USE OF A RADIO TRANSMITTER RECEIVER UNIT FOR THE TREATMENT OF NEUROGENIC BLADDER

A PRELIMINARY REPORT*

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Urinary sepsis, secondary to neurogenic vesical dysfunction associated with trauma of the spinal cord, is a well recognized clinical problem. Prolonged use of indwelling catheters in paraplegic patients produces significant bacteriuria, vesicular calculi and pyelonephritis. Kass and Sossen have shown that use of an indwelling catheter for 24 hours results in bacteriuria in 50 per cent of patients, and in 98-100 per cent of patients after 4 days. With antibiotic therapy and closer attention to rehabilitation of the bladder during and after World War II, mortality rate in paraplegics from urinary sepsis has declined. However, of approximately 746 veterans with spinal-cord injury who died during the period of 9 years following World War II, death was attributed to urinary-tract infection in 64 per cent. In another series of patients urinary-tract damage was found in 65 per cent dying from other causes.

Ruch, in a review of the physiology of micturition, described bladder tonus or the response of smooth muscle of the bladder to the stretch imposed by filling (shown in the slowly ascending limb of a cystometrogram) at the intrinsic property of smooth muscle and not reflex in nature. Changes in this phase of the cystometrogram are shown to follow physical alterations in the tissue of the bladder. Regular, complete evacuation of the neurogenic bladder with avoidance of infec-

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ELECTRICAL STIMULATION OF NEUROGENIC BLADDER

Stimulating electrodes of stainless-steel discs 0.5 cm. in diameter were used. Using a Model Grass III* stimulator, bipolar, monophasic and biphasic stimuli were applied to the bladder and optimal-stimulation parameters were determined for emptying.

Chronic Experiments. A total of 31 mongrel dogs, weighing 10–12 kg., were used. Spinal cord was transected at the C8-T1 level in 24 dogs. The cauda equina below the level of the 7th lumbar vertebra was destroyed in 2 dogs. Five control dogs, without neurological injury, were implanted with a receiver and electrodes to test reaction of tissue over a period of 8 months. Receiver and electrodes were sterilized by overnight immersion in tincture of Zephiran and washed with sterile saline. The receiver was implanted subcutaneously as shown in Fig. 1, lateral to the sheath of the rectus muscle, using interrupted silk sutures. Two to six connecting electrodes were attached to the external surface of the fundus of the bladder using interrupted silk sutures sewn through the outermost layer of the wall of the bladder. Electrodes were placed on the anterior and posterior surfaces of the fundus in its superior portion. In the dog it was difficult to implant the electrodes extraperitoneally.

Bladders were emptied at 4 to 8 hourly intervals using the radio transmitter to trigger the receiver-stimulator. Stimulation periods ranged from 1 to 3 min. Urine was collected and measured and frequent estimations of residual urine were made. Cystograms and cinerentgenologic films were made before, during and after evacuation of the bladder following instillation of a radio-opaque dye.

Antibiotics were given during the first week postoperatively and discontinued after removal of sutures in the skin. In some dogs control cultures of urine were made pre-operatively and after discontinuation of antibiotics. Postoperative hypotension occurred in some animals and was treated with intramuscular Neo-Synephrine. Plaster body casts were used to prevent the development of decubitus ulcers. Dogs were sacrificed and autopsied at intervals of 1 week to 3 months. Bladders and kidneys were saved for gross and histologic examination.

Instrument. The transmitter, receiver and electrodes shown in Fig. 2 were designed in association with Medtronic Inc., Minneapolis. The transmitter is of conventional design. The signal is transmitted by a flat, circular-loop antenna held 1 to 2 inches from the skin directly over the receiver. A timer may be used to trigger the transmitter every 4 hours for a period of 3 min.

The receiver is round, approximately 6 cm. in diameter and 1.5 cm. at its greatest width. It is coated with nonirritant material. No battery supply for receiver is required. Power for the receiver output is derived from the transmitted signal. The transmitter requires power supplied by the alternating current mains. The receiver is tuned to the transmitted signal. The transmitted signal is altered by the receiver components and the stimulus is applied to the electrodes on the bladder. The wires connecting the receiver output to the bladder are coated with the same nonirritant insulating material as the receiver. Electrodes consist of stainless-steel circular discs, 0.5 cm. in diameter, embedded in an insulating material base. Two to four leads may be connected from the receiver to the bladder, depending upon the size of the bladder.

