MEDICAL PRACTICE

Occasional Survey

Clinical Experience with the Elema Vario Pacemaker

P. R. ROY, EDGAR SOWTON

British Medical Journal, 1974, 4, 637-640**Summary**

Early problems after implantation of an endocardial electrode for permanent pacing occur in many patients. Difficulties can be anticipated in many of these patients and their management made much easier by a knowledge of the daily endocardial threshold obtained in patients with an implanted Elema Vario pacing unit by a simple non-invasive technique using a magnet and electrocardiogram. Twenty patients are described in whom permanent pacing with an Elema Vario unit was undertaken. The practical advantages of this unit can be readily seen in the patient who develops exit block or in the patient with obstructive airways disease, in whom frequent coughing or right ventricular hypertrophy may make stable electrode placement difficult. The chief advantage of the Elema Vario pacemaker is the extreme simplicity with which knowledge of the endocardial threshold can be obtained.

Introduction

Since the first implantation of a permanent cardiac pacemaker in 1959 many technical refinements have led to the improvement of cardiac pacing so that the expected mortality for a large group of paced patients is about 2.5% a year.¹

A large group of patients still develop early problems after implantation of an endocardial electrode for permanent pacing. Early failure of pacing can be due to electrode tip movement, rise in endocardial threshold, insulation break, and, rarely,

failure of the pacing unit itself. Any one of these causes often first becomes evident with a sudden failure of pacing and a return of symptoms.

This report is based on the use of the Elema Vario pacemaker in 20 patients who have had permanent cardiac pacemakers implanted. This pacemaker provides a means for testing the threshold of the implanted unit externally by the simple application of a magnet over the pacemaker. In many cases this enables early failure of pacing to be detected and allows remedial action to be taken before symptoms occur.

TECHNICAL DETAILS OF THE ELEMA-SCHÖNANDER VARIO PACEMAKER

The Elema-Schönander Vario pacemaker, first described by Meibom in Copenhagen² functions in the normal fashion of a "demand" pacemaker in that it is inhibited by the patient's own QRS complex and discharges after a fixed interval if there is no spontaneous ventricular activity; the basic pacing rate is about 70/min and there is no rate hysteresis. The Vario mechanism is activated by placing a magnet over the pacemaker. This causes the pacemaker to discharge at a fixed frequency of about 100/min (varying slightly with each individual pacemaker, the exact rate being supplied by the manufacturer (Elema-Schönander AB, S-171, 95 Solna, Sweden).³ At the same time it lowers the amplitude of the stimulation impulses successively in 15 steps from 5.2 to 0 volts so that each impulse has a voltage of 0.35 volts less than the preceding impulse. The impulse representing 0 volts has reversed polarity and a wider profile than the other impulses and is easily recognized on the external electrocardiogram. Thereafter the pacemaker immediately returns to full impulse amplitude and repeats the step-down process, this cycle continuing until the magnet is withdrawn.

The basic rate and the rapid fixed rate both depend on battery voltage, and the actual value can therefore be checked. The anticipated changes from loss of one cell are provided for individual pacemakers by the manufacturers.

Cardiac Department, Guy's Hospital, London SE1 9RT
P. R. ROY, M.R.C.P., M.R.A.C.P., (supported by a fellowship from the Post-graduate Committee, University of Sydney).
EDGAR SOWTON, M.D., F.R.C.P., Consultant Cardiologist

By simultaneously recording the patient's external electrocardiogram while the magnet is applied the point during the 15-step reduction in amplitude at which the stimulation impulse no longer causes a ventricular contraction can be used to determine the threshold for stimulation. The technique is illustrated in the diagram, where the pacemaker fails to capture the ventricle on the 10th impulse. This corresponds to a threshold between 2.05 and 2.40 volts. The technique is non-invasive with a minimum of apparatus (electrocardiograph and magnet), and it allows the early detection of increase in threshold before it becomes clinically apparent. The pacemaker returns to normal function, with full amplitude, as soon as the magnet is removed.

Electrocardiogram showing application of magnet and where Elema-Schöndar Vario pacemaker fails to capture ventricle on 10th impulse.

