Risks of Spontaneous Injury and Extraction of an Active Fixation Pacemaker Lead

Report of the Accufix Multicenter Clinical Study and Worldwide Registry

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Background—The Telectronics Accufix pacing leads were recalled in November 1994 after 2 deaths and 2 nonfatal injuries were reported. This multicenter clinical study (MCS) of patients with Accufix leads was designed to determine the rate of spontaneous injury related to the J retention wire and results of lead extraction.

Methods and Results—The MCS included 2589 patients with Accufix atrial pacing leads that were implanted at or who were followed up at 12 medical centers. Patients underwent cinefluoroscopic imaging of their lead every 6 months. The risk of J retention wire fracture was ~5.6%/y at 5 years and 4.7%/y at 10 years after implantation. The annual risk of protrusion was 1.5%. A total of 40 spontaneous injuries were reported to a worldwide registry (WWR) that included data from 34 672 patients (34 892 Accufix leads), including pericardial tamponade (n = 19), pericardial effusion (n = 5), atrial perforation (n = 3), J retention wire embolization (n = 4), and death (n = 6). The risk of injury was 0.02%/y (95% CI, 0.0025 to 0.072) in the MCS and 0.048%/y (95% CI, 0.035 to 0.067) in the WWR. A total of 5299 leads (13%) have been extracted worldwide. After recall in the WWR, fatal extraction complications occurred in 0.4% of intravascular procedures (16 of 4023), with life-threatening complications in 0.5% (n = 21). Extraction complications increased with implant duration, female sex, and J retention wire protrusion.

Conclusions—Accufix pacing leads pose a low, ongoing risk of injury. Extraction is associated with substantially higher risks, and a conservative management approach is indicated for most patients. (Circulation. 1999;100:2344-2352.)

Key Words: pacemakers ■ pacing ■ complications
TABLE 1. Age Distribution for Patients at Continued Risk in MCS

<table>
<thead>
<tr>
<th>Age, y</th>
<th>n*</th>
<th>%</th>
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<tbody>
<tr>
<td>≤40</td>
<td>22</td>
<td>2.1</td>
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<tr>
<td>41–50</td>
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<td>61–70</td>
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<td>71–80</td>
<td>420</td>
<td>39.3</td>
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<tr>
<td>81–90</td>
<td>327</td>
<td>30.6</td>
</tr>
<tr>
<td>&gt;90</td>
<td>51</td>
<td>4.8</td>
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</tbody>
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*Age missing for 9 patients.

Methods

Multicenter Clinical Study
A total of 44 897 Accufix leads (models 329-701, 330-801, and 033-812) were distributed between 1988 and 1994, of which ~91% (41 000) were implanted. The MCS included 2589 patients in whom 2612 Accufix leads had been implanted or were fluoroscopically screened at 12 centers in the United States (n=7), Europe (n=4), and Canada (n=1) on or before September 30, 1996. Patients in the MCS were invited to undergo cinefluoroscopic imaging of their leads every 6 months. The lead-related variables that were prospectively collected include date of manufacture and J retention wire material (Elgilo or MP35N), cinefluoroscopic shape of the lead (true J shape, almost J shape, L shape, and almost straight), and range of motion during the cardiac cycle parallel and transverse (swing) to the plane of the J retention wire (minimal, mild, moderate, or extreme).

Fracture Classification
At each cinefluoroscopic screening, the J retention wire was classified as class 1, no fracture; class 2, fracture of the J retention wire without protrusion; class 3, protrusion of the J retention wire; or class 4, migration or embolization of any portion of the J retention wire.24–26 The Physician Advisory Committee proposed an initial set of management strategies in 1994 that were based on clinical judgment in the setting of limited data regarding the relative risks of injury from J retention wire protrusion and lead extraction. These recommendations were revised as data became available and advised consideration of lead extraction when there was a protruding J retention wire, when the patient was ≤60 years of age, or at the insistence of the patient. A conservative approach was recommended for leads with J retention wires that were fractured without protrusion; a case-by-case approach was advised for leads with a migrated J retention wire. Management of patients in the MCS was left to the individual physicians and patients involved but was generally within the context of the Physician Advisory Committee recommendations.

