A Conductive Catheter to Improve Patient Safety During Cardiac Catheterization

MARTIN J. LIPTON, M.D., ALLEN K. REAM, M.D., AND BRUCE H. HYNDMAN, M.S.

SUMMARY A 60 Hz current, as small as 20 μA (rms) is capable of causing ventricular fibrillation when directly applied to the heart. Significant cost and engineering effort has been spent to construct monitoring equipment which satisfies the safety regulations requiring maximum leakage currents below this value. Patients undergoing cardiac catheterization are particularly at risk from electrical hazards, primarily because catheters are made from nonconductive materials. A conductive catheter should allow externally applied currents to leak through its walls before reaching the catheter tip. A new electrically conductive catheter was compared with a standard nonconductive catheter.

Five dogs were studied, with 81 attempts to cause fibrillation. Sixty-hertz voltage between the catheter and an external electrode was increased until fibrillation occurred or 130 V was reached. Eight states were studied in randomized sequence: conductive or nonconductive catheter, guidewire or saline-filled and tip touching wall, or free in left ventricle (verified by fluoroscopy and cineangiography). The saline-filled conductive catheter was safer in that fibrillation never occurred, while fibrillation nearly always occurred with the nonconductive catheter. A conductive guidewire negates the protection of the conductive catheter. The application of conductive catheters could reduce instrumentation costs in laboratories and intensive care units and improve patient safety.

ADVANCES IN BIOMEDICAL ENGINEERING have resulted in a progressive increase in the number and complexity of hospital electrical monitoring devices. These devices are particularly available in specialized centers, such as intensive care and cardiac catheterization units. Such devices are important in the provision of health care, but have brought about an increased danger of accidental electrocution. This hazard has received attention in the past few years, but the incidence of electrical complications in hospitals remains a very controversial issue. Such electrocutions may be far more common than realized,1,2 because proof of such incidents is very difficult to obtain. However, incidents of ventricular fibrillation and hospital deaths from electrocutions have been documented during cardiac catheterization and also in patients with myocardial pacemakers.3-11 Studies have shown that 60 Hz alternating currents of as little as 80 μA, with typical values below 1 mA, can produce ventricular fibrillation in humans.12-15 Considerable effort has been spent to construct monitoring equipment which draws maximum leakage currents of less than the established safety standard threshold of 10 μA.16-20 The increasing importance of such safety is immeasurable. One common opportunity for fibrillation with minimum current is provided by intracardiac catheters used during cardioangiographic studies and monitoring.2,15,21

Macroshock and Microshock

There are two modes of possible electric shock in hospitals. Macroshock is due to externally applied currents and can cause ventricular fibrillation with currents > 100 mA. Hence, direct or commercial alternating power frequencies with 75–120 V are dangerous. All hospital patients may be exposed to such macroshock hazards, just as they would be in their own homes — for example, from a defective electrical appliance.
Microshock results from small-magnitude currents (μA) which involve electrode contact within the body and, in particular, the heart. The two requirements for the conduction of electric current through the heart are a current path and a current source. A pathway is provided by a saline- or other fluid-filled cardiac catheter or pacemaker electrode. The walls of cardiac catheters are excellent insulators of electricity. The current source is most often a leakage from electrical equipment, a static discharge, or currents due to physical contact with the catheter by a nurse or physician. Currents as small as 50 μA produced by voltage levels as small as 5 mV can produce ventricular fibrillation under these circumstances. Such an electrically sensitive patient is schematically represented in figure 1. Most safety requirements limit the amount of current which could flow into the patient. This problem would not exist, however, if a method could be devised to prevent the current from reaching the heart via the catheter.

Methods and Materials

A new conductive catheter material developed by Medtronic, Inc., of Minneapolis, Minnesota, incorporates polyvinylchloride and carbon black with added barium sulfate for radiopacity. The material can be extruded to form standard-sized catheters. Such a catheter with a conductive wall should enhance patient protection against electrically induced ventricular fibrillation by leaking away externally applied current before it reaches the catheter tip.

Mongrel dogs weighing 15–25 kg, were anesthetized with sodium pentobarbital (25 mg/kg body weight). Intravenous supplemental doses were given to assure a depth of anesthesia permitting stable spontaneous ventilation. The experimental sequence lasted 2–4 hours. An intravenous catheter was maintained with 5% dextrose in water. A catheter was placed in the left femoral artery, and mean pressure was measured via an aneroid manometer. Typical mean blood pressure was 130 torr. The ECG was monitored via external electrodes on the shaved skin. The dogs were intubated with a cuffed endotracheal tube and were permitted to breathe spontaneously in room air. Controlled ventilation for four to eight breaths using 100% oxygen was imposed after defibrillation.

