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Occasional review

Spinal cord stimulation in the United Kingdom

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SUMMARY All the medical, surgical and engineering personnel in the UK who have used spinal cord stimulation (SCS) in patients, attended a workshop to discuss their results. The major use of SCS has been for multiple sclerosis and intractable pain. It was concluded that the technique benefited up to two thirds of patients with bladder dysfunction, and that pain and possibly spasticity also responded to SCS, but other manifestations of multiple sclerosis did not. Further information on long term benefit is needed and the use of SCS in other conditions, such as spinal injury and peripheral vascular disease, is not yet established. SCS cannot be recommended for use outside large centres as x-ray screening, urodynamic and neurophysiological assessment facilities are required as well as biological engineering assistance.

The first important use of electrical stimulation in Man was that of cardiac pacemaking in the 1960s with the advent of therapeutically useful, reliable and eventually implantable stimulators. In neurology, the clinical therapeutic application of electrical stimulation (other than for physiotherapeutic procedures) stemmed from Melzack and Wall's[1] illuminating theory of the gate control of pain. Electrical stimulation was applied by electrodes on the skin (transcutaneous stimulation—TNS), directly to the nerve (peripheral nerve stimulation—PNS), implanted in the central nervous system, usually over the dorsal columns (spinal cord stimulation—SCS), or in other places in the central nervous system. Stimulation devices were first used by Shealy *et al*[2] and since that time peripheral nerves, phrenic nerves, spinal cord, cerebellum, midbrain, thalamus and cerebrum have been subjected to stimulation to reduce pain, to improve diaphragmatic function, bladder function, reduce neurological deficit, alter peripheral blood flow, aid the blind and deaf, and treat intractable epilepsy.

In this short review we are concerned solely with the use of spinal cord stimulation and specifically the UK experience. Although the major centres are agreed as to the value and drawbacks of SCS in pain and neurological disease (notably multiple sclerosis) there have been a minority of adverse reports and it was felt that a review of the experience of workers in the UK was timely and would help to clear up some controversial points. This report summarises the proceedings of a meeting held at Southampton on 21 November 1981, under the auspices of the International Spinal Research Trust. The meeting was attended by representatives of all the major centres in the UK which carry out SCS for pain and neurological disease and several uninvolved specialists.

SCS was initially carried out for intractable pain, and this remains one of the major indications. A chance observation by Cook and Weinstein[3] of improvement in the neurological deficit of a patient with multiple sclerosis led to a world wide study of repetitive stimulation in patients with chronic and supposedly fixed neurological deficit. In 1976, the first cases of SCS in patients with multiple sclerosis in the UK were reported, and the first objective neurophysiological data which argued against a placebo effect were demonstrated[4] and further neurophysiological data were subsequently presented.[5–8]

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SPINAL CORD STIMULATION IN PAIN

Spinal cord stimulation in pain is now established as part of the management of intractable pain where other procedures have failed in appropriately selected patients.[9] Results presented at the meeting (mainly from Liverpool) confirmed that overall about 50% of such patients would get pain relief from SCS. Good results can be expected in phantom limb pain, arachnoiditis and the pain associated with multiple sclerosis. The response tends to wane after about a year.

SPINAL CORD STIMULATION IN MULTIPLE SCLEROSIS

In the UK 90 patients with multiple sclerosis have had SCS carried out since 1976 (Liverpool, London, Oxford and Southampton). The diagnosis of multiple sclerosis was made on the basis of Schumacher's criteria.[10]

Indications for SCS in multiple sclerosis

1 Bladder dysfunction It is likely that bladder dysfunction will eventully turn out to be the main indication for SCS in the multiple sclerosis patient. Improvement in bladder dysfunction is mentioned in practically all the papers on SCS in multiple sclerosis, whether or not any specific assessment of this aspect was made. The symptomatic and objectively measured results, culled only from those papers where at least some attempt was made to document changes in bladder function, have been set out in tables 1 and 2

Only two of the many American papers on this subject have made specific mention of tests of bladder function and these have been included for comparison;[11,12] the published data are, however, inadequate for any valid conclusion to be drawn, other than that there appears to be a measurable improvement in bladder dysfunction in response to SCS.

