Sacral neuromodulation in the treatment of severe anal incontinence

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SUMMARY

Introduction — Sacral neuromodulation is a recognized therapeutic option in severe anal incontinence from neurogenic origins, when medical treatment has failed.

Methods — We report the results of this procedure applied in 40 consecutive patients operated on by a single surgeon from August 2001 to June 2004. Mean duration of incontinence was 5 years. There were 33 women and 7 men of mean age 59 (range 29-89). All patients had had medical treatment, 26 had had physical therapy and 9 had been previously operated on for that problem. Neuromodulation consisted in a temporary electrical stimulation test followed by implantation of a stimulator in case of efficacy.

Results — Twenty nine patients had a positive test and were implanted. Ten had a negative test and one is waiting for implantation. From the 29 patients, 23 had an evenful postoperative course. Incontinence score varied from 17 before neuromodulation to 6 after in the 24 patients who were improved. Mean resting pressure, mean maximum squeeze pressure and mean duration of squeeze pressure did not change from pre to postoperative period.

Conclusion — Sacral neuromodulation is a safe and efficacious procedure in properly selected anal incontinent patients. However, we observed no correlation between clinical and manometric data.

RÉSUMÉ

La neuromodulation sacrée dans le traitement de l’incontinence anale sévère : à propos de 40 cas consécutifs traités dans une seule institution

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Méthodes — Nous rapportons les résultats de ce traitement chez 40 malades consécutifs traités par le même chirurgien entre août 2001 et juin 2004. La durée moyenne de l’incontinence était de 5 ans. Ils s’agissait de 33 femmes et 7 hommes, d’une moyenne d’âge de 59 ans (29-89). Tous les malades avaient eu un traitement médical, 26 une rééducation et 9 une intervention chirurgicale. La neuromodulation consistait en un test temporaire de stimulation sacrée, suivi en cas d’efficacité par l’implantation définitive d’un neurostimulateur.

Résultats — Vingt-neuf des 40 malades ont eu un test positif, qui a conduit à l’implantation définitive. Parmi les 11 autres malades, 10 ont eu un échec de la stimulation externe et le onzième attend l’implantation. Parmi les 29 malades, 23 ont eu des suites simples. L’incontinence anale, jugée sur le score de Vaizey, est passée de 17 à 6 après l’implantation chez les 24 malades ayant eu une amélioration. La pression moyenne de repos chez ces malades est passée de 57 à 46 cm d’eau (NS) et la pression moyenne de contraction de 92 à 84 cm d’eau (NS). La durée moyenne de contraction volontaire est passée de 19 à 18 secondes (NS).

Conclusions — La neuromodulation est une technique sûre et efficace chez les malades incontinents sélectionnés. Cependant, il ne semble pas y avoir de corrélation entre les résultats cliniques et les résultats manométriques.

Introduction

Surgical treatment of anal incontinence includes direct repair of the sphincter in case of rupture [1, 2], substitution of the sphincter by muscle plasty which may be dynamic [3] implantation of an artificial sphincter when the sphincter cannot be repaired, [4] and for the last ten years or so, sacral neuromodulation, which is mainly indicated in anal incontinence from neurogenic causes [5].

The first implantations of a stimulator for sacral nerve neuromodulation were performed in 1981 for the treatment of certain types of effort induced urinary incontinence and certain dysurias [6]. The efficacy of this technique on anal incontinence was discovered nearly fortuitously in patients treated for urinary incontinence who showed improvement of their associated digestive symptoms [7]. As a result neuromodulation was proposed in 1995 in the treatment of anal incontinence alone [5].

We report the surgical and functional results of this treatment in 40 consecutive patients with severe anal incontinence who did not respond to other techniques.

Patients and methods

From August 2001 to June 2004, 40 patients including 33 women, an average of 59 years old (range 29-89) underwent a test period of sacral nerve stimulation for severe anal incontinence that had lasted for an average of at least 5 years (range 1-31 years). All patients had
already received medical treatment associated with a diet and 26 had received biofeedback training. Nine of the patients had already undergone surgery for anal incontinence (two requiring more than one intervention) that had been effective from a morphological standpoint, and four underwent dynamic muscle plasty before neuromodulation came into use. The cause of anal incontinence is summarized in Table I.

