Permanent Ventricular Pacemakers

Comparison of Transthoracic and Transvenous Implantation

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SUMMARY
In the series of 86 patients with the Stokes-Adams syndrome or with symptomatic bradycardia managed with permanently implanted ventricular pacemakers reported on, 35 patients had primary implantation of epicardial leads at thoracotomy and 51 had transvenous endocardial electrodes passed via the jugular venous system for permanent ventricular pacing. The transvenous method of permanent pacemaker implantation appears to be easier to apply with less serious complications and provides the same overall mortality as the transthoracic approach. However, pacemaker failure, both permanent and temporary, is more likely to occur with the transvenous approach.

A series of unique complications and findings noted in the transvenous group were thought to be related to the permanent pacing electrode catheter. These included myocardial perforation, pericardial friction rubs, intermittent ventricular pacing, and diaphragmatic stimulation.

The experience suggests that it is reasonable to employ a transvenous pacemaker initially, recognizing that replacement with a transthoracic pacemaker will be necessary in approximately 16% of the patients and remanipulation of the electrode catheter will be needed in another 13%. Therefore, to undertake transvenous permanent implantation of a pacemaker, one must also be prepared to employ the transthoracic approach in a small but significant number of patients.

Additional Indexing Words:
Complete heart block Transvenous pacemaker Congestive heart failure
Electrode-catheter Stokes-Adams syndrome Complications: Pacemakers
Renal failure Arrhythmia Diaphragmatic pacing

PACEMAKERS for the long-term management of symptomatic bradycardia have been widely applied since Chardack and associates in 1960 reported the successful use of intrinsically powered electronic devices as permanent pacemakers.

This report details the experience with implantable cardiac pacemakers in 86 patients managed at the Duke University Medical Center. The major purpose of the report is to compare two alternative techniques of achieving permanent implantation: (1) direct placement of the electrodes on the epicardium at the time of thoracotomy (transthoracic method) with (2) placement of the electrodes on the endocardial surface by means of a permanent venous pacing catheter (transvenous method).

Description of Patients

Patient Population
The 86 patients included in this report were studied between July 1961 and October 1966.
The average age was 66.5 years (range, 13 to 89 years). Seventy-nine per cent were above 60 years of age; 40% were above 70 years. The patient follow-up from the time of the implantation to October 1966 was 100.

**Indications for Pacemaker**

The two indications for implantation were syncope or presyncopal episodes, and congestive heart failure thought to be related to bradycardia. Syncope or presyncopal attacks were the major indication in 77 of 86 patients (90%). Such episodes had occurred for more than a week in 83% of the patients and for more than a year in 42%. Congestive heart failure was the sole indication for establishing ventricular pacing in the remaining nine patients (10%). Both syncope and congestive failure were present in 29% of the series.

**Etiology**

The suspected etiologies of the bradycardia, complete heart block, or Stokes-Adams episodes in these 86 patients were coronary artery disease (20%), unknown etiology (47%), associated diseases such as rheumatoid arthritis, gout, valvular heart disease, diabetes, hypertension, and pulmonary disease (33%). Patients with digitalis intoxication or acute myocardial infarction were excluded from this study.

**Electrocardiograms**

Permanent, third degree heart block was present in 49 of the 86 patients (57%); alternation between second degree and third degree A-V block in eight (9%), and sinus rhythm, first degree block, or atrial fibrillation was present at some time in the tracings of the remaining 29. Of the 77 patients with symptomatic Stokes-Adams attacks, 27 (35%) had tracings at some time during their hospitalization which showed an intermittent supraventricular mechanism as well as third degree block or asystole.

**Drug Management**

All patients received oral or intravenous isoproterenol prior to pacemaker implantation; in the majority this failed to prevent Stokes-Adams attacks or improve congestive failure. In eight of the nine patients with congestive heart failure but without syncope, high doses of oral isoproterenol were tried for several weeks without success. This failure of effective drug management may well have been prejudiced by selection since many patients were referred because previous pharmacological therapy had failed.

