Summary and Conclusions

A retrospective survey of all cardiac pacemakers sold over a 12-month period in Britain was carried out and an 81% return achieved.

Of the pacing systems which failed the cause was not the generator itself in 43% of cases.

Long-term Transvenous Cardiac Pacing with Chardack–Greatbatch (Medtronic) Pacemaker


Brit. med. J., 1968, 2, 13-16

It is now accepted that the rational treatment for chronic atrioventricular block is continuous pacing of the heart with an implanted pacemaker. The logic of this was first put into practice by Elmqvist and Senning (1960) and by Zoll and Linenthal (1960), followed later that same year by Chardack et al. (1960). Since 1962 implantable pacemakers have been used in Glasgow (Glass et al., 1963a, 1963b; Bain et al., 1967) and a variety of types tried. The earlier epicardial pacing systems were attended by a high rate of failure, necessitating in many cases two or more changes of pacemaker. In the last few years, however, advances in technology and increasing experience in the use of pacemakers have combined to produce more reliable generators and catheter electrode systems. Furthermore, the demonstration of the simplicity and effectiveness of the transvenous method of permanent cardiac pacing (Parsonnet et al., 1962; Siddons and Davies, 1963; Lagergren and Johansson, 1963), requiring no thoracotomy, made the transvenous method immediately attractive.

In 1964 we in Glasgow became impressed with the superiority of the Medtronic generator and bipolar electrode catheter for endocardial pacing, and since then we have used this exclusively as the unit of choice for fixed-rate pacing.

Between October 1964 and 17 November 1967 53 Medtronic fixed-rate endocardial pacemakers have been implanted in 44 patients in the Glasgow area. One pacemaker has been inserted in each of 37 patients, two pacemakers in five patients, and three in two further patients. These pacemakers have been implanted for periods of time varying from 1 to 33 months. The ages of the patients (24 men and 20 women) at the time of first implantation ranged from 32 to 84 years. Over 70% were 60 years of age or more.

Presenting Symptoms.—(1) Stokes–Adams attacks occurred in 25 patients; it was combined with dizziness in three others and with angina in one more patient. (2) Fatigue was the only symptom in five patients; it had been present for one year in three others and had developed during the previous year in two others. (3) Dizziness was the sole complaint in three cases. (4) Intermittent claudication was the only symptom in one man. (5) Dyspnoea associated with congestive cardiac failure was the chief symptom in two patients, but occurred in combination with Stokes-Adams attacks in 12 others.

Clinical Findings (Table I)

Persistent complete heart block was found in 32 patients and intermittent complete heart block in the remaining 12. Superimposed on these atrioventricular dissociations nine patients had developed dangerous tachyarrhythmias, either before temporary pacing or during insertion of the temporary catheter electrode. Ventricular tachycardia occurred in five of these cases and bursts of ventricular extrasystoles in four others. Of these nine patients three developed ventricular fibrillation and one asystole. In addition to these nine patients another man had developed ventricular fibrillation during implantation of a previous epicardial pacemaker unit. These five patients were successfully resuscitated and were alive and well at the time of writing.

There was a history of myocardial infarction in eight patients and of generalized ischaemic heart disease in 13. In the remaining 23 no obvious cause was found for the heart block. A basal blood-pressure recording of 160/95 mm. Hg

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent complete heart block</td>
<td>32</td>
<td>72.7</td>
</tr>
<tr>
<td>Intermittent complete heart block</td>
<td>12</td>
<td>27.3</td>
</tr>
<tr>
<td>Dangerous tachyarrhythmias</td>
<td>10</td>
<td>22.7</td>
</tr>
<tr>
<td>Sinoatrial arrest</td>
<td>5</td>
<td>11.4</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8</td>
<td>18.2</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>13</td>
<td>29.3</td>
</tr>
<tr>
<td>Diastolic hypertension</td>
<td>20</td>
<td>44.4</td>
</tr>
<tr>
<td>Non-cardiovascular disease</td>
<td>15</td>
<td>34.1</td>
</tr>
</tbody>
</table>
or more was found in nine patients before pacing. In addition, symptoms of diseases other than of the cardiovascular system were found in 15.