Injuries and Extraction Complications
The occurrence of injuries related to the J retention wire in the MCS before the recall was determined by review of medical records. After the MCS was initiated, patients were evaluated by clinic visit every 6 months. Lead extraction data were prospectively collected, with complications classified as major if there was mortality or morbidity, including requirement for an additional surgical procedure, infection, cardiac arrest, admission to an intensive care unit, blood transfusion, or other high level of medical intervention. Minor complications included those that extended the procedure time, caused additional discomfort to the patient, or adversely affected quality of life. Extracted leads were inspected to determine the status of the J retention wire and returned to the manufacturer (Telectronics) and later to the nonprofit Accufix Research Institute for analysis.

In addition to the MCS, a voluntary registry of injuries related to the J retention wire and the outcome and complications of lead extraction was established and maintained by the Accufix Research Institute.

Statistical Methods
Data regarding the MCS population were compiled from November 1994 through April 12, 1999. Comparisons were performed by use of t tests and ANOVA or their nonparametric equivalents for continuous variables and chi² or Fisher’s exact test for categorical variables. The Wilcoxon rank-sum or Kruskal-Wallis test was used to compare ordinal categorical variables. Multivariate analyses were performed by use of stepwise logistic regression. Time-related events, such as patient survival and J retention wire injury, were analyzed by use of the Kaplan-Meier method with comparisons using the log-rank statistic. Because the exact date that a change in fracture classification occurred between 2 consecutive cinefluoroscopic screenings could not be known with precision, a nonparametric generalization of the Kaplan-Meier estimate proposed by Turnbull27 and a parametric method that assumes a Weibull distribution of time to event were used for time-related analyses. Cumulative hazard curves (the negative logarithm of the event-free survival function) were generated to present the risk of time-related events (J retention wire fracture, protrusion, and injury). Projection of future events was based on MCS data with the Gompertz28 distribution.

Although the MCS provides substantial information on fracture and protrusion, because of the rarity of J wire injury (2 cases in the MCS), statistical estimates of injury were based on the 40 injuries reported worldwide. The cumulative hazard curve represents only a potential risk of J retention wire injury. The competing risk of
mortality in elderly patients from other causes is high, and most patients will not live long enough to experience a lead-related injury. The cumulative incidence of injury is an estimate of the risk of actually experiencing an injury during a patient’s remaining lifetime.29 Because the risk of injury appeared to be relatively constant through 8 years after implantation, Poisson regression with age and sex covariates was used to determine the cumulative incidence of J retention wire injury. Combining the Gompertz28 model for survival and the Poisson model for injury resulted in a family of cumulative incidence of injury curves stratified by age at implant and sex. The cumulative risk of fatal or life-threatening extraction complications was determined by fitting a logistic regression model to the postrecall intravascular extraction data with use of the risk factors of sex and logarithm of implant duration. The cumulative risk of extraction complications was then compared with the cumulative incidence of injury curves to determine potential thresholds of extraction versus injury risk.

Results

A total of 2612 Accufix atrial leads were implanted in 2589 patients (58.5% men and 41.5% women) at the 12 MCS centers between 1988 and November 1994. The WWR included data for 34,672 additional patients with 34,892 Accufix leads. The age of the MCS population ranged from 4 to 105 years (mean, 68.8±14.2 years) at the time of lead implantation, somewhat younger than the WWR (71.7±12.4 years, P<0.0001). As of April 12, 1999, the mean age of the MCS population who remained alive with an implanted lead was 75.3±12 years (range, 9 to 98 years), with 869 patients (34%) having died and 643 patients (25%) having undergone lead extraction. The age distribution of the patients at continued risk for J retention wire injury is shown in Table 1.
Among the remaining 1077 patients (41%), 847 were undergoing active follow-up with cinefluoroscopy. At the latest follow-up, a total of 230 patients were not undergoing active cinefluoroscopic surveillance because of marked physical or mental limitations or other contraindications to lead extraction. The observed (Kaplan-Meier) and estimated (Gompertz) survival curves for the entire MCS population are shown in Figure 1. The observed probability of survival was 65% at 5 years after lead implantation and 37% at 10 years. The survival 15 years after implantation was projected to be 14%.

