

Electrical Stimulation Of the Paraplegic Bladder

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DESPITE SIGNIFICANT improvements within the last 20 years, in both patient care and antibiotic therapy, the major cause of death among victims of paraplegia is still urologic disease.

In addition to this everpresent threat, many paraplegics live with chronic high urine residuals and concomitant urinary infections and suffer, as well, the embarrassment caused by lack of voluntary control of micturition.

The estimated 150,000 paraplegics in the United States, therefore, challenge the physician to consider more ingenious methods than those of enhanced drug regimens and improved patient management as the sole means of prolonging life. Spurred on by the miniaturization of electronic circuitry, investigators have begun a series of investigations into the feasibility of using electric stimulation for the treatment of neurogenic bladders.

Our own research, begun in 1962, at the Surgical Research Laboratory of Maimonides Hospital of Brooklyn, State University Downstate Medical Center, consists of a series of studies, experimental and clinical, using an implantable radio-linked bladder stimulator.

Developed in collaboration with the Avco-Everett Research Laboratories of Everett, Massachusetts, the stimulator consists of an electronic unit in two separate parts. The transmitter portion, shaped like a boy-scout flashlight, is powered by four 9 volt batteries that transmit voltage

at 100 kilocycles per second with a 20 cycle modulation. This compact unit with its simple push button can be operated easily by any dextrous patient. The receiving unit is implanted in a subcutaneous pocket created in the patient's abdomen during a relatively simple operative procedure under general anesthesia.

The disc-shaped receiver is approximately $\frac{1}{3}$ " thick and $1\frac{1}{4}$ " in diameter. Coated with silicone rubber, it is well tolerated by the body and the implantation procedure eliminates the need for transcutaneous wire connectors which, in addition to enhancing its flexibility, reduces the risk of infection. Two or four silastic-insulated leads extend from the receiver to the bladder wall where they are implanted in loop-like fashion with the atraumatic suture needles which are attached to the end of the electrodes.

The target of the stimulation can be either the motor nerves of the bladder or the detrusor muscle surrounding it which, when contracted spontaneously or artificially, exerts the pressure which precipitates micturition.

Animal Experiments

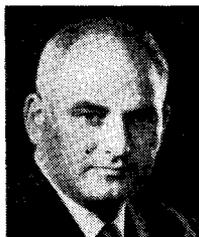
We began our animal experiments with a large series of mongrel dogs in order to evaluate the effectiveness of these two methods. While the urinary tract function of dogs and men is not entirely comparable because the former lacks man's urogenital diaphragm—the function of the external sphincter in the human being equivalent in the dog to the striated musculature located below the apex of the prostate and extending to the bulb of the urethra—results were encouraging enough to warrant more extensive testing and, eventually, clinical trials.

From a theoretical point of view, nerve stimulation has certain advantages over detrusor stimulation. However, experimenting we found that this method could not be employed in dogs for more than 60 days without subsequent nerve deterioration.

Detrusor muscle stimulation has been maintained in animals for more than one year with isometric bladder pressures of up to 50-90 centimeters of water obtained. While this method of stimulation requires higher voltages in order to activate those parts of the bladder most distant from the electrode sites, it presently carries less risk than direct nerve stimulation and in our clinical cases was used exclusively.

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Dr. Kantrowitz is director of the Department of Surgery at Maimonides Hospital of Brooklyn and professor of surgery at the State University of New York Downstate Medical Center. A pioneer in the now burgeoning field of bioelectronic assistance devices for the disabled, he has developed, among others, the cardiac pacemaker, a prosthetic left ventricle or "booster heart," and the bladder stimulator described above. Envisioned, experi-



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mented with, but not yet fully developed, is an electronic device to assist coordinated limb movement in paraplegics.

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uate of the University of Copenhagen, where he began his work on the electrical stimulation of neurogenic bladders.

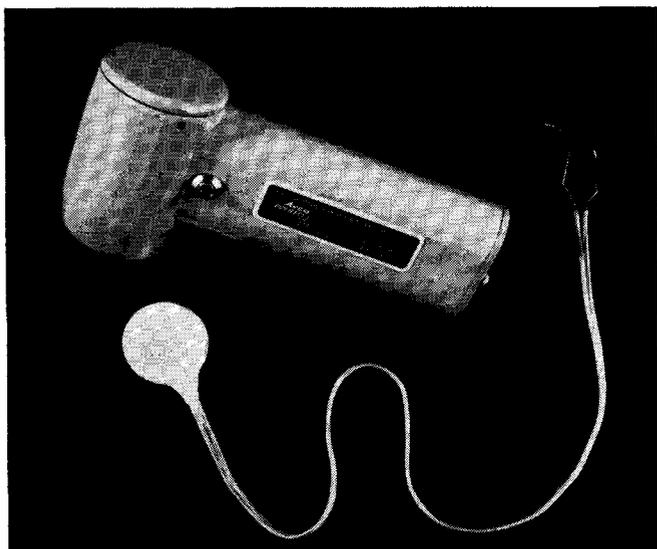
Clinical Studies

These studies, undertaken with the cooperation of Joseph Benton, M.D., Ali Khalili, M.D., were begun in 1963. To date, the Kantrowitz-Avco bladder stimulator has been implanted in four patients.