Management of Patients with Complete Heart Block

Before insertion of the permanent implant all patients were made as fit as possible by medical means and had a temporary bipolar pacing catheter (U.S.C.I. 51) inserted into the apex of the right ventricle. A few patients were treated with Sennetrine (isoprenaline hydrochloride) before temporary pacing. The temporary pacing catheter was inserted through an antecubital vein and connected to a conventional external pacemaker. In most cases a Medtronic generator, strapped to the patient's wrist, was substituted for the bedside external pacemaker. The small size of this generator allowed the patient to move his arms without restriction and the non-infarct patient to be ambulant. These Medtronic generators had been removed after implantation from other patients, cleaned, and tested before being put to use externally. After two to six weeks of external pacing a new "permanent" Medtronic pacemaker was implanted.

Testing and Sterilization of Pacemaker

All pacemakers were carefully examined and tested in the regional physics department before clinical use. Sterilization was carried out in ethylene oxide at 30° C. for a minimum of three hours, followed by removal of adsorbed gases under vacuum for at least six hours.

Implantation of Pacemaker

Under general anaesthesia a small crease incision was made in the neck, and the catheter of the permanent pacemaker was introduced through the right external jugular vein into the apex of the right ventricle under fluoroscopic control. The catheter was fixed in position by ligation around the vein. Measurement of the myocardial threshold voltage was obtained by connecting the catheter to a pulse generator while the external pacemaker was temporarily switched off. The pulse generator simulated the output of the Medtronic generator which was to be implanted. A threshold of 1.5 volts or more suggested that the catheter tip was not in optimal position and that readjustment was necessary. Most thresholds were found to be about 1 volt (range 0.4–1.4 volts). As a further check to ensure that the catheter tip would not move, the anaesthetist carried out a Valsalva manoeuvre on the patient, and careful watch was made for any intermitency of pacing. On two occasions it proved more suitable to use the cephalic vein as the route for insertion of the permanent electrode catheter.

A loop was fashioned on that part of the catheter which still lay outside the vein and was stitched down to the tissue in the neck underneath the platysma. Both stylets were removed. An incision 2 in. to 3 in. (6.3 to 7.5 cm.) long was then made in the skin of the chest wall, on the right side below and lateral to the breast, and a pocket made beneath the deep fascia to receive the generator. A subcutaneous tunnel was made between the neck and chest wounds and the end of the catheter brought down through it. The new generator was then connected to the catheter and simultaneously the temporary external pacemaker was switched off. The patient's heart was from that moment paced from the permanent generator. As that point the current threshold of the myocardium was again measured by reducing the output of the generator until pacing became intermittent. From a calibration graph provided by the manufacturer the threshold current was determined. In practice this threshold was usually not greater than 1.4 mA. The amplitude of the pacemaker pulses was then reset at maximum and the rate of pacing set between 70 and 76 per minute in most cases. The generator was placed in the subfascial pocket and both skin wounds were closed.

The electrocardiograph was monitored continuously for 48 hours postoperatively, the temporary pacing catheter being withdrawn several days later. The patient was taught to count his pulse rate before leaving hospital and requested to return if the rate varied by more than five beats per minute.

Follow-up

An attempt was made to see every patient at two-monthly intervals whenever possible, and on no account to let this interval extend beyond three months. At each attendance, in addition to a full clinical examination, particular attention was paid to the pulse rate and the E.C.G. of the patients. In addition, the amplitude and width of the pacemaker pulses were recorded by means of a Polaroid camera and oscilloscope, the technique of Knuckey et al. (1965) being followed. Any significant change in these measurements from the preceding ones was correlated with clinical observations and a graphic record of the signal amplitude was updated at each visit.

