The Effect of Electroshock on the Passage of Bacteria From a Contaminated Transducer Past a Protective Membrane into a Disposable Chamber Dome

Patricia K. Taylor Pothier

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Abstract

THE EFFECT OF ELECTROSHOCK ON THE PASSAGE OF BACTERIA FROM A CONTAMINATED TRANSDUCER PAST A PROTECTIVE MEMBRANE INTO A DISPOSABLE CHAMBER DOME

by

Patricia K. Taylor Pothier

Infection related to use of Intra-arterial Hemodynamic Monitoring Devices is a serious complication. In an attempt to decrease the risk of infection presterilized chamber domes were developed to isolate the patient vascular system from the pressure transducer. Users were informed by manufacturers of the domes that routine decontamination of transducer heads was not necessary. Since the development of these disposable chamber domes infection outbreaks have continued to occur. Epidemiological investigation has implicated contact transmission of bacteria due to poor handling techniques in some outbreaks. However, in other outbreaks the source of the epidemic was found to be contaminated transducer heads and no mode of bacterial transmission was identified. It appeared that transmission occurred at the transducer-dome junction.

In an attempt to identify whether electroshock, such as a patient might undergo during cardiac defibrillation, could allow bacterial transmission at the dome-transducer junction a number of domes were subjected to 400 watt seconds of electroshock. It was hypothesized that
electroshock might damage the dome membrane or dome membrane seal in such a way as to permit bacterial passage past the membrane.

Domes were selected to represent two different manufacturers. Two series of domes were shocked once each and one series of domes was shocked 25 times each. The shocked domes and their controls were all mounted on a contaminated transducer while the domes were filled with sterile fluid. After undergoing electroshock the test domes and the unshocked control domes were placed on a contaminated wick for 48-72 hours, after which the fluid in the chamber domes was cultured to determine if bacteria had passed the dome membrane. The results of the first two series showed that one control and one shocked dome had bacterial contamination in the dome innerspace with the test organism, Enterobacter cloacae. Both domes were of the same manufacturer and lot number. Two untested domes of that lot number remained and they were treated as controls. Following bacterial challenge both had the test organism cultured out of the dome innerspace. None of the other six lot numbers of domes demonstrated bacterial contamination.

In conclusion there was no evidence to suggest that electroshock at 400 watt seconds (joules) facilitated the passage of bacteria from a contaminated transducer past the disposable dome membrane. However, there was evidence to suggest that of the seven different lot numbers, one had a defect which permitted bacterial passage past the membrane into the presterilized chamber dome. Because of the possibility of such a defect to be present it is recommended that transducers be decontaminated prior to use with a disposable chamber dome, and that if used, any fluid in the dome-transducer junction be sterile.
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by

Patricia K. Taylor Pothier

A Thesis in Partial Fulfillment of the Requirements for the Degree Master of Science in Nursing

June 1984
Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree of Master of Science.

Frances P. Miller, Associate Professor of Nursing

Harvey A. Elder, Professor of Medicine

Grenith J. Zimmerman, Professor of Biostatistics Epidemiology
ACKNOWLEDGEMENTS

Many people helped me complete this thesis, and I thank them one and all. I especially express my sincere appreciation to the following: F. Penny Miller, my research advisor, encouraged me, read and critiqued the paper, gave me excellent suggestions for improvement, and taught me a great deal about the thesis process. Harvey Elder gave me the original idea for the thesis, provided an environment in which I could do the testing, and as a member of my research committee read the paper and gave valuable comments and suggestions. Grenith Zimmerman, a member of my research committee, reviewed the paper and was especially helpful in her suggestions and recommendations on the methodology and statistical aspects. Ira Roy, Puring Mabaquiao, and Mary Stumpf, in the research laboratory, shared their knowledge with me and taught me what I needed to know to perform the microbiological portion of the study. Robert Butterfield provided his expertise in the medical electronics field to help me with the electrical aspects of the study and paper. Helen Little edited my rough draft and provided a valuable lesson in composition and final polish. I also thank my husband, John, who helped out in test equipment fabrication and mechanical drawing, and who gave me the confidence to go to graduate school in the first place and then encouraged me through.
# Table of Contents

<table>
<thead>
<tr>
<th>List of Tables</th>
<th>vii</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Figures</td>
<td>viii</td>
</tr>
</tbody>
</table>

Chapter

1. Introduction to the Problem .................................................. 1
   Background of Problem and Need for the Study ................. 4
   Risk of Infection ............................................................. 4
   Outbreaks of Infection ....................................................... 5
   Problem Statement ............................................................. 6
   Objective of the Study ........................................................ 7
   Conceptual Assumptions ....................................................... 7
   Theoretical Framework ........................................................ 8
   Delineation of the Research Problem .................................. 10
   Research Question and Statement of Hypothesis ................. 11
   Importance of the Study ...................................................... 12
   Definition of Terms ........................................................... 13
   Bacteremia ................................................................. 13
   Bacterial Contamination .................................................... 13
   Chamber Dome Membrane ..................................................... 13
   Disposable Chamber Dome ................................................... 13
   Indwelling Arterial Hemodynamic Monitor (IAHMD) ................. 13
   Local Infection ............................................................... 13
   Septicemia ................................................................. 14
   Sterile ................................................................. 14
   Systemic Infection .......................................................... 14
   Transducer (Transducer Head, Pressure Transducer) .......... 14
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Review of the Literature</td>
<td>15</td>
</tr>
<tr>
<td>Introduction</td>
<td>15</td>
</tr>
<tr>
<td>Overview of Incidence</td>
<td>15</td>
</tr>
<tr>
<td>Purpose and Design of Intra-arterial Hemodynamic Monitoring Devices</td>
<td>17</td>
</tr>
<tr>
<td>Purpose</td>
<td>17</td>
</tr>
<tr>
<td>Basic Design and Function of IAHMD</td>
<td>18</td>
</tr>
<tr>
<td>Outbreaks Related to Reusable Domes</td>
<td>23</td>
</tr>
<tr>
<td>Outbreaks of Infection Associated with Use of Disposable Domes</td>
<td>27</td>
</tr>
<tr>
<td>Nursing Implications</td>
<td>33</td>
</tr>
<tr>
<td>Prevention of Infection</td>
<td>35</td>
</tr>
<tr>
<td>Potential for Electrical Current</td>
<td></td>
</tr>
<tr>
<td>Damage to Membrane</td>
<td>42</td>
</tr>
<tr>
<td>Medical Electronic Usage</td>
<td>43</td>
</tr>
<tr>
<td>Current Flow</td>
<td>45</td>
</tr>
<tr>
<td>Causes of Current Leakage</td>
<td>45</td>
</tr>
<tr>
<td>Electrical Injuries of Patients</td>
<td>46</td>
</tr>
<tr>
<td>Electrical Hazard with Invasive Monitoring Device</td>
<td>49</td>
</tr>
<tr>
<td>Application to Nursing</td>
<td>50</td>
</tr>
<tr>
<td>3. Research Method</td>
<td>52</td>
</tr>
<tr>
<td>Sample Criterion</td>
<td>52</td>
</tr>
<tr>
<td>Sample Selection</td>
<td>52</td>
</tr>
<tr>
<td>Rationale for Sample Criterion</td>
<td>55</td>
</tr>
<tr>
<td>Chapter</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
</tr>
<tr>
<td>Data Collection Procedure</td>
<td>53</td>
</tr>
<tr>
<td>Trials to Select Bacterial Challenge</td>
<td></td>
</tr>
<tr>
<td>Culture Technique</td>
<td>53</td>
</tr>
<tr>
<td>Wick Challenge Trial</td>
<td>54</td>
</tr>
<tr>
<td>Agar Pour Trial</td>
<td>58</td>
</tr>
<tr>
<td>Summary and Rationale for Choice of Wick Method</td>
<td>60</td>
</tr>
<tr>
<td>Setup of Equipment</td>
<td>60</td>
</tr>
<tr>
<td>Stand</td>
<td>61</td>
</tr>
<tr>
<td>Transducers</td>
<td>61</td>
</tr>
<tr>
<td>Shock Box</td>
<td>62</td>
</tr>
<tr>
<td>Testing of the Domes</td>
<td>64</td>
</tr>
<tr>
<td>Experiment Preparation</td>
<td>64</td>
</tr>
<tr>
<td>Setup of Equipment</td>
<td>65</td>
</tr>
<tr>
<td>Bacterial Analysis</td>
<td>71</td>
</tr>
<tr>
<td>Unforeseen Events and Results</td>
<td>71</td>
</tr>
<tr>
<td>4. Findings</td>
<td>73</td>
</tr>
<tr>
<td>Culture Results of Tests and Controls</td>
<td>73</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>77</td>
</tr>
<tr>
<td>Problems Encountered</td>
<td>79</td>
</tr>
<tr>
<td>Summary</td>
<td>80</td>
</tr>
<tr>
<td>5. Outcome of Study</td>
<td>81</td>
</tr>
<tr>
<td>Summary</td>
<td>81</td>
</tr>
<tr>
<td>Conclusion</td>
<td>82</td>
</tr>
<tr>
<td>Recommendations</td>
<td>84</td>
</tr>
<tr>
<td>Bibliography</td>
<td>86</td>
</tr>
</tbody>
</table>
# List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Infection Outbreaks Related to Use of Intra-Arterial Hemodynamic Monitoring.</td>
<td>34</td>
</tr>
<tr>
<td>2. Manipulation of Domes and Results</td>
<td>75</td>
</tr>
<tr>
<td>3. Number of Domes by Lot Number and Culture Result</td>
<td>78</td>
</tr>
<tr>
<td>4. Chi-Square Test Analysis</td>
<td>79</td>
</tr>
</tbody>
</table>
## List of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Arterial Pressure Manometer</td>
<td>19</td>
</tr>
<tr>
<td>2.</td>
<td>Direct Arterial Pressure Monitoring System</td>
<td>20</td>
</tr>
<tr>
<td>3.</td>
<td>Parts of a Disposable Dome and Transducer</td>
<td>22</td>
</tr>
<tr>
<td>4.</td>
<td>Growth of the Medical Electronics Industry</td>
<td>44</td>
</tr>
<tr>
<td>5.</td>
<td>Wick Challenge Setup</td>
<td>55</td>
</tr>
<tr>
<td>6.</td>
<td>Setup of Equipment</td>
<td>63</td>
</tr>
</tbody>
</table>
CHAPTER 1
Introduction to the Problem

Infection is a serious complication associated with intra-arterial hemodynamic monitoring devices (IAHMD). Infections documented in literature range from localized cutaneous infection at the catheter insertion site to life-threatening bacteremia (Band and Maki, 1979, p. 736).

While this problem of infection related to these devices has been recognized and studied since the use of IAHMDs began in 1973, the actual mechanism of bacterial entry into the system is still in controversy. Some infections have apparently been directly related to faulty sterilization of reusable transducer domes. To decrease the potential for infections resulting from faulty sterilization of reusable equipment, a disposable chamber dome was developed and put into use in 1976 (Baxter, 1979, p. 206; Retalliau, 1979, p. 5). The disposable dome was designed to isolate the patient's vascular system by means of a presterilized chamber with a pressure sensitive membrane. The membrane relays any pressure changes in the patient's vascular system to a reusable transducer to which the membrane is coupled (Figure 3, p. 22). In spite of the development and widespread use of the presterilized disposable domes, however, outbreaks of bacteremia persist. Contamination of the system resulting from poor handling has been documented as the cause of some of the infection outbreaks, but this has accounted for only part of the problem. Investigation of some of the outbreaks indicates that bacterial contamination may occur right at the transducer and membrane junction, with bacteria crossing at the membrane. It is this possibility which was investigated in this study.

