Sacral Neuromodulation in Children With Urinary and Fecal Incontinence: A Multicenter, Open Label, Randomized, Crossover Study

M. Haddad,* R. Besson, D. Aubert, P. Ravasse, J. Lemelle, A. El Ghoneimi, J. Moscovici, F. Hameury, K. Baumstarck-Barrau, G. Hery and J. M. Guys

From the Departments of Pediatric Surgery, Hôpital Jeanne de Flandre, Lille (RB), Hôpital Saint Jacques, Besançon (DA), CHU Caen, Caen (PR), CHU Nancy, Nancy (JL), Hôpital Robert Debré, Paris (AEG), Hôpital des Enfants, Toulouse (JM), CHU Lyon, Lyon (FH), and Hôpital d'Enfants de la Timone (MH, GH, JMG) and Department of Public Health, Université de la Méditérranée (KB-B), Marseille, France

Abbreviations and Acronyms

CIC = clean intermittent catheterization

SNM = sacral neuromodulation

Submitted for publication October 30, 2009.

Study protocol was approved by a French ethics committee and registered as a clinical trial (AFSSAPS 2005/04/003) at the French Ministry of Health.

Study was supported by grants from French Ministry of Health (PHRC 2004 program hospitalier de recherche clinique).

* Correspondence: Department of Pediatric Surgery, Hôpital d'Enfants de la Timone 264, rue Saint Pierre, 13005 Marseille Cedex 5, France (telephone: 33-4-91-38-66-82; FAX: 33-4-91-38-47-14; e-mail: mirna.haddad@ap-hm.fr).

See Editorial on page 417.

Purpose: The clinical benefit of sacral neuromodulation is unclear due to the paucity of randomized trial data. The purpose of this study was to evaluate sacral neuromodulation for management of urinary and fecal incontinence in a pediatric population.

Materials and Methods: This multicenter, open label, randomized, crossover study included children older than 5 years. After trial stimulation of the S3 root a neuromodulator (InterStim®) was implanted on the S3 foramen. Clinical examinations, voiding and bowel diaries, and urodynamic and manometric evaluations were performed at the beginning (t1) and end (t2) of the first period, and at the beginning (t3) and end (t4) of the second period.

Results: A total of 33 patients (24 boys) with a mean ± SD age of 12.22 ± 5.09 years were randomized. Etiologies were mainly of neurological origin. Incontinence was mixed urinary and fecal in 19 cases, urinary only in 9 and fecal only in 5. Cystometric bladder capacity increased during sacral neuromodulation (delta +24.27 ml vs −37.45 ml, $p = 0.01$). There was no significant change in other urodynamic or manometric parameters. Overall positive response rate was more than 75% for urinary (81%) and bowel (78%) function. Crossover analysis indicated that sacral neuromodulation is more effective than conservative treatment for both types of incontinence ($p = 0.001$).

Conclusions: In a pediatric population sacral neuromodulation is effective for bladder and bowel dysfunction and should be considered before irreversible surgery.

Key Words: congenital abnormalities, electric stimulation therapy, fecal incontinence, lumbosacral plexus, urinary incontinence

Sphincter disorders can have many etiologies in children but the most frequent (95%) is congenital vertebral and medullary malformation, eg spinal dysraphism.[1] Neurogenic bladder is characterized by loss of ability to control voiding. With age most patients have obstructive uropathy with increase in bladder pressure during filling and vesicosphincteric dyssynergia. Since the lower urinary and gastrointestinal tracts have the same embryological origin and innervations, sphincter disorders are frequently associated with fecal incontinence (80%).[1,2]

SNM has been used for management of sphincter disorders in adults.[3–8] However, only 3 groups have reported results in children.[4,9–11] Most pediatric

0022-5347/10/1842-0696/0
THE JOURNAL OF UROLOGY®

Vol. 184, 696-701, August 2010
Printed in U.S.A.
DOI:10.1016/j.juro.2010.03.054

studies have involved small patient populations and data have been mainly clinical. In a previous study describing SNM in children with neurogenic bladder, we reported improvement in bladder and bowel function.[9] These encouraging results led to the present study, which was designed to evaluate the efficacy and tolerance of SNM for management of urinary and fecal incontinence in a pediatric population.