Results

All patients in this series benefited from the implantation of the pacemaker, most of them showing dramatic improvement in well-being and in physical fitness. There were no deaths in the immediate postoperative period and no instances of hospital infection, phlebitis, thrombembolism, or recurrence of dangerous tachyarrhythmias. Fifteen patients who were in congestive cardiac failure preoperatively all improved after implantation, eight no longer required diuretics, and the other seven remained free of congestive failure on a much reduced dosage.

Complications (Table II)

These can be divided into early and late features. The early complications occurred while the patient was still in hospital—that is, within the first 14 postoperative days. They included arrhythmias, movement of the electrode tip, and penetration of the myocardium. Ventricular extrasystoles were observed in the majority of patients when they were monitored carefully in the first 48 hours after the implant. Their frequency gave rise to anxiety in 10 patients. In six of these this complication had also been noted preoperatively, but in the other four they occurred for the first time in the postoperative period. These ventricular extrasystoles were controlled with either procainamide or quinidine, and in eight patients this treatment was continued on leaving hospital.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number of Patients</th>
<th>Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventricular extrasystoles (more than 12 per minute)</td>
<td>10</td>
<td>22.7</td>
</tr>
<tr>
<td>Intermittent pacing</td>
<td>8</td>
<td>18.2</td>
</tr>
<tr>
<td>Penetration of the myocardium</td>
<td>2</td>
<td>4.5</td>
</tr>
<tr>
<td>Catheter lead breakage</td>
<td></td>
<td>11.3</td>
</tr>
<tr>
<td>Extrusion of the generator</td>
<td>4</td>
<td>9.1</td>
</tr>
<tr>
<td>Primary wound infection</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Infection secondary to extrusion of the generator</td>
<td>3</td>
<td>6.8</td>
</tr>
<tr>
<td>Generator failure</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Peroperative deaths</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Late deaths</td>
<td>6</td>
<td>13.6</td>
</tr>
</tbody>
</table>

Rеманipulation of the catheter was necessary in eight patients in whom pacing became intermittent. This usually occurred within the first 48 hours, but in one case remanipulation was necessary on the seventh day.
Penetration of the myocardium occurred in two cases, resulting in contractions of the muscles of the chest wall. Thoracotomy was carried out and the catheter withdrawn back into the ventricle and repositioned by manipulation at the neck. The ventricular wall was closed with a single stitch in each case. The reason for penetration of the myocardium was probably overzealous placing of the electrode tip.

The late complications included breakage of the catheter lead, extrusion of the generator, and generator failure. Breakage of the conducting lead occurred in six patients at the beginning of the series and was due to leaving one of the steel stylets inside the catheter. This was done on the manufacturer’s instructions to provide increased catheter stiffness. These pacemakers were replaced, and subsequently both stylets have been withdrawn after positioning of the catheter and no further breakages have occurred.

One generator was found to be faulty at the time of implantation and was not used. Apart from this only one generator has failed in use to date. This failure occurred six months after insertion and was preceded by a period of rapidly increasing pacemaker rate. The patient unfortunately developed irreversible ventricular fibrillation and died.

The Medtronic generator has two protrusions which house the rate and amplitude controls. In four patients these protrusions eroded through the skin two to eight months after implantation, resulting in infection in three of them. In one patient another pacemaker was inserted on the opposite side; in the remaining three cases the generators were exteriorized and without interruption of pacing each was immersed in a surgical glove filled with a powerful antiseptic (Portrex D.C.R.) for 20 minutes, after which the wounds were irrigated with Noxyflex and drained. After removal from the antiseptic the generators were replaced at a new site without further complication.