The current path was completed through a subcutaneous electrode in the left hind limb of the dog. This terminal was connected to a variable current source, as shown in figure 2. The other side of the
current source was connected to the proximal end of the catheter. The current level applied to the catheter could be controlled and monitored using a digital multimeter (model 30, Data Technology).

The catheter was introduced through a right femoral artery approach and advanced until the tip position was satisfactory, as verified by ﬂuoroscopy and cineangioigraphy in two planes. Two tip positions were studied: free in the left ventricle, and wedged against the left ventricular wall. When spontaneous arrhythmias were observed with wall contact, the catheter tip was moved to a new location before applying voltage to the catheter. The catheters were ﬁlled with normal saline (0.9% NaCl) or with a guidewire. Two 7 French 100 cm catheters were used: a conductive catheter (Medtronics model 3X005A-39 diagnostic catheter) and a standard nonconductive catheter (Cook Inc. polyethylene catheter, model 66073-2). Sterile catheters were used in each animal and for each bench study. Baseline pressures and ECG recordings were obtained, and then the current was steadily increased for each event. Fibrillation was induced via a 60 Hz voltage applied between the external end of the catheter and the return path through the left hind limb. The applied voltage was slowly increased with continuous measurement of applied current until fibrillation occurred (as determined by ECG activity and fall in mean blood pressure) or until a maximum of 130 V was reached. After fibrillation current was noted, the current was immediately disconnected and the heart defibrillated, using a Hewlett-Packard DC defibrillator with levels set in a range between 40–100 watt/sec stored. The next episode was initiated after blood pressure, cardiac rhythm, and ventilation had returned to normal. Defibrillation was usually successful on the first attempt.

Eight states were studied in a randomized sequence: conductive or nonconductive catheter, with the catheter tip free in the ventricle or against one of its walls, and saline or guidewire ﬁlled. Eighty-one attempts to cause fibrillation were made in ﬁve dogs.

The catheters were examined in vitro and demonstrated to conform to theory. Previously unused catheters were used in each animal and also for each bench study.

Table 1. Incidence of Ventricular Fibrillation (Incidents/Atempts) for the Possible Combination of Catheter Composition, Contents and Tip Location

<table>
<thead>
<tr>
<th></th>
<th>Tip free</th>
<th>Tip touching wall</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) Catheter containing normal saline</td>
<td>0/10</td>
<td>0/10</td>
</tr>
<tr>
<td>Conductive</td>
<td>4/11</td>
<td>10/10</td>
</tr>
<tr>
<td>Nonconductive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B) Catheter containing metal guidewire</td>
<td>9/9</td>
<td>10/10</td>
</tr>
<tr>
<td>Conductive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconductive</td>
<td>10/10</td>
<td>11/11</td>
</tr>
</tbody>
</table>

Results

Table 1A shows the results for the saline-ﬁlled catheters as the number of ﬁbrillations per number of attempts with a saline-ﬁlled catheter. Table 1B shows the same results for the catheters with guidewire. Table 2 presents the ﬁbrillation current threshold average in μA for each of the eight states studied. Episodes in which ﬁbrillation did not occur are not included in the averages.

While these catheters did not exhibit ideal memory and torque control, the necessary modiﬁcations appear feasible. The catheters have been evaluated for thrombogenicity and appear satisfactory.

Discussion

A schematic diagram of a presently used nonconductive catheter is illustrated in ﬁgure 3. The current entering the catheter remains within the lumen because the catheter wall is an insulator, and the current emerges distally at the exit hole. The resistance of the patient and the wires is so low compared with the resistance of the catheter under normal conditions that one can ignore all other resistance values. A schematic diagram for the conductive catheter is shown in ﬁgure 4. In this case, the electric current can leak away through the catheter wall. The current leaks away more rapidly near the skin because the current is the result of voltage, and the voltage is highest near the skin and falls off toward the catheter’s tip; the form of the decay is approximately exponential. Hence, very small current values can be rapidly achieved. The value of lumen current at a distance x from the catheter tip is represented by the equation:

\[
i(x) = \left( \frac{R_{mx}}{G} \right)^{1/3} \left[ \frac{R(I-L)}{V_{mx} \tanh(KL)} + \frac{R(I-L) \cosh(Kx)}{V_{mx} \sinh(KL)} \right]
\]

where \( R \) = longitudinal catheter resistance, \( G \) = lateral catheter conductance, \( K = \sqrt{RG} \), \( L \) = total catheter length, \( L \) = catheter length beneath skin, \( V_{mx} \) = source voltage, \( i(x) \) = current in catheter at point x (0 ≤ x ≤ 1), and \( i(0) \) = current at catheter tip.