1
The proper handling and maintenance of the intra-arterial hemodynamic monitoring system presents a real challenge to nursing. Not only is the system itself complicated, with multiple lines, stopcock positions, and the need to calibrate the transducer, but patients requiring such monitoring are usually critically ill or have undergone a procedure, such as open heart surgery, which requires careful monitoring (Weinstein et al., 1976, p. 338; Buckbinder, 1976, p. 146). In such patients an infection can present a life-threatening hazard.

Nurses have the most constant responsibility for direct patient care. The patient is dependent on nursing care not only for maintenance of any monitoring systems but also for protection from infections resulting from improper equipment maintenance or from breaks in aseptic technique. Instructions on proper maintenance of intra-arterial monitoring systems are available in nursing literature and manufacturer publications (Lamb, 1977, pp. 65-71; Bentley Trantec Operating and Maintenance Instructions, Hewlett Packard Operating Guide). However, this literature is primarily concerned with the in-use maintenance of monitoring devices to give accurate pressure readings; it is not specifically directed at prevention of infection. Also, there is no consistent standard for cleaning the transducer sensor. Since the disposable dome membrane comes in direct contact with the sensor, theoretically the membrane will prevent bacterial access to the system.

Another aspect impacting nursing care on which there are no standards concerns whether or not a disposable dome should be changed if the patient has undergone cardioversion with electroshock. In cases of cardiac arrest, patients may receive as much as 400 ws. of electroshock.
for cardioversion. However, cardioversion itself is not the only potential source of electroshock to a membrane. Some systems have a possibility of current leakage from the monitoring system, especially if the system gets wet. This current can be transferred from the transducer site across the membrane to the fluid column in the disposable dome chamber and from there can travel up the fluid line directly to the heart as a defibrillator shock (Health Devices, 1979, p. 215). In the university medical center where this study was conducted, there was a "word of mouth" recommendation from sales representatives of one manufacturer to change the transducer dome if the patient involved underwent cardioversion with electroshock, because the effect on the dome was unknown. The nurses interviewed on the cardiac surgery unit stated, however, that this was not routinely done, since it was a very "mild" recommendation. Review of the medical literature did not reveal any information on the safety of using domes which have undergone electroshock.

The significance of this to nursing relates specifically to the handling of the monitoring system. If bacteria are able to cross a membrane from a contaminated transducer into the sterile chamber dome with a fluid line consistent with the patient vascular system, the transducer, as well as any fluid in the interspace, should be sterile whenever contact between transducer and membrane is made. If electroshock facilitates bacterial contamination, it becomes critical that disposable domes be changed whenever a patient with such a monitoring device undergoes electroshock; and patients' electrical environment
should be evaluated for possible stray current leakage which may affect this mechanism.

Since nurses are responsible for the safe and restorative care of patients, it is important that they be aware of the potential problems involved with intra-arterial monitoring systems and be skilled in the proper methods of handling them to prevent infections to the patient.

The question of whether electrical energy resulting from electroshock or stray currents can facilitate bacterial contamination across the membrane of IAHMDs has not been reported in the literature. The purpose of this study was to evaluate the effect of electroshock on transmission of bacterial contamination across the membrane of a sterile disposable dome.

**Background of Problem and Need for the Study**

Discussion of the problems of IAHMD will be in two parts: (1) the risk of infection, and (2) a summary of outbreaks of bacteremia in patients undergoing intra-arterial hemodynamic monitoring.

**Risk of Infection**

In a recent study of 130 indwelling arterial catheters placed for hemodynamic monitoring in 95 patients, 23 catheters produced local infection. Of these 23 catheters, five produced bacteremia (Band and Make, 1979, pp. 737, 738). According to Retailiau, the risk of developing a local infection from an indwelling arterial catheter is as high as 18 percent, while the risk of developing a secondary bacteremia from this local infection site is as high as 22 percent (1979, p. 15).
Outbreaks of Infection

The Centers for Disease Control (CDC) have investigated, or been notified of, at least nine IAHMD-associated outbreaks of bacteremia from 1973 to 1978 involving a total of 126 patients. Of these outbreaks, five occurred in the period when reusable monitoring equipment was used prior to the development of disposable domes in 1976. Four of the outbreaks occurred between 1976 and 1978 and involved the use of presterilized disposable chamber domes (Retalliau, 1979, p. 15). A recent unreported outbreak involved eight cases of IAHMD-associated bacteremia in patients who had undergone surgery during a four-month period. All of these patients had AIHMDs in place (using disposable domes), and in all but one the organism causing the bacteremia was Enterobacter cloaca (unpublished surveillance date, LLUMC, 1980). Other common factors found included post cardiac surgery and nursing care in an intensive care unit for seven of the eight cases.

Faulty sterilization of transducers and reusable domes was found to be the common factor in all the outbreaks of bacteremia prior to 1976 (Buxton et al., 1978, p. 508). Disposable domes have been involved in at least seven outbreaks since then. In five outbreaks which the CDC investigated involving presterilized disposable domes the epidemic organism was recovered from the interspace between the membrane of the disposable chamber dome and the reusable transducer. In some of the cases the epidemic organism was also cultured from some of the stopcocks and ports of the system, although fluid aspirated past these contaminated stopcocks and ports remained sterile (Retalliau, 1979, pp. 15,
Since the fluid path and fluid-blood interface remained sterile, the question of mechanism by which bacteria actually entered the patient's vascular system to cause bacteremia remains unanswered.

The possible effect of electroshock on the passage of bacteria through a plastic membrane is not reported in the literature. A consulting electrical engineer stated that there is a possibility of microscopic membrane breakdown in cases of high electroshock. In addition, the possibility exists that a high electroshock, such as the upper limit used in cardioversion, could temporarily unseal the membrane from the rigid dome where it was electrically sealed (Butterfield consult, 1980). The most commonly recognized source of electroshock in a hospital is that resulting from cardiac defibrillation with direct application of electrical potential to the patient's chest. However, there are multiple possible sources of current leakage in the hospital, such as faulty equipment grounding or insulation in electrical beds, electrically driven respirators and pumps, and the transducers themselves (Butterfield, verbal, 1980; Herzog, 1982, p. 31). While nursing personnel are not directly involved in the electrical maintenance of patient-associated devices, they are directly responsible for the patient and should recognize the potential for current leakage which could affect the patient.

**Problem Statement**

Two problems were addressed in this study.

1. Could bacteria pass from a contaminated transducer past an unused membrane into a presterilized chamber dome?
Could electroshock allow the passage of bacteria from a contaminated transducer past a membrane into a presterilized chamber dome?

**Objectives of the Study**

The immediate objective of this study was to develop data regarding infection potential of IAHMDs.

The overall objective of this study was to improve the quality of nursing care by prevention of infection (either local or systemic) in the patients with IAHMDs. This objective was to be met by first determining whether identified bacteria could cross from a contaminated transducer across the membrane into the patient's vascular system, in cases of cardioversion with electroshock or possibly with stray current leakage. If this could be determined, then recommendations for nursing care could be made to protect these patients.

**Conceptual Assumptions**

This study made the following assumptions:

1. Bacterial contamination could migrate from a nonsterile transducer past the membrane of a damaged presterilized dome.
2. The disposable domes were free from defect at the time of the study.
3. An energy level of 400 watt seconds (joules) was within the possible range for a patient to receive in case of cardioversion.
4. The fluid used to fill the domes was sterile at the time of the study.
5. The electrical device used for shocking the membrane actually delivered the current indicated on the gauge.

6. Enterobacter cloacae were capable of multiplying in the D5W Lactated Ringers solution (D5WLR).

7. The ionic concentration of D5WLR was high enough to transmit an electrical current through a fluid line.

8. As set up, the experiment equipment would actually shock the membranes tested.

**Theoretical Framework**

The membrane in the disposable chamber domes studied is made of mylar (a plastic) and electrically sealed to a rigid plastic dome. Theoretically a high electrical current could temporarily or permanently unseal the bond between the rigid plastic and the mylar membrane. The mylar is typically manufactured in large sheets and then cut to fit onto the domes. When examined under high magnification, the mylar surface appears irregular, giving the potential for some areas to be thinner than others. In theory these thinner areas of the membrane might break if traumatized by electric shock (Butterfield, 1980).

Hemodynamic pressure changes in the artery are transmitted by deflections to the thin mylar membrane and transferred to the transducer. The fluid path is maintained under proper pressure with assorted equipment and can be flushed and filled by adjusting stopcocks that control and direct the fluid. With the turn of a stopcock, the fluid line is switched from the patient to the transducer. When pressure is not monitored, the stopcock is turned so that the fluid flows from a pressurized
source (I.V. bottle) into the patient's vessel. Most intravenous fluids contain sodium or other ions which can conduct electrical current through the fluid. Therefore, if a patient with an IAHMD in place undergoes cardioversion with electroshock, then theoretically current could go through the patient's body, up the fluid line, to the transducer. In the same way, a current could also go down a fluid-filled catheter and cause cardiac fibrillation (Health Devices, 1979, p. 208; Lipton, Ream and Hyndman, 1978, p. 1190).

If the insulation of the transducer were impaired, current could pass through the membrane to the transducer, thus submitting the membrane to electroshock. If the transducer were not properly insulated, current from the transducer could go from the transducer across the membrane to the patient. Manufacturers of the transducers recognize this potential, and most transducers are specially insulated to minimize the risk of current flow from the transducer to the patient (Health Devices, 1979, pp. 202, 208). However, a consulting engineer described circumstances in which impaired insulation could allow current leakage. While most transducers are designed to minimize this problem, independent testing of a number of systems showed that in some, leakage of current from the monitoring system is possible, especially if the transducer becomes wet. This leakage current can be transferred across to the saline-filled catheter and have direct access to the patient's heart, as in the case of defibrillation (Health Devices, 1979, p. 215). During nursing care of these patients the transducer and dome are coupled by fluid, either a heparinized flush solution or water, and it is very easy to wet the system (Lamb, 1977, p. 67).
In addition to electrical current caused by cardioversion and from the transducer monitoring system, current leakage can occur from any number of electrical devices in the hospital setting, such as the electric bed, respirator equipment, intravenous fluid pumps—if they should be ungrounded or have faulty insulation. If an IAHMD is in use, these devices could be a source of current which could potentially damage the chamber dome membrane.

Delineation of the Research Problem

The specific problem which this study addressed was whether electro-shock with defibrillation current, such as a patient might conceivably receive, could be a predisposing factor in the passage of bacteria through the mylar plastic membrane separating a nonsterile (contaminated) pressure transducer from a line of fluid in direct communication with a patient's bloodstream.

This study recognized the following variables:

1. Dependent variable: Passage (or nonpassage) of bacteria through the membrane of a disposable dome.

2. Independent variable: Electrical shock of at least 400 watt seconds (joules).

3. Controlled variables:
   a. criteria for selection of sample;
   b. number of electroshocks applied to the membrane;
   c. voltage of electroshock;
   d. type of bacteria used;
e. number of days of bacterial challenge of membranes;
f. a single person doing the study and laboratory work.

4. Recorded data were:
   a. the lot number of each dome used;
   b. the voltage used;
   c. the number of shocks delivered.

5. Measured variable: Bacterial recovery from the inside of a presterilized disposable chamber dome.

6. Uncontrolled variable: Integrity of mylar membrane in the disposable dome prior to manipulation during the experiment.

**Research Question and Statement of Hypothesis**

The research question was stated as follows: What is the effect of electroshock of 400 watt seconds (joules) to a disposable dome membrane on the passage of bacteria across the dome membrane from a non-sterile transducer into the sterile fluid-filled dome?

