ICON

INDIAN
CONTINENCE
FOUNDATION

ICON

Vol.2 No.1 July 2000

EDITORIAL

In the first two issues of ICON, we had covered the currently acceptable Urodynamic terminology - the first stepO towards achieving standardisation of Urodynamic practice. We had also featured an exposition on the parameters for assessing outcome of therapies for Benign Prostatic Hyperplasia.

Persons with Neurovesical dysfunction, and those treating such patients, have waited for technology to yield a tool that would substitute their deranged neural mechanisms. The ideal substitute would be a living image of what nature has - but that would be out of question. Technology has yet to come up with circuits so intricate, feedback so sensitive and responses so accurate as to imitate nature. In this issue, we cover the present status of electrical neuromodulation of the sacral nerves with implantable devices. Both the material and the technology need further refinement and we are optimistic that will happen.

We also carry in this issue a critique of a new therapeutic modality - Magnetotherapy. This is a novelty in Neuro-urology. The first work will obviously stir up an animated debate; we will have to wait a while before the last word emerges on its efficacy and applications.

Designating a parametric attribute to physiologic functions is a vexing task in medical science. Micturition is no exception to this. We carry the normal ranges for some of the voiding functions, as culled from different sources.

We hope this issue continues to provoke and interest you. As always, we welcome your comments and criticism. Do write to us, and let us know what you think.

K. Sasidharan
Manipal

"MODULATION OF BLADDER FUNCTION THROUGH ELECTROSTIMULATION"

"Featured here is an adaptation of M.M. Hassouna's article in International Continence Survey (Vol.7 No.1). This is an exciting new area in Incontinence as well as bio-medical engineering. We are sure to hear more of this every year."

The urinary bladder has two functions: storage and elimination. Although the detrusor and the bladder outlet are two distinct entities, their function depends on a complex central neural network that renders their functions susceptible to any alteration in the nervous system. The lower urinary tract has two functional units dedicated to the storage and periodic elimination of the urine.

However, urodynamic studies have shown that a physiological internal sphincter is responsible for maintaining urinary continence through closure of the bladder neck and the proximal urethra. The continence mechanism is thought to be dependent on several factors, such as elasticity of the urethral wall, the calibre of the urethral lumen and the functional length of the urethra.

Normally, the periurethral striated muscle fibres are not essential for maintaining continence. However, some of these striated muscle fibres are recruited if the bladder neck has been damaged, or under physiological circumstances such as straining or a sudden increase in intra-abdominal pressure. The periurethral striated muscle fibres play an important role in continence and the initiation of voiding.

Neurostimulation of the bladder is discussed according to whether the voiding dysfunction is secondary to spinal cord injury (Neurogenic bladder), or if it occurs in a patient with an intact spinal cord. Based on this classification, stimulation of the sacral nerve roots has two distinct actions:

1. To induce direct evacuation of the bladder, particularly in patients with supra-sacral spinal cord injury;
2. A modulatory effect on the behaviour of the bladder, i.e. to control unnecessary detrusor instability or to improve bladder voiding in-patients with an otherwise normal spinal cord.

PERCUTANEOUS NERVE EVALUATION TESTING

Not all patients presenting with voiding dysfunction will benefit from a permanent implant of a neuro-stimulator. A screening test is recommended to maximise the number of good responders. Schmidt et al introduced the Percutaneous Nerve Evaluation (PNE) test in the 1980s. The test is carried out as an outpatient procedure under local anaesthesia and helps to assess the integrity of the sacral reflex arc of the second and third nerve roots.

SURGICAL TECHNIQUE

The patient is placed in the prone position with a 30º flexion at the hip and knees, with the knees and ankles supported using pillows. The lower part of the back including the sacrum and the coccyx are draped and prepared. The anal region and the feet are left exposed for monitoring any muscular activity.

The greater sciatic notch and the superficial curvature of the sacrum are identified by palpation. A skin mark is made two finger-breadths above and medial to the greater sciatic notch, corresponding to the foramen of S3. The border of the sacrum is also marked. Each foramen is probed gently before 1% lignocaine is injected around it. A specially designed, insulated needle (Medtronic ® Foramen Needle 20 gauge, Medtronic Inc; Minneapolis, USA) is inserted in the foramen corresponding to the S3 nerve root. A 30-40º angulation of the needle is sometimes necessary to reach inside the foramen. Fluoroscopy can be used to verify the position of the needle. This is particularly helpful in obese patients, or when there is doubt about the location of the sacral foramen.