Comparison of various sets of published data is difficult because there is no standard way of assessing bladder function, though some of the tests will be common to all protocols. Moreover, despite a qualitively similar urodynamic pattern, the symptomatic spectrum of bladder function is so wide[13] that not all the patients will be capable of performing all the tests required, thus diminishing the amount of information acquired. Adequate objectively measured published data on the effects of SCS on the multiple sclerosis bladder are available on only three groups of patients, all from the UK.[5,7,8,14] The results underline the need for measurements and observation, as subjective estimates of improvement (especially frequency) could often not be substantiated by any objective changes. An exception to this is incontinence, which can not be reliably measured without specialised electronic apparatus and reported subjective improvement must be taken at its face value. The use of weighed pads is currently under investigation by the International Incontinence Society which hopes to develop a simple satisfactory protocol for objective measurement of incontinence.

As can be seen from the tables, there is a considerable degree of qualitative agreement in both the symptomatic and the objective measurable changes produced. Symptomatically, incontinence, urgency,

Table 1 *Symptomatic improvement*

Author	*No of patients*	*Incontinence*	*Urgency*	*Hesitancy*	*Frequency*	*Stream*	*Retention*
Hawkes *et al* 1980, 1981 UK	28	3	13/26	10/26	10/26	19/26	—
Illis *et al* 1980 UK	25	10/17	14/22	5/7	14/22	5/7	1/2
Read *et al* 1980 UK	16	4/4	8/11	4/10	5/10 (S) 1/10 (M)	10/14	1/2
Abbate *et al* 1977 USA	40	No figures available "77·5% subjective improvement"					
Dooley *et al* 1978 USA	38	7/12	—	—	8/38	—	—

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Table 2 *Objective urodynamic changes towards the normal*

Author	*No of patients studied*	*Dyssynergia*	*Flow rate*	*Detrusor instability*	*Urethral closure pressure*	*Bladder capacity*	*Residual volume*	*Sphincter EMG*
Hawkes *et al* 1980, 1981 UK	23	1/6	14/19	6/19	8/14	—	6/13	1/6
Illis *et al* 1980 UK	13	—	—	6/11	—	6/13	6/12	—
Read *et al* UK 1980	16	4/11	8/11	5/16	14/16	11/16	1/3	3/11
Abbate *et al* 1977 USA	34	No figures available "42·5% objective improvement"						
Dooley *et al* 1978 USA	—	—	—	—	—	7/12	—	—

hesistancy, poor stream and frequency may improve; of these, only frequency is easily verifiable, though hesitancy and urinary stream can be assessed by use of the mictiograph (DISA) or similar apparatus. Objectively, SCS is associated with undoubted physiological changes in bladder/sphincter function as measured by standard cystometrography with simultaneous external sphincter EMG and cineurethrocystography and these are set out in table 2. The most consistent finding is of increased flow rates which have been shown to be statistically significant and are thought to be largely due to decreased abnormal sphincter activity and decreased bladder outflow obstruction and urethral closure pressure, and these are illustrated in figs 1, 2 and 3. The other notable changes was a reduction in detrusor instability (fig 4).

Unfortunately, it is not possible to predict, from a detailed knowledge of pre-stimulation symptoms and urodynamic findings, which patients will achieve a favourable response to SCS,[15] and there still appears to be no alternative to a short trial of temporary stimulation with adequate urodynamic assessment before and during stimulation.

2 Motor symptoms There have been reports of improvement in motor disability and this may be striking in individual cases. Spasticity and flexor spasms may be markedly reduced.[7] However, the general experience is that overall improvement in motor function is slight[8] and is seen only in a proportion of patients. Quantitative studies of walking speed, Tourtelotte tests and timed activities of daily living in 23 multiple sclerosis patients before and during SCS have been made.[16] There was some increase in walking speed in five out of nine patients but as a group the measured 30% increase did not reach statistical significance. There was no measurable improvement of performance of either the Tourtelotte or timed activities of daily living tests. Of these 23 patients, 14 reported subjective improvement in motor function, often stating that tasks seemed "easier" and less fatiguing. These aspects of motor function are not measurable. Motor disability, with the exception of spasticity, is not therefore an indication for spinal cord stimulation.

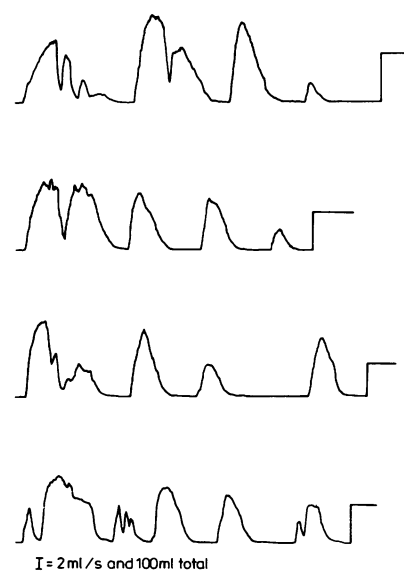

Fig 1 *The traces show four mictiograph tracings from a male patient with multiple sclerosis. The abscissa is time and the ordinate is rate of flow of urine. The flow rate is slow and variable with many interruptions and micturition took about 30 s to pass 300 ml. The step response at the end of the trace indicates total volume of urine passed. (Reproduced from* Brain *with permission.)*