The research hypothesis was stated as follows: There will be no evidence of bacterial contamination occurring across a disposable dome membrane after electroshock of 400 watt seconds (joules). This problem could also be stated in the form of a directional hypothesis: the experimental group will have a significantly higher incidence of bacterial contamination in the presterilized disposable chamber dome after undergoing electroshock than will the group not undergoing electroshock ($\alpha=0.05$). The results were analyzed using the Chi-Square Test.
Importance of the Study

Since, according to Retailliau, the infection rate of arterial monitoring systems has been shown to be as high as 18 percent, with bacteremia resulting in 22 percent of those instances, a study such as this could of great importance to patient care if it identifies a contributing factor to the problem. If electroshock facilitates bacterial contamination across a dome membrane, then nursing can improve patient care by changing domes in the event of defibrillation. Also, specific measures can be taken to prevent and control the possibility of stray current leakage. If no cause/effect relationship can be identified, nursing can look for another potential source of the problem. If bacterial contamination does occur from a contaminated transducer, independent of electroshock, two questions emerge; (1) Are defective membranes a common problem? (2) Is it the responsibility of those working with the transducers, most specifically nursing personnel, to assure proper decontamination of the transducers prior to coupling the dome? Current practice does not require the use of sterile fluid to couple the transducer diaphragm and the disposable dome membrane (Lamb, 1977, p. 67). If there is demonstrated bacterial passage from a contaminated transducer, whether from the use of defective membranes, non-sterile fluid or from their handling, this might indicate the need for decontaminating the transducer and the use of only sterile fluid in the transducer-dome interspace. In addition, the need for a routine of changing domes may be indicated.
**Definition of Terms**

**Bacteremia**

Systemic infection demonstrated by bacteria in the blood.

**Bacterial Contamination**

Presence of bacteria in a formerly sterile site.

**Chamber Dome Membrane**

A thin membrane which separates the dome from the transducer head. The membrane is pressure sensitive and relays pressure changes from the fluid-filled dome to the transducer.

**Disposable Chamber Dome**

A presterilized plastic dome with a fluid-filled chamber continuous with an intravascular line. A pressure-sensitive membrane isolates the fluid in the chamber from the transducer. The dome comes packaged in a sterile cover from the manufacturer and is designed for single patient use.

**Indwelling Arterial Hemodynamic Monitor (IAHMD)**

An intravascular monitoring system which relays pressure changes in the patient's vascular system through a pressure-sensitive membrane to an electrical transducer which converts the vascular pressure to a measurable electronic signal displayed on a monitoring screen.

**Local Infection**

Infection localized to one specific site and not involving bacteremia.
Septicemia

Synonymous with bacteremia.

Sterile

The absence of living organisms and spores.

Systemic Infection

Used synonymously with bacteremia.

Transducer (Transducer Head, Pressure Transducer)

In this study, an electrical pressure-sensitive device which picks up pressure changes from the vascular system and transfers it to a monitor.
CHAPTER 2
Review of the Literature

Introduction

Infection as a serious complication of invasive monitoring devices is well documented in the literature. Some of the predisposing factors for development of infection were explored, and control and preventive measures were developed. However, one aspect not discussed in the literature is the effect of electrical current on the integrity of the monitoring system as a possible predisposing factor for development of infection.

To bring the problem into perspective, this chapter is organized in the following manner. First, the problem of infection is discussed in terms of a brief overview of infection incidence, followed by review of the purpose and design of IAHMDs. Reported outbreaks of IAHMD-associated infection will then be discussed, followed by a review of the potential problem of electrical current access to the monitoring system. Finally, the nursing implications and a review of the preventive and control measures which have been developed and recommended will be covered.

Overview of Incidence

Infection, particularly bacteremia, is one of the most serious complications associated with IAHMDs. Case fatality associated with bacteremia of all origins has been reported in one study as 20 percent (Scheckler, 1978, p.754), while case fatality ratio from bacteremia related to intravascular devices ranges from 20 to 40 percent (Stamm, 1978, p. 765). While the exact bacteremia rate relating to IAHMDs is
not known, several studies are reported. A 1978 study included 130 arterial catheters used in 95 patients for hemodynamic monitoring. Of these catheters, 17.7 percent (23 catheters) demonstrated local infection and 3.8 percent (5 catheters) resulted in septicemia (Band and Maki, 1979, p. 735). In 1978 it was estimated that approximately 76,000 patients per year were monitored for arterial pressure (Stamm, 1978, p. 764). On the basis of these figures, one could estimate that in 1978 there were approximately 2,900 cases of bacteremia related to intra-arterial monitoring, with between 600 to 1,200 deaths as a result of IAHMD. These hypothetical numbers, based on one study, give some estimate of the size of the problem, a problem well recognized both by users and manufacturers of IAHMD's (Band and Maki, 1978, p. 735; Buxton, et al., 1978, pp. 508-513; Lamb, 1977, p. 65; Lantiegne and Civetta, 1978, p. 611; Stamm et al., 1975, pp. 1009-1015; Weinstein, 1976, pp. 267-268). Bacteremia associated with IAHMD can be prevented when the exact method of bacterial contamination of the system which progresses to patient infection is identified. In some outbreaks the method was improper sterilization of reusable equipment; this will be discussed later. In others inappropriate handling of the equipment caused contamination of stopcocks and ports. (Retailliau, 1979, pp. 15, 16). However, in some outbreaks, although infecting organisms were recovered from the dome membrane and transducer interspace, the mechanism of transmission was not discovered (Retailliau, 1979, p. 16).
Purpose and Design of Intra-arterial Hemodynamic Monitoring Devices

Electronic pressure monitoring devices are widely used to measure intravascular, intracranial, and intrauterine pressure (Retailliau, 1979, p. 13). However, for the purpose of this paper, only intravascular monitoring will be considered.

**Purpose**

Direct monitoring of intravascular pressure with IAHMDs provides for more accurate and reliable data for clinical assessment than does the more commonly used indirect pressure monitoring done with a sphygmomanometer. The disparity ranges from 30-70 mm/hg between direct and indirect monitoring (Harrington, 1978). In critical care situations where accurate monitoring is needed, it is necessary to use direct pressure monitoring. In patients with poor cardiac output, it may not be possible to measure hemodynamic pressure by indirect methods, and the alternative is to use direct intra-arterial monitoring (Buckbinder and Ganz, 1976, p. 146).

Accurate assessment of the circulatory status is necessary when the ultimate goal of treatment is normal cardiac output. Some of the uses of IAHMDs are as follows:

During surgery it provides immediate monitoring to assess the patient's responses to anesthesia, drugs, and the procedure (Prys-Roberts, 1981, p. 767; Buckbinder and Ganz, 1976, p. 146; Lindop, 1979, pp. 2.27). Based on pressure finding, therapy can be instituted and patient responses to therapy, e.g., medication or fluid, evaluated quickly (Armstrong and Baigrie, 1980, p. 1060; Haas, 1979, pp. 2-5;
Olmstead, 1981, p. 11; Russell, Mantle, Rogers and Rackley, 1981, pp. 3, 7; Dean, 1979, p. 45). Assessment of left ventricular function is another important benefit of monitoring (Dean, 1979, p. 45; Russell et al., 1981, p. 1). In coronary care it is used to measure patient cardiac response to vasodilating drugs such as those used for congestive heart failure (Spence and Lemberg, 1980; Russell et al., 1980, p. 7; Haas, 1979, pp. 2-5). Ongoing monitoring also provides a method to detect and treat cardiac dysrhythmias (Russell et al., 1981, p. 8; Dean, 1979, p. 47) and evaluate for pulmonary embolism (Buckbinder and Ganz, 1976, pp. 151-152; Russell, et al., 1981, p. 10).

**Basic Design and Function of IAHMD**

As the heart pumps blood into the aorta, it propagates pressure waves throughout the body. The strength of the pulse pressure varies with the size and pathway of the arteries. At different body locations blood pressure can be measured in the vessel by a fluid-filled catheter introduced into the artery and attached to a pressure-sensitive transducer (Health Devices, 1979, p. 200). The pulse pressure waves in the artery are transmitted to the pressure-sensitive transducer through the fluid-filled catheter. The transducer transforms the pressure to electrical impulses transmitted by wire to a monitor where the pressure is interpreted, giving a direct numerical readout of the pressure wave on a screen (Health Devices, 1975, pp. 19-20).

Early monitoring devices were relatively unsophisticated, with a simple gauge connected to a fluid-filled catheter. As pictured in Figure 1, there was a pressure gauge attached to a pressure sensitive
"bladder" which was filled with anhydrous propylene glycol. This bladder was inserted and screwed into a sleeve filled with a heparinized solution. On the end of the sleeve was a three-way stopcock to which was attached an I.V. line going into the patient's artery, and when the stopcock was opened, I.V. fluid flowed. When the stopcock was turned off, the fluid line leading to the patient was opened to the manometer, and pressure in the patient's arterial system could be relayed through the I.V. line filled with heparinized solution. This pressure would be transferred through the bladder and measured on the gauge.

Figure 1. Arterial Pressure Manometer (Anaesthesiology Vol. 3, No. 1, July, 1975.)
In contrast, the components of the IAHMDs in common use today are pictured in Figure 2. The direct arterial pressure monitoring system in

Figure 2. Direct arterial pressure monitoring system. (Retailliau, 1978, p. 15.)
Figure 2 works in the following manner. A heparinized flush solution runs through I.V. tubing via a continuous flow device and into the patient through an intravascular catheter. Connected to the continuous flow device by one of two connectors is a disposable transducer chamber dome coupled to a transducer. On the other connector of the dome is a stopcock through which I.V. fluid flows to the patient. When the stopcock is turned off, I.V. fluid flows into the patient, and any pressure in the patient's vascular system is transmitted through the fluid in the tubing to the fluid in the chamber dome and past the dome membrane, to be picked up by the pressure-sensitive transducer. Originally, the transducer was not separated from the patient by a chamber dome, and the fluid which went into the patient vessel was also in contact with the transducer. A number of outbreaks of bacteremia occurred as a result of contamination from contaminated transducers. In recognition of the problem, chamber domes were developed to separate the patient vascular system from direct contact with the transducer. The first chamber domes were reusable and were supposed to be sterilized between patient use. However, as a result of faulty sterilization, outbreaks of infection continued to occur. In 1976 disposable plastic chamber domes were developed so that after use on a patient they could be discarded. These were made with a thin pressure-sensitive membrane which separated the heparinized fluid in the intravascular system from the transducer head. They were coupled to the transducer head with a small amount of fluid in the interspace to transmit pressure from the built-in membrane to the sensing diaphragm of the pressure transducer see (Figure 3).
As with the reusable domes, pressure was transmitted through the membrane and passed through the fluid coupling the dome with the transducer. It was first thought that the disposable domes would eliminate much of the risk of infection associated with IAHMDs, and it does appear, after a review of reported outbreaks, that there was a definite decrease in the number of outbreaks reported. However, infections continued to occur.

In order to define the problem of infections related to these IAHMDs, the reported outbreaks of bacteremia will be discussed. First, those related to reusable domes and transducers will be covered. Then
the outbreaks involving disposable chamber domes and reusable transducers will be reviewed, followed by a table summarizing all of the reported outbreaks.

**Outbreaks Related to Reusable Domes**

One of the first documented outbreaks of bacteremia related to IAHMD was reported in 1971. In this outbreak three patients in an intensive care unit (ICU) developed clinical and culture-positive evidence of bacteremia with Pseudomonas cepacia following cardiac surgery. Upon careful investigation it was found that the source of the organism which caused the bacteremia was from the "blood pressure monitoring apparatus," which contained a non-autoclavable pressure transducer. The transducer had been cleaned with a quaternary ammonium compound which did not sterilize the unit. After careful and thorough disinfection with a gluteraldehyde solution was instituted, there were no further cases noted with that organism (Phillips, Eykyn, Curtis and Snell, 1971, pp. 375-377).