**J Retention Wire Fracture Classification**

The cumulative risk of J retention wire fracture is shown in Figure 2. On the basis of combined fluoroscopic imaging and analysis of returned leads, there were 459 fractured J retention wires among 2023 leads (23%) at the most recent evaluation. At the most recent fluoroscopic imaging (n=1938), 78.6% of the leads were in class 1, 16.3% were in class 2, 4.5% were in class 3, and 0.5% were in class 4. The risk of J retention wire fracture decreased slightly over time from 5.6%/y at 5 years after implantation to 4.7%/y at 10 years after implantation. Thus, at 10 years of follow-up, the cumulative risk of fracture was \( \approx 56\% \). The risk of protrusion of the J retention wire was constant over time, \( \approx 1.5\%/y \) (Figure 3). Thus, the cumulative risk of protrusion was \( \approx 15\% \) at 10 years after lead implantation. If the lead was initially in class 2, the risk of progressing to protrusion decreased from \( \approx 8.7\%/y \) at 5 years after implantation to \( \approx 6.3\%/y \) at 10 years (\( P = 0.03 \)).

**Predictors of J Retention Wire Fracture**

The shape of the lead on fluoroscopy and the absence of prior cardiac surgery were predictive of both time to fracture and protrusion of the J retention wire by univariate analysis (Table 2 and Figure 4). In addition, a subclavian implant approach and any lead swing predicted J retention wire fracture but not protrusion. By multivariate analysis, J shape, lead swing, and prior cardiac surgery were independent predictors of fracture, with patients having a true J shape, no lead swing, and prior cardiac surgery at lowest risk of fracture. Because of the low event rate, there were no significant multivariate models for J retention wire protrusion.

**Injuries Related to the J Retention Wire**

As of April 12, 1999, a total of 40 spontaneous injuries related to an Accufix lead had been reported to the Accufix Research Institute, including 2 patients in the MCS and 38 patients in the voluntary WWR (Table 3). There were 6 deaths directly attributable to a protruded J retention wire. In each case of injury in which the J retention wire could be examined, there was a clear class 3 fracture with protrusion of the wire through the right atrium into the pericardial space. In 2 patients, the J retention wire had penetrated the aortic wall.

No spontaneous injuries have been observed in the MCS population after enrollment in the prospective strategy of cinefluoroscopic screening. In the WWR, injuries were reported before any screening fluoroscopy in 24 patients and after initiation of fluoroscopic screening in 14 patients, including 2 deaths (Table 4). Figure 5 illustrates the cumulative hazard of J retention wire injury in the MCS and the entire WWR as a function of duration after lead implantation. The risk of injury in the MCS was 0.020%/y (95% CI, 0.0025 to 0.072); in the WWR, the risk was 0.048%/y (95% CI, 0.035 to 0.067). The risk of injury (Figure 6) ranged from 0.156%/y for patients <50 years of age (95% CI, 0.071 to 0.297) to 0.025%/y for patients >70 years of age (95% CI, 0.011 to 0.047). Because older patients have a significantly higher risk of mortality from competing causes (a lower expected lifetime in which to experience the risk of injury from the J retention wire) and a lower intrinsic risk of injury, their future probability of injury decreases progressively with time (Figure 7). The probability of future injury, conditional
on the fact that no injury had occurred until the present, is projected to decline for all age groups in the MCS. For patients >50 years of age, the projected risk of a future injury declines over time to a level that is significantly lower than the risk of a major complication of lead extraction.

**Lead Extraction**

Within the MCS population, extraction of an Accufix lead was attempted after recall in 642 patients (25%). The primary extraction procedure involved an intravascular technique in 632 patients (98%) and a primary thoracotomy in 10 patients (2%). The voluntary WWR has received reports of attempted lead extraction after recall in 4262 patients, including 4136 patients (97%) with an intravascular procedure and 126 (3%) patients with a primary thoracotomy. An additional 395 leads were extracted before recall, leading to a total of 5299 leads that are known to have been removed (13% of all leads). The complications of lead extraction are shown in Table 5. Major extraction complications from an intravascular approach after lead recall have included 16 deaths, usually as a result of a tear in the superior vena cava or subclavian veins or myocardial perforation leading to pericardial tamponade. Nonfatal, life-threatening, and other major complications included pericardial tamponade (19 patients), hemothorax or pneumothorax (19 patients), vascular injuries treated medically (5 patients) or requiring surgery (14 patients), and requirement for a secondary thoracotomy (41 patients). The risk of fatal or life-threatening complications was significantly higher with a primary thoracotomy than with intravascular extraction (3.4% versus 0.9%, \( P = 0.02 \)). The risk of a major complication increased progressively with implant duration (\( P = 0.0001 \); Table 6). By multivariate analysis, the predictors of life-