RESULTS

Acute experiments showed that optimal stimulating parameters of 10–15 volts peak to peak, 1–5 msec. always resulted in complete emptying of the bladder both during

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* Grass Instrument Company, Quincy, Massachusetts.
and after the period of spinal shock. Intraluminal pressure rises abruptly to about 50 mm. Hg (equivalent to about 68 cm. water) and declines with the onset of micturition. Although stimulation with monophasic impulses was effective at a lower threshold, damage of the tissue occurred at the site of the electrodes. With biphasic stimulation, no evidence of such damage was seen. As expected, overdistension of the bladder increased the threshold for emptying.

Chronic experiments, using the implanted receiver-stimulator, showed effective emptying of the bladder with no residual urine in dogs made paraplegic by section of the spinal cord or cauda equina. Confirmation of effective complete emptying is shown in roentgenographic studies. Fig. 3 demonstrates a typical emptying sequence in a paraplegic dog. Dye is absent from the bladder at the end of stimulation. Ureteral reflux is not observed during the period of stimulation.

A majority of paraplegic dogs were sacrificed after 1 week for observation of reaction of the electrodes or testing of the design of the receiver. Several of the dogs’ bladders sacrificed at 1 week revealed damage of tissue secondary to flow of direct current. This arose from damage to the receivers from high temperatures (250°F.) used in sterilization. Later receivers were sterilized with Zephiran. Three dogs were sacrificed after 1 month, 1 after 2 months and 1 after 3 months. There is no gross difference in bladders subjected to repeated electrical stimulation and those implanted with sham electrode receivers for 3 months. Minimal reaction of tissue is seen in the region of the electrodes. In the paraplegic group microscopic sections of the mucosa showed mild inflammatory changes after 3 months. Thickening of the subcutaneous tissue up to 0.25 cm. in thickness around the site of implantation of the receiver is seen after 3 months.

Bacteriologic Studies. Cultures of the urine were sterile in 4 dogs studied up to 8 weeks postoperatively. One dog showed a few gram-negative rods 1 week postoperatively. Later cultures were sterile.

DISCUSSION

In the acute experiments with electrical stimulation, pressure curves of the bladder were recorded for purposes of comparison with those recorded by others during voiding. These pressures were similar in magnitudes and indicated the capacity of electrical
stimulation to initiate micturition. No search for areas in the wall of the bladder of differing threshold of electrical excitability was conducted. Rather, the attempt was made to select the most easily accessible portions of the bladder. These were the anterior and posterior surfaces of the fundus and its superior surface. The level of spinal-cord section was chosen arbitrarily.

Major problems encountered in chronic experiments were hypotension, decubitus ulcers and spread of stimulating current from the bladder to nearby structures. Confining the dog to a recumbent position during the first week postoperatively and the use of vasopressor agents controlled hypotension in most cases. Various methods, including maintaining the dogs in an upright position by using plaster body casts for the prevention of decubitus ulcers, were tried, but they were not successful uniformly. Results paralleled the vigilance and interest of the attendants. Current spread to the nerve plexuses of the pelvis during stimulation caused contraction of the muscles of the legs. Spread was more marked at the end of the stimulation when the bladder had contracted and the electrodes had moved deep into the pelvis. Spread of stimulating current was controlled by decreasing the size of the electrode contact and by altering the placement of the electrodes.

Denny-Brown and Robertson\(^1\) showed that the internal sphincter in humans opens and closes in sequence with contraction and relaxation of the detrusor muscle. This sequence appears to be organized intrinsically in the tissue of the bladder. Therefore, it seemed reasonable that after destruction of the cauda equina, evacuation of the bladder could be performed with electrical stimulation. This has been shown to be correct in brief preliminary trials in cauda-equina dogs.

The features of the instrument have been described. Two principal advantages are the absence of wires through the skin and no necessity for batteries. Further modifications are envisaged for clinical use. At present, the transmitter is large and could be used only for in-patient care. In mobile patients, a small lightweight transistorized transmitter could be used to trigger a suitable receiver. Devices for sensing filling of the bladder can be developed in conjunction with the receiver-stimulator. At present, emptying is time-cycled but with emptying in response to filling or pressure of the bladder natural processes may be duplicated more closely.

It is hoped that the instrument or a modification of it will prove useful in patients with neurogenic bladders. Because of the lengthy period of catheterization, urinary-tract infection and its sequelae are common in paraplegic patients and others in spite of the use of antibiotics. At present, rehabilitation of the bladder is aimed first at removal of the catheter. A surgical procedure to render the patient incontinent may be necessary. With passage to the catheter-free state there still may occur progressive renal damage.\(^2\) The use of the transmitter-receiver to empty the bladder at regular intervals during the stage of spinal shock, and later, would avoid infection and subsequent changes in the tissue of the bladder, help maintain tonus and preserve an intact organ and sphincters. Whether pain will occur in patients with only partial spinal-cord injury cannot be predicted. Experiments will be conducted to explore this possibility.