Between 1971 and 1973 no outbreaks were reported in the literature, but between May 1 and June 15, 1973, six patients in a hospital ICU were found to have Serratia marcescens bacteremia. All of these patients were undergoing mean arterial pressure monitoring with a reusable pressure monitoring system. Investigation of this outbreak revealed that a heparinized solution in the sleeve of the manometer was contaminated with Serratia marcescens, and even though this fluid was not supposed to come in contact with the I.V. fluid going into the patient, it was felt that the organism had migrated against a pressure gradient from
the manometer into the patient's arterial line (Walton et al., 1975, pp. 113-114). A third outbreak was investigated which started in July 1973. In this outbreak 11 patients undergoing dialysis developed Hepatitis B surface antigen negative Hepatitis. It was found that the index case had developed the infection on an outpatient basis and was responsible for contaminating a pressure gauge at one dialysis station. Subsequently, 10 of the 11 dialysis patients had exposure to that particular dialysis station and developed disease within the incubation period compared to 13 of 25 noninfected patients. The only permanent piece of equipment at the dialysis station was a venous pressure monitoring gauge. During dialysis the gauge was connected to the patient's venous return line. The gauges were not disinfected routinely, and the gauges suspected in the outbreak had dried blood in them. Epidemiologic investigation related this outbreak to a single contaminated venous pressure gauge. After the investigation all gauges were sterilized following use and milipore filters placed in the tubing to prevent blood reflux. After these control measures there were no further cases of hepatitis infection (Weinstein, Stamm, Kramer and Corey, 1976, pp. 937-938).

An outbreak of 10 cases of primary Pseudomonas aeruginosa in a hospital occurred between July and August in patients undergoing hemodynamic monitoring. Phage and pyocin typing indicated that the organisms were the same strain, indicating a common source outbreak. The attack rate was 50 percent. Investigation revealed that the index case contaminated the transducer. Prior to the outbreak, the monitoring
equipment was decontaminated with a gluteraldehyde. However, the transducer domes were not completely filled during the disinfecting process; therefore, a reservoir of the epidemic organism remained (Weinstein, 1976, pp. 288-289).

Another bacteremia cluster of eight cases occurred over a 24-day period in 31 ICU patients following open heart surgery, the attack rate was 26 percent. All the positive cultures grew Pseudomonas cepacia with a common antibiogram pattern, suggesting a common source exposure. All of the patients had intra-arterial monitoring lines placed in the operating room and attached to reusable pressure monitoring systems for constant hemodynamic monitoring during surgery. Following the surgical procedure, the patient lines were disconnected from the operating room transducer and transferred with the patient to the ICU, where the lines were reconnected to transducers. Careful investigation, including multiple cultures, revealed that the source of the outbreak was the contaminated transducers in the operating room. Prior to the outbreak the operating room transducers had been cleaned by flushing a detergent through the system after each procedure. Cultures of fresh detergent in use during the epidemic period revealed Pseudomonas cepacia as the probable source of the infecting organism (Weinstein, Emori, Anderson, and Stamm, 1976, pp. 338-344).

All of the outbreaks of bacteremia discussed so far have occurred in adult patients. However, infants undergoing hemodynamic monitoring are also at risk for bacteremia, as demonstrated when over a period of a month four infants with umbilical catheters for pressure monitoring
developed systemic candidiasis, resulting in two deaths. Sequential monitoring was the only common factor so the transducers were suspected as the source of contamination. Candida was cultured from two of the transducers, one after routine cleaning, the other while in use. After routine sterilization of transducers was done between uses, there were no further cases of Candida bacteremia (Winstein, Stamm, Kramer and Corey, 1976, pp. 936-937).

The last outbreak of bacteremia associated with reusable pressure monitoring devices reported in the literature occurred in an acute care unit. Five of 44 thoracic surgery patients developed primary Pseudomonas acidivorans bacteremia with identical antibiograms. Two of the five also had Enterobacter cloacae (EC) isolated from blood cultures with the same antibiogram. All five patients had undergone thoracic surgery procedures, and each had venous and arterial catheters in place for cardiovascular monitoring with a pressure transducer while they were in the operating room. When the patients were transferred to the acute care unit (ACU), the monitoring lines were connected to pressure transducers in the ACU. Pressure transducers in the operating room were routinely decontaminated with an alkalinized gluteraldehyde for 30 minutes between patients, but in the ACU there was no cleaning routine. Cultures showed that five of six pressure transducers in the ACU were contaminated with the epidemic organisms, three with Pseudomonas acidivorans and two with Enterobacter cloacae. Once a routine was established for disinfecting ACU transducers with an alkalinized gluteraldehyde between patient use, this epidemic ended. (MMWR, 1975, p. 295).
Outbreaks of Infection Associated with Use of Disposable Domes

As previously discussed in the first part of this chapter, the risk of infection resulting from use of the pressure transducers became a recognized problem. To eliminate this risk, disposable chamber domes were developed and put into wide use in 1976. However, while this may have decreased the number of outbreaks, it did not completely eliminate the outbreaks. Not all outbreaks are reported, and small outbreaks of bacteremia have not caused much public concern. Also, the CDC investigated most bacteremia outbreaks in the early 1970s, but more recently many hospitals have infection control practitioners with the ability to deal with outbreaks, and thus CDC assistance has not been requested. The outbreaks are handled within the hospital and usually are not reported.

During the six-month period between January and June 1976, eight cases of primary Enterobacter cloacae bacteremia developed in patients who had undergone open heart surgery. All patients had undergone continuous hemodynamic pressure monitoring during the surgical procedures. Prior to January 1976 reusable metal transducers were used. In January a new transducer with a disposable plastic dome was introduced. Investigation of the epidemic included culture of medications and environmental cultures in the operating room. On three separate days, Enterobacter cloacae was cultured from all of the transducer diaphragms in the operating room and recovery room; the antibiograms matched those of the epidemic strain. It was found that before surgery the disposable domes were attached to the transducer with a 5 percent solution of
dextrose and water between transducer and dome; they were not cleaned between operations. Consequently, the transducers tended to remain moist and became a good reservoir for the organism. Evaluation of this outbreak posed the probability that bacterial contamination crossed by some unknown mechanism from the contaminated diaphragms of the transducers to the arterial line across the membranes of the disposable domes, although laboratory studies done on 36 domes did not demonstrate that bacteria crossed. (Buxton, Anderson, Klimick, and Quintiliano, 1978, pp. 508-513).

The second report involved 17 patients who developed primary Serratia marcescens bacteremia associated with pressure monitoring. The cases occurred between January and July 1978 and involved 10 cardiothoracic surgery patients, four general surgery patients, and three neurosurgical patients. Intra-arterial pressure monitoring with disposable transducer domes was the one common factor among all patients. The cultured organisms had identical antibiograms, suggesting a common source. Epidemiologic investigation showed an increase in Serratia marcescens bacteremias from 0.3 per 100 admissions to the ICU during January to July 1977, to 2.4 per 100 admissions during the January to July 1978 epidemic period. Epidemiologic culture showed eight of eight in-use transducer heads (100 percent) contaminated with Serratia marcescens, all with identical antibiograms to the epidemic strain. It was believed that the contaminated transducer heads were the source of the infecting organism, but no mechanism of transmission from transducer to patient was identified. A laboratory experiment directed at detecting
contamination occurring from contacting transducer heads through the disposable dome membrane was performed but showed no evidence of passage through the membrane. In that particular study hand contamination from the transducer and the stopcocks was considered a possible source of contamination to the system. This mechanism has been described as a possible mechanism of contamination in other outbreaks. Recognizing the central role of the transducers in the Serratia marcescens bacteremia epidemic all the transducer heads were routinely disinfected by soaking for 20 minutes in an alkaline gluteraldehyde solution and rinsing with sterile water. The transducers were then covered with a sterile protective cap. This procedure resulted in an immediate end to Serratia bacteremia infections, and no cases occurred during the two months of observation which followed (Donowitz et al, 1979, pp. 1749-1751).

The third outbreak took place over a five-month period, probably in late 1977 or early 1978 (date not specified by the CDC) and involved 25 patients, all of whom developed primary bacteremia with multiply resistant Serratia marcescens. All of the patients were in the ICU and 21 had undergone a major surgical procedure before the onset of bacteremia. During the epidemic period 214 patients were admitted to the ICU; for these, the attack rate for bacteremia was 13 percent. Cases and controls were studied and the risk factor found was the use of an intravascular pressure monitoring system. Further investigation revealed that the transducers were cleaned only when visibly dirty. In addition, when monitoring was discontinued, the used dome was usually
left on the transducer to protect the transducer diaphragm. When the transducer was again used, the old dome was removed and a clean one installed. Although the domes were designed for single use, they were often washed and resterilized with ethylene oxide for reuse. During the outbreak investigation, both new and resterilized domes were available for examination. Of 25 resterilized domes examined, 33 percent were found to have membrane defects ranging from cracks in the membrane to disruption of the weld between the membrane and dome. In addition to study of the domes, cultures of the transducers were performed. Six sets of transducer domes cultured grew Serratia marcescens with the epidemic sero type and antibiogram. In addition, five transducers were culture-positive for Pseudomonas aeruginosa and Klebsiella pneumoniae. Following institution of the CDC "Recommendations for Prevention of Infection with Invasive Monitoring Systems," there were no further cases.

The largest reported outbreak occurred in a large community hospital and involved 37 patients with primary bacteremia caused by Citrobacter diversus. All 37 patients had undergone intra-arterial hemodynamic pressure monitoring in one of the several ICUs. Of the 37 patients, 13 had multiple (two to four) other gram-negative organisms isolated from their blood. An epidemiological investigation which included review of assembly and use of the equipment found that after use the monitoring equipment was taken to a utility room for storage and reassembly. The used dome was left on the transducer to protect the sensing membrane. If the dome was grossly contaminated, it was
replaced with a cleaned used dome. The transducers were not cleaned unless visibly dirty. Before assembly for reuse all disposable equipment was discarded and replaced with new equipment; the domes were not reused. When epidemiological cultures were performed on components of the monitoring systems and on the assembly environment, the space between the dome and transducer was found to be heavily contaminated with a variety of gram-negative organisms, including many of those causing bacteremia in patients. Upon institution of recommended preventive measures, including cleaning, storage, assembly, and insertion techniques, no further cases of bacteremia occurred. In both of these outbreaks infection remained a significant hazard associated with intraarterial hemodynamic pressure monitoring in spite of the use of disposable chamber domes. In both instances contaminated transducers were apparently the reservoir for the infecting organisms. The mechanism of bacterial access in the first outbreak was probably due to membrane defects. However, in the second, the exact mechanism is unknown (CDC: NNIS Report, 1977 [6-month summary] issued November 1979, p. 33).

A sixth outbreak of transducer-associated bacteremia was identified in the routine monthly nosocomial surveillance data gathered in a teaching university medical center. Over the four-month period from January to April 1980, seven cases of primary Enterobacter cloacae bacteremia occurred in patients undergoing hemodynamic monitoring. All seven patients had undergone cardiac surgical procedures, all were monitored with similar equipment, and all were cared for in the same cardiac surgical ICU following surgery. Sterile disposable chamber domes were
used, but transducer heads were not routinely decontaminated after use. Prior to and during the outbreak, it was common practice to store the transducers capped with the used disposable dome when hemodynamic monitoring was discontinued. Although the intent of this practice was to protect the delicate sensing mechanism of the transducer, it provided a moist environment selective for Enterobacter cloacae, and cultures documented Enterobacter cloacae from the stored transducers. It was thought that the contaminated transducers were the source of the infecting organism. After identification of the epidemic organism on the transducers, the storage technique was changed. A few disposable chamber domes were marked and the dome membranes removed; these were designated as storage covers. After use on a patient, all transducers were carefully cleaned with alcohol and then covered with the designated storage domes. Following this change in cleaning and storage of the transducers, no further incidence of bacteremia with the epidemic organism occurred (unpublished surveillance data, LLUMC Dep. of Epidemiology, 1980).