**Methods**

Effective permanent pacing was achieved in each patient during the primary hospitalization by means of a fixed rate ventricular device.* In 35 patients the primary technique of implantation was the transthoracic method. The procedure was carried out under general anesthesia by the recommended surgical approach. In 51 patients a specially designed bipolar pacing catheter† was passed by the jugular venous system under local anesthesia to the apex of the right ventricle and then connected to the fixed rate pulse generator* for permanent implantation in the infraclavicular region.

Regardless of whether the transthoracic or transvenous method was planned, satisfactory pacing with a temporary venous bipolar pacing catheter and an external pulse generator was first employed in all patients.

To allow for direct comparison between the transthoracic and the transvenous approach, arbitrary definitions were assigned for assessing pacemaker function. Failures to maintain successful pacing were divided into two groups according to the cause: (1) component failure, that is, malfunction of battery, electrode, or circuitry resulting in interruption of satisfactory pacing; minor percutaneous voltage adjustments in the first several weeks were not considered failures and (2) technical failures, that is, adequate mechanical performance of the components occurred but due to some other technical reason satisfactory pacing was not achieved. The technical failures could be further subdivided into (a) permanent technical failures, that is, an entirely new procedure had to be undertaken to restore pacing and (b) temporary technical failure, that is, a relatively simple procedure was sufficient to reestablish satisfactory pacing.

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†Medtronic, Inc. Minneapolis, Minnesota. Char-\dack bipolar endocardiac electrode (Model 5816).
Results

Hospital Course
The average hospital stay for the 35 patients with the transthoracic method was 19.1 days (range, 10 to 90 days). In the 51 patients in whom transvenous implantation of a pacemaker was accomplished, the average stay was 12.3 days (7 to 35 days). In both groups this encompassed all who sustained complications and also included the time for the diagnostic tests and the observation period required before finally establishing the need for permanent ventricular pacing.

The immediate postoperative convalescence in the two groups also differed in the rate of return to normal activity. The majority of the patients for whom the transvenous approach was used were ambulatory and returned to a previous or improved functional status by 24 to 72 hours following implantation. Patients for whom the transthoracic method was used required weeks to attain their previous level of performance.

Major Complications
Eleven of the 35 patients (31%) with the transthoracic method experienced major complications (table 1). Four serious complications were encountered in the 51 patients who had a transvenous approach (8%).

Transthoracic Method
Renal failure was a significant feature contributing to a long hospital stay in four patients. It was of sufficient magnitude to require dialysis for one patient and management as acute renal failure for the other three. Each patient regained preoperative renal function, and none developed chronic renal failure.

Table 1

<table>
<thead>
<tr>
<th>Major Complications</th>
<th>Transthoracic Type</th>
<th>Cases</th>
<th>Transvenous Type</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal failure</td>
<td>4</td>
<td></td>
<td>Myocardial perforation</td>
<td>2</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>4</td>
<td></td>
<td>Lateral sinus thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Embolism</td>
<td>1</td>
<td></td>
<td>Infection</td>
<td>1</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td></td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

Serious cardiac arrhythmias were a prominent complication in four patients. Following the operation one patient had 87 separate episodes of ventricular tachycardia which on many occasions deteriorated to ventricular fibrillation. A second patient had 14 episodes of ventricular fibrillation in the first 24 hours after operation, all of which required DC shock. A third patient had an excess of 30 episodes of ventricular tachycardia, many resulting in ventricular fibrillation, requiring repeated external shocks. A fourth patient had repetitive ventricular arrhythmias and a shocklike picture for 7 days which ultimately resulted in the loss of the distal portions of all four extremities. He eventually recovered but has required four artificial limbs. Certain features were common in the four patients: All occurred in the immediate period following implantation of a transthoracic pacemaker; none had a clinical picture suggesting myocardial infarction; in three of the four patients in whom the mechanism of the Stokes-Adams attacks was known, it was transient ventricular tachycardia or fibrillation; all were poorly controlled by rather large doses of antiarrhythmic agents during this period.

A cerebral vascular accident occurred in one patient on the fourth day after thoracotomy. He developed sudden loss of consciousness, confusion, and difficulty with speech which cleared promptly.