Once the needle has been judged to be positioned correctly in the foramen, a monopolar electrode is hooked to it and then connected to a stimulator (Medtronic® Screener model 3625). This delivers monopolar pulses that can be adjusted to a maximum of 10 volts, at a fixed rate of around 20-25 pulses per second. The amplitude is gradually increased until either the patient feels sensations around the rectum or the vagina, or an appropriate contraction of the levator ani is elicited. Occasionally, stimulation of the S3 foramen will have a clamp-like effect on the anal canal, eliciting ventriflexion of the toes of the ipsilateral foot. Appropriate stimulation of the S3 foramen will result in a bellow movement of the anal canal with sensation referred to the inside of the rectum or the vagina.

In patients with complete spinal cord injury (paraplegic or quadriplegic), the intravesical and intraurethral pressures are recorded during the stimulation. In these patients, stimulation has to be increased to > 10 volts to increase intravesical pressure by at east 15 cmH2O.

Patients who show an increase in bladder pressure and ability to void during the stimulation are good candidates for permanent implantation of the anterior nerve root stimulators. Such patients are usually paraplegic and have a supra-sacral complete spinal cord injury.

Stimulation trial

Patients with an intact spinal cord who demonstrate appropriate levator ani function are given a trial period of stimulation for 4-5 days. A 3-0 Flexon ® wire (Davis & Geck Inc., Danbury, USA) is inserted through the needle, after discarding the attached needles, and then allowed to coil around the S3 nerve root. The needle is removed and the wire is meticulously taped onto the skin of the back and connected to an external pulse generator (Medtronic® Screener) for 3-7 days. The patient fills out a detailed voiding diary describing the frequency of voiding, degree of urgency and number of episodes of incontinence, if applicable. If the wire moves during this period, steps are taken to re-establish the correct position.

The location and number of temporary wires inserted can vary from patient to patient depending on the degree of voiding dysfunction, associated pelvic pain and the skill of the urologist. If the trial proves successful in terms of patient response, the wire is taken out at the end of the trial and the patient is considered to be a good candidate for a permanent implant. It is generally preferable to wait for the original symptoms to return to the baseline level (i.e. before the PNE test) before implanting a permanent neurostimulator.

IMPLANTATION OF A NEUROSTIMULATOR IN PATIENTS WITH AN INTACT SPINAL CORD

The procedure is carried out under general anaesthesia. After endotracheal intubation, a catheter is left in the bladder during the procedure

for drainage. The patient is transferred to the prone position on a laminectomy frame and a beanbag.

Before making any incision, the greater sciatic notches are identified on each side. The level of the S3 foramen is identified with a skin marker. A midline incision, of no more than 10 cm, is made in the skin, with two-thirds of the incision above the level of the S3 foramen. The incision is taken down to the underlying lumbodorsal fascia. Probing the fascia with an insulated needle identifies the level of the S3 foramen. The attachment of the gluteus maximus is of great help in locating the S3 foramen - the foramen usually lies at the upper border of the gluteus maximus. Once the foramen has been identified, monopolar stimulation is delivered to the S3 nerve root and the levator ani action is recorded. It is preferable to use the side that showed a good response during the PNE trial.

Once the site of the S3 foramen is decided upon, the thoracolumbar fascia is incised longitudinally about 1.5 cm laterally to the midline. The paraspinous muscles lying underneath the fascia are separated longitudinally by blunt dissection. Care must be taken to avoid any injury to the periosteum overlying the sacrum. The membrane covering the foramen is then pierced and a permanent electrode (Medtronic ® Lead model 3080) is inserted through the opening into the S3 foramen. The electrode is directed laterally once it has entered the foramen; studies on cadavers have shown that the ventral root of the sacral nerve deviates laterally as it exits through the ventral foramen.