The last reported occurrence of IAHMD-associated bacteremia was a very small outbreak involving three cases of primary Enterobacter cloacae bacteremia which occurred within a 10-day period. Three patients in a CCU developed elevated temperatures shortly after insertion of Swan-Ganz catheters which were hooked up to pressure monitoring devices. Cultures of the Swan-Ganz catheter tips revealed a high growth of Enterobacter cloacae. Cultures of the transducers in storage between patient use revealed a high growth of the bacteria. Investi-
gation revealed that upon discontinuation of monitoring, all I.V. tubing was detached from the dome, leaving the dome still attached to the transducer to protect the delicate pressure-sensitive head. The transducers were so stored until use on the next patient, whereupon the used dome was removed and a sterile dome attached for patient use. However, the bacteria grew within the moist interspace. When transducers were disinfected and stored dry between patient uses, the incidence of transducer-related contamination disappeared (Bond and Caldwell, 1982, pp. 48-49).

In order to summarize the outbreaks discussed above, they have been outlined in Table 1 according to the dates of occurrence, where they occurred, the number of documented cases, the attack rate (if known), agent involved in the outbreak, pertinent comments, and a reference to additional information available. The six outbreaks occurring with the use of reusable IAHMD systems are marked with an asterisk. Seven were associated with the use of IAHMD systems using disposable chamber domes.

**Nursing Implications**

In considering nursing management of infections associated with IAHMDs, two major aspects will be discussed in this paper. The first is the prevention of infections associated with invasive therapy, specifically prevention of bacterial invasion at the insertion site and contamination through the indwelling catheter. The second has to do with the untested hypothesis that some aspect of patient care, in this case electrical current, can in some way damage the protective chamber dome membrane, thus permitting bacterial access which could result in patient infection.
<table>
<thead>
<tr>
<th>Dates</th>
<th>Where Occurred</th>
<th># of Cases</th>
<th>Attack Rate</th>
<th>Agent</th>
<th>Comments</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>May-June 1973</td>
<td>ICU</td>
<td>6*</td>
<td></td>
<td>Serratia marcescans</td>
<td>Reusable equipment used.</td>
<td>Walton et al., 1975.</td>
</tr>
<tr>
<td>July-Aug 1974</td>
<td>ICU</td>
<td>10*</td>
<td>50%</td>
<td>Pseudomonas aeruginosa</td>
<td>Reusable transducer was contaminated.</td>
<td>Weinstein, 1976.</td>
</tr>
<tr>
<td>May 1975</td>
<td>Neonatal ICU</td>
<td>4</td>
<td>16%</td>
<td>Candida species</td>
<td>All had IAHM through umbilical catheters.</td>
<td>Weinstein, Stamm, Kramer &amp; Corey, 1976.</td>
</tr>
<tr>
<td>Apr 29-June 9, 1975</td>
<td>ICU</td>
<td>5*</td>
<td>11%</td>
<td>Pseudomonas acidovorans</td>
<td>(5 also had E.C.)</td>
<td>Centers for Disease Control, MMWR Aug. 30, 1975.</td>
</tr>
<tr>
<td>Month not specified 1980</td>
<td>ICU</td>
<td>8</td>
<td></td>
<td>Enterobacter cloacae (2 patients also had one other organism)</td>
<td>Disposable chamber domes were in use.</td>
<td>Unpublished surveillance data, LLUMC, 1980.</td>
</tr>
<tr>
<td>Date not specified 1982</td>
<td>CCU</td>
<td>3</td>
<td></td>
<td>Enterobacter cloacae</td>
<td>Disposable chamber domes were in use.</td>
<td>Bond &amp; Caldwell, 1982.</td>
</tr>
</tbody>
</table>

*Reusable IAHMD systems, including domes.
Prevention of Infection

Nursing literature on IAHMDs generally focuses on three major aspects: indications and uses of monitoring; monitoring techniques, including accurate reading and recording; and in-use maintenance of the system. The in-use maintenance of the system includes infection control measures to prevent contamination via fluid delivery access or at the cannula site. Because the purpose of this paper is to discuss nursing implications, focus will be on the infection control aspect. First the general magnitude of invasive monitoring line associated infections will be presented, followed by description of modes of bacterial access and measures specifically aimed at preventing contamination through those points of access.

Invasive-device epidemics have increased dramatically over the past decade and a half. Prior to 1965 device-related epidemics were rare. However, between 1970 and 1975, 42 percent of all the epidemics investigated by the CDC were related to invasive devices (Stamm, 1978, p. 765). One of the most important factors which predisposes patients to nosocomial infection is exposure to invasive medical devices. Approximately 45 percent of the nosocomial infections are associated with an invasive device, accounting for over 850,000 infections a year (Stamm, 1978, p. 764). Included in these figures are infections related to IAHMDs. In an ICU up to 70 percent of the patients have at least one intravascular device other than an I.V. catheter. In these patients, the infection rate from that invasive device ranged widely, from 3 to 90 percent (Crow, 1982, p. 20).
The most common life-threatening infection, as described earlier in this chapter, is bacteremia (Band and Maki, 1979, p. 735). One author found that over a four-year period the mortality rate for nosocomial bacteremias of all etiologies was 20.3 percent (Scheckler, 1978, p. 754). Stamm reported a mortality rate of 20 to 40 percent (1978, p. 765), and Crow a mortality rate of 30 to 50 percent (1982, p. 20).

While nosocomial bacteremia may result from various sources, one predisposing factor to the development is localized infection at a vascular line insertion site. In a study of 107 arterial catheters, Band and Maki found 23 local infections as demonstrated by positive semi-quantitative culture. Five of these localized infections also produced bacteremia in the patients (1979, p. 737). The reported incidence of localized infection varies, although Stamm estimated in 1978 that approximately 35,000 patients develop phlebitis per year (p. 766). The reported incidence of bacteremia related to intravascular devices also varies. According to Band and Maki, bacteremia related to infusion or cannula is often poorly recognized and therefore poorly reported. However, one of their studies showed that the incidence of septicemia related to radial artery catheterization was 5 out of 80 catheters left in place for more than four days, with an attack rate of 6.25 percent (1979, p. 737). Stamm found an infection rate related to intravascular devices ranging from .2 percent to 27 percent, with peripheral arterial lines having the lowest rate of infection and central lines placed for total perenteral nutrition (TPN) having the highest. Subclavian lines placed for central venous pressure monitoring had an attack rate ranging from 3 to 7 percent (1978, p. 765).
Several modes of bacterial access are provided by use of an invasive device, and nursing management to prevent infection has focused on intervention based on these modes. First, by entrance through a break in the skin, the monitoring system serves as a portal of entry for bacteria, damaging epithelial or mucosal barriers and providing direct access to the vascular system or tissue below the protective skin (Walrath, Abbott, Caplan and Scanlan, 1979, p. 100; Stamm, 1978, p. 764). Bacteria can pass through the line or through the break in the skin around the invasive device (Haughly, 1978, p. 638). Once an invasive device is in use it can support bacterial growth and serve as a protective reservoir for bacteria (Stamm, 1978, p. 764). For example, when a vascular line is placed, fibrin deposits form at the tip of the catheter and gradually produce a clot which can trap and hold bacteria coming through or around the intravenous line, or even circulating in the blood. The bacteria can multiply in the clot, which serves as a reservoir for infection (Walrath, et al., 1979, p. 102; Levine and Roderick, 1980, p. 75).

A localized demonstration of this phenomenon can be seen in the case of septic phlebitis, which can also serve as a source of bacteria for systemic infection. Occasionally the source of infection is manufacturer contamination of products used in conjunction with an invasive procedure. This is the exception rather than the rule. It is estimated that at least 83 percent of device-related hospital infections were due to in-hospital contamination of medical devices rather than to manufacturer or other sources (Stamm, 1978, pp. 764, 765).
Nursing intervention to prevent infection is based largely on measures to prevent bacterial access through or around the invasive catheters by careful handling and management of the system. Figure 2 shows a typical monitoring system. Points of access are at the indwelling catheter insertion site, any tubing connection site which can be disconnected, stopcock sites, and ports for removing blood or adding substances. Bacteria can find access also through contaminated fluids or equipment or through defective equipment or supplies. Based on these, general nursing interventions to prevent in-use contamination are as follows:

1. Prevent contamination upon insertion of the invasive catheter. Most recommendations include careful skin cleansing prior to catheter insertion, sterile technique when inserting the line, and application of a sterile dressing (Shipley, 1979, pp. 846, 847; Schroder and Daily, 1976, p. 62; Luckman and Sorenson, 1980, p. 263; CDC Guidelines, 1982, pp. 31-34).

2. Maintain sterile dressings by changes at appropriate frequency. This recommendation varies from author to author, some recommending a daily change (Shipley, 1979, pp. 845-856; Schroder and Daily, 1976, p. 84; Luckman and Sorenson, 1980, p. 263), some a 24 to 72-hour change (Haag, 1979, p. 54), and others a 48 to 72-hour change (CDC Guidelines, 1980).

3. Maintain a sterile insertion site by application of antimicrobial ointment at the insertion site. This is recommended by some (Shipley, 1979, pp. 854-856; Pictorial Review, 1980,
p. 83), but the method is controversial (Haughly, 1978, p. 638). An iodophore is the usual ointment employed (Haag, 1979, p. 54), and it must be reapplied at each dressing change (CDC Guidelines, 1982, pp. 31-34).

4. Maintain sterile tubing and stopcocks by changing every 24 hours (Shipley, 1979, pp. 854-856; Luckmann and Sorenson, 1980, p. 263; Schroder and Daily, 1976, p. 84). Aseptic handling of the system as a whole is also an important infection prevention factor (Shipley, 1979, pp. 854-856).

5. Avoid contamination of stopcocks. The external system can be a source of contamination when there are breaks in the system, such as withdrawing blood, handling stopcocks, or changing the tubing. One outbreak of bacteremia in 1973 involved 14 separate patients with Flavobacterium species Group 11-b organism isolated from their blood. Careful investigation revealed that the probable source was chilled syringes used to draw blood samples from arterial lines. The syringes were first chilled in ice, the probable source of the organism, and then attached to the arterial line stopcock to draw blood. The contaminated stopcocks provided the reservoirs of bacteria which caused the bacteremias (Stamm, et al., 1975, pp. 1099-1102). A later and unrelated prospective study on bacterial contamination of 58 stopcocks revealed a 59 percent bacterial contamination rate in venous and a 38 percent bacterial contamination rate in arterial system stopcocks (Walrath et
Although this study showed only a 3 percent congruence between organisms isolated from both the stopcocks and circulating blood (Walrath, et al., 1979, p. 103), it does point out a significant reservoir of bacteria which, with manipulation of the system, can lead to life-threatening sepsis.

6. Change flush solutions every 24 to 48 hours to prevent the possibility of the fluid reservoir becoming contaminated (CDC Guidelines, 1982, pp. 31-34). In addition, recent recommendations from the CDC suggest that the transducer be sterilized between uses, the disposable domes be changed every 48 hours, and the disposable domes never be reused. It is also recommended that alcohol or bacteriostatic water be used in the dome-transducer interspace if a fluid is required (CDC Guidelines, 1982, pp. 31-34).