Infection occurred in a patient after an uneventful transthoracic insertion of a pacemaker, which functioned adequately for 10 months and then ceased to pace. The pulse generator was replaced at a community hospital, but pacing could not be accomplished. Thoracotomy was performed and localized staphylococcal abscesses were found at the sites of the electrode implantations in the myocardium. New electrodes were applied but the patient died of complications of the surgery.

One patient developed hepatitis 45 days after transthoracic implantation and required a 30-day hospitalization for treatment. Twenty-four months later he is doing well.
Transvenous Method

Acute myocardial perforation with the development of cardiac tamponade occurred twice at insertion of a permanent transvenous catheter. Both patients suddenly developed arterial hypotension, venous hypertension, and paradoxical pulses, and both responded to pericardiocentesis. Successful pacing continued in one, but the other failed to pace as tamponade developed. They were treated with direct myocardial application of electrodes at thoracotomy.

One patient experienced cerebral vascular symptoms suggestive of basilar artery insufficiency 8 days after a transvenous catheter had been permanently implanted in the right internal jugular vein. Complete recovery followed in several days. Six weeks later transient visual blurring with bilateral papilledema was noted. Cerebral angiograms demonstrated no filling of the right transverse sinus and poor filling of the posterior region of the sagittal sinus. It was assumed that at the original implantation thrombosis of the internal jugular system occurred and extended to the lateral and sagittal venous sinuses on the right. Conservative treatment with repeated lumbar punctures resulted in reduction of the elevated spinal fluid pressure and elimination of the visual symptoms and papilledema. After a 6-month period the patient has remained well and free of cerebral symptoms. The lack of a satisfactory external jugular system for passing a permanent transvenous catheter has been noted in approximately one fifth of the patients.

Another patient developed infection at the infraclavicular site of the pulse generator 8 days following intravenous implantation. The entire pacing device and catheter were removed and a second unit was implanted via the contralateral external jugular vein.

Pacemaker Failures

Since the transthoracic and transvenous methods shared the same components, the major difference in pacemaker performance should be evident in what we have termed technical failures. These technical failures are discussed separately and the component failures are discussed jointly for the two methods.

Technical Failures

Transthoracic Method. Permanent technical failures have not occurred when satisfactory pacing was achieved. It has always been possible to continue effective pacing. Temporary technical failures occurred only once; this occurred in the patient, referred to previously, who developed an infection at the electrode sites 10 months post insertion. Reoperation with selection of new epicardial sites resulted in resumption of effective pacing. As thoracotomy was required, this case could be called a "permanent technical failure," but we have classified it as temporary. Thus no permanent technical failures were encountered in the transthoracic group and only one (3%) of 35 patients had temporary technical failure (fig. 1).

Transvenous Method. Permanent technical failures occurred in eight patients of the 51 patients on whom a transvenous approach was used. All eight patients underwent thoracotomy with permanent placement of epicardial leads. These included four patients in whom cardiac perforation was suspected and who were operated on within 24 hours of the initial transvenous attempt. In two

![Figure 1](https://example.com/figure1.png)

**Figure 1**

Comparison of successful ventricular pacing after transthoracic and transvenous implantation. See text for definition of temporary and permanent failures.
of these patients, referred to previously, there was immediate development of cardiac tamponade; the other two developed intermittent failure to pace and diaphragmatic stimulation within the first 24 hours post insertion. No evidence of perforation was found in these latter patients. The remaining four patients presented as intermittent pacing failures. These failures occurred from the first day to as late as 7 months after implantation. Despite attempts made to reposition the permanent pacing catheter, by exposing it surgically in the neck, intermittent pacing recurred and thoracotomy was eventually done in each case.

Temporary technical failures occurred in seven patients. They consisted of failure to stimulate the heart or of bothersome diaphragmatic stimulation. All were successfully managed by remanipulating the permanently implanted catheter at a second surgical procedure. These temporary technical failures occurred from the second day to as late as the third month post insertion. The reasons for these failures are clear in only two cases: in one the catheter migrated to the pulmonary artery after 3 days, and in another the catheter moved to the right atrium after 3 months of pacing. Thus, in 15 of the 51 patients (29%) technical failures occurred. Sixteen percent of the failures were permanent and eventually the transthoracic approach was required; 13% were temporary and were corrected by remanipulation (fig. 1).