Table 2. Average Fibrillation Current (sd) in Microamperes for Each State

<table>
<thead>
<tr>
<th></th>
<th>Tip free</th>
<th>Tip touching wall</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) Catheter containing normal saline</td>
<td>133 (66)</td>
<td>71 (51)</td>
</tr>
<tr>
<td>Conductive</td>
<td>3,710 (3,900)</td>
<td>13,150 (26,380)</td>
</tr>
<tr>
<td>Nonconductive</td>
<td>9,690 (10,910)</td>
<td>9,650 (20,570)</td>
</tr>
<tr>
<td>B) Catheter containing metal guidewire</td>
<td>8/11</td>
<td>9/11</td>
</tr>
<tr>
<td>Conductive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconductive</td>
<td>10/10</td>
<td>11/11</td>
</tr>
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</table>
Tip Current = $\frac{C}{\sinh (KL)}$

where $C$ expresses the reduction in current due to the resistance of the external portion of the catheter and internal catheter characteristics. The current, therefore, leaks away along the length of the catheter. Furthermore, because leakage current is proportional to the driving voltage (which decreases along the catheter), leakage current is largest near the skin and least near the tip, providing additional protection. In practical terms, the importance of this is shown in figure 5, where catheter length is plotted against skin resistance. Two results are graphically represented, one for the nonconductive and one for the conductive catheter. The curve for the conductive catheter shows that resistance becomes constant after the length exceeds a certain value. This means that the tip current is negligible compared with the total. This is strikingly different from the normal, nonconducting catheter where resistance rises and all the current must pass through the tip. This is better illustrated by plotting the logarithm of tip current against catheter length (fig. 6); this curve is obtained from the equations given earlier. After a minimum length, the graph becomes a straight line, which means that for a given catheter a distance can be specified such that increasing the catheter by that length decreases tip current by a power of 10, no matter how long the catheter. This result is based upon the assumption that $G$, the conductivity of the catheter wall, is constant, which is true for the clinical range studied experimentally.

Normal saline was used within the catheter because this has the greatest conductivity of any common in-
FIGURE 5. The relationship of catheter length beneath the skin to catheter resistance. The resistance (R) (thousandths of ohms), seen at the skin is plotted on the y axis against length, l, beneath the skin (cm) on the x axis. The curve for the conductive catheter shows that resistance becomes constant after the length exceeds a certain value; hence, tip current is then negligible compared with the total. The resistance for a conventional catheter progressively rises and all the current must pass through the tip.

FIGURE 6. The relationship between tip current and length of immersed catheter for a fixed applied voltage. The logarithm of tip current is plotted on the ordinate and the length beneath the skin is given on the abscissa. The solid line represents the theoretical calculation. The points are direct measurements taken from an actual conductive catheter. The dotted line is 20µA threshold.
travenous solution. One hundred thirty volts was chosen as a practical maximum in our animal studies because the highest voltage to which a hospital patient is likely to be exposed is powerline, which is 120 V. The condition of greatest clinical interest is the unanesthetized human subject. This study involved anesthetized dogs, but it has been suggested that, at least in one dog, there is no significant difference between the conscious and anesthetized fibrillation thresholds using sodium pentobarbital. Furthermore, the intracardiac fibrillation thresholds for the dog appear similar to the threshold in man, and may even be smaller. Details of the mathematical analysis of the catheters have been documented.

Conclusion

The data from these experiments have shown that a suitably designed conductive catheter can substantially reduce patient risk of microshock-induced ventricular fibrillation. As the fibrillation threshold for patients could be as low as 20 μA, a catheter which only allows a tip current lower than this amount should be safe. It is possible to design a saline-filled catheter for any specified maximum voltage which, for practical purposes, will not electrically cause fibrillation when the tip is within the heart. The specifications for such a catheter can be met easily for both infants and adults, so that the dimensions are similar to those catheters presently in routine clinical use. As expected, the safety of a conductive catheter is negated by a highly conductive guidewire (table 1B), although in practice this lies within the heart for a much shorter time than the catheter, and often the guidewire is not placed within the heart. Ideally, conductive catheters should be used with nonconductive guidewires; their manufacture should not be technically difficult. If conductive catheters could replace presently used nonconductive ones, they should assure better protection against cardiac fibrillation from failed or noncurrent-limited electrical sources.

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