Editorial

Ambulatory Pacemaker Procedures

The cardiologists who struggled through the early
days of cardiac pacing were painfully aware of
the multitude of problems that faced both the
implanting physician and the patient. The early
pacing systems were large, brief in longevity, and
prone to the catastrophes of lead dislodgment,
perforations, and wound infections. To intervene
with cardiac pacing was a critical decision. Post-
operatively, because of the foregoing concerns,
patients were managed with extreme caution.

In this issue of the Proceedings (pages 236 to
240), Hayes and associates consider the feasibil-
ity and safety of ambulatory pacemaker pro-
dcedures—a concept that at first thought seems
heretical. Today, however, the aforementioned
complications seem to be the exception. Currently
available pacemakers are small and have a
modest longevity. The necessary surgical inter-
vention for implantation is minor. With the per-
cutaneous sheath set technique, venous access is
extremely easy and expeditious. The recently
described combination sheath set and cutdown
technique seems to avoid the risks of the blind
percutaneous technique in the high-risk patient.4
State-of-the-art electrode systems with positive
and passive fixation have reduced the dislodg-
ment toward zero.5-11 In addition, cardiac pacing
is no longer reserved for the absolute pacemaker-
dependent patient. Indications have expanded so
that many more non-pacemaker-dependent pa-
tients may benefit from permanent pacing. The
strongest incentive for the ambulatory approach
comes from the issue of cost containment. The
very technology that has made cardiac pacing
physiologic, reliable, and safe has resulted in a
dramatically accelerating cost, which has im-
posed inappropriate constraints on cardiac pacing.
Cost containment has resulted in rigid peer re-
view and directives from hospital administrators
about which pacing systems can be used, at times
resulting in suboptimal patient care. It would
seem logical that the ambulatory approach should
dramatically diminish the cost and provide opti-
mal care.

Hayes and colleagues, also citing the minor
nature of the procedure and the issue of cost
containment, reviewed 100 consecutive pace-
maker implantations for complications and the
feasibility of a brief overnight hospital stay. Only
procedures involving the manipulation of one or
more electrodes were considered. The study in-
cluded an equal number of single-chamber and
technically more difficult dual-chamber pro-
dcedures. Atrial electrodes had predominantly
positive fixation, whereas most ventricular elec-
trodes had passive fixation. Only six complica-
tions necessitated invasive intervention, and all
were recognized within 24 hours (but not all
during the working day). The investigators
thought that all the minor abnormalities man-
aged noninvasively could be effectively detected
and managed in the Pacemaker Clinic with no
untoward effect to the patient.12-14 Early post-
operative follow-up was considered essential for
detecting complications. Although not advocat-
ing an ambulatory approach to cardiac pacing
in all patients, Hayes and associates concluded
that dismissal at 24 hours is safe and that the
ambulatory approach may become routine in
selected patients.

Of importance, the “safe” dismissal at 24 hours
as judged by Hayes and co-workers conforms
to the Health Care Financing Administration’s
definition of ambulatory or outpatient surgical
procedures for reimbursement in the United
States (Table 1). In the analysis of the data of
Hayes and associates, it is important to realize
that their report was based on a retrospective
study and record review. None of the pacemaker
implants was ever intended as an outpatient
procedure or actually approached from an ambu-
latory standpoint. This type of study introduces
some error into the timing of discovery of a
complication and the determination of feasibility
for early hospital dismissal. Perhaps none of
the six patients with complications would ever have
been considered for early dismissal, nor is there
any way of knowing whether a complication was
suspected before its discovery—because antici-
Table 1.—Definition of Outpatient or Ambulatory Surgical Procedures

“When a patient with a known diagnosis enters a hospital for a specific minor surgical procedure or other treatment that is expected to keep him in a hospital for only a few hours (less than 24), and this expectation is realized, he will be considered an outpatient regardless of the hour of admission; whether or not he occupied a bed and whether or not he remained in the hospital past midnight.”

From Hospital Manual, Health Care Financing Administration, Publication 10, Section 210 A.

pted problems or experienced difficulties at the time of implantation may have gone unrecorded.

The data of Hayes and colleagues strongly support the ambulatory pacing experience of other investigators. In Europe, Zegelman and co-workers have performed ambulatory pacemaker implantations routinely since 1980, and their experience now exceeds 1,000 ambulatory pacemaker procedures. In 1984 alone, 538 of 672 new implants (80%) were performed on an ambulatory basis. The major concerns of ventricular lead dislodgment and exit block were shown not to be important factors. From 1980 to 1984, almost 3,000 total implantation procedures were done by this group. In their series, only 13 cases of exit block (0.7%) and 2 cases of lead dislodgments (0.1%) occurred with 1,866 screw-in electrodes. Likewise, only 6 cases of exit block (0.6%) and 3 cases of lead dislodgments (0.3%) occurred among 1,054 passive fixation ventricular electrodes. Even more impressive was their extremely low rate of complications. In 1984, only 3 complications and no deaths occurred in the outpatient group of 538 procedures. Zegelman and associates followed a simple protocol for managing an ambulatory pacemaker implant. Their experience clearly demonstrates the feasibility and safety of ambulatory pacemaker implantation.