Deaths (Table III)

Six patients in this series died at intervals of from 3 to 22 months after insertion of a pacemaker. Four of these units were recovered at post-mortem examination, and in two cases no faults were found in the generators or catheters. The third generator, referred to above, was found to be faulty; the fourth generator was functioning perfectly, but the catheter insulation was broken, and it was thought that this damage had been caused at the post-mortem examination. In the remaining two cases the pacemakers were not recovered, but each was reported to be functioning normally up to the time of death. One of these patients was known to have had sinus interdependence; he died in hospital after prostatectomy. In this case an electrical death could not be excluded. The other patient died at home after a second myocardial infarction.

Table III. Cause of Death in Six Patients in Series and Function of their Pacemakers at Necropsy

<table>
<thead>
<tr>
<th>Patient</th>
<th>Months after Last Implant</th>
<th>Causes of Death</th>
<th>Pacemaker Tested</th>
<th>Generator</th>
<th>Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>3</td>
<td>Left ventricular failure</td>
<td>Perfect</td>
<td>Perfect</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>6</td>
<td>Myocardial infarction</td>
<td>Perfect</td>
<td>Component</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>Pacemaker failure</td>
<td>Perfect</td>
<td>Damaged due to removal</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>7</td>
<td>Left ventricular failure</td>
<td>Perfect</td>
<td>Not available for testing</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>16</td>
<td>? Electrical death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>22</td>
<td>Myocardial infarction</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussion

Reports on the efficacy and safety of long-term transvenous pacing are now beginning to appear in the literature (Lagergren et al., 1966; Furman et al., 1966; Morris et al., 1967). The surgical simplicity of implantation lessens the mortality and morbidity in this high-risk and vulnerable group of patients. On the whole, most of the patients in our group were sick and elderly. The majority of them were over 60 years of age, about half had evidence of ischaemic heart disease, and some had a raised diastolic blood pressure. Several patients had had a cardiac arrest, and many had other diseases (Table I) in addition. Despite this formidable background all these patients survived the operation and the immediate postoperative period.

The three main complications—movement of the electrode tip, penetration of the myocardium, and extrusion of the generator—are largely avoidable. The first probably occurred because in some cases the tip was placed in a suboptimal position, while in others a less than generous loop of catheter was left in the neck. Penetration of the myocardium has been mentioned by other workers (Zoll and Linenthal, 1963; Port and Sharp, 1965; Furman, 1966). We believe that in our cases it may have been due to overzealous wedging of the electrode tip in the apex of the right ventricle. In each of the two cases in which this complication occurred it was noted at thoracotomy that the myocardium was soft and fatty. Extrusion of the generator, we believe, could have been avoided if it had been placed beneath the deep fascia and secured so that the control protrusions pointed inferiorly and not posteriorly. The only cases of sepsis in this series occurred after extrusion of...
the generator external control point several months after
implantation.

There have been no further breakages of the catheter in
the Medtronic generators which we have implanted since
October 1964 only one has failed. Thirty-three have been in
use for more than six months (see bar Chart) without failure.
To date, our duration of pacing has not taken the majority of
our patients into the phase of normal battery depletion.
We have, however, had no generator or catheter failures since
May 1966. In an attempt to monitor the function of the
generators we have been recording the pacemaker
rhythm at intervals of two to three months. We also hope
that the measurement of generator pulse characteristics will
provide a more accurate estimate of battery depletion.
However, measurement of pacemaker rate may be an equally
reliable index of battery function.

Twelve patients in this series presented with a diagnosis of
intermittent complete heart block. They were also treated
with the standard fixed-rate pacemaker, and 11 were alive and
well at the time of writing. The remaining patient died after
prostatectomy. In other words, patients with intermittent block
in this series were satisfactorily treated with a fixed-rate
pacemaker. There may, however, be a case for using a "demand"
pacemaker in younger patients.

It is our experience that the Medtronic endocardial implantable
pacemaker is reliable and offers an effective remedy for
chronic complete heart block. This is also the finding of other
workers (Castberg and Rasmussen, 1963; Marchand et al.,
1967).