Patients and Methods

The Vario pacemaker was used particularly in patients in whom there was difficulty finding a stable pacing threshold during initial electrode insertion, and this group of 20 patients was therefore selected as being likely to have an unusually high incidence of complications (see table I).

Implantation was carried out under local anaesthesia using 1% lignocaine, the electrode being inserted via cutdown on the right or left brachiocephalic vein. In some patients a suitable brachiocephalic vein could not be found and the right or left external jugular vein was used. The electrode was positioned in the apex of the right ventricle using single-plane image intensification, and the threshold determined using a portable adjustable pacemaker. The output of the adjustable pacemaker was gradually reduced and the threshold was taken as that voltage at which stable pacing still occurred. The impulse generator was implanted in the deep subcutaneous tissue of the corresponding pectoral region and the threshold checked by the Vario method after wound closure.

After implantation daily threshold checks were made in most patients for the next seven to 10 days by application of the magnet over the pacemaker. This was done when the patient was supine and at rest and during deep inspiration. A penetrated chest x-ray examination was performed on all patients two to three days after implantation to check the electrode position. In uncomplicated cases patients were mobilized in 24 hours and discharged after 10 days. This was much longer than the usual period of hospital stay because the patients were specially selected as being at particular risk for early loss of pacing. Follow-up checks were made at one, six, 12, and 18 months. The first Vario unit was implanted 20 months before the time of writing, and to date no patient has required replacement for battery cell discharge.

Results

The value of the Vario unit can best be shown by a closer consideration of some of the patients (see table).

Case 4.—This patient presented with a typical history of Stokes-Adams attacks and was found to be in complete heart block. Under local anaesthesia an Elema electrode (EMT 281) and Vario pacemaker were implanted in the subcutaneous tissues of the right pectoral region. There was some difficulty in establishing a stable stimulation threshold, but eventually a threshold of 0.5 volts was obtained (with an impulse of 2 msec duration). On the second day after implantation a routine chest x-ray examination showed the electrode tip to have retracted from its position at the apex to a position much closer to the tricuspid valve. The threshold varied, presumably due to minor changes in electrode position, but by day 8 it was again stable. On day 10 a value of 2.8 volts was obtained. Allowing for the physiological rise in threshold which occurs after pacemaker implantation⁴ this gave a safety margin of 2.4 volts. In view of stable pacing and a satisfactory threshold the electrode was not repositioned. At follow up six months later the pacemaker was functioning satisfactorily with a threshold of 2.4 volts.

Case 7.—This patient was admitted in complete heart block after a Stokes-Adams attack. After implantation of the Elema Vario pacemaker the threshold, measured by activating the Vario mechanism, increased steadily over the next four days to a level of 4 volts. The patient was treated with a course of oral prednisone but in spite of this the threshold on the eighth day was over 5 volts. The electrode tip position remained constant on chest x-ray examination. A new electrode was therefore inserted and a threshold of less than 1 volt could not be obtained. To maintain a reasonable safety level between the output of the pacemaker and the threshold needed, a high output Medtronic (7.5 volts) unit was inserted. Use of the Vario system in this patient allowed