The position of the variable contacts on the permanent electrode is tested by stimulation and by visual recording of the activity of the levator ani. After satisfactory electrode positioning, a specially designed collar is attached to the permanent electrode using non-absorbable sutures. This collar is then tacked down to the periosteum above the level of the S3 foramen. Every effort should be made to fix the collar to the periosteum properly; the various contact points of the electrode should be checked again. Responses should be obtained in the range 0.5-2mA.

The free end of the electrode is inserted through a separate incision in the lumbodorsal fascia, and then tunnelled beneath the skin to a point above the iliac crest midway between the anterior and the posterior iliac spine. The incision is then closed, the patient is turned to the lateral position and a subcutaneous pouch is created for the neurostimulator at the level of the umbilicus. For ease and accessibility, the patient would have chosen the site himself/herself.

PATIENT SELECTION

Patients who will benefit from the implantation of such a neuroprosthesis are those with:

1. Urge incontinence;
2. Chronic retention with no evidence of neurological disease;
3. Frequency and urgency with minimal incontinence;
4. Pelvic pain combined with any of the above.

ELECTRICAL STIMULATION OF SACRAL ROOTS FOR MICTURITION IN SPINAL CORD INJURY PATIENTS (BLADDER PACEMAKER)

Surgical technique

The patient is positioned in the supine position. After the induction of anaesthesia, a specially designed catheter with two microtip transducers is inserted via the urethra. The transducers are connected to a polygraph to record the changes in intravesical and intraurethral pressure. The catheter is drawn gradually and slowly through the urethra until the proximal transducer lies in the area of the external sphincter, as shown by increased pressure readings.

A sacral laminectomy is made extending from S1 down to S3, which will expose the various sacral nerves. Neurostimulation is used to identify the nerves that are capable of producing a detrusor contraction, as shown by changes in intravesical pressure. The bladder volume should be kept at around 200-250 ml. The S3 roots are invariably the principal nerves concerned with bladder innervation. Dorsal rhizotomies are carried out bilaterally, for both S2 and S3, to increase bladder compliance and reduce the chance of a concomitant sphincteric contraction when the S3 nerve is stimulated.

In certain cases, intradural separation has been performed via a small incision in the terminal dura

and combined with extradural electrode placement. However, both steps can be performed intradurally. In the latter situation, careful closure of the dura must be carried out to minimise cerebrospinal fluid-related complications.

Electrodes (cuff or spiral) are placed on each of the S3 ventral roots, as well as on any nerve root that has been found to give significant bladder contraction 915 cmH2O) with the stimulation. The electrodes are then connected to a pulse generator (Medtronic X-TREL ® which is tunnelled under the skin to a location in the flank that is convenient for the patient's comfort and accessibility. The implanted stimulator has no batteries and is powered and controlled by radio transmission from a portable controller operated by the patient.

Brindley performed his procedure completely intradurally, with intradural division of the posterior roots of S2 through S5. In rare cases, selective peripheral neurotomy of the Pudendal nerve is carried out by a separate approach. Internal sphincterotomy has been tried in those patients having severe outlet spasticity in an attempt to reduce the outlet resistance.

RESULTS

Voiding dysfunction with intact spinal cord (foramen implant)

Most patients in this category have urge incontinence and have previously been treated unsuccessfully with Anticholinergics, pelvic floor exercises and bio-feedback. Patients who do not respond to these conventional lines of treatment are often offered more invasive procedures such as augmentation ileocystoplasty, bladder transection, transvesical phenol injection and even urinary diversion.

Neurostimulation of the sacral nerve root has been shown to be effective in controlling symptoms on a long-term basis in these patients. In 1991, Thon et al reported the results of 57 patients followed up for a minimum of one year after implantation of a neurostimulator. Of these, 32 patients showed marked improvement, defined as 75-100% benefit. These patients had a combination of urge incontinence, urinary retention and urge frequency with and without pelvic pain.

In a subgroup of patients presenting with chronic urinary retention, S3 stimulation proved to be effective in restoring normal voiding. These patients had an intact spinal cord but were not able to trigger a voiding reflex. By stimulating S3, the patients were able to trigger a voiding reflex in the presence of a completely normal motor pathway. Two separate studies showed that chronic nerve stimulation of S3 resulted in voiding with near complete emptying, provided that patients felt the stimulation.