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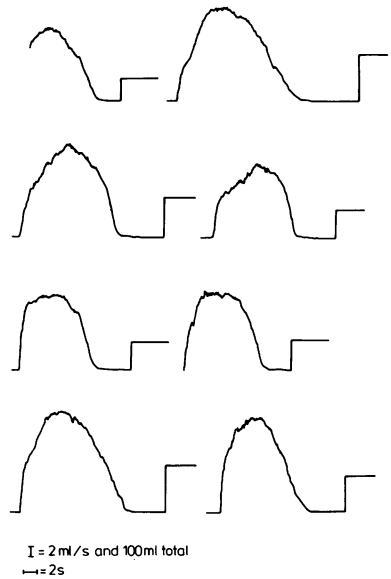

Fig 2 *Eight mictiograph tracings of the same subject as shown in fig 1. High uninterrupted flow rates are shown and micturition is accomplished in approximately 10 s (Reproduced from* Brain *with permission.)*

3 Pain Pain is not an unusual feature of multiple sclerosis and appears to respond well to SCS.

4 Other symptoms such as cerebellar, brain stem and sensory symptoms have been reported to show response to SCS, but the general experience suggests that this response is rare. These manifestations are not therefore indications for stimulation.

LONG-TERM BENEFIT

The long-term effect of SCS is still uncertain because of poor follow-up information. Of the 14 patients in the Southampton series who went on to permanent stimulation, 12 have been followed for a year or more. Of these, eight discontinued at about 12 months. In six cases this was due to technical problems (displaced or broken electrodes). One patient found the apparatus unacceptable. In only one case was it due to failure of clinical response. However, although all six technical failures were re-stimulated through new electrodes, only one responded clinically to this second period of stimulation. Four patients still continue stimulation. Three of these (12 months, 22 months, 46 months) still respond and one patient continues to use the stimulator despite loss of clinical response at 9 months.

It appears that in about three-quarters of patients undergoing long-term stimulation the beneficial

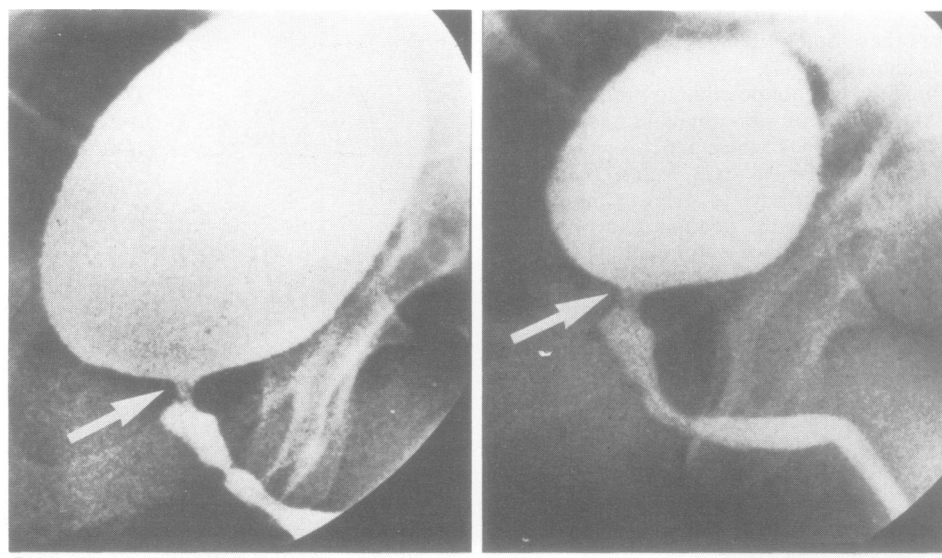

Fig 3 *Micturating cystogram of a patient with multiple sclerosis before and after a period of spinal cord stimulation. There was increased relaxation of the internal sphincter resulting in reduced outflow obstruction after treatment.*