Details of 20 Patients who were implanted with the Elema Vario Pacemaker

Case No.	Sex	Age	Symptoms	Electrocardiogram	Initial Threshold (V)	Comment
1	F.	72	S.-A. attacks	2:1 block	0.35	
2	M.	59	S.-A. attacks	Complete heart block	0.4	
3	M.	89	S.-A. attacks	2:1 block	0.5	
4	M.	70	S.-A. attacks	Complete heart block	0.5	Movement of electrode tip; no threshold change
5	F.	83	S.-A. attacks	2:1 block	0.6	
6	M.	60	S.-A. attacks	Sinus rhythm; R.B.B.B.	0.8	Electrode tip moved; threshold rose to 3 V and stabilized
7	M.	62	S.-A. attacks	Intermittent/complete heart block	0.5	Threshold rose to exceed 5 V; prednisone not effective; high output box inserted; stiff electrode used; threshold 1 V
8	M.	70	S.-A. attacks	Intermittent/complete heart block	0.5	Sudden failure after 4 months due to electrode displacement
9	M.	63	S.-A. attacks	Intermittent/complete heart block	0.25	Missed beats after 1 month; insulation break in electrode
10	F.	36	S.-A. attacks	Congenital complete heart block	0.25	
11	M.	53	S.-A. attacks; cardiomyopathy; tachycardia syndrome bradycardia/	Left axis; L.B.B.B.	0.8	Died suddenly on 6th day after implant
12	M.	71	Dizzy spells	Left axis deviation; 1st degree block	0.2	
13	M.	73	Dizzy spells	Left axis deviation; 1st degree block	0.8	Gradual rise in threshold; wire repositioned
14	M.	57	S.-A. attack	1st degree block; sinus arrest	0.7	
15	M.	57	Dizzy spells; dyspnoea	Left axis deviation	0.6	Electrode tip movement on x-ray examination; threshold remained 2 V
16	M.	69	S.-A. attacks; emphysema	Complete heart block	0.5	Sudden failure after 4 months due to electrode displacement
17	F.	75	S.-A. attacks	Complete heart block	1.0	Difficulty obtaining initial threshold
18	F.	74	Dizzy spells	Complete heart block	0.5	
19	F.	81	S.-A. attacks	Complete heart block	0.8	
20	M.	67	Dizzy spells	Complete heart block	0.3	

S.-A. = Stokes-Adams. R.B.B.B. = Right bundle-branch block. L.B.B.B. = Left bundle-branch block.

impending loss of pacing to be detected before clinical failure and later stable pacing was maintained.

Cases 8 and 16.—In these two patients displacement of the electrode in both cases occurred four months after implantation. Both patients had coexistent emphysema, and electrode displacement occurred during an exacerbation of acute bronchitis. The Vario pacemaker was used in both patients because of our previous experience of more frequent initial electrode instability in patients with emphysema and right ventricular hypertrophy. The Vario units allowed regular threshold measurement in the early implantation phase, normal thresholds confirming a stable initial electrode position. Late electrode displacement is uncommon in patients with no evidence of respiratory disease or right ventricular hypertrophy. Sudden displacement after four months in both cases was presumably due to violent movements of the right ventricular during coughing and could not have been predicted using the Vario pacemaker.

Case 13.—In this patient a gradual rise in threshold, with the threshold varying greatly from day to day, indicated an unstable position despite an apparently constant position on chest x-ray examination. This allowed replacement of the electrode before symptoms occurred.

Case 15.—Electrode tip movement was observed on routine chest x-ray examination in this patient two days after implantation. Daily threshold measurements showed that the threshold did not rise above 2 volts, and stable pacing was maintained. Knowledge of a stable threshold allowed the electrode to be left in position and prevented unnecessary repositioning of the electrode.

Case 9.—Missed beats were noted on the external electrocardiogram one month after implantation in this patient even without application of the magnet. An insulation break in the electrode was found at reoperation and a new electrode inserted.

Case 11.—In this patient sudden death in asystole occurred on the sixth day after implantation. Daily routine threshold testing had not shown any abnormal rise in threshold. At the onset of asystole the pacemaker site was reopened almost immediately and the electrode connected to an external pacemaker. There was no ventricular response even at 10 volts and the patient died. A clinical diagnosis of cardiomyopathy had been made but no necropsy was performed and the cause of death remained unknown.

The pacemakers from these last two patients (cases 9 and 11) were functioning normally and were returned to the manufacturer, who confirmed that they were both completely within specification.

Discussion

The particular value of the Elema Vario pacemaker is the ease with which the actual pacing threshold can be established with a minimum of equipment (electrocardiograph and magnet) by a totally non-invasive technique. The clinical value of repeated threshold measurements in this way is greatest in the early stages after pacemaker implantation, particularly in patients where technical difficulties have complicated the initial electrode placement. The threshold for stimulation normally rises during the first few days after insertion of a new pacing electrode, but it is unusual for this rise to exceed the output of the pacemaker provided the initial electrode tip position was satisfactory. Occasionally, however, an undue threshold rise leads to loss of pacing, often between the seventh and 10th day. The development of exit block of this type can be foreseen by repeated threshold measurements available with the Vario system though we do not consider this to be an important application because of the rarity of exit block. In some patients, however, where the initial threshold at implantation is high, or the electrode position is anatomically unsatisfactory, or exit block has previously occurred after an apparently satisfactory electrode position, or the heart is very large and presents pacing difficulties there is an unusually high risk of pacing failure from rising threshold. In such cases the use of a Vario pacemaker may be extremely useful, and early detection of an abnormal rise may allow prophylactic treatment, as illustrated in case 7.