Component Performance

Only pulse generators implanted after January 1964 are included in the analysis of component failures (table 2) as the elective replacement of earlier units would have unfairly weighted the information.

After 2 years of service 53% of the patients had uninterrupted component service while 47% had failures which required hospitalization and repair. Pulse generator failures were responsible for the majority of these failures. They were most often manifested as permanent failure to pace or a prominent slowing of the pulse generator impulse (decreased by 10 beats/min or more). Acceleration of the pulse generator occurred in two instances. Five patients experienced electrode breaks. These accounted for 25% of the component failures. These patients most often presented clinically as sustained failure to pace. The break was detectable radiographically in all but two patients. In these two patients the failure to pace was intermittent.

Late adjustments in voltage after 12 months have been a sign of impending pulse generator failure. In five such instances, all generators ultimately failed within the ensuing month. Four of these were successfully replaced, but in one instance the failure (subsequently confirmed by the manufacturer) resulted in sudden death 7 days after a voltage adjustment. Therefore, the need to

Table 2

<table>
<thead>
<tr>
<th>Component Performance</th>
<th>1 year</th>
<th>1½ years</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>31</td>
<td>22</td>
<td>17</td>
</tr>
<tr>
<td>Uninterrupted service</td>
<td>91%</td>
<td>77%</td>
<td>53%</td>
</tr>
<tr>
<td>Pulse generator failure</td>
<td>6%</td>
<td>18%</td>
<td>35%</td>
</tr>
<tr>
<td>Electrode breaks</td>
<td>3%</td>
<td>9%</td>
<td>12%</td>
</tr>
</tbody>
</table>

Figure 2

Comparison of survival after the transthoracic and the transvenous insertion of a pacemaker. The numbers in parentheses give the number of patients by each technique followed for specific numbers of months after implantation.
change a pulse generator voltage after 3 months of successful pacing is considered a sign of component failure and warrants replacement.

Mortality

No deaths which could be attributed to the implantation of either type of pacemaker occurred during the primary hospitalization. The period of follow-up for the 56 patients varies from at least 2 months to over 3 years; the group has been followed for a total of 1,261 months. Six late deaths occurred in the transthoracic group and three in the transvenous group. The duration of follow-up is considerably longer in the transthoracic group, so that this difference cannot be attributed to the difference in technique. As shown in figure 2 with comparable periods of follow-up, there is no difference in mortality for the two approaches.

Transthoracic Method

Six patients with a transthoracic pacemaker expired (A in table 3). Two deaths (patients 3 and 6) can be truly classified as pacemaker deaths. Patient 3 expired in the postoperative period after having infected electrodes re-placed at a thoracotomy 10 months following primary implantation. Patient 6 had a pacing failure at 15 months. He was seen because of a single recurrent syncopal episode; the voltage was increased by percutaneous adjustment and successful ventricular pacing ensued. Seven days later he expired suddenly. Postmortem examination of the pulse generator showed complete failure of the unit due to deterioration of the collector lead to the oscillator. The other four patients expired during subsequent hospitalizations, and although postmortem examinations were not obtained in each case, ventricular pacing was satisfactory. In two patients (nos. 1 and 2) the rate and voltage output of the generator were exactly those noted at the time of the original implantation.

Transvenous Method

Of the three deaths in the 51 patients subjected to transvenous method (B in table 3), one death occurred during the initial hospitalization, patient 7. This patient had severe renal disease and complete heart block with syncope. Despite 7 days of effective ventricular pacing, the renal disease progressed and ultimately ended in the patient’s death despite

Table 3

<table>
<thead>
<tr>
<th>Number</th>
<th>Age (yr)</th>
<th>Race; sex</th>
<th>Duration (mo) of</th>
<th>Postmortem</th>
<th>Cause of death and how established</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syncope</td>
<td>CHF</td>
<td>pacemaker examination</td>
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<tr>
<td>A.—Transthoracic method</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>83</td>
<td>WM</td>
<td>4</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>72</td>
<td>NF</td>
<td>6</td>
<td>12</td>
<td>5</td>
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<tr>
<td>3</td>
<td>64</td>
<td>WM</td>
<td>36</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>53</td>
<td>WF</td>
<td>1</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>5</td>
<td>72</td>
<td>WM</td>
<td>1</td>
<td>½</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>67</td>
<td>WM</td>
<td>1</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>B.—Transvenous method</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>69</td>
<td>NM</td>
<td>48</td>
<td>36</td>
<td>½</td>
</tr>
<tr>
<td>8</td>
<td>70</td>
<td>WM</td>
<td>2</td>
<td>0</td>
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</tr>
<tr>
<td>9</td>
<td>67</td>
<td>WM</td>
<td>0</td>
<td>12</td>
<td>9</td>
</tr>
</tbody>
</table>