The recommendations on care and management of these invasive devices for infection prevention are well developed and published, the problem being that the guidelines are often in journals not read by the persons doing direct IAHMD management, such as medical journals and specialty journals, rather than in general nursing journals. A more significant problem is that there is a lack of consistency in the recommendations. Examples of contradictions already alluded to concern use versus nonuse of antimicrobial ointment at insertion site, interval for dressing changes, and use of prophylactic systemic antibiotics. Also, a recommendation some years ago in a popular nursing journal that plain
water could be used in the dome-transducer interspace (Lamb, 1977, p. 67) is directly contraindicated in the more recent guidelines by the CDC. This article, although outdated, is an excellent source of information on the technique of intra-arterial monitoring. Since it is in a widely-used nursing publication, it is readily available in reference centers, whereas the CDC Guidelines are not.

Many care and management procedures emphasize one important aspect to the neglect of another infection control procedure. Nursing management has focused on the major areas which relate to I.V. infusion therapy and management, such as aseptic insertion, site and dressing management, and fluid and tubing change. However, some of the critical aspects, such as stopcock management, dome and transducer decontamination or changing, and methods of storage, have not been emphasized. At one facility known to the author where transducers, domes, and stopcocks were in constant use, it was a common practice for nurses to carry extra unpackaged stopcock covers in their uniform pockets in case one was needed. Also, the procedure of changing domes every 48 hours was not followed, and transducers, instead of being decontaminated before reuse, were merely covered with a nonsterile used dome for protection. Before the next patient use, the dome was removed and a sterile one applied, but the transducer remained contaminated. Another author noted that a similar technique in dome handling resulted in several cases of bacteremia. The outbreak was discussed earlier in the Outbreaks section (Bond and Caldwell, 1982, pp. 48-49).
Part of this lack of aseptic technique may have come from contradictory manufacturer guidelines. One manufacturer will state that with the use of a disposable chamber dome cleaning or sterilization of the transducer is not necessary (Bentley Laboratories, 1977, p. 11), whereas some other manufacturer will give guidelines for both cleaning and sterilization (Hewlitt Packard, 1979, p. 4). The practice of storing transducers with used domes as a protective cover is recommended by some of the manufacturers (Bentley, 1977, p. 11) and is so recommended by some sales persons.

It seems apparent that domes and transducers have not been considered a potential infection risk, since the usual recommendations for in-use system maintenance focus on insertion site, tubing, and fluid changes. The significance of this lack of information can be emphasized by pointing out that in a culture study of 102 pressure monitoring system, Maki and Hassemer found 16.7 percent (17) to have contamination in the chamber dome fluid, this in spite of the fact that all tubing was routinely changed every 48 hours and infusion containers changed every 24 hours. There was no schedule for changing transducer domes (Levine and Roderick, 1980, p. 79).

**Potential for Electrical Current Damage to Membrane**

In considering the hypothesis that electrical current could damage a transducer dome membrane in some way and thus permit bacterial access to a patient, it is necessary to discuss the potential problems of current in the monitoring setting. The discussion will deal first with the scope of electrical device usage, which includes indwelling hemody-
namic monitors, then with the problem of electrical current leakage, and finally with the application of nursing.

**Medical Electronic Usage**

During the first half of this century, instruments commonly used to monitor vital signs were the thermometer, stethoscope, and sphygmomanometer. However, with the technical advances of the 1960s, this changed, and there has been a rapid rise in the development and use of medical instrumentation, especially in critical care areas (Heuther, 1978, p. 561). One of the earliest uses of medical electronics was the development of the x-ray in 1876. After that the electrocardiograph (ECG) was clinically useful by 1903, the centrifuge in the 1920s and the electron microscope in 1939 (Harrison, 1982, p. 7). Of these, only the ECG had direct patient contact. The next major growth in medical electronics occurred during World War II, and later with the subsequent development and refinement of computer systems (Harrison, 1982, p. 10).

In a discussion of infections associated with invasive medical devices, Stamm estimated that at least 16.8 million medical devices are used in the United States every year (1978, p. 766). The increase in financial expenditures for medical electronics also demonstrates a huge increase. In 1950, medical electronic expenditures made up 4.5 percent of the gross national product (GNP). By 1978 this had risen to 9.1 percent of the GNP (Harrison, 1982, p. 15). This rise in expenditures is illustrated in Figure 4.

While the increase in medical electronics benefits patient care, it also increases the potential for electrical current access to the patient.
Some of the types of medical devices in common use which are common sources of electrical current leakage (and therefore potentially hazardous) are electrosurgical units, isolated power systems, defibrillators, ECG monitors, pumps, x-ray units (Patrick, 1973, p. 1127), and electrical monitoring devices (Hull, 1981, p. 177).

Figure 4. Growth of the Medical Electronics Industry (Harrison, 1982, p. 15)

The problem with electrical monitoring devices is that there is always a small amount of current leakage. Also, electrical hazards tend to be greatest where beds are clustered in patient care areas and where multiple electrical devices are in use (Herzog, 1982, p. 31).
Current Flow

Low level current leakage is intrinsic to all electrical circuits, although usually it can be controlled so that harm is not caused. However, patients with punctures, moist skin, and/or abrasions are most sensitive to harm from current leakage (Meth, 1980, pp. 1345). This includes all patients undergoing hemodynamic monitoring with an invasive line.

Electrical current will pass along a conductor if there is a voltage difference between points on the conduction path (McIlwraith, 1975, p. 803). This can occur when there are multiple electrical devices attached to one patient and plugged in different grounds. Because there is a difference in the ground potential between different devices plugged into different grounds and used on a single patient, current can flow through the patient. To eliminate the difference in ground potential, all electrical devices must be plugged into a common ground, such as in the same cluster of wall outlets (Schroeder and Daley, 1976, p. 57; Meth, 1080, p. 1348).

Causes of Current Leakage

A major source of current leakage in the hospital is defective electrical appliances (Lipton, Ream, and Hyndman, 1978, p. 1190). Appliances can become defective through inappropriate "fixing" or adjusting of equipment by persons not qualified to repair them. Further, the manner in which electrical equipment is used can pose a hazard. If cable is knotted or left where it can be damaged or run over, it can become cracked and cause ground faults (Hull, 1981,
p. 191). Mechanical damage can occur to an electrical conduit if the conduit is run over by heavy objects (e.g., a trolley), resulting in exposed wires or cords. Also, at the plug site, cords can become frayed or otherwise damaged (Marshall, 1981, pp. 721, 722). Frequent handling and mechanical abuse may weaken insulation of electrical devices (Schneider, Apple, and Braun, 1977, p. 74). If there is deterioration of the insulation around the electrical load, a conductive pathway will be formed to the enclosure and a leakage current will flow to ground through the point of least resistance (Hull, 1981, p. 181) or into the instrument housing (Mlrea, 1976, p. 53). Mechanical damage to cables or plugs can occur in patient areas when nurses do not understand potential patient risks and do not respect the devices. Behaviors such as pulling electrical monitor plugs out by the cord rather than by carefully unplugging the unit at the wall socket are common careless abuses (Meth, 1980, p. 1340).

**Electrical Injuries to Patients**

The types of injuries most frequently associated with medical devices are (1) burns to patients and/or personnel, (2) ventricular fibrillation by direct gross electroshock or by microshock by way of intracardiac catheters or electrodes, and (3) respiratory arrest (Hull, 1981, pp. 177, 185; Sances, Larson, Myklebust, and Cusick, 1979, p. 102). Sources of stray electrical current in the clinical setting applicable here are intra-arterial monitoring devices. Many of the cases mentioned in the literature have occurred in the operating room where electrocautery and other electrical appliances and monitors are
used. One case was a 27-year-old female who underwent surgery to control intraperitoneal hemorrhage. Blood from the wound soaked linen and drapes, and when the surgeon used the suction unit, the patient was electrocuted and the ECG monitor to which she was attached was destroyed. A change in the foot pedals of the suction device caused an insulator to break down and the metal case attached to the operating table became "live." The patient was grounded to the table by the blood-soaked linens and the circuit was completed through the patient to the cardiac monitor (Chambers and Saha, 1979, pp. 173-175). A report of two cases of ventricular fibrillation related to use of electrocautery hypothesized that the cause of injury was inadequate grounding. When cautery was used, the electrical current caused the patient to have ventricular fibrillation (Hungerbuhier, Swopo, and Reeves, 1974, pp. 422-435). Another report noted that nine patients suffered from electrical burns at the ECG electrode sites while undergoing electro-surgery (Becker, Malhotra, and Hedley-Whyte, 1973, pp. 106-121). Reference has been made to the dangers in critical care areas from use of electrical equipment. An example of such danger is described in the following case report: A patient in a critical care unit was electrically shocked when a urine-filled receptacle spilled onto the bed, wetting the electrically powered hand controls for the bed. The patient had a cardiac monitor with ECG leads on his chest. Upon noticing the patient in cardiac arrest, the nurse came in to do cardiac compression and received a shock. Examination of the system revealed that the switch for the bed controls was faulty and when the switch was wet with
the urine, the current went from the switch through the patient to ground via the ECG monitor. Fortunately the patient recovered (Arnow et al. 1969, p. 31).

When internal catheters or electrodes are used, the patient is particularly at risk for microshock from stray current. Hull describes three examples of patients going into ventricular fibrillation when faulty ground connections permitted current leakage in patients with pacemakers while hooked up to ECG monitors (Hull, 1978, p. 652). In a similar instance, a patient undergoing diagnostic cardiac study went into fibrillation due to electroshock. The saline-filled catheter used during the study conducted electrical current from a leakage potential in the infusion pump. The current went through the saline-filled catheter, through the patient, to the ECG lead on the patient's right leg, and then to ground (Herzog, 1982, pp. 19, 20). An example of more subtle stray current is described in the following case: A male patient in an intensive care unit had an internal electrode connected to an ECG and an intracardiac monitor to measure intracardiac blood pressure. The intracardiac catheter was connected to an electrical transducer. The transducer and the ECG monitor were grounded through different outlets. When there was no leakage currents through either ground wire, there was no problem. However, when an electric floor polisher was plugged onto an outlet near the ECG outlet, a current leakage caused a potential difference of 160 mv between the ground of the ECG monitor and the ground of the intracardiac blood pressure monitor probe. This subjected the patient's heart to a theoretically measured current of 0.05 m.a. (Herzog, 1982, p. 20).
Electrical Hazard with Invasive Monitoring Devices

Patients with IAHMDs invasive devices are at particular risk to injury from stray current. A current pathway can be established with a fluid-filled catheter or with pacemaker electrodes (Lipton, Ream, and Hyndman, 1978, p. 1191). Penetration of the skin by needles, electrodes, wires, and catheters provides a low resistance access to the heart from the electrical bed or from other electrical equipment hooked up to the patient (Schroeder and Daily, 1976, p. 56). A normally harmless current can be dangerous. For example, if a patient with implanted electrodes or a physiological monitor turns off a lamp switch where there is leakage, the current can pass through the patient and cause ventricular fibrillation when the current goes from the lamp through the patient to the monitor or electrical appliance (Herzog, 1982, p. 17). Patients with intracardiac leads or catheters must be especially cared for to prevent electrical injury. They must be insured an electrically safe environment by having appropriate grounding provided and not having more than one electrical device handled at a time (Hull, 1981, pp. 191, 192).

There is potential for major damage to patients undergoing cardiac catheterization and monitoring due to exposure to current leakage from faulty plugs or from inefficient wiring systems (Biship, 1979, p. 20). A real hazard of electroshock is associated with leakage of current during intravenous recording techniques. For example, when there is venous and arterial pressure monitoring and there is a leakage current from one or the other monitoring systems, the shock can pass through
the heart and damage the transducer (Graystone and Towell, 1971, p. 79).

ECG monitors frequently interact with other equipment such as infusion pumps, suction devices, x-ray units, hypothermia machines, and lamps (Patrick, 1973, pp. 1129, 1130). Patients requiring intra-arterial hemodynamic monitoring usually have at least one or more of these devices in place at the same time and thus run a higher risk of problems caused by stray current leakage.