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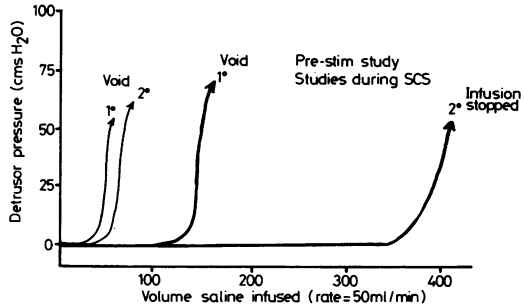

Fig 4 *Four cystometrograms of a female patient with incontinence due to multiple sclerosis have been superimposed. Those drawn with a thin line were recorded before treatment and show detrusor contraction and voiding at bladder volumes of 50–60 ml. During spinal cord stimulation the bladder volume increased to 120 ml before voiding and eventually 350 ml without voiding.*

effect is lost at about one year. The results in the London series are similar (CH Hawkes, personal communication). The reason for this is unknown but the loss of response in the Southampton series usually coincided with technical failure. Despite this, re-stimulation does not usually produce a consistent response. Nevertheless, the alleviation of bladder symptoms, even for one year, represents a significant contribution to patient management. If one compares this kind of response with the response to therapy in other progressive neurological conditions, then it becomes less disappointing. For example, a recent review of Parkinson's disease[17] indicates that 62 of 178 patients had stopped levodopa treatment within two years because of side-effects and inadequate response. No neurologist would regard this poor response as an indication for not treating patients with levodopa.

SPINAL INJURY

The beneficial effect of stimulation on the neuropathic bladder, spasticity and pain in multiple sclerosis indicates that a careful trial in spinal injury should be carried out. Since spinal injury is a non-progressive disorder any initial improvement is more likely to be maintained. In the UK experience of SCS in spinal injury is very limited. The USA experience [18–20] of SCS in spinal injury is much more extensive and shows encouraging results but is incompletely documented.

PERIPHERAL VASCULAR DISEASE

There is clinical evidence of an apparent increase in peripheral blood flow in the lower limbs during SCS. This has been utilised by Cook[21] in the management of peripheral vascular disease. The UK experience in this field is again limited but a current study at Southampton shows marked improvement in seven out of 11 patients with advanced arterial disease in whom conventional therapy had failed.[22]

FAILURE OF RESPONSE

The feature which unites all favourable reports is the response of bladder symptoms. Two major series from the USA[22 23] have reported failure of SCS in multiple sclerosis. In neither of these papers, however, was bladder function adequately studied, and this may explain the discrepancy between these reports and other large series.

COMPLICATIONS

There have been no significant complications of SCS (Liverpool, Oxford, Southampton, Zurich). Minor skin infection has been reported. The electrode lead may erode through the skin and will need replacing. Transient, reversible, neurological deterioration has been occasionally noted. However, three patients from one centre have had relapses during the first few days of SCS, including speech disturbance, optic neuritis and increased spasticity. The major problems are due to electrode slippage and breakage of the electrode lead. A method for locating lead damage in implanted systems has been described.[24] Engineers have strongly recommended that stimulus strength is measured as current (mA) rather than voltage.

COMPARISON WITH OTHER EUROPEAN COUNTRIES

The number of patients receiving stimulation at a single European centre (Zurich—J Siegfried, personal communication) exceeds the total of the number of patients treated in the UK. It was, therefore, interesting to compare results. In summary, the proportion of patients responding and going on to permanent stimulation was similar: bladder dysfunction was the major indication for SCS in multiple sclerosis: pain, spasticity and spasms responded well: the proportion of long-term success was about the same.

CONCLUSIONS

1 SCS has an objective and beneficial effect on the bladder dysfunction of multiple sclerosis in about two-thirds of patients. This improvement was seen in patients who had previously been treated by standard techniques.

2 Other manifestations of multiple sclerosis are unlikely to respond to SCS, with the exception of pain and possibly spasticity.

3 More information is required before long-term benefit can be assessed.

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4 There is sufficient indication for further investigation of the application of SCS in spinal injury and in peripheral vascular disease.
5 There is room for technical improvement since the need for accurate placement and the tendency for later slippage of electrodes makes SCS a time-consuming procedure.
6 Further detailed studies of the effect of SCS are necessary in order to arrive at a clearer understanding of the mechanism of action, so that this form of treatment can be exploited more effectively. Precise reporting of electrode positions and stimulus parameters, especially current, is crucial for different studies to be properly compared.
7 For the above reasons, and because SCS is a potentially hazardous technique, the procedure should only be carried out in centres where adequate facilities and staff are available for X-ray screening (with image intensification), urodynamic assessment and the measurement of neurological disability. Preferably the investigative group should include and engineer, neurophysiologist, urologist and neurologist.

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