The underlying pathological mechanism in this subset of patients is not understood clearly; it is believed to be related to the fact that the patients are not aware of the pelvic floor muscles. Neuromodulation results in an increased awareness of the pelvic floor muscles, which enables voluntary relaxation of the levator ani and initiation of voiding.

In Europe, experience with neuromodulation of the S3 nerve has been favourable. In 1993, Dijkema et al presented a study of 23 patients implanted with a neuroprosthesis connected to the S3 nerve root to modulate bladder function. All patients had voiding dysfunction in the form of incontinence, urinary retention and chronic pelvic pain. Nineteen of the 23 patients showed a 50% improvement in their predominant symptoms, an objective increase in functional bladder capacity from 135 to 227 ml and a decrease in the number of leaks from 7.4 to 1.5 times per 24 hours. They were followed up for 12 months.

In 1995, Bosch et al presented their experience of a similar technique in 18 patients. The average follow-up was 29 months. They showed that stimulation of the S3 significantly decreased the average voiding frequency and the number of pads used. An improvement in urodynamic parameters was seen; however, the correlation between symptomatic and urodynamic improvement as incomplete.

Another study is based on 23 patients with implanted stimulators. The first 17 patients were followed up for 52 months, with pre-operative and post-operative evaluations of quality of life questionnaires, voiding diaries and urodynamic evaluations. There was a remarkable improvement in quality of life as well as the number of leakage episodes per day.

To date, several theoretical models exist to explain the mechanism of neurostimulation in humans with

chronic lower urinary tract dysfunction. One theory is that bladder overactivity is due to a defective or insufficient central inhibitory control system. Electrical stimulation of the pelvic floor might enhance inhibition of detrusor activity by reinforcing alternative inhibitory systems.

Other authors attribute the detrusor overactivity to an insufficient striated urethral sphincter tone. Enhancing the sphincter tone through electrical stimulation would suppress the irritable detrusor muscles by enhancing reflex inhibitory response.

Bladder overactivity may also result from an imbalance between stimulatory and inhibitory reflex mechanisms. In animal studies, intravesical electrical stimulation directly activates the afferent bladder mechanoreceptors (Ad fibres) which may elicit a reflex detrusor contraction. In patients with chronic urinary retention, electrical stimulation of the spinal roots through the sacral foramina is also believed to activate these mechanoreceptor afferents.

SACRAL NERVE STIMULATION TO INDUCE BLADDER EVACUATION IN PATIENTS WITH SPINAL CORD INJURY

Over the past 20 years, stimulation of the anterior sacral nerve root has been used extensively in patients with a suprasacral spinal cord lesion. The essential requirement in selecting a patient for an implant is that he/she must have intact parasympathetic efferent fibres in the sacral anterior roots that are capable of producing bladder contractions. The lesion(s) must also be complete suprasacrally because patients with incomplete lesions might be sensitive to the amount of electrical stimulation used.

The main problem with this technique is the simultaneous contraction of the urethral sphincter when the sacral nerve roots are stimulated. To overcome this problem, posterior rhizotomies of S2 and S3 are usually performed during the procedure. Posterior rhizotomy has been shown to significantly increase the bladder capacity by reducing the bladder spasticity; however, it's disadvantage is the development of erectile dysfunction in men who are otherwise potent.

In a study by Schmidt of 27 patients with suprasacral cord lesions varying between the cervical and the upper thoracic spinal segments, 10 patients showed >90% improvement in their voiding capabilities. Of the patients studied, 64% were continent following the implant. The patients were followed up for 5 years and there were no adverse long-term consequences. In the long-term, a mean increase in bladder capacity of 375% was seen. The spastic responses were dampened, but not completely eliminated, after dorsal rhizotomy.

In 1990, Brindley presented the results of his first 50 patients to receive a sacral anterior nerve root stimulator for bladder control; follow-up varied from 5 to 11 years. Of the 50 patients, 29 had no symptoms of urinary tract infection, 41 used the implant regularly for micturition, and 37 patients were always, or usually always, continent. Side effects were minor. In 1994, Brindley updated his series to include 500 patients, representing one of the largest series in the world to use the stimulator to evacuate the bladder. The results were impressive.

