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Sacral Neuromodulation in Elderly Patients

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1. Introduction

Urinary Urge Incontinence (UUI) is a common condition among women and increases its prevalence in relation to age.It is estimated that more than 200 million women worldwide live with this problem, which results in limitations in daily activities with impaired Quality of Life (QoL). Although the incidence and prevalence of UUI are higher in the elderly population, this condition should not be considered normal or unavoidable in the aging process of women. In fact, as reported by an epidemiological study carried out in the elderly community, the average cost per year of the UUI is 2.2-2.5 times greater than that of the general population. International guidelines recommend pharmacotherapy as a first option; unfortunately the elderly in many cases(40%) do not respond to the therapy or are not compatible with this approach for several reasons, including concomitant use of many other drugs, side effects, and, in this historical moment, even the economic aspect. Furthermore, about 20% of those who have an initial improvement with drug treatment suspend the therapy within 6 months due to the presence of side effects or lack of efficacy. In the literature there are few studies that evaluate minimally invasive proceduresfor UUI in elderly patients, and only one about the Sacral Neuromodulation System (SNS), which, however, did not evaluate the QoL.

Therefore, this prospective study evaluated theimprovement of the quality of life with the questionnaire validated in Italian Over Active Bladder (OAB) -questionnaire in elderly women affected by UUI and subjected to the SNS. The primary end point of our study was to report the objective recovery rates and the QoL; moreover, the secondary end point was the feasibility and safety of SNS in women of geriatric age affected by UUI who had not responded or had refused pharmacological treatments.

2. Materials and Methods

From October 2008 to April 2010, we consecutive enrolled the patientsaged> 65 years and with UUI confirmed by urodynamic tests, and who had side effects or non-response to drug treatment. The study had been approved by the Institute's internal review committee, and patients had signed informed consent. The exclusions criteria were: fecal incontinence, recurrent cystitis, stage 1 urogenital prolapse (according to the POP-Q system), senile dementia, and Alzheimer's disease. The preoperative evaluation included a history of urogynecological problems, a general medical evaluation, an urinary clinical examination, an urinalysis and an urine culture, a bladder Ultra Sound (US) and a cytological Fluorescence hybridization (FISH test) on urine to exclude bladder neoplasms. During the overall assessment, the anesthetic risk was assessed according to the score of the American Society of Anesthesiologists (ASA). All patients were required to have a MRI scan and a Mental State examination to excludeneurological or psychiatric problems. During the urogynaecologic history, all patients were asked to complete the OAB questionnaire HR-QoL and

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to fill in a 3-day void diary. During the urogynecological clinical examination, the severity of vaginal defects was assessed using the POP-Q system. All patients underwent stress tests in the supine position and in orthostatism at 300 ml of bladder filling to evaluate the presence of Stress Urinary Incontinence (SUI). The UUI was defined as involuntary loss accompanied or immediately preceded by urgency and was confirmed by the urodynamic evaluation. Other symptoms, such as inter-micturition frequency or nocturia, have been recorded. After the preoperative evaluation, the patients underwent the surgical procedure according to the percutaneous technique described by Spinelli, inserting an electrocatheter in the third sacral foramen (S3) with fluoroscopy control and modulated by an external screener. If, within 30-40 days, there was a clinical improvement> 50% compared to the pre-existing condition with a voiding diary performed in 3 days, the neuromodulator (Medtronic) was inserted into the gluteal region. Perioperative and postoperative complications were recorded at the end of each phase of the procedure. Twelve months after surgery, patients were asked to undergo a new clinical examination, fill out a 3-day voiding diary, and complete the OAB-questionnaire. Success rates and complication rates were evaluated at that time. Complete care was evaluated with the administration of a 3-day urinary diary with the absence of OAB symptoms. The improvement was defined as a reduction of between 50% and 90% of incontinence episodes. The assessment of subjective efficacy was assessed with the OAB-questionnaire. Statistical variations were analyzed using the Mann-Whitney test and the Fisher test. Statistical significance was given with$p<0.05$.