METHODS

Patients and Setting

This prospective, national, randomized, open-label, crossover study was conducted in the pediatric surgery departments of French university hospital centers in Marseille, Lille, Besançon, Caen, Nancy, Paris, Lyon and Toulouse. Patients with urinary incontinence due to neurogenic bladder and/or fecal incontinence due to congenital malformation were eligible. Children or teenagers under surveillance for fecal and/or urinary incontinence were included if they presented with at least 2 of the following conditions—duration of continence 90 minutes or less, post-void residual volume greater than 50% of functional bladder capacity, bladder compliance less than 15 and bladder overactivity with pressure peaks exceeding 40 cm H_2O. Ability and motivation of patient and family to comply with keeping a voiding and bowel diary, and attend followup examinations throughout the study were also taken into account for inclusion. All treatment, especially anticholinergic medication, was discontinued during the screening period. The main exclusion criteria were local risk factors for device implantation (scar and sacral agenesis involving greater than 50% of the sacrum) and failure to detect the S3 roots.

Before inclusion all patients underwent renal ultrasound, urethrocystography and renal scintigraphy (dimercapto-succinic acid) to evaluate bladder and kidney status. Routine preanesthetic laboratory tests (including creatininemia) were performed preoperatively. If clinical status of the patient changed during followup, testing was repeated to detect deterioration.

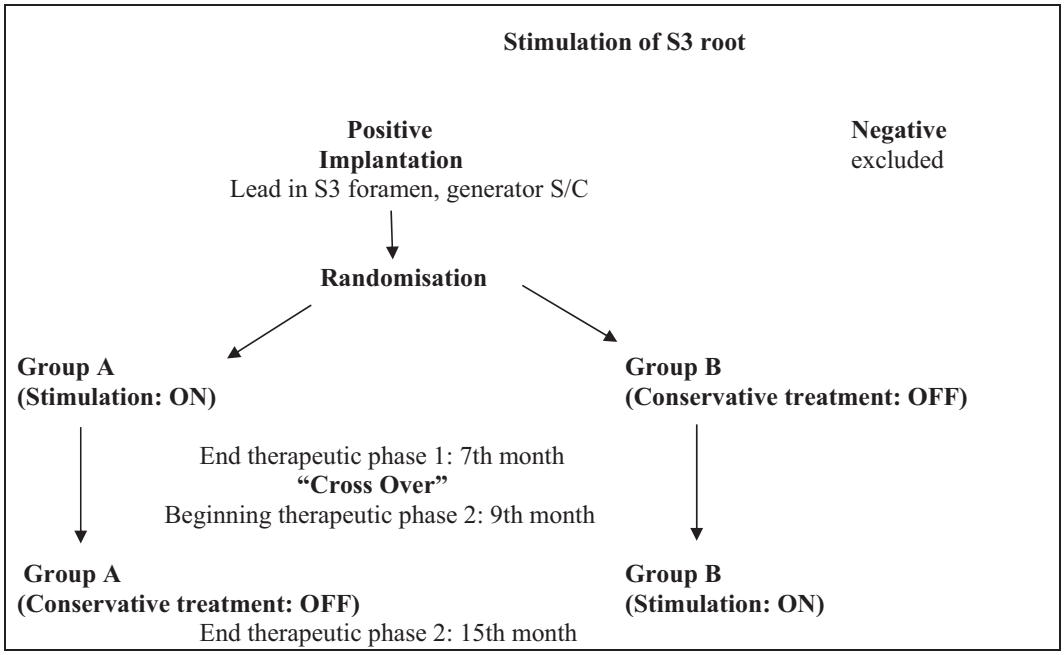
Written informed consent was obtained from the parents and patients according to age. The study protocol was approved by a French ethics committee and registered as a clinical trial (AFSSAPS 2005/04/003) at the French Ministry of Health.

Implantation Technique

As described previously, S3 roots were stimulated percutaneously with the patients under general anesthesia.[9] If responses were acceptable, the neurostimulation device and lead were implanted immediately. The test stimulation period used in adults was not applied because we consider it too short to induce a response in children with neurological conditions. Patients were discharged home after 48 hours, provided that general status and pain level allowed.

Randomization

A randomization list was generated by computer using a permuted block design. Subjects were randomly assigned to 1 of 2 neuromodulation groups, 6 months ON followed by 6 months OFF (group A) or the opposite sequence (group B). The 2 phases were separated by a 45-day washout period to return to baseline status (see figure).



Study design