**Methods**

Neuromodulation includes two surgical steps which can be performed under general or local anesthesia.

The first step involves implantation of a finned electrode into the 3rd or 4th right or left sacral roots, with the patient in the decubitus ventral position, their feet off the table with the perianal region in the operating field. The correct positioning of the electrode is defined clinically and by an X-ray of the profile under a brilliance amplifier. Clinically, successive stimulation of the 4 contacts of the electrode by an external electric stimulator administering 1 to 10 volts should cause a sensation in the perineum which is difficult to describe (and which is obviously absent under general anesthesia), an anal contraction associating closure and leaving the frequency around 10 Hz. A detailed record of all stools is then attached to an extension, connected to the external stimulator and emerging from the supero-external quadrant of the controlateral buttock. The patient is then rapidly and easily trained to use the external stimulator at home and during all normal activities. The patient must wear the stimulator night and day on his waist, increasing the voltage to maximum amplitude and leaving the frequency around 10 Hz. A detailed record of all stools is necessary, including a clinical examination and questions to determine the Vaizey score [8], pelvic examination, endoanal ultrasound, anorectal manometry and an electromyogram. Other examinations may be performed if necessary: dynamic colposcopic endoscopy (to eliminate the presence of a static or dynamic pelvis) [9], a colon transit (in case of rectal bleeding, transit problems or a family history of cancer), colon transit time (to differentiate transit constipation from dyschezia, for example), sacral X ray (if a traumatic, tumoral or other bone lesion is suspected), pelvic Tomodensitometry, MRI, or an MRI of the medullary canal (if a medullary lesion is suspected). These examinations can then lead to more sophisticated tests (EMG of the lower limbs, if neurological disease is suspected for example).

After the second operation, all the patients were seen at 1, 3, 6, 12, 18 and 24 months. Besides a clinical examination to establish the Vaizey score, manometry was obtained during the 3rd and 6th months. If electrode displacement was suspected, three dimensional sacral TDM was performed.

### Statistical Analyses

All the quantitative data were compared using the Wilcoxon test.

### Results

#### Surgical results

None of the patients were lost to follow up. Twenty nine of the 40 patients tested for severe anal incontinence had implantation of a neurostimulator. There were no deaths.

After the first intervention, there was no morbidity in any of the 40 patients. Most complications occurred after the second intervention. Infection at the remote control site resulted in removal of the implant in two cases; in one obese patient with diabetes that had not been stabilized; despite the infection, the patient insisted on keeping the stimulator for 9 months because it was effective. The surgeon convinced her to remove the implant, and a new implant was successfully put in place 11 months later. In the fifth case, sudden worsening of the functional score was suspected for example).

### Table I. – Causes of anal incontinence.

<table>
<thead>
<tr>
<th>Cause</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pudendal neuropathy</td>
<td>16</td>
</tr>
<tr>
<td>Idiopathic incontinence *</td>
<td>7</td>
</tr>
<tr>
<td>Cauda equina syndrome</td>
<td>5</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>3</td>
</tr>
<tr>
<td>Sphincter repair</td>
<td>3</td>
</tr>
<tr>
<td>Other **</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>40</td>
</tr>
</tbody>
</table>

* Incontinence was considered idiopathic when there was no identified organic cause and the EMG did not show any increase in the distal latency of the pudendal nerve.

** Radiation and postoperative fibrosis; 2: rectoscopy; 1: stroke; 1: sacral resection ; 1 and traumatic medullary lesion ; 1.
new electrode, 3 years and five months after the first implantation. This may be because the configuration of the parameters of the four electrode contacts were not optimal — the electrode was not in a good position — so that an elevated amplitude (more than 3 volts at all times, and up to 8 volts) was necessary for effective neurostimulation.