In a recent report from The Netherlands, 47 patients had implantation of the Finetech-Brindley anterior sacral root stimulator together with posterior rhizotomy. The patients were followed for a minimum of 6 months. Complete continence was attained in 43 of the 47 patients. A significant increase in bladder capacity was noted in all patients. The reduction in postvoid residual volume resulted in a significant reduction in the incidence of urinary tract infection.

Conclusion

Electrical stimulation of the sacral nerve roots has been shown to be a beneficial and promising treatment in patients with chronic voiding dysfunction. In selected patients with suprasacral spinal cord injury, electrical stimulation of the sacral nerve roots can produce micturition with minimal residual volume of urine, and hence reduce the incidence of urinary tract infections. In occasional cases, external sphincterotomies with or without dorsal rhizotomies will increase the bladder capacity and reduce the outlet resistance.

The technology has been in use for the past 15 years with no evidence of damage to the nerve roots from long-term stimulation. With technological advances in microprocessors and electrodes, an even lower rate of technical failure of the implantable device is anticipated in the future.

VOIDING DYSFUNCTION IN MALES: URODYNAMIC EFFECTS OF FUNCTIONAL MAGNETIC STIMULATION

(Original article: Neuromodulation of detrusor hyper-reflexia by functional magnetic stimulation of the sacral roots. *Sheriff MKM, Sah PJR, Fowler C, Mundy AR, Craggs MD.*)

We carry a review of an article contributed to the Br J Urol (78 : 39 - 46). In the ever increasing search for a solution to the problems of voiding dysfunction, this modality was used by Alternate systems extensively. It is now entering the realm of modern systems, too.

Summary

This study investigates the acute urodynamic effects of functional magnetic stimulation in seven male patients with a complete suprasacral, lower thoracic spinal cord injury and established detrusor hyper-reflexia, which was refractory to anticholinergic drugs.

The authors found that supramaximal magnetic stimulation (20 pulses for 5 seconds) with a coil placed over the S2-S4 roots on one side of the sacrum resulted in a profound suppression of detrusor hyperreflexia. The area under the detrusor pressure curves could be reduced by 82.6 – 92.6%. The reduction was most profound if stimulation was begun at a detrusor pressure of about 15 cm H2O. When the stimulation was started at about 70 cm H2O, the reduction was less than 50%. The efficacy of stimulation in suppressing hyperreflexia decreased almost linearly with increasing detrusor pressure at moment of initiation of the magnetic stimulation.

Comment

This is an interesting study of the role of magnetic stimulation as a treatment modality aimed at bladder inhibition. However, before this technique can be applied clinically and on a larger scale, several problems need to be resolved.

Because continuous magnetic stimulation does not seem to be feasible as yet, the authors have used supramaximal stimulation. The efficacy of this type of stimulation depends very much on its timing, i.e. the particular pressure in the bladder when the stimulation was given. It would therefore be necessary to insert an intravesical pressure sensor that could trigger the stimulation in order to adapt this technology for chronic application in patients with detrusor hyperreflexia. If acute supramaximal stimulation were to result in a more persistent effect, as occurs with electrical neuromodulation, then the immediate future of this technique would certainly look promising.

The authors state that they are now investigating the chronic effects of magnetic neuromodulation. However, we are not aware of any convincing studies that have shown such a chronic effect in patients with detrusor hyperreflexia as a result of spinal cord injury, as opposed to patients with idiopathic detrusor instability. If such a chronic effect could be demonstrated in spinal cord injury patients, this would be a significant breakthrough.

The authors also mention another possible role of this technique, i.e. as a means of assessing patients for implantable devices for electrical neuromodulation. Electrical neuromodulation with implantable electrodes is a more selective technique in which an electrode is implanted in one sacral foramen, preferably S3. The feasibility of this technique has been shown in patients with idiopathic instability and in patients with detrusor hyperreflexia due to multiple sclerosis. A favourable response to magnetic stimulation of S2-S4 would not necessarily predict an equally good response to the more selective unilateral electrical S3 spinal nerve stimulation.

No response to magnetic stimulation would probably also mean no response to electrical stimulation, although further studies would need to be carried out to establish firmly such a correlation. This technique could also be of possible value in attempting to empty the bladder in a non-invasive way in patients with spinal cord injury. When used in this way, there would be no need for a chronic effect.