Our first, a seven-year-old boy with lumbar myelomeningocele, had undergone surgery in the first month of life, resulting in urine and fecal incontinence. He had a hypertonic bladder with 125 cc capacity and 50-75 cc residual urine. In April 1963, two wire electrodes were implanted in his bladder. Isometric bladder pressures of 170 cm of water were obtained during stimulation with 10 volts and his bladder was completely emptied.

This successful preliminary trial was followed by implantation of the receiver four months later. Unfortunately, infection developed around the device, which finally had to be removed after an attack of pyelonephritis. Several bladder calculi due to a perforating electrode were removed during the operation.

Because of his age and general condition, his parents felt that reimplantation should be delayed. The patient is



Kantrowitz-Avco bladder stimulator. The transmitter section is shown on top; below is the implantable receiver with two electrodes.

an excellent candidate, however, and for the entire eight-month period of treatment responded well to bladder stimulation. Even with the limited clinical experience reported to date, it appears that children with this lesion may eventually be primary candidates for bladder stimulation.

Our second patient was a 15-year-old boy with flaccid paralysis which followed transverse myelitis eight months prior to admission. Pressure and capacity measurements showed a hypertonic detrusor muscle, 300 cc capacity and residual urine up to 200 cc, but no reflex activity of the bladder. A severe inflammation of the glans was present.

A stimulator was implanted in September 1963. During contraction, bladder pressure resulting in 135 cm of water was obtained. Perforation of the urethra secondary to the catheter treatment occurred and the sphincter activity decreased and residual urine was reduced to 40 cc. Reflex bladder activity has developed but the patient still requires the support of the stimulator for satisfactory bladder evacuation.

Renal function remains normal and there is no backflow from the bladder to the ureters. (It is vesico-ureteral reflux, or backup of urine into the ureters and kidneys,

that is responsible for the severe and non-eliminable infections which frequently lead to renal failure in paraplegics.) The patient is still using his device after two and a half years.

Beneficial results were also obtained in a third patient, a 50-year-old man who had become paraplegic 18 months prior to admission. Concerning our fourth patient, a 40-year-old man who sustained a fracture of the lower thoracic vertebrae with cord compression, the stimulator failed after four months of treatment, because of technical difficulties; however, he was very satisfied with the device, and we are considering reimplantation.

Discussion

Though our patient series is small, we feel that results are satisfactory enough to warrant discussion at this time. Comparison with the published cases from other laboratories, where disc shaped electrodes sutured to the outside wall of the bladder were used, would seem to indicate that the bladder stimulator used by us greatly enhances the remaining expulsive force in the neurogenic bladder.

The principal problem we encounter is outflow obstruction. This appears to be due to activation of the striated muscles of the pelvic floor. In selecting appropriate candidates for our procedure, it is of especial significance that patients are chosen with special reference to good detrusor contractility as well as the condition of the pelvic musculature.

Patients with lower motor neuron lesions or those with convertible upper motor neuron lesions are the best candidates for this treatment. If the latter group have no external sphincter function or an exaggerated sphincter function which could be diminished significantly through surgery, we would consider them as well. Among our patient group, one had an autonomic bladder and responded favorably to the procedure without further urological procedures. Three others (with upper motor neuron lesions) had great sphincter trouble. Neurectomy improved the results in one.

However, because activation of the striated sphincter musculature is the greatest obstacle to good results, patients with autonomic bladders remain our first choice.

Conclusion

Our experimental and clinical experiences with electronically-induced micturition indicate to us that the long-term successful use of a radio-linked stimulator in patients with neurogenic bladder is entirely feasible. The method used by us involves little operative risk and, even where results do not warrant continued use, leave the patient as he was prior to implantation. While using this device, we saw no ureteral backflow so hazardous to paraplegics, nor any severe decrease in bladder capacity. While urinary infection was not reduced, these patients were frequently catheterized during testing, which we feel accounts for this.

Therefore, it seems to us that, with continued exploration into methods aimed at reducing sphincter resistance without inducing paralytic incontinence, and ongoing daily improvements in equipment, the future of the bladder stimulator as a valuable clinical tool is assured.

We are in the beginning stages of our work with electronic assistance devices and part replacement. In the very near future we will witness an impressive increase both in the development and use of a wide variety of these devices as well as their clinical application for the handicapped, and will then be capable of dealing with a wide range of rehabilitation problems hitherto considered insoluble. ■