| TABLE 3. WWR Reported Accufix Injuries Related to J Retention Wire |
|-----------------------------|-----------------|-----------------|
| Injury                        | Classification at Previous Fluoroscopy | Classification at Injury |
| Death                        | I               | III             |
| Pericardial tamponade (nonfatal) | I               | III             |
| Pericardial effusion without tamponade | I               | III             |
| Atrial perforation without tamponade | I               | III             |
| Embolism of J-wire fragment | I               | III             |
| Tricuspid valve perforation and insufficiency | I               | III             |
| Aorta–right atrial fistula   | I               | III             |
| Right atrial thrombus with pulmonary thromboembolism | I               | III             |

Total injuries = 40.
threatening or fatal extraction complications were longer implant duration (odds ratio, 1.3 compared with each prior year; 95% CI, 1.1 to 1.5), female sex (odds ratio, 3.5; 95% CI, 1.7 to 7.9), and protrusion of the J retention wire (odds ratio, 2.7; 95% CI, 1.3 to 5.3).

**Discussion**

Although several models of pacing leads have been recalled for unacceptably high rates of failure, the nature of the risk posed by the Accufix leads is fundamentally different. Although leads with insulation failure or conductor fracture may result in loss of pacing function with catastrophic sequelae, those leads can be abandoned with little additional risk to the patient once they have been replaced with a new lead. In contrast, the Accufix leads must be explanted to remove the risk posed by the J retention wire. Because extraction of pacing leads is associated with significant morbidity and mortality, the risks of spontaneous injury and extraction must be weighed for each patient individually when appropriate management is being considered. These considerations are analogous to those facing patients and physicians when deciding on the proper management of recalled heart valves. The MCS and WWR indicate that the risk of J retention wire protrusion has been a relatively constant rate
over time. Despite this, the risk of spontaneous injury may be decreasing while the risks associated with extraction are increasing with longer implant duration. Furthermore, because the population implanted with these leads is now quite elderly (median age, 78 years), the balance of risks favors a conservative management approach for most patients.

Fracture of the J Retention Wire

The natural cardiac motion of the beating right atrium creates cyclic stresses on the J retention wire, which leads to metal fatigue. In general, the greater the cardiac motion, the greater the amplitude of the cyclic stress. In addition to cyclic stress, the J retention wire is under a mean stress as a function of its shape within the heart. The cyclic and mean mechanical stresses imposed on the J retention wire have been studied in patients implanted with an Accufix lead through biplane cinefluoroscopic and 3-dimensional reconstruction. Leads with an open J shape had a greater mean stress than leads with a closed J shape. The combination of stress amplitude and mean stress during the cardiac cycle was near the limits of metal fatigue in 5 of 8 patients whose leads were studied by finite-element analysis during rest and exercise. When one considers that there are >1 million cardiac cycles every 10 days (assuming an average heart rate of 70 bpm), these in vivo mechanical studies indicate a high likelihood of J retention wire fracture given a sufficient implant duration. Leads under the greatest stress will fracture with fewer cardiac cycles; those with lower stress may not fracture during the expected lifetime of the patient. The time-related analysis of the MCS population suggests a cumulative fracture rate of ≈56% at 10 years of follow-up, confirming the predictions of these in vivo engineering studies. The clinical variables associated with J retention wire fracture (open shape of the lead) also correlate well with these finite-element analyses.