**Functional results**

Anal incontinence improved in twenty four of the 29 implanted patients at the sixth month of follow up. In these patients, the Vaizey score went from an average of 17/24 before the test to 6/24, six months after implantation of the stimulator. Details for each patient are found in figure 1. Of the 11 patients who underwent the test but who were not implanted, the indication was considered inappropriate in 5 cases a posteriori. The first patient had become incontinent after undergoing radiotherapy and a proctectomy followed by a coloanal anastomosis complicated by suppuration. The second patient presented with moderate anal incontinence from a pudendal neuropathy associated with perineal-buttocks pain which was not relieved. The third patient was 89 years old, with anal soiling cause by severe dyschezia with the development of scatomas requiring laxatives. Besides anal incontinence, the fourth patient had numerous sequelae from a rectopecty by laparotomy for rectal prolapsus, performed in another institution. The fifth patient had anal incontinence with radiation induced rectitis. These five cases were among the first 20 patients. Five other patients who underwent an external neurostimulation test were considered to be real failures, because there was no reduction in the number of anal leakages or less than 50% reduction in the number of anal leaks when the electrode was functioning and correctly placed. The eleventh patient is waiting for implantation.

The alleged clinical improvement of 24 patients based on the Vaizey score was not accompanied by improvement in manometric parameters (table II). The average resting pressure, the average pressure during voluntary squeezing and the average duration of this contraction were even lower after implantation of the stimulator than before the test.

**Discussion**

The indications for neuromodulation were recently described in a review of the literature performed by Jarret et al. [10]. In this same paper the authors identified 106 articles on the subject of sacral neuromodulation for the treatment of anal incontinence. When only those articles that responded to strict, well defined criteria were taken into account, 29 series were studied including 266 patients. All of these patients received all possible medical treatments. One hundred nine of them (56%) had a permanent stimulator, and the rate of implantation of the different teams varied from 55% [11] to 80% [12]. Our series confirms these data with a rate of implantation of 72.5%. The average age of patients in our series was similar to that in published series. The percentage of women in our study (82.5%) was also similar to rates reported in the literature (70 to 88%).

Incontinence improved in eighty three percent of the patients implanted in our study, but the Vaizey score did not reach zero in any of them. Our results were not as good as those in the literature, since certain teams showed a return to normal continence in...
41 to 75% of cases [10]. The first explanation is that incontinence for gas persisted in some of the patients in our study resulting in significant discomfort, especially socially. The second reason could be because many of our patients continued to use protection, either out of habit or unfounded fear (which they admitted to) or because of persistent urinary incontinence, although there was no anal soiling in any of these cases. The third explanation is that we used a very sensitive score of anal incontinence and although patients often noted a reduction in the number of stool leaks, and an improvement in their well-being, this was not true for incontinence for gas and the use of protection. The improvement would have been considered more significant (but perhaps less real?) if we had simply considered the reduction in the number of loss of stools during the study period, like for example Rosen [12] or Vaizey [13].

In this study the clinical improvement was not associated with a manometric improvement. Stimulation of the sacral nerve, in particular during the test electrode implantation acted directly on the pudendal nerve resulting in a contraction of the anal sphincter apparatus. But chronic stimulation at a low frequency (around 15Hz) probably acts on several levels and on both the efferent and afferent nerves [14]. In fact, the physiological explanation for the efficacy of neuromodulation on anal incontinence is not clear [11]. Considering the great variations in manometric results found in the major published studies: 5 studies show an increase in resting pressure and voluntary contraction pressure [12,15-18], 6 studies show an increase in the contraction pressure alone [5, 11, 13, 19-21] and two studies do not show any significant modification in resting or contraction pressures [14, 22], like our series. Neuromodulation probably acts by a complex mechanism associated with stimulations and inhibitions in varying degrees; actions on the anal sphincter as well as the upper colon, modifications in rectal motricity, but also of its sensitivity and of compliance [14]. Other studies on should be performed to investigated physiological criteria with more of its sensitivity and of compliance [14]. Other studies on should be performed to investigated physiological criteria with more sensitivity and compliance. Other studies on should be performed to investigated physiological criteria with more sensitivity and compliance.

In conclusion, neuromodulation of the sacral nerves seems to be a safe and effective technique for the treatment of anal incontinence in selected patients. However, there does not seem to be any correlation between clinical and manometric results. Other physiological studies should be performed for a better understanding of the mechanism of action.

REFERENCES

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