**SUMMARY**

Electrical stimulating parameters for emptying the bladder in paraplegic dogs were determined. Bladder-pressure recordings during stimulation and emptying were made.

An implantable receiver-stimulator triggered by a radio transmitter was designed based on the predetermined electrical parameters. No wires passing through the skin were needed and no batteries were required.

Paraplegic dogs were implanted with the instrument. Bladders were emptied at regular intervals.

Studies of residual urine, cystograms and cineroentgenologic films showed complete emptying of the bladder following electrical stimulation with no ureteral reflux. Reaction of tissue to the implanted receiver and elec-
trodes was minimal up to a period of 3 months.

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REFERENCES


DISCUSSION

Dr. C. DAVID SCHEIBERT: The authors are to be congratulated for an important new concept and method to be used in the care of the paralyzed bladder and I also want to thank them for the privilege of discussing their paper.

This afternoon we have been privileged to witness one of the important technical advances in the care of the neurogenic bladder with the possibility of immediate extensive clinical application. The demands of aerospace medicine and micro-electronic techniques promise further refinement and miniaturization of the materials used.

Let us review for a moment an incomplete summary of methods for bringing the human neurogenic bladder to a catheter-free state. Comarr has demonstrated that 70 per cent of all patients with spinal-cord injury should obtain freedom from drainage of the bladder with a catheter, with or without tidal drainage. Hoen in 1945 was able to reestablish function of the bladder in a patient with spinal-cord injury by section of the anterior sacral root of the 3rd sacral root bilaterally. Freeman, Heimbarger and Wilde demonstrated the major importance of the 3rd sacral nerve root with reference to function of the bladder. Simultaneous work on sacral-block studies and sacral neurotomy at Kennedy Veterans Hospital, together with pudendal-block studies and neurotomy at the Long Beach Veterans Hospital, revealed the efficacy of these procedures in freeing a patient with spinal-cord injury of his urethral catheter.

The phase of destruction of neural elements then passed on to more co-operative means, such as vesical mucosal anesthesia, as described by Bors. It also was found that repeated sacral-nerve block with local anesthesia or pudendal blocks with possible judicious transurethral resection might establish lasting freedom from catheter drainage. More recently the use of chlorpromazine in facilitating removal of catheter has been described by O’Hare. However, all of the above techniques have the disadvantage of being used late after catheter drainage of the bladder has been in existence for some time and secondary infection or other complications may have occurred.

The advantages of the authors’ technique are multiple, but one might primarily stress the following: (1) Early use after spinal-cord injury, even before catheter drainage is necessary, will give freedom from secondary infection and allied complications such as urinary-tract calculi, pyelonephritis and ureteral reflux. (2) The authors’ technique in no way interferes with the virginity or the continuity of the urinary tract and in no way interferes with later efforts to establish a functioning reflex or automatic bladder.

Although there may be disadvantages, it would seem that the primary worry at this time might be that the paraplegic patient so treated would find himself embarrassed in case another nearby radio-activated device should be tuned in on the same frequency.

In closing, two questions might be proposed to the authors:

1. Has there been any attempt or experience with direct implantation of electrodes on the sacral nerves?
2. Has clinical application of this technique to the human patient been carried out and, if so, what was the result?

DR. LEONARD T. FURLOW: Is there any more discussion? I should like to ask one question. Do you have all these 45 dogs on the same wave length?

DR. SHEELER N. CHOW: Thank you very much, Dr. Scheibert and Dr. Furlow.

I would like to answer Dr. Furlow’s question first, because I think it certainly poses a problem if we were to use the same frequency. Somebody may drive up a driveway, push the radio control, and there they go!

The senior author of this paper, Dr. Bradley, who just arrived here, has indicated that we can tune this into a certain frequency particular for a receiver. I think in this presentation I showed we have one such dial for the tuning, so that one receiver is sensitive to only one certain frequency.

Relative to Dr. Scheibert’s question, we have not tried stimulating directly the nerve supplying the bladder. I want to emphasize here that this is an end-organ stimulation, namely, stimulating the muscles of the bladder but not the nerves of the bladder.

I think the implication is fairly clear in that, if we have acquired injury, we may have all sorts of nerve damage in this area, and the nerves may not respond to stimulation.

The second question is the clinical application. Last Friday we tried the first one, and I regret to say it was unsuccessful. We can speculate as to why. I think the reason it was not successful is because of the fact that it did not have enough juice.