Summary

Forty-four patients with chronic complete heart block have
been treated by the insertion of the fixed-rate Chardack-
Greatbatch endocardial pacemaker.

The preoperative mortality was nil, the postoperative
morbidity low.

Of the 53 generators implanted there was one failure (1.9%).
There were six catheter failures (11.3%), all at the beginning
of the series, owing to a steel stylet being left inside each
pacemaker.

There have been no catheter or generator failures since May
1966.

The cases reported in this series were treated in four major
hospitals in the Glasgow area, and a considerable portion of
the initial management and subsequent follow-up of these patients
has been the responsibility of several of our medical and surgical
colleagues. We are glad to have this opportunity of acknowledging
their collaboration and their permission to refer to cases under their
care. We wish, in particular, to thank Professor W. A. Mackay
(Glasgow Royal Infirmary), Dr. R. M. Thomson (Glasgow Royal
Infirmary), Mr. R. S. Barclay (Mearnskirk Hospital), Dr. A. S.
Rogers (Stobhill General Hospital), Dr. J. A. Kennedy (Glasgow
Royal Infirmary), Dr. A. J. V. Cameron (Western Infirmary),
Dr. A. C. Kenmure (Western Infirmary), and Mr. A. A. Turner
(Western Infirmary).

References

Bain, W. H., Forbes, W., Greene, D., Shaw, G. B., and Thomson, R. M.

643.

Elmqvist, R., and Senning, A. (1960). In Medical Electronics, edited by


Amer. Heart J., 71, 408.


483.


41, 23.

Morris, J. J., jun., Whalen, R. E., McIntosh, H. D., Thompson, H. K.,
Brown, I. W., jun., and Young, W. G., Jun. (1967). Circulation, 36,
587.

Amer. J. Cardiol., 10, 261.


Porter's Neck

LAURENCE F. LEVY,* M. SC., M.B., B.S., F.R.C.S., F.A.C.S.


Several million sacks of mealie meal are produced annually in
Rhodesia together with almost as many bags of beans, monkey
nuts, potatoes, fruits, etc. A very large proportion of these
sacks are manhandled from granary to truck, from truck to
salesroom, and from salesroom to consumer. This transportation
is often performed by one man carrying the sack on his
head. The usual routine is for four men to stand at the corners
of a 200-lb. (90.7-kg.) bag with the porter just in front of them.
At a given signal the four loaders hoist the bag into the air and
the porter quickly walks underneath. The sack is then gently
lowered on to his head, where it balances, steadied by his hands,
until he arrives at his destination.

Once loaded, the porter walks at a steady pace towards his
objective. Up to 30 yards (27 metres) is a convenient distance,
well within the range of the ordinary porter—if the distance
is increased to 50 yards (46 metres), most find difficulty in
covering it without strain. When he arrives at his unloading
point the porter leans slightly forward and eases the sack off
his head with his hands.

Difficulty occasionally arises at the moment of loading if the
loaders drop the sack too quickly, or if the porter does not
get the centre of gravity of the sack more or less vertically over
the articular facets of the foramen magnum, or simply if the
sack is too heavy for an ageing neck. Trouble may arise during
the journey to the unloading point if the man should slip or
fall or lose his balance through fatigue, while it sometimes
happens that some jolt while unloading causes loss of balance
and injury.

In the event of an accident, and if he is lucky, the porter
may escape with nothing worse than a badly strained and
painted neck which may put him off work for some days; if he
is less lucky the injury may be more serious and he may
suffer fracture or dislocation of the bones or discs of the neck
with injury to the spinal cord. The disaster may be compounded
by the bag landing on top of him.

Incidence

Over the past 10 years 13 such serious injuries have been
seen on the neurosurgical ward at the Harare Central Hospital,
Salisbury, and one further case was brought to the hospital.

* Consultant Neurosurgeon, Salisbury Hospitals Group and Department
of Surgery, University College of Rhodesia.