3. Results

Between October 2008 and April 2010, 33 women aged> 65 years, affected by UUI, and who had side effects or ineffectiveness to drug treatmentwere admitted in this prospective study. Eleven patients (33.3%) were excluded for refusing to sign informed consent, two (6.1%) hadprevious neoplastic diseases, and two (6.1%) had a post-micturition residue> 100 ml. Eighteen patients (54.5%, mean age 76±6.1, median 75 - range 65-86 years) participated in the study.The characteristics of the patients have been reported in Table 1. After the first phase of the procedure, 13 patients (72.2%) showedimprovement> 50% assessed with the 3-day-threatening diary and underwent the implantation of a permanent sacral neuromodulator ("bladder pacemaker"). Five patients (27.8%) did not fully respond to the therapy, but three(16.7%), have had a subjective improvement and have been subjected toa contralateral procedure: two of them showed a good response assessed with a voiding diary and were sent to the second phase of the procedure. No perioperative complications were recorded. Twelve months after surgery (12.8 ± 3.7, range 7-19 months), all implanted patients improved (five patients, 27.8%) or healed (ten patients,55.5%), with a success rate of 83.3% and a decrease in episodes of mean incontinence from 6.3±2.06 to 0.5±0.7 ($p<0.0001$) **(Figure 1).**

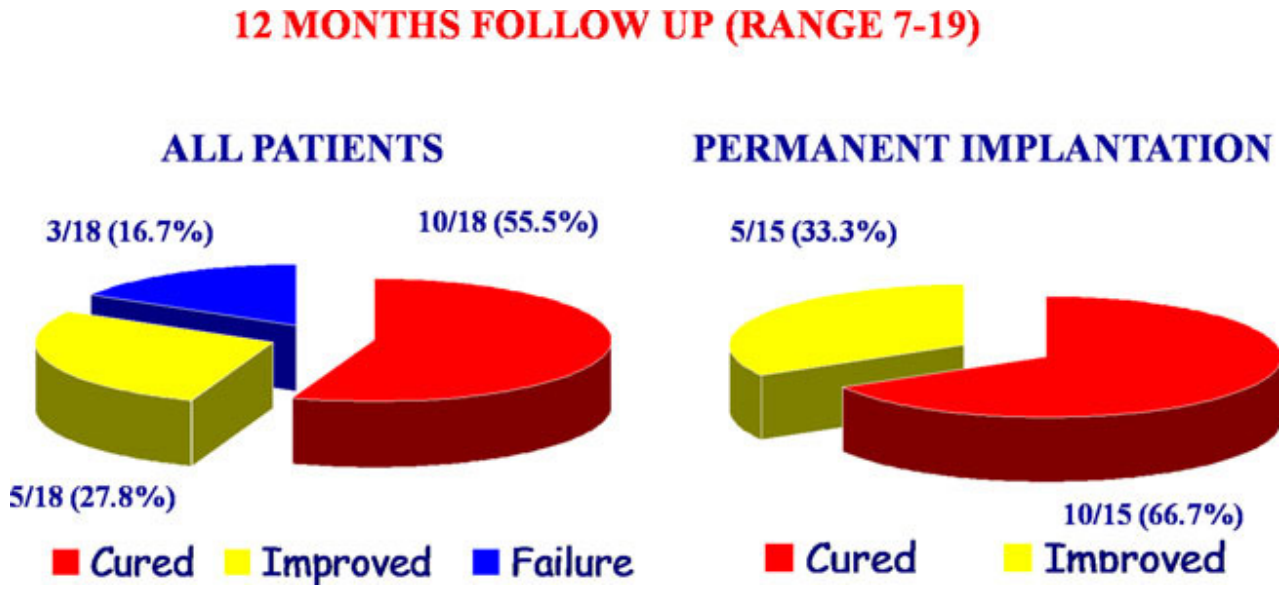

Figure 1: Results at 12 months follow-up

In addition, 3-day micturition diaries showed a statistically significant reduction in incontinence episodes, micturition frequency, nocturia episodes, and the number of pad used daily ($p <0.0001$) **(Figure 2)**. Among all the women who underwent to the neuromodulation implant, a statistically significant increase was recorded compared to the period before the implant ($p<0.0001$) of the HR-QoL and the OAB-questionnaire. No major long-term complications occurred; two minor complications were recorded in 2 patients (13.3%), complaining of pain at the surgical site, resolved after 3 months of local anti-inflammatory therapy.

