Implantable Cardiac Pacemakers

EDGAR SOWTON*

Since implantable artificial cardiac pacemakers were first produced in Sweden and the United States in 1958, there has been continual improvement in manufacturing techniques, and reliability of modern apparatus has increased to the extent that pacing is generally accepted as the treatment of choice for a high proportion of patients with complete heart block. Nevertheless the use of pacemakers is restricted in Britain, so that though there are approximately 12,500 patients with heart block only some 800 are actually being treated in this way. This restriction is particularly noticeable by comparison with other countries where pacemakers are used more freely, and though the population of Sweden is only one-seventh that of the United Kingdom there are twice as many patients with cardiac pacemakers, while the total number implanted each year in Spain approaches that in Britain.

There appear to be several main reasons accounting for the slow increase in pacing in Britain. Early experience was accompanied by a high incidence of pacemaker failure, premature battery exhaustion, infection, and broken electrodes, and these complications resulted in a conservative approach to the treatment of heart block so that many patients are not referred for consideration of pacing. In some areas this is combined with a shortage of facilities, so that patients cannot easily be referred locally. The hospital work load associated with pacing can be very large and involves many departments and personnel, including surgeons, physicians, technicians, and radiographers. Many hospitals are unable or unwilling to undertake this load, particularly since a large proportion of the work must be carried out at night or at weekends as emergency procedures.

The financial cost of providing a pacing service is considerable and is undoubtedly a factor in limiting the facilities. If the cost of the pacemaker and the time in hospital alone are considered, approximately £12 per month will be needed for every patient; this figure is almost unaffected by the choice of apparatus unless the more expensive demand pacemakers are

used, in which case the cost rises to £16 per month. A hospital dealing with only 50 patients will thus incur a financial load of over £7000 a year in addition to the cost of providing and maintaining the original facilities and equipment.

The clinical aspects of pacing have become clearer over the past two years, and opinions based upon experience of 3 or 4 years ago are no longer necessarily valid. The present situation regarding the apparatus itself is that it should now be an extremely rare event for pacemaker failure to occur within 1 year, and several commercially available models offer a high chance of trouble-free performance for over 2 years. The complications due to fractured electrodes have been almost eliminated by the introduction of coiled instead of braided wires. Improvements continue to be made by manufacturers and it is likely that in the near future implanted pacemakers will function reliably for more than 3 years.

The one-year mortality for patients with heart block treated with pacemakers is approximately one-quarter that of those treated medically, while the quality of life during successful pacing is also greatly improved. Many patients who had been severely restricted or even bedridden are enabled to resume active lives, earning their own living and enjoying normal leisure activities without the constant fear of Adams-Stokes attacks. An important aspect in achieving this result is the use of drug treatment to improve cardiac function during pacing. Digitalis and diuretics are frequently needed before the full benefit can be achieved, and pacing should be regarded only as one of the principles of treatment.

Until recently the indications for pacemaker implantation in patients with heart block have been the failure of medical treatment to prevent Adams-Stokes attacks or to control symptoms related to bradycardia and low cardiac output. These indications remain valid, but the demonstration that long-term mortality is greatly reduced by pacing (Chardack *et al.*, 1965; Sowton, 1967; Gadboys, Lukban, and Litwak, 1968) suggests that the criteria should be widened.

It is known that patients with a history of Adams-

*Address: The Institute of Cardiology and National Heart Hospital, London.

Stokes attacks are three times as likely to die suddenly as those without (Penton, Miller, and Levine, 1956) and that the first syncopal attack may be fatal. Since it is not possible to predict which patients will have attacks it has been suggested that all patients with heart block should have long-term pacemakers, irrespective of the absence of symptoms (Kitchell, 1967). Though this view would receive widespread support if pacemakers were completely reliable and could be utilized with no mortality or morbidity, this stage has not been reached, and it is the general opinion that patients who are symptom-free even on effort should not be paced. At the present time it is reasonable to accept one recent Adams-Stokes attack occurring despite medical treatment as an indication for pacing; at many centres throughout the world the proviso regarding medical treatment would be considered unnecessary, and a single syncopal episode would be regarded as an urgent indication for pacing (Zoll, 1967). Other indications are the development of dyspnoea on effort, impaired cerebration, and the presence of cardiac or renal failure associated with bradycardia.