Spontaneous J Retention Wire Injuries

The most frequent injuries associated with the presence of an Accufix lead have been related to laceration of the atrial myocardium by a protruded J retention wire, resulting in pericardial tamponade. Although 6 deaths have been reported, the true incidence of fatal complications from this lead is likely to be considerably higher because of difficulties in the diagnosis of a protruding J retention wire without

<table>
<thead>
<tr>
<th>TABLE 5. Complications of Lead Extraction*</th>
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<tr>
<td>Extraction Complication</td>
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<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>Major</td>
</tr>
<tr>
<td>Fatal</td>
</tr>
<tr>
<td>Life threatening</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Minor</td>
</tr>
<tr>
<td>Total complications</td>
</tr>
</tbody>
</table>

*Patients with known extraction outcome data.
high-resolution imaging. This is highlighted by the recognition that several cases of previously unexplained pericarditis or pericardial tamponade could be attributed to the J retention wire only in retrospect after formal recall of the Accufix leads. The inability to diagnose a protruding J retention wire on most routine chest radiographs is also likely to have resulted in an underreporting of injuries. The reduction in the reports of injury after widespread publicity of the risks posed by the Accufix leads suggests that the risk of injury may be decreasing. Indeed, in the MCS, there have been no injuries since November 1994 despite serial cinefluoroscopic imaging. The voluntary WWR has received only 1 injury report over the last 17 months. The mechanism for this apparent decrease in the risk of injury over time is not clear but may relate to a lower mechanical stress on the J retention wire for leads that fracture later than for those that fracture earlier. Whether the program of cinefluoroscopic screening of these leads and the recommendations of the Physicians Advisory Committee for selective extraction have resulted in a decrease in the risk of spontaneous injury is uncertain. It is clear, however, that an Accufix lead that is intact on cinefluoroscopy continues to present a risk to the patient: There have been 1 death and 4 nonfatal cases of pericardial tamponade since the lead was classified as class 1 between 3 and 13 months earlier. The risk of injury appears to be highest for patients <50 years of age (0.156%/y) and lowest for patients >70 years of age (0.025%/y). Patients having undergone prior cardiac surgery, in whom the presence of pericardial adhesions may limit the potential risk of pericardial tamponade, may be at an even lower risk of injury.

### Extraction Risks

Extraction of the Accufix leads has been accompanied by significant complications, including 16 deaths among 4023 intravascular procedures (0.4%). The risk of life-threatening or fatal extraction complications increases with the duration of lead implantation, female sex, and protrusion of the J retention wire. It is likely that the risks of extracting the remaining Accufix leads may be higher than those observed so far because the minimum implant duration of these leads is now ≥4.5 years. Although new technologies have become available for lead extraction that have made it possible to remove more leads with an intravascular approach, these advances have yet to be proved safer than older techniques. In fact, of the 16 deaths resulting from extraction of an Accufix lead, a laser technique was used in 4 patients. When these observations are balanced with the relatively low risk of spontaneous injury from the J retention wire and the advancing age of the population at risk, a conservative management strategy appears to be warranted for most patients. The Physician Advisory Committee has recommended that leads with a protruding J retention wire be considered for extraction unless the clinical status of the patient would preclude the procedure. Although this approach has been associated with a very low risk of spontaneous injury in the MCS, class 3 leads pose a greater risk of extraction complications, and the balance of these competing risks is unclear even in this subgroup. Because of an increased duration of exposure to J retention wire injury, patients <40 years of age who are otherwise in good health should be considered for elective extraction, especially because the risks of extraction increase with each year that the lead has been implanted.

### Utility of a Cinefluoroscopic Screening Program

The MCS has allowed an appreciation of the risks of J retention wire fracture, protrusion, and spontaneous injury and the outcome of lead extraction. However, despite a greater understanding of these factors, the overall utility of a strategy of screening and selective extraction for limiting injuries to the patient has not been conclusively proved. Although 16 deaths have been related to extraction of Accufix leads and only 6 deaths to spontaneous injury, it is likely that the rate of spontaneous injury has been underreported. It is also likely that there would have been further spontaneous injuries if many of the extracted leads had not been removed.

### Conclusions

Accufix atrial pacing leads have a high rate of J retention wire fracture. Results of these analyses suggest that a conservative approach is warranted for most patients with these leads, supporting the initial recommendations of the Physicians Advisory Committee in 1994. Despite the high risk of J retention wire fracture, the conditional probability of injury from an Accufix lead is considerably lower than the risks associated with lead extraction for most patients.

### References


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