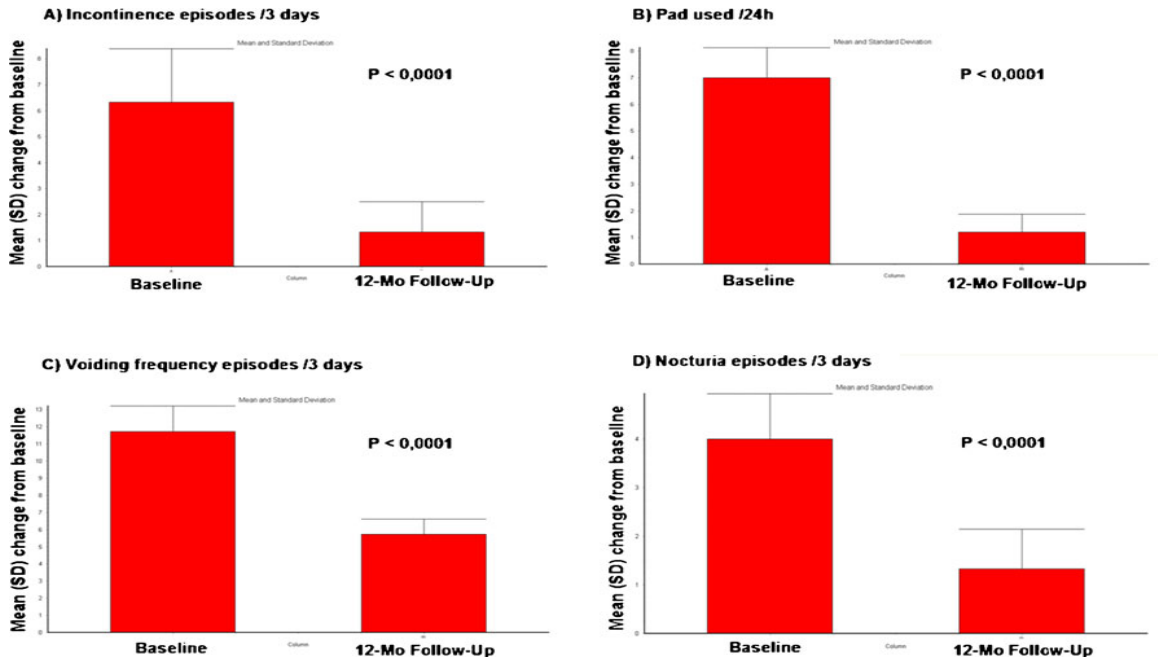

Figure 2: Effects of SNS before and 12 months after therapy A) Incontinence episodes in 3 days, B) Pad used in 24 hours, C) intermicturition frequency episodes in 3 days, D) Nocturia episodes in 3 days

Table 1: Patients characteristics.

VARIABLE	PATIENTS (18)
Median age (range)	76 (65-86)
Median parity (SD)	3 ± 1.7
Previus isterectomy (%)	10 (55.6)
PopQ-system	
• Stage 0 (%)	10 (55.6)
• Stage 1 (%)	8 (44.4)
Non responders therapy (%)	9 (50)
Refuse pharmacological therapy due to costs (%)	6 (33.3)
Pharmacological side effects (%)	3 (16.7)
Comorbidity*	
• Hypertension (%)	13 (72.2)
• Previous AMI (%)	5 (27.8)
• Diabetes melliltus (%)	3 (16.7)
• Respiratory disease (%)	2 (11.1)
• Parkinson's disease (%)	1 (5.6)
• Multiple sclerosis (%)	1 (5.6)
ASA 2 ** (%)	11 (61.1)
ASA 3 ** (%)	7 (38.9)