Patients with apparently minor symptoms may merit a trial of pacing, which can be carried out with a temporary transvenous electrode while the patient spends a few days in hospital. The improvement in clinical state produced by an increase in ventricular rate occasionally surprises both the patient and his doctor. Patients who have become used to living a restricted life may have few symptoms and only fully appreciate the extent of their disability when it is relieved. Clinical judgement is usually perfectly adequate for assessing improvement during a trial of pacing but if haemodynamic measurements of cardiac output and pulmonary capillary wedge pressure at different heart rates can be obtained they may be very helpful in difficult cases.

It has recently become apparent that the use of cardiac pacemakers will not be restricted to the treatment of patients with heart block. A number of reports have now been published concerning pacing in the management of rapid dysrhythmias such as ventricular tachycardia, paroxysmal supra-ventricular tachycardia, or Wolff-Parkinson-White syndrome (McCallister, McGoon, and Connolly, 1966; Cohen, Kahn, and Donoso, 1967; Sowton, 1968). Pacing is used in these patients for long-term suppression of irritable foci and may be combined with antidysrhythmic drugs such as propranolol. The indications for these applications of pacemakers are not yet fully established, but this approach should certainly be considered for any patient with repetitive rapid tachycardia, of ventricular or supra-ventricular origin, in whom conventional drug treatment has failed.

There are three main types of fully implantable pacemaker available. The most physiological is the atrial-triggered unit which behaves essentially as an artificial bundle of His, detecting the atrial depolarization via one electrode and delivering a pacing stimulus to the ventricle via a second electrode after a delay corresponding to the P-R interval. These pacemakers are indicated for young patients with damage confined to the conducting system and who are expected to return to a normally active life, such as those with congenital or surgically-induced heart block. They are contraindicated in patients with angina or atrial fibrillation.

The second type is the asynchronous pacemaker in which the ventricle is stimulated independently of atrial activity; these pacemakers are usually referred to as fixed-rate units, since though the rate can be altered in several commercial models it is not under physiological control. These pacemakers are entirely satisfactory for the great majority of patients and a fixed rate of 70/min. usually allows the patient to indulge in a moderate level of exercise.

The third type is a development of the fixed-rate pacemaker, so that it does not stimulate the heart following a spontaneous contraction until a fixed interval has elapsed; in this way competition between natural and artificial pacemakers is avoided. These demand pacemakers may be of two types, ventricular-triggered or ventricular-inhibited, but the indications at the moment are similar. Demand pacemakers are indicated for patients with intermittent heart block or with multiple non-paced ectopic beats. They have been shown to possess reliability comparable to that of conventional pacemakers and so are theoretically indicated for many patients who would otherwise have simple fixed-rate units, since approximately 25 per cent of all patients with heart block have intermittent AV conduction.

A demonstration that the prevention of competition by the use of demand pacemakers results in a considerably lower mortality has been provided by Parsonnet (1967). In a group of 24 patients with competition and fixed-rate pacemakers there were 6 sudden deaths of unknown cause (in addition to 3 further patients with aortic stenosis who died suddenly), whereas there were no deaths in a similar group of 41 patients with ventricular-triggered pacemakers. The electrodes and output of the two types of pacemaker were the same, and the most likely explanation of Parsonnet's data seems to be that pacemaker-induced ventricular fibrillation occurred in his group with competition. At the moment, however, demand pacemakers are considerably more expensive than fixed-rate units and some types are in short supply. Demand pace-

makers are unnecessary for patients who are known to have stable block, and in other patients the risk of competition when fixed-rate units are used can be minimized by the use of antidysrhythmic drugs, though this is a less satisfactory alternative which should soon become obsolete.

An alternative approach to long-term pacing depends upon the use of an external pulse generator with transfer of power across the intact skin by induction or by a radio-frequency link. The clinical results are similar to those obtained with fully implanted pacemakers, but the induction method has not been widely adopted and only a small proportion of paced patients are maintained with this technique, which so far provides for asynchronous pacing only.