A similar experience in the United States at our pacemaker center reinforces the experience of Zegelman and colleagues. During a 46-month period, 181 of 410 new pacemaker implantations were performed on an ambulatory basis. This series reflected the confidence gained with experience. In 1983, 34% of the total annual pacemaker implantations were done on an ambulatory basis in comparison with 59% in 1986. Most of the implants (107 of 181 or 59%) were the more complicated dual-chamber systems. The complication rate was low; no major complications or pacemaker emergencies occurred in the ambulatory group. In only three instances, the ambulatory approach failed or patients intended for outpatient management were detained in the hospital for more than 24 hours. As in the other cited experiences, age, sex, and pacemaker dependence were not important factors. This study similarly supported the safety and practicality of the ambulatory approach for pacemaker implantation, and again a simple protocol was followed (Table 2). In reference to the concerns about the retrospective nature of the study by Hayes and co-workers and the time of discovery of major complications, in our experience when an ambulatory procedure is considered, we are sensitized to potential problems and the high-risk patient. Even though a complication might have been confirmed much later, we were always immediately aware of its potential presence. This awareness or suspicion prompted us to detain the patient. Therefore, this concept leads to the first and only rule of ambulatory pacing—if any doubts or concerns exist, hospitalization of the patient should always be extended.

Of a total of 520 pacemaker implantations in our experience, 247 (48%) have been performed as ambulatory procedures. In 1987, 63 of 96 new implantations (66%) were done on an outpatient basis, and only one failure (a hemothorax that was recognized immediately) occurred in this ambulatory group. The patient was detained for observation and subsequently dismissed. At present, because of the proven safety, all pacemaker elective and nonelective procedures, including new implants, pulse generator changes, upgrades, and repositioning of electrodes, are

Table 2.—Protocol for Outpatient Pacemaker Implantation Procedure

1. Surgery scheduled as outpatient with outpatient number assigned
2. Preoperative blood work, electrocardiogram, and chest x-ray done as outpatient approximately 24 hours prior
3. Patient instructed to remain fasting after midnight of evening prior to procedure
4. Patient instructed to report to outpatient department in the morning
5. Postoperative electrocardiogram and chest x-ray
6. Discharge when fully awake and vital signs stable
7. Instructed to report to pacemaker center the following morning

From Belott. By permission of Elsevier Science Publishers B.V.
approached on an ambulatory basis. The confidence gained has also prompted the dismissal of the patients who have undergone nonambulatory pacemaker procedures on the same day as the surgical procedure.

Logically, it would seem that the ambulatory approach to cardiac pacing should result in substantial cost savings to all parties concerned. Unfortunately, this is not the outcome (Table 3). Currently, Medicare—the prime reimbursement vehicle for pacemakers—offers no incentive for performing a pacemaker implantation on an ambulatory basis. It primarily reimburses pacemakers under the diagnosis-related group (DRG) system. Medicare spends approximately 50% more per pacemaker implantation under the DRG system than for the ambulatory approach. Paradoxically, the institution barely meets its expenses with Medicare's reimbursement of an ambulatory pacemaker procedure. For the hospital, reimbursement is considerably better under the DRG system. At least expenses are met, and if the hospitalization is brief, substantial gain may be realized. An additional problem is encountered with the current system. In an attempt to meet expenses of an ambulatory procedure, hospitals characteristically inflate their charges. Even though Medicare reimburses approximately 50% of allowed charges (on the basis of a complicated cost-to-charge adjustment), the patient is still responsible for 20% of the inflated allowed charges. Thus, the patient may be at a disadvantage economically if an ambulatory procedure is performed. All parties would benefit if the reimbursement policies for permanent cardiac pacemakers were restructured. The incentive of improved profit margin would promote the more cost-effective ambulatory approach, and the result would be a shift of pacemaker procedures from the more expensive DRG system to the potentially cost-effective ambulatory approach. In addition, a reduction in patient copayment would lend further support through better patient acceptance.

**Conclusion.**—The discussed experiences with ambulatory cardiac pacemaker implantation and the feasibility study of Hayes and associates clearly support the safety and practicality of the ambulatory pacemaker procedure. The realization of the “obvious cost savings” remains to be seen. The Health Care Financing Administration and other third-party carriers should restructure their reimbursement policies to provide the necessary incentives to the hospital and the patient for the development of ambulatory pacemaker implant programs.

Peter H. Belott, M.D.
The Pacemaker Center
El Cajon, California

---

**REFERENCES**

5. Furman S, Pannizzo F, Campo I: Comparison of active and passive adhering leads for endocardial pacing. PACE 2:417-427, 1979

---

**Table 3.—Economics of Cardiac Pacemaker Implantation at AMI Valley Medical Center, El Cajon, California**

<table>
<thead>
<tr>
<th>Medicare method of reimbursement</th>
<th>Hospital expenses</th>
<th>Hospital charges</th>
<th>Medicare reimbursement</th>
<th>Patient responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part A—diagnosis-related group (DRG)</td>
<td>$6,000</td>
<td>$12,200 (irrelevant)</td>
<td>$12,000</td>
<td>$540 (Medicare part A deductible)</td>
</tr>
<tr>
<td>Part B—ambulatory procedure</td>
<td>$6,000</td>
<td>$12,200</td>
<td>$5,000</td>
<td>$2,675 (Medicare part B deductible [$75] + 20% copayment [$2,600])</td>
</tr>
</tbody>
</table>