* Some patients have more than 1 co morbidity

**American Society of Anaesthesiologists (ASA) classification

4. Discussion

Urinary Urge Incontinence (UUI) is a common clinical condition in the geriatric population; moreover, this population is increasing all over the world. Indeed,according to data from the World Health Organization, the numberof individuals aged> 65 years increased by 140 million between 1975 and 1995. Consequently there is a growing interest in this particular group of patients, since they involve considerable economic burden and are often not adequately treated. The international guidelines currently recommend pharmacological treatmentas a first-line option in patients with UUI, however, many elderly patients do not solve their problem. In fact, up to 40% are refractory to a satisfactory clinical response, about 20% have an initial improvement but subsequently this result is not preserved also due to the presence of side effects. In our study, we observed that 50% of patients do not respond to drug treatment, that 33.3% have refused drug treatment because of excessive costs and that 16.7% are unable to tolerate drug therapy due to the concomitant use of many other drugs. For these reasons, being able to find a useful treatment for the population in geriatric age is often a clinical success: in fact many health care professionals hesitate to consider surgical therapy in this age group due to the presence of comorbidities. The international guidelines also state that in case of insufficient improvement with conservative therapies, age is not an absolute contraindication to surgery. This recommendation has a type C type of evidence, as there are currently few studies evaluating minimally invasive surgical procedures in geriatric patients and only one on SNS. This prospective study provides further evidence that can help improve the level of recommendation. The existing mini-invasive techniques are the transcutaneous electrical stimulation of the tibial nerve (TTNS) and the intravesical injection of botulinum toxin type A, with success rates of 68% and 76.2%, respectively. However, according to the International Consultation on Incontinence, SNS is the only minimally invasive treatment used for refractory UUI and therefore a type A recommendation grade is assigned. Although there is literature on the evaluation of the efficacy of SNS, its use in patients of geriatric age is very limited. There is only one prospective, longitudinal study, which includes 19 elderly women aged ≥70, and the authorsreport a 89.5% improvement in symptoms. Even our results are similar to the study reported, in fact we have achieved an

overall rate of success of 83.3%. However, this result is superior to those reported with other minimally invasive techniques, such as TTNS and intravescical injection of botulinum toxin type A, moreover lasting over time. It is important to stress that careful patient selection is essential. In fact, according to our experience, if the patients are carefully selected during the first phase of the procedure (Figure 2), excluding patients unable to give a correct answer, all the implanted women are likely to obtain a positive result. Another fundamental aspect to consider is that the UUI impacts negatively on QoL. To our knowledge, this is the first SNS study with an assessment of QoL improvement in elderly patients, assessed through validated questionnaires in the Italian language (OAB-questionnaire and HR-QoL). Considering that UUI is a benign condition, we believe that QoL is an additional criterion relevant to the assessment of the effectiveness of the SNS. The limitation of this study could be the reduced sample size, however, the high success we have achieved is a strong point of this study. In fact, we recorded a statistically significant improvement in the QoL ($p<0.0001$) in the HR-QoL and the OAB-questionnaire score compared to the period before the intervention. Another very interesting aspect that emerges from our study is the statistically significant reduction of nocturia episodes, reducing disturbances on sleep quality and above all the risk of possible falls with possible fractures. Indeed, onestudy on older people revealed that 27% of falls occurat night, with 54% correlated to the route taken to the toilet.Furthermore, the overall complication rate of SNS is low, with rare intraoperative complications and with about 30% minor postoperative complications. The most commonly reported complications in the literature are surgical site pain,wound infections, trauma, and lead migration. In the onlystudy on SNS in elderly patients, White et al. reported a complication rate of 29.4%. In our experience, the complication rate was nevertheless found in the lower limits of the literature; in fact, we did not have perioperative complications,and we recorded only two minor late complications (13.3%). Therefore, in our opinion the SNS seems to be a safe and feasible intervention in geriatric patients. Although our results are encouraging, prospective and randomized studies are required to confirm these preliminary results. A possible criticism that can be made to this type of treatment is the high cost of therapy, but evaluating all direct and indirect costs related to the disease are certainly well repaid over time, given that the life expectancy of women currently it has definitely increased.