Improvements in pacemakers cannot alone improve treatment and nearly half the pacing failures in Britain are at present not due to the generator failing. Infection has been a common cause of failure and may be associated with an undue tissue reaction in some cases. Such reactions can be minimized by scrupulous care of the pacemaker before sterilization; even holding the unit in clean hands leaves traces of salts and perhaps grease in fingerprints, and this is especially so if the pacemaker is being tested in a hospital workshop. Very careful cleansing and degreasing will be needed for any pacemaker removed from its original packing before sterilization.

Sterilizing should preferably be carried out in ethylene oxide which penetrates into such sites as the threads of screw-holes. Subsequently the pacemaker must be left for about a week to degas before implantation, or an excessive tissue reaction may lead to early rejection. This delay results in either a prolonged stay in hospital for the patient or the need for pacemakers to be kept pre-sterilized in readiness, a policy that can only be justified by hospitals implanting appreciable numbers of units. The situation is eased by the increasing provision of pacemakers in sterile packs from the manufacturer, though this prevents testing of the pacemaker by the hospital before use; the benefit from testing does not compensate for the increased risk of subsequent pacemaker rejection due to contamination except in centres with considerable experience and facilities. Most pacing centres give antibiotic cover during the actual implantation, but this need not be continued beyond 48 hours. If the pacemaker does become infected, intensive antibiotic treatment, possibly combined with drainage for a few days, should be instituted, and rejection may be avoided in such cases.

Movement of a transvenous electrode is a common cause of pacing failure and accounts for much wasted

time in hospital. This is usually an early complication occurring within a day or two of initial passage of the electrode. The incidence is related to the experience of the operator and is considerably lower in hospitals implanting large numbers of pacemakers than in those dealing with only occasional patients. It can be reduced by ensuring that the electrode tip is well out in the right ventricular apex and that the electrical threshold is very low in the position finally accepted. Manipulation of the electrode to the pulmonary artery before it is finally positioned in the right ventricular apex ensures that it does not lie in the coronary sinus or an anterior coronary vein. These sites are unacceptable because of large increases in threshold which usually develop over the subsequent few days and lead to failure of pacing.

Obtaining a suitable position for the transvenous electrode may occasionally take several hours, and because of this there is a reawakening of interest in direct surgical attachment of electrodes to the heart. This need not entail a thoracotomy, since a sub-diaphragmatic approach has proved very satisfactory; the electrodes are attached to the inferior aspect of the right ventricle and the pacemaker is implanted in the anterior abdominal wall.

It is highly desirable that implanted pacemakers are replaced before pacing ceases, so that dangerous pacemaker failure or emergency admission of the patient are avoided. For this reason a date should be set for elective replacement before the patient leaves hospital after pacemaker implantation, the time of replacement being chosen so that there is at least a 90 per cent chance of continuing normal function. Dangerous and time-wasting emergencies can be further reduced by a careful follow-up policy, planned to detect pacemakers that are likely to fail prematurely. By far the most important measurement in this respect is the rate of fixed-rate pacemakers which should not vary by more than 5 beats/min. from the original value; the same limit is applicable to the stand-by rate of demand pacemakers, but other methods are used in testing atrial-triggered units. If pacemakers are changed as a result of follow-up tests or because the elective time has arrived, admission of patients and allocation of surgical time can be undertaken as a planned procedure to the great benefit of patients and hospital alike.

It is apparent that the whole complex of trained personnel, equipment, and ability to undertake a pacing service cannot be available at every hospital, and an attempt to provide this would result in wasteful dissipation of limited resources. One alternative that is already proving satisfactory in practice is for patients to have pacemakers implanted at a specialized centre, but then to return to the care

of the referring physician until the date for elective replacement arrives. During the expected lifetime of the pacemaker, simple follow-up procedures are carried out at intervals of about 3 months and any abnormality is investigated at the specialized hospital. In this way, the periods of implantation and replacement are covered by hospitals with full facilities, but the primary clinical responsibility remains with the general practitioner and local consultant.

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