Abbreviations: W = white; N = negro; M = male; F = female; CHF = chronic heart failure; N = normal (rate and voltage output) same as noted at time of initial implantation; ABN = abnormal pulse generator function; and NT = generator not tested at time of death.

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dialysis. Postmortem examination showed severe renal parenchymal disease. The venous electrode catheter showed a minimal surrounding reaction and a small 1.5-cm endothelial sleeve covered its termination in the apex of the right ventricle. No in situ thrombosis or pulmonary emboli were discovered. Two other patients (nos. 8 and 9) expired suddenly after 2 and 9 months of ventricular pacing. No cause for the deaths was evident. Examination of the pulse generators in both cases showed rates and voltage outputs comparable to those recorded at the time of the implantation.

**Sudden Death**

Other authors have commented on the frequency of sudden death occurring in patients with competition between a ventricular pacemaker and a supraventricular focus. In this series 55 patients had permanent third-degree block and 31 had varying degrees of competition. Death could be classified as "sudden" in four patients (nos. 1, 6, 8, and 9). Two of these patients had permanent block, and two had competition between the pacemaker and a supraventricular focus. Although the series is small, these data do not support the notion that sudden death is more frequent in patients with competition between a pacemaker and a supraventricular focus.

**Peculiarities of the Transvenous Method**

Certain complications occurred which were related to the use of an endocardial permanent electrode catheter: (1) migration of the pacing electrode, (2) diaphragmatic pacing, (3) pericardial friction rubs, and (4) myocardial perforation.

Migration of the pacing catheter occurred in 13 of the 51 patients who had a permanent transvenous catheter. This occurred from 1 day to as late as 7 months after primary implantation. In two of these 13 instances there was sufficient movement to displace the electrode catheter from the right ventricle: once to the right atrium and once to the pulmonary artery. In the other cases in which effective pacing stopped or was intermittent, it was assumed that movement within the chamber had occurred. In seven of the 13 instances, simple repositioning by a cutdown under local anesthesia over the site of entry into the jugular system was successful in re-establishing ventricular pacing. Minor degrees of movement of the electrode catheter tip within the ventricular chamber can produce dramatic changes in threshold, that is, an increase from 1 to 6-ma threshold with less than a few centimeters displacement. It has been suggested that once satisfactory pacing has been achieved for a period of days or weeks, late migration of the catheter electrode should be uncommon, since the catheter is enveloped in a sleeve of endothelium. Postmortem examination indicated that such an endothelial sleeve had begun to encompass the catheter by 7 days. In the failures, due to presumed migration of the catheter, eight of 13 occurred within 1 day after placement. The remaining five occurred as late as 1 to 7 months after permanent implantation, thus suggesting that fixation by an endothelial sleeve is not a uniform occurrence.

Diaphragmatic pacing occurred in six patients (11%). With the catheter in the right ventricular apex, it is closely approximated to the left leaf of the diaphragm, and it is conceivable that an impulse of sufficient magnitude could simultaneously stimulate the myocardium and the muscles of the left leaf of the diaphragm. This possibility was confirmed in one patient using a temporary pacing catheter and an external pulse generator. The threshold for myocardial stimulation was 1.2 ma; by progressively increasing the milliamperes to 6, the heart and left leaf of the diaphragm could be repeatedly and simultaneously stimulated. Commercially available pulse generators for transvenous implantation are frequently set with high outputs, 4.5 to 7.0 ma.