5. Conclusions

The SNS can be considered a valid alternative for the treatment of UUI in well-selected elderly women. The overall success rate was high (83.3%), and all implanted patients showed a statistical improvement in QoL. The SNS appears to be a safe and feasible procedure in the geriatric age population with a low complication rate (13.3%).

References

1. Irwin DE, Milsom I, Hunskaar S, Reilly K, Kopp Z, Herschorn S, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol. 2006;50(6):1306-15.

2. Schreiner L, dos Santos TG, Knorst MR, da Silva Filho IG. Randomized trial of transcutaneous tibial nerve stimulation to treaturge urinary incontinence in older women. Int Urogynecol J. 2010;21(10):1065-10703.

3. DuBeau EC. The aging lower urinary tract. J Urol. 2006;175:S11-5.

4. Kraus SR, Bavendam T, Brake T, Griebling TL. Vulnerable elderly patients and overactive bladder syndrome. Drugs Aging. 2010;27(9):697-713.

5. Griebling TL. Urinary incontinence in the elderly. Clin Geriatr Med. 2009;25(3):445-57.

6. Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, et al. Members of committees; fourth international consultation on incontinence. Fourth international consultation on incontinence recommendationsof the international scientific committee: evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn. 2010;29(1):213-40.

7. Basra RK, Wagg A, Chapple C, Cardozo L, Castro-Diaz D, Pons ME, et al. A review of adherence to drug therapy in patients with overactive bladder. BJU Int. 2008;102(7):774-9.

8. Saliba D, Elliott M, Rubenstein LZ, Solomon DH, Young RT, Kamberg CJ, et al. The Vulnerable Elders Survey: a tool for Identifying vulnerable older people in the community. J Am Geriatr Soc. 2001;49(12) :1691-9.

9. Bosch JLHR, Groen J. Sacral nerve neuromodulation in the treatment of patients with refractory motor urge incontinence: long term results of a prospective longitudinal study. J Urol. 2000;163:1219-22.

10. White WM, JD Mobley 3rd, Doggweiler R, Dobmeyer-Dittrich C, Klein FA. Sacral nerve stimulation for refractory overactive bladder in the elderly population. J Urol. 2009;182(4):1449-52.

11. White WM, Pickens RB, Doggweiler R, Klein FA. Short-term efficacy of botulinum toxin a for refractory overactive bladder in the elderly population. J Urol. 2008;180(6):2522-6.

12. Spinelli M, Giardiello G, Arduini A, van den Hombergh U. New percutaneous technique of 222 J. R. Vignes et al. sacral nerve stimulation has high initial success rate: Preliminary results. Eur Urol. 2003;43:70-4.

13. Zullo MA, Montera R, Plotti F, Guzzo F, Angioli R. Sacral neuromodulation after stabilization of L2-S1 vertebrae with metallic fixation

devices: is it feasible?. Int Urogynecol J. 2011;22(3):373-5.

14. Thom DH, Nygaard IE, Calhoun EA. Urologic diseases in America project: urinary incontinence in women - national trends in hospitalizations, office visits, treatment and economic impact. J Urol. 2005;173:1295-301.

15. Castro-Diaz HF. Persistence with antimuscarinic therapy in patients with overactive bladder. Int J Clin Pract. 2005;59:931-7.

16. Macdiarmid SA. Concomitant medications and possible side effects of antimuscarinic agents. Rev Urol. 2008;10(2):92-8.

17. Watanabe JH, Campbell JD, Ravelo A, Chancellor MB, Kowalski J, Sullivan SD. Cost analysis of interventions for antimuscarinic refractory patients with overactive bladder. Urology. 2010;76(4):835-40.

18. Van der Vaart CH, de Leeuw JR, Roovers JP, Heintz AP. The effect of urinary incontinence and overactive bladder symptoms on quality of life in young women. BJU Int. 2002;90:544-9.

19. Brazzelli M, Murray A, Fraser C. Efficacy and safety of sacral nerve stimulation for urinary urge incontinence: a systematic review. J Urol. 2006;175:835-41.