)	*0.185
<b>MINCIR score (maximum 36)</b>			
Median (range)	18 (16-28)	19 (14-34)	*0.783
<b>Impact factor</b>			
Median (range)	2.36 (1.84-47.7)	3.44 (2.03-10.24)	*0.063

Data are numbers with percentages in parentheses or medians with ranges in parentheses

\*Nonparametric test (Mann-Whitney U test); † Chi-squared test

From time to time, health technologies assessment has been stated as a methodology for the introduction of new devices or therapies in hospitals or health institutions [17]. This methodology uses as a main source of information, the scientific evidence supported as much as is possible using the results of RCT. Moreover, RCT represents a key research activity, with the potential to improve the quality of healthcare in comparison to other alternatives. Thus, we found a bibliometric analysis of RCTs a practical tool for decision-making.

Interestingly, and compared to other therapies, there is a relative abundance of multicenter and cross-over trials in SNS. Both designs are very useful when wanting to assess the external validity of a new treatment. We used two scores in addition to the journal impact factor; the Jadad scale and the MINCIR score. In comparison to previous bibliometric analysis [16] we did not find correlation between these scores and the Journal impact factor. Our belief is that editors in all journals are nowadays considering, as mandatory, the standards on reporting RCT such as CONSORT guidelines. Thus, the differences in this period of time are scarce and only regarding number of patients enrolled and multicenter design.

The use of journal impact factor has evolved from year to year as a method to measure quality of authors' curriculum vitae. However, its utility has been questioned and other metrics such as H-index, are recently supported [18,19].

The present study is the first analyzing the quality of design and reporting RCT of SNS for pelvic floor diseases. The aim was to make a step further to achieve enough scientific evidence to support the introduction of this treatment in daily practice. The uses of two methods for evaluating the quality with journal impact factor are key for the conclusion. However, this study also has some limitations. First, the number of studies is scarce. Secondly, as a result of new requirements for publishing RCT in all journals, very slight differences were found in quality in recent years.

## Conclusion

In conclusion, in the last ten years there were a slightly increase of quality of reported randomized controlled trials focused in Sacral Nerve Stimulation. Thus, only MINCUR score was significantly higher in RCTs of last period. There is a need for strategies to improve the quality of the reported studies in all therapies that are introduced in daily clinical practice.

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