One of the more common problems after implantation of a transvenous system is movement of the electrode tip, and though the new position may appear perfectly satisfactory on the x-ray picture the threshold is normally unknown. The Vario system provides a method by which the new threshold can be assessed and a decision made whether the electrode has settled in a satisfactory new position or whether the incision must be reopened and the electrode repositioned. Under these circumstances daily checking of the threshold will confirm that satisfactory endocardial contact has been achieved and maintained. Confirmation of a stable electrode position, as judged by a consistent threshold level, may also be valuable in patients who have chronic respiratory disease with persistent coughing. Confirmation that the electrode remains satisfactory after particularly severe episodes of coughing or respiratory infection may be very reassuring, both to the physician and to the patient. This reassurance is not available with conventional pacemakers but can be rapidly provided with the Vario system. In two of our patients exacerbations of coughing were so severe that the electrodes were displaced at a late stage, and under extreme circumstances of this type the threshold-testing ability of this or any other pacemaker become irrelevant.

Non-invasive measurements of threshold can be achieved with several alternative pacemakers, including the General Electric, the Cordis Omnicor series, and some models in the Vitatron series. In all of these the amplitude is reduced by the use of fairly complex external equipment which is expensive and requires a trained operator. An alternative approach is used by Medtronic, in which the impulse duration is progressively shortened, and in theory the threshold can be measured using this technique. The strength-duration curve is so steep at short impulse durations, however, that the technique is not well suited to accurate repetitive threshold measurements. The advantage of the Elema Vario at present is its great simplicity in use, but this would be of dubious clinical value if the overall reliability of the pacemaker was impaired. The addition of any further circuitry must inevitably reduce reliability to a small extent, but the Vario circuits are not used in any way by the pacemaker until the activating magnet is applied, so that the overall reliability of the pacemaker might be expected to be very similar to that of the same manufacturer's demand unit.

A fault in the reed switch by which it remains closed after the magnet is withdrawn would leave the Vario mechanism running continuously. This is a theoretical risk to the patient whose threshold might be near the upper limit for the pacemaker. In this event the reduction of pacemaker output would continue for the full 15 impulses even though the patient might have failed to respond to an early stimulus. Conceivably ventricular asystole for 10–12 seconds could therefore occur and this would be a cyclical event occurring some four times a minute. Such a failure is extremely unlikely and the risk could be virtually eliminated by the use of two reed switches in series since it is inconceivable that both would fail in the closed position simultaneously. The additional battery drain due to activation of the Vario mechanism is negligible under normal conditions since the time when the magnet is applied amounts to only a few seconds every few months. Up to the time of writing we have not had to replace any of the Vario units owing to battery cell failure; the longest time of continuous normal function has been 22 months and we expect these pacemakers to have about the same useful lifetime as non-Vario models, which has been found in a small series of patients to be 27–30 months.⁵

A further theoretical advantage of the Vario system will arise towards the end of the battery lifetime. It would be helpful to know whether the threshold is near the level provided by the depleted pacemaker or whether there is still a large safety margin; the decision to replace the pacemaker

urgently or to schedule replacement for a convenient time in the near future depends upon this information, which cannot usually be obtained at present. When one cell in the Vario pacemaker fails the discharge rate alters appreciably (as in most other pacemakers) and the new voltage can therefore be deduced. It will of course be necessary to calculate the threshold after application of the magnet taking into consideration the reduced amplitude of the initial impulse.