**Application to Nursing**

Nursing responsibility has focused on in-use aspects of medical electronic devices. This includes gaining a knowledge of types of monitoring equipment, specific types of catheters and their placement, maintenance of the in-use equipment, and interpretation of monitoring results (Olsmstead, 1981, p. 22). In general, though, the users of these devices are "electrically naive." (Hull, 1979, pp. 145-146).

Because of the progressive increase of electronics in medicine, it can be expected that nurses will be exposed to an increasing use of medical electronic devices (Harrison, 1982, p. 7; Lenihan and Abby, 1979, p. 592). With this increase in development and use, however, there has not been a concurrent increase in the teaching of electrical safety in nursing and medical schools (Herzog, 1982, p. 25). The increase in bio-electronics has changed the nursing role and its knowledge needs (Huether, 1978, p. 564). Now nurses need technical knowledge in medical electronics as a part of their education (Lenihan and Abby, 1979, p. 594). Everyone involved in the direct care of patients must be familiar with the safe use of electricity and the potential for
injury to the patient. This is especially true when multiple electrical devices are in use on the patient (Meth, 1980, p. 1344). Nurses and all other persons who work with invasive monitoring equipment must be aware of the potential dangers such as infection, electrical burns, or current leakage to the heart (Murray, 1981, pp. 88, 89). With the appropriate knowledge, nurses can take the necessary steps to prevent current leakage by demanding appropriate equipment maintenance; using electrical equipment in a manner that prevents damage to the equipment, housing, and wiring; and by recognizing and taking faulty equipment out of use and getting it replaced. Also, nurses need to assure that current sources are handled in such a manner as to prevent conductive pathways to susceptible patients.

The effect of current leakage has been well demonstrated and documented on patients. However, in patients with IAHMDs, current access would be through the membrane from the transducer and then down a fluid-filled catheter to the patient. The potential for damage to the membrane would be at the transducer-dome junction, with hypothetical damage to the dome-membrane seal.

Chapter 3 will describe an experiment in which dome membranes were subjected to a defibrillation current, such as that used to cardiovert a patient in cardiac arrest, and then subjected to a bacterial challenge. The purpose of this experiment was to determine if electroshock would damage the domes in some way, permitting bacterial contamination to occur.
CHAPTER 3
Research Method

This study used the quasi-experimental method of research. The experiment took place in a microbiology laboratory at a large university medical center.

Sample Criterion

The target population for the experiment was a sample taken from the two types of disposable transducer domes in use at a large university medical center. The domes were model number 2180 A manufactured by the Hewlett-Packard Company (H-P), and model number D241 manufactured by the Bentley-Trantec Company (B).

Sample Selection

The sample was a convenience sample of domes drawn from different lot numbers of domes representing the two manufacturers. Three boxes of domes, each of a different lot number, were selected to represent each company. When the domes from one box were all used up another box of domes from the same manufacturer was used. The lot number was different from the used up lot number. This resulted in one manufacturer having three lot numbers represented and one manufacturer having four lot numbers represented. The lot numbers were as follows:

Manufacturer B: Lots #28166, #7108, #33427
Manufacturer H-P: Lots #795, #749, #732, #739

The six boxes which contained six domes each were arranged on a counter in alternating order by manufacturer. A dome was drawn from each of the six boxes for testing. Then a dome was taken from two of
the boxes to be controls. (When lot #795 was used up lot #739 was added to complete the number of samples needed.)

**Rationale for Sample Criterion**

The two different manufacturer types of domes were chosen because those were the two types of domes in use at the university medical center where an outbreak of septicemia had occurred. A convenience sample of domes was chosen from those in use at the time of the study.

**Data Collection Procedure**

For the sake of clarity, the method and data collection will be organized in the following order. First, the method of bacterial challenge and the reason why that particular method was chosen will be discussed. The setup of the equipment will then be discussed, including the modifications of some of the equipment. The whole method of attaching the domes to the transducers and the method of shocking the test domes and handling the controls will be covered. Finally, the bacterial challenge method and final typing of the bacteria will be discussed.

**Trials to Select Bacterial Challenge Culture Technique**

A method of challenging the dome membranes had to be found. Needed was a method to bring the membrane into contact with a moist media contaminated with Enterobacter cloaceae (E.C.) in such a way that if there were a defect or opening in the membrane, bacteria from the contaminated media could pass through and be recovered from the previously sterile fluid-filled chamber of the dome. The method of challenge needed to assure that no extraneous contamination occurred. The method
had to prevent physical damage of the membrane. The domes were filled with sterile D5LR solution during the electroshock prior to bacterial challenge and not all the port caps were water tight, so this provided quite a challenge. Two methods were attempted to determine which would provide the more accurate results with fewer problems. The first trial method is called the Wick Challenge; the second is called the Agar Pour Method.

**Wick Challenge Trial**

It was hypothesized by this author that a wick could draw up a contaminated solution which if pressed against the membrane could provide continued bacterial contact to the membrane. In part this hypothesis was based on a study published in 1952 which demonstrated that wet cotton fabric could "wick" bacteria through the fabric, allowing contamination to pass from one side of the fabric to the other (Beck and Colletti, 1952, pp. 125, 126). Simply stated, in this method a wick which was pressed against the dome membrane on one end had the other end immersed in a broth contaminated with E.C as pictured in Figure 5. The steps of the procedure were as follows:

1. Preparation of wick:
   a. 10 standard plastic test tubes with screw-on caps were collected.
   b. Laboratory filter paper was cut to form wide strips which were about 1½ inches longer than the test tubes.
c. The filter paper was rolled and stuffed down into each test tube. The test tube caps were attached.

d. The test tubes were placed into plastic sterilizer bags and sterilized with Ethylen Oxide gas. To assure sterility, spore strips and color strips were checked for sterilizer performance. All quality assurance tests indicated that appropriate sterilizer function had occurred.

2. A bottle of sterile Muller Hinton broth (M-H broth) was inoculated with E.C. and allowed to incubate for 24 hours. This provided the contaminated fluid for the wick.
When steps 1 and 2 were completed, three disposable chamber domes were selected for the actual trial.

3. Wick Challenge Trial

a. Three sterilized test tubes with wicks inside were placed upright in a standard laboratory rack. The caps were removed, and by means of a sterile syringe needle, the wicks were pulled above the top of the tube by at least one-half inch.

b. With a sterile pipette, M-H broth contaminated with E.C. was run into the tubes. Time was allowed for the E.C. broth to be soaked up by the wick, and E.C. broth was added until the test tubes were completely full. Care was taken not to touch the test tube top or wick with the pipette. There was no handling of the test tube above one inch from the top, so the upper inch of the tube was not contaminated by external handling.

c. Each chamber dome was packaged in a sterile paper wrap. The paper covering was pulled apart to reveal the sterile disposable plastic chamber domes. Each dome was picked up by the covered port; and the mylar membrane was punctured with one prick using a sterile insulin needle for each dome.

d. Each dome was carefully placed on top of one of the three test tubes. In the process the moist wick was pressed down and came in close contact with the membrane.
e. By use of a sterile needle and syringe, each dome inter-
    space was filled with sterile M-H broth through one of
    the dome ports.

f. Tape was placed over the top of each dome and down each
    side of the test tube to secure the unit in place. The
    B domes fit tightly over the tube without the taping, 
    but the H-P domes were loose. It was decided to tape
    both types to assure that they remained in close contact
    with the wick.

g. Each dome was given a number. Recorded was the assigned
    number, the lot number, the type of manipulation, and
    manufacturer.

h. The rack of three test tubes was placed in an incubator
    for 48 hours.

i. After 48 hours, the domes on the test tubes were removed
    from the incubator and placed on a clean work surface.
    Fluid was aspirated from the port of each dome with a
    sterile syringe and needle and one drop placed on a blood 
    agar plate. The rest was injected into sterile test tubes
    of M-H broth. The corresponding laboratory number from
    the domes was written on the blood agar plate and test 
    tube. The drop on agar was streaked out on the agar
    plate, and the agar and test tubes were incubated for 48 
    hours.
4. Of the three punctured domes placed on the wick with E.C., all demonstrated bacterial contamination in the previously sterile dome interspace. The conclusion was that the wick challenge provided a reliable bacterial challenge to the dome membrane.

**Agar Pour Trial**

The second trial was based on a theory that agar contaminated with E.C. could be brought into direct contact with a dome membrane. If there was a defect in the membrane, bacteria would pass from the agar into the sterile dome. The trial proceeded as follows:

1. **Preparation of the agar**:
   a. Sterile firm agar was warmed until liquid and set aside to cool slightly.
   b. When cooled, but still liquid, the agar was inoculated with M-H broth containing heavy growth of E.C.

2. **Agar membrane challenge**:
   a. Three sterile domes were used in this trial. The packages were opened and domes were handled only by their covered ports. Each dome was assigned a laboratory number which was written on the dome. Data recorded were number, lot number, laboratory number, manufacturer, and type of manipulation.
   b. Each dome was held upside down and the membrane was punctured with a sterile insulin needle. A new needle was used for each dome.
c. While the dome was still upside down, some of the inoculated agar was drawn up with a sterile pipette; then the inverted dome was filled with agar to completely cover the membrane and form a slightly convex bubble on the bottom of the dome. The domes were placed upside down on a rack in a clean area to harden. As a control to assure that bacteria were present in the agar, it was cultured on a blood agar plate. E.C. were isolated from the agar.

d. When the agar was firm, the domes with the contaminated agar against the transducer side of the membrane were placed right side up on blood agar plates.

e. Each dome interspace was filled with sterile M-H broth through an opened port. The ports were recapped.

f. The domes were then incubated for 48 hours.

g. After 48 hours, the domes were removed from the incubator. With a sterile syringe and needle for each dome, fluid was aspirated from a port. One drop from each was dropped on a blood agar plate and streaked out. The remainder of each was placed in a sterile test tube of 55 cc M-H broth. The corresponding laboratory number from each dome was written on the blood agar plate and test tube.

h. The tubes and plates were placed in an incubator for 48 hours.
3. Culture results:

Of the three domes with punctured membranes, one had bacteria recovered from the dome intraspace. Bacterial passage through the membrane defect occurred in one case.

Summary and Rationale for Choice of Wick Method

The wick challenge demonstrated that three of three tested had bacterial passage from the contaminated wick through the punctured membrane. The agar pour method demonstrated one of three with this result. Bacteriologically, the wick challenge appeared to provide the more reliable method. A hypothesis about why the agar pour method did not work is that perhaps the agar pressing against the membrane sealed the puncture in the membrane or possible an undetected bubble in the agar protected the defect, thereby preventing bacterial passage. Another problem with the agar pour method was the high potential for contamination. The domes would be filled with fluid while mounted on the transducer prior to the bacterial challenge phase. With the agar pour method these filled domes had to be inverted to be filled with agar. Since the caps of half of the domes were not watertight and one port of the other half was not covered, the fluid would leak out and have to be replaced. With fluid leaking and the associated handling, it was thought that there was too much potential for extraneous contamination occurring. Thus, the wick bacterial challenge was chosen.

Setup of Equipment

The experiment demanded a method of shocking the chamber dome membrane. This involved some modification of the transducers to permit
current flow from an outside source through the membrane. It also involved devising a method of delivering the current and finding a method of holding the apparatus during the experiment.

**Stand**

A plastic stand was constructed to hold the transducers while they were being shocked. The stand was made six inches high on a wide plastic base. The length was nine inches and the width three and one-half inches. The top of the plastic stand had two holes cut at either end, specifically sized to hold the two different makes of transducers. So the transducers were held firmly in place, plastic screws tightened a lip around the holes for each transducer. No metal was used in the stand to prevent conduction of electricity from the transducers during shock, and to prevent any possibility of extraneous current from a source other than the controlled shock from reaching the transducers and domes.