NORMAL VALUES IN URODYNAMICS

UROFLOW

PEAK FLOW RATE (Qmax)

Group	Normal (ml/s)	Author
All persons	> 20	Kiesswetter (1981)
Persons with catheter	> 15	Jones et al. (1980)
Male	24 (±8)	Palmtag (1977)
Age < 40 years	> 22	Abrams et al. (1990)
Age 40 - 60 years	> 16	Abrams et al. (1990)
Age > 60 years	> 13	Abrams et al. (1990)
Age > 60 years	15.6 (± 6.5)	Neubauer et al. (1992)
Female	> 26 (± 8)	Palmtag (1977)
Age < 50 years	> 25	Abrams et al. (1990)
Age > 50 years	> 18	Abrams et al. (1990)
Children*	23 (± 10)	Palmtag (1977)
Age < 10 years	> 15	Siroky et al. (1990)
Age 10 - 20 years	> 20	Siroky et al. (1990)
* girls	34.3 (±7.2)	Toguri et al. (1982)
* boys	25.9 (± 7.3)	Toguri et al. 91982)
*(micturition volume > 175 ml, body size < 1.1 m^2)		

AVERAGE FLOW RATE (Qavg)

Group	Normal (ml/s)	Author
All persons	10 - 15	Kiesswetter (1981)
Persons with catheter	> 7.5	Jones et al (1980)
Male Age > 60 years	7.8 (±3.2)	Neubauer & Melchior (1992)
Children* *Girls*	14.1 (±3.3)	Toguri et al (1982)
Boys	19.5 (±3.6)	Toguri et al. (1982)
*(micturition volume > 175 ml, body size < 1.1 m^2)		

TIME TO PEAKFLOW

Group	Normal	Author
All persons	<33% of voiding time	T. Poll and G. Frohlich

VOIDING TIME

Group	Normal (s)	Author
Male	24 (±8)	Palmtag (1977)
Age > 60 years	26.2 (±13.9)	Neubauer & Melchior (1992)
Female	23 (±8)	Palmtag (1977)
Children	16 (±10)	Palmtag (1977)

RESIDUAL URINE

		Author
Normal < 15% of maximal bladder Capacity		Jones et al. (1980)
Normal 10 - 30 ml		
Abnormal > 100 ml		

ANNOUNCING OUR WEBSITE LAUNCH

We are happy to announce the launching of the Indian Continence Foundation website - www.indiancontinencefoundation.org. The site will be operational by the end of July 2000. We welcome all of you to visit us there.

The site has been developed to provide an extended platform for discussing issues associated with continence and related subjects. It is our vision that the site will not only provide members of the public & professionals with the latest information, it will also bring together all persons working in this area together.

Some of the highlights of the site are:

1. Public information on Incontinence and related subjects
2. List of Incontinence experts in India, city-wise
3. Directory of Institutions providing investigative and therapeutic facilities for Incontinence patients
4. Directory of manufacturers of pharmaceutical products used by Incontinent patients
5. Directory of manufacturers of incontinence appliances
6. Listing of Periodicals and Journals on the subject
7. Book-reviews and critiques
8. Practice guidelines as laid down by the I.C.S. and other bodies
9. Medical content in related areas of Urology, Neurologic sciences, Gynaecology and Behavioural science.

We invite contributions from readers on any of these subjects. Submissions may be electronically transmitted, or mailed to our office. We also wish this website to provide a platform for academic interaction between Indian professionals, and those in other countries. To this end, we request you to send us the names and details of your colleagues and contacts abroad who are working on Incontinence and related areas. We shall include them in our directory, too.

We await your responses, and participation in the evolution of the website - www.indiancontinencefoundation.org.

The Indian Continence Foundation is organising a course "Current Management of Incontinence" for Nurses and Care-providers on 24th and 25th November 2000 in Bangalore. It will be an interactive platform of Lectures, Demonstrations and practical problem solving sessions For further details kindly contact

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We welcome readers' comments & suggestions about this publication. Please write to the address given below

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This Publication is supported by an Educational Grant from **Pharmacia & Upjohn**

Printed and published on behalf of

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