References

- ¹ Sowton, E., Spurrell, R. A. J., and Roy, P. R., *Proceedings of International Congress on Ventricular Conduction, Porto, Portugal*. In press.
- ² Meibom, J., *Medical Instrumentation*, 1973, 7, 68.
- ³ Elema-Schönander, Product information, 1972.
- ⁴ Sowton, E., and Barr, I., *Annals of the New York Academy of Sciences* 1969, 167, 679.
- ⁵ Grant, A. F., et al., *Medical Journal of Australia* 1973, 2, 257.

Contemporary Themes

Solutions to the Problem of the Dangerous Offender

P. D. SCOTT

British Medical Journal, 1974, 4, 640-641

In so far as the dangerous offender can be classified as mentally abnormal, the Mental Health Act of 1959 permits him to be transferred from court or prison to hospital. This solution has been a clear failure for two reasons. The hospitals (other than special hospitals and a few special units, usually of sub-normality hospitals¹) do not want these patients; 150 transfers a year of psychopathic patients is scratching the surface of the problem. The fact that the administrative possibility exists of transferring the difficult prisoner to hospital removes therapeutic responsibility from the prisons and effectively retards the therapeutic capacities which they so obviously possess, and should develop.

Flexibility

It has been argued that if the needs of the dangerous offender lie between hospital and prison, then let him be in hospital when he needs treatment and in prison when he does not—that is, keep the custodial prison and the therapeutic hospital and shuttle the convict-patient between the two. This is the solution favoured by the Lord Chief Justice in *Regina v. Horan*² and in his remarks when sentencing Ian Ball who shot four men while attempting to kidnap Princess Anne. He indicated that the time may be approaching when such dangerous patients, even though mentally abnormal, should be subject to an indeterminate prison sentence to secure the protection of the community, and that any requisite treatment should be through temporary transfer to a secure hospital. Since the establishment of new methods of reviewing discharge from special hospitals under the Aarvold Committee a hospital order—with restriction of release unlimited in time to a special hospital—theoretically should and does provide just as effective protection for society as prison. But the scheme lacks an essential element in that it fails to stimulate therapeutic endeavours within the prison system.

The Department of Health and Social Security, after long cogitation, has produced its answer.³ Faithful to the philosophy

of the Mental Health Act it proposes semisecure units in association with mental hospitals, at the rate of 20 places per million of population. These are to be staffed by forensic psychiatrists; they are to be small (50 to 100 patients), and they will be short term (18 months). It is recognized that they must be staffed very generously in "quantity and quality." Forensic psychiatrists, like any good parents, are expert at being firm without being retributive and would welcome such units, which would certainly be interesting and rewarding. Nevertheless, this Janus-like capacity to control and at the same time encourage is basic to all psychiatry, which may be emasculated if it delegates too far. Security is immensely expensive, materially and in staff. The hospital system is already desperately short of nurses. It is acknowledged that these units would need highly experienced and skilled grades of nurses, and these would be very difficult to find. Most important, the units, even before the first is open, are showing unmistakable signs of selecting the nicer band of the psychiatric spectrum of patients—who are to be short term and requiring only intermediate degrees of security.

Disadvantages of Units

These units may go some way to meet the parochial needs of hospitals, but they will not relieve overcrowdings in special hospitals and they will do nothing for the mentally abnormal, long-term dangerous convicts who are so difficult to help in any constructive way in the prisons. The units will do nothing at all to encourage therapeutic developments in prisons and, indeed, are likely to retard any such effort. If the units ever succeed in opening in significant numbers (which is doubtful) they would only be repeating the same basic errors which led to their conception and would be a costly drain on the system. The fault was not in the Department's report but in its terms of reference. The problem should have been considered by a joint committee of the Prison Department and the D.H.S.S. and perhaps with lawyers and social service administrators as well.

The situation, then, is that the present discrete prison and hospital systems both fail to meet the practical requirements of dangerous persons. To shuttle the inmate between the two is impracticable and inefficient. To make the hospitals like prisons will not be tolerated. It remains to make the prisons more like hospitals, and thus to fulfil the requirements of the law and of the protection of society, while doing as little harm

Maudsley Hospital, London SE5 8AZ

P. D. SCOTT, F.R.C.P., F.R.C.PSYCH., Consultant Forensic Psychiatrist