Synchronous pacing of the ventricle and the left leaf of the diaphragm occurred in three patients. At thoracotomy no perforation was found in one patient; in the other two, minor remanipulation of the catheter reduced
or stopped the diaphragmatic stimulation and effective ventricular stimulation persisted. Diaphragmatic stimulation without ventricular contraction occurred in three patients; in two, myocardial perforation was demonstrated at thoracotomy. In the third patient, after 3 months of successful pacing, the heart rate slowed and the patient experienced an uncomfortable twitching in the muscles of the right chest. Fluoroscopy and x-ray examination showed the catheter tip against the lateral wall of the right atrium, where it was stimulating the right atrium and the right phrenic nerve. Simple manipulation resulted in successful ventricular pacing which has continued for 5 months. Thus, stimulation of both heart and diaphragm can be treated conservatively, that is, by reducing the milliampere output or repositioning the transvenous catheter. Diaphragmatic stimulation without ventricular stimulation probably means perforation and the transthoracic approach should be resorted to.

Asymptomatic pericardial friction rubs were noted in five patients within 2 to 48 hours after insertion of the transvenous permanent catheter. Signs of pericardial tamponade were uniformly absent, right atrial injection of CO₂ and radioisotopic precordial scans in three of these patients failed to reveal signs of pericardial fluid. No serial changes in electrocardiograms or serum enzymes were noted. The rubs subsided in 6 to 72 hours without loss of effective pacing. A conservative approach without manipulation of the catheter was followed. After 5 to 14 months the patients have all done well without sequelae and effective ventricular pacing has been maintained. Numerous patients with temporary and permanent right ventricular pacing catheters developed high pitched "squeaking" types of systolic sounds which were intermittent and dependent on position and respiratory phase. These sounds were distinct from the pericardial friction rub which has been described. The mechanism of the pericardial friction rub is unknown. However, in view of the lack of evidence of pericardial effusion or symptomatic difficulty and the transient and benign nature of the pericardial rub in all five patients, a conservative approach appeared justified.

Cardiac perforation by the electrode catheter is known to have occurred in four patients; two who developed acute cardiac tamponade have already been discussed. A third patient experienced failure to pace and stimulation of the diaphragm after insertion; at thoracotomy 12 hours later, the catheter was seen to be protruding through the right ventricular wall. A fourth patient had 6 months of successful pacing and then failure to pace developed concomitantly with intermittent stimulation of the left leaf of the diaphragm. X-ray examination indicated that the catheter had obviously migrated. Cineangiograms with right atrial injection of contrast material clearly revealed that the catheter was outside the right ventricular chamber. The catheter was removed and replaced by a temporary pacing catheter; 3 days later thoracotomy with direct myocardial application of electrodes was performed. At surgery

![Figure 3](image_url)

**Figure 3**

Comparison of survival of three populations. (Upper line) A population drawn from U. S. vital statistics table with age, sex, and race matched to the patients reported in this article. The Duke-pacemaker group comprises the 86 patients in this series managed with permanent implantation of pacemaker. The Friedberg-medical group comprises 100 patients with Stokes-Adams syndrome who were treated medically.18

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a small amount of clear pericardial fluid was found together with a small 1-cm patch of epicardial scar at the apex of the right ventricle. The postoperative course was benign and the patient was doing well one month following thoracotomy.

Discussion

A permanently implanted cardiac pacemaker is the method of choice in managing symptomatic heart block and the Stokes-Adams syndrome. This is apparent after comparing the present series with a comparable group of patients managed medically by Friedberg. The medically managed patients (Friedberg) and the pacemaker managed groups reported in this article were matched in regard to sex, age, and race with a sample population obtained from the U. S. vital statistics tables for 1965 (fig. 3). The hospital mortality in the patients with the Stokes-Adams syndrome managed by drugs was 35%; our series with permanent pacemaker implantation had a 1.1% hospital mortality. At 1-year follow-up the drug group had a 50% mortality versus a 9% mortality in the pacemaker patients. The divergence of the drug managed and the pacemaker groups appears to increase with progressive length of follow-up. Another feature evident from this figure is that the slope of the line or the percentage of deaths per year in patients with symptomatic complete heart block treated with an implanted pacemaker is similar to that noted in the normal U. S. age, sex, and race-matched population. Despite the numerous technical and component failures, the very high mortality due to Stokes-Adams syndrome seems to be almost obliterated by the implantation of a ventricular pacemaker.

Not only is survival strikingly improved but the symptomatic improvement achieved in the patients was impressive even though it cannot be precisely quantitated. Nearly 100% of our patients have improved exercise tolerance. When congestive heart failure was a clinical problem, a number of patients responded with a disappearance of symptoms as a result of pacing alone. In other paced patients digitalization has resulted in added clinical response.

Economically, there appears to be minor, if any, difference in cost between drug management and permanent pacemaker implantation. Thus, the mortality is reduced, the morbidity is considerably decreased, much wider therapeutic latitude is afforded, and at worst the cost to the patient is increased only slightly when a permanently implanted pacemaker is used.

The technical aspects of pacemaker function are encouraging. Ninety per cent of the patients in this series have had uninterrupted service for 1 year and over 50% had uninterrupted component service for 2 years. The simplest type of unit, a fixed rate ventricular pacemaker, was purposely used in these patients to reduce component failures and to provide a background against which to judge other more complex units.

One of the prime interests in this study was to compare the transthoracic and transvenous methods for establishing ventricular pacing. The age, sex, race, etiology, duration and severity of symptoms, and presence or absence of congestive heart failure were comparable in the 35 patients managed by the transthoracic approach and the 51 patients managed with the transvenous method. Thus, comparison of the two methods is valid.

The transvenous method was accomplished in a shorter period of hospitalization; the stay was reduced by one third from that following use of the transthoracic method. The period and extent of postoperative disability in the transthoracic and transvenous groups were strikingly different because of avoiding general anesthesia and a major surgical procedure in the latter group. Serious complications were present in 31% of the transthoracic patients in this series. In the majority of other reported series of transthoracic pacemakers, similar significant operative mortality and postoperative morbidity have been noted. In our group of patients with transvenous pacemakers, 8% had serious complications, and in other series available in the literature, a similar low figure.
was noted with this technique.⁸⁻¹⁰,¹³ In summary then, transvenous implantation of a pacemaker can be carried out during a shorter hospital stay with fewer serious complications, sooner ambulation, and a quicker return of the patients to their previous or improved functional status than the transthoracic method. Furthermore, the transvenous method had a wider range of applicability, as it can be applied to a patient too ill or too unstable to withstand thoracotomy.

If the ease of carrying out the procedure were the only consideration, there would be little doubt as to the choice of method for implanting a permanent pacemaker. However, reliability and dependability must always be the hallmark for a pacemaker procedure. It is here that the transthoracic approach outperforms the transvenous approach. Permanent failures have not occurred and a temporary failure occurred on only one occasion in the 35 patients. With the transvenous method 16% of the patients had permanent failures, requiring subsequent thoracotomy, and 13% had temporary failures requiring re manipulation of the electrode-catheter at a subsequent time. However, two thirds of the 15 failures in the transvenous group occurred during the primary hospitalization and thus could be promptly and safely corrected.

The present study does not answer a major question. Will late failures continue to accumulate among the transvenous group as these patients are followed for a longer period? In this study 20 patients in the transvenous group were followed for 9 months or longer. Long-term performance appears stable, but additional experience is needed.

The transvenous approach produces a unique series of problems, including cardiac perforation, catheter migration, pericardial friction rubs, and diaphragmatic pacing. These problems have been reported by others with permanent implantation⁸⁻¹⁰,¹²,¹³ and have been likewise seen in temporary transvenous pacing.²⁷⁻²⁹ These complications are reiterated to enforce the impression that considerably more post-insertion care, close follow-up, and reevaluation are involved with transvenous than with transthoracic pacemaker implantation. With thoracotomy the major complications are centered around those usually seen in the immediate postoperative period. With the transvenous method the complications are centered around the electrode catheter. In reality, one does not have a choice between a transvenous or transthoracic pacemaker. If the transvenous method is used, one must also be prepared to apply the transthoracic method in a certain number of these patients. When a skilled catheter team is available, it seems wise first to attempt the transvenous method. If this can be achieved and satisfactory pacing is established, a major surgical procedure is avoided. If this is not accomplished, the more certain but more serious transthoracic approach can be used.

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