**Transducers**

The transducers needed modification to permit current passage through the domes to the transducer and on to an electric cord to complete the circuit. Because the particular transducers used were constructed to minimize electrical current leakage, some modifications were made to assure that a full current of 400 watt seconds could be conducted through them. Transducer "B" was insulated so thoroughly that a simple modification of the transducer would not work. To assure full conduction, an exact replica of the transducer was made out of aluminum. Threads were placed in the top identical to the original model. At the
base of the replica a hole was drilled in which an electrical cord was attached by a screw. At the end of the cord an electrical plug was attached. The transducer from company "H-P" permitted current to pass from the dome through the transducer with a simple modification which was made by placing a wire directly under the strain-gauge of the transducer. The insulation was stripped off of a section of copper wire. The wire was positioned under the strain-gauge and twisted around the transducer. Electrical tape was used to assure insulation and prevent stray current leakage. The cord was near the top of the transducer and hung over the side of the stand. At the end of the cord an electrical plug was attached.

To deliver the current into a fluid-filled line, 18 gauge 1½ inch stainless steel syringe needles were used. A copper wire was inserted into the end of each needle (about ¼ inch) and sealed in place. This prevented the possibility of bacterial contamination through the needle and improved the conductivity of the needles. The hub and 1½ inch of the needle were hollow.

**Shock Box**

The shock box was a 50-ohm resistance box which actually received the electroshock and transmitted it by way of two electrical cables. One cable from the shock box was fitted with a two-inch copper wire which was made to fit snugly into the modified needles previously described. This cord transmitted current delivered to the shock box.
The other cable of the shock box was a pick-up lead fitted with an electrical plug. This received the current passing through the transducer, making the current complete. The equipment is pictured in Figure 6.

Once the equipment modifications were made and the acceptable bacterial challenge with the "wick method" chosen, the domes were tested.
Testing of the Domes

The experiment took place in a microbiology research laboratory. Supplies necessary were readily available, as were equipment needed for the bacteriological culture and typing necessary. Preparatory to the experiment, the following was done.

Experiment Preparation

1. The eight 18-gauge, 1½-inch stainless steel needles with the copper wire insert were rinsed, dried, and wrapped in 4 x 4 gauze in such a manner that the hub was exposed but the needle was completely protected. These were placed in a plastipack sterilizing package and then sent to the Central Supply Department for steam sterilization. After the sterilization, the indicator tapes were checked to be sure that the colors had changed, indicating that the appropriate temperature had been reached. In addition, spore test results were checked to assure that spore cultures were negative indicating sterility.

2. For each test episode a total of 10 test tubes were prepared for the wick challenge. The test tubes used had a screw-on cap and were plastic. Filter paper was cut and folded into a narrow configuration to fit snugly in the test tube. The half-inch piece of paper protruding above the top of the test tube was "stuffed" down into the tube and the top screwed on. The 10 tubes were placed in "gas autoclave" packaging material and taken to the Central Supply Department for sterilization.
with the regular sterilizing supplies for the hospital. Upon receipt of the sterilized package, the indicator-tape was checked to assure that the package had gone through the sterilization process. In addition spore tests done on the loads were reviewed to assure that sterilization had occurred. When the wicks were to be set up for use, they were placed in a rack and the tops unscrewed. The wick was pulled up with a sterile needle.

3. At room temperature, a sterilized loop was introduced into the reservoir of E.C. and inoculated into 100 ml of Muller-Hinton broth. The broth was allowed to incubate for four hours to permit growth of E.C. For purposes of a control, the innoculated broth was cultured just before use. In all cases, E.C. and only E.C. were grown from the broth.

**Setup of Equipment and Testing**

1. The plastic stand was placed on a cleaned work deck and the modified "B" and "H-P" transducers fastened in the stand. The 50-watt shockbox was placed on the deck by the stand. The transducer heads were cleaned very thoroughly with alcohol and then filled with alcohol and allowed to dry completely to eliminate any bacteria on the surface. The transducers were cultured after cleansing with the alcohol process. No bacteria were recovered.

2. After the transducer head was completely dry, a loop of pure growth E.C. was placed in the well and just enough sterile Muller-Hinton broth added to fill the well.
3. The boxes of domes (6 per box) were lined up on the counter alternating by manufacturer. One dome was pulled from each box to be shocked. One additional dome was pulled from any two boxes to make up two controls. This made a total of eight domes. Each time an experiment was done the boxes were lined up. No attempt was made to keep them in a specific order except that they alternate by manufacturer. Each dome was removed from the sterile wrapper and a code number written on the top with a waterproof pen. Without allowing the dome membrane to be contaminated, the dome was screwed on the appropriate transducer head.

The "B" domes used in this study had a 2½-inch, three-way stopcock and extender pre-attached. This was important because it provided a place to insert the copper-filled needles delivering current without allowing the dome membrane to be touched or damaged by the steel needle. Because the "H-P" domes did not come with a stopcock attached, a similar sterile disposable three-way stopcock was attached to one port of the "H-P" domes.

4. The cap at the end of the stopcock extender was removed and placed on a fresh alcohol swab.

5. With a sterile needle and syringe, sterile D5LR solution was aspirated from a 500 cc bottle and the disposable transducer dome was filled through the open stopcock port.
6. A laboratory test tube rack was set on the work deck and eight of the pre-sterilized test tubes with the filter paper wick were arranged, well spaced in the rack. A supply of sterile syringe needles was placed in easy reach. Ten of the test tubes were sterilized and prepared so that if there were any break in aseptic technique, there would be another tube to use in place of one contaminated. One of the tubes was opened. With a sterile needle, the wick was pulled up so it would stand above the top of the tube. By means of a sterile pipette and a laboratory suction bulb, the Muller-Hinton broth which was inoculated with E.C. was drawn up in the pipette and the open test tube was filled. The fluid was put in very slowly to allow the wick to draw up the inoculated broth. When the tube was completely filled, the pipette was discarded.

One of the sterilized stainless steel needles was removed from the plastic covering. The shock-box cord with the copper wire end was inserted into the needle through the hub. The sterile needle was then pulled from the protective gauze and inserted into the DSLR-filled stopcock port of the disposable dome. To assure that the needle did not damage the membrane, it was inserted into the stopcock extender.

7. At this point, the pick-up lead of the shock box was attached to the base of the transducer in use. Lead #2 of the shock
box was attached to the needle inserted into the fluid-filled disposable dome.

8. A defibrillator was used which had been tested and showed a reading of 400 watt seconds. The paddles were applied, one to either side of the shock-box, and the current was discharged.

9. The needle was removed from the stopcock and the sterile cap replaced. The needle was placed aside for cleaning and resterilization. Lead #2 was removed from the needle. Lead #1 was removed and attached to the other transducer head. The shocked disposable dome was unscrewed from the transducer head and placed gently but firmly on top of the wick on the tube with E.C. broth. Tape was used over the top of the dome, down the sides of the test tube, to secure it in place. The tape was not in contact with any part of the dome membrane or lip of the tube as the domes fit down and over the top of the tubes. This was significant because the tape was not sterile and could have been a potential source for contaminating organisms had it contacted the wick.

10. This process was repeated, alternating from a "H-P" dome and the "H-P" transducer to a "B" dome and the "B" transducer until all dome to be shocked were completed. Six domes were shocked. Two domes attached similarly were not shocked. The transducers were alternated so at no time were the transducers of one manufacturer shocked or used more than the others.
Domes for two testing lots were shocked only once each. Domes for one testing lot were shocked 25 times each. Each dome was assigned an identification number. Documented by each identification number were manufacturer, lot number, whether it was a control or shocked dome, and if the latter, the number of shocks.

11. The domes on the wicks of E.C. were transferred to a standard laboratory rack and were covered with clear plastic and left at room temperature for 48 to 72 hours. (The variable in the time was not thought to be a significant factor, for if any bacteria were to grow they should do so within 48 hours.)

12. After 48 to 72 hours, the domes on the wick tubes were brought to the work surface, which had first been cleaned with a phenolic solution.

13. Tubes of 5 cc of sterile Muller-Hinton broth in test tubes were assembled in a standard laboratory test tube rack at the work area. With strict aseptic technique, the cap of one part of each dome was removed and placed on a moist alcohol swab. The lid of one test tube of broth was removed and placed upside down out of the immediate work area in a clean area. With a sterile needle and syringes, fluid (1½ to 2 ml) was aspirated through the open dome port from the chamber inside the transducer dome. The fluid was then squirted into the test tube of M-H broth and the tube capped. With a wax pencil, the number of the dome was written on the test tube
of broth. The tube was then placed in a rack. This same process was followed with all the domes, controls as well as shocked domes. After all the domes were handled thus, the rack of test tubes with "dome fluid" in the broth were placed in the incubator for 48 to 72 hours.

13. After incubation the test tubes were removed and examined against room light for cloudiness, evidence of bacterial growth. By a standard laboratory method, each tube was opened and plated on blood agar regardless of evidence of cloudiness or not. Each agar plate was labeled with the test number assigned the dome from which the test fluid originated. The test tube was opened, and with a sterile loop, 0.01 ml fluid from the test tube was removed and streaked on the blood agar plate. The plate was covered and placed in a rack for incubation. All tubes were plated in like manner. When all tubes were streaked and plated, they were incubated for 48 hours.

14. At the end of 48 hours, the plates were removed from the incubator. Growth or no growth was documented on the laboratory record for each test number.

15. Any growth was subjected to visual inspection to ascertain whether more than one type of organism was present. In addition, biochemical analysis was performed on any growth to type the organism.
Bacterial Analysis

All cultures were plated on divided plates of blood agar and MacConkey media and in Muller-Hinton broth. Cultures which showed growth revealed a single type of organism growing. Gram staining and inspection indicated the organism was a gram negative rod resembling Enterobacter cloacea. Positive cultures were further biotyped by use of TSI, Simmons slant, urea slant, motility test, ODC, LDC, and Indole tests. The bacteria all were Simmons slant positive, Indole nitrate negative, ODC negative, non-motile, LDC negative, and TSI showed acid with gas. These analyses confirmed that the organisms were Enterobacter cloacea, the same organism used in the bacterial challenge. No other organisms were cultured from the chamber domes or from the innoculated M-H broth indicating that no extraneous contamination had occurred.

Unforeseen Events and Results

After the first two groups which underwent one shock each for test domes and none for controls were processed, it was discovered that one test dome of the first group and one control of the second group showed bacterial growth in the chamber dome. These were Enterobacter cloacea. Both contaminated domes were of the same manufacturer and lot number. Because one was a control and the other a test, it was decided to challenge the two remaining domes of that particular manufacturer and lot number with the wick challenge. No electroshock was used. This was in an attempt to determine if some reason other than manipulation, e.g. defect in the domes, was responsible for the positive findings. The
remaining two domes were removed from the sterile packaging and placed on wicks according to the wick challenge method already described. By sterile technique, they were filled with sterile Muller-Hinton broth. The sterile port caps were replaced and the domes were covered with a clean plastic sheet and left at room temperature for 48 hours. After 48 hours, the fluid in the dome was cultured and typed according to previously-described procedures. In spite of no manipulation or shock, both domes grew E.C. cultured from the inside of the dome. The only source of E.C. was from the wick challenge.

Since there were no remaining domes of "H-P" lot #795 left, a box of "H-P" lot #793 was obtained to provide for six different boxes of domes from which to draw from for the remainder of the study. Only one dome of that lot number was used. The study was divided into two main groups. The first group included the 12 domes which had been shocked once each and their controls. The second group included 6 domes which had been shocked 25 times each and their controls. After the testing was completed the results were analyzed as presented in Chapter 4.
CHAPTER 4

Findings

A total of 26 disposable chamber domes from two different manufacturers were used in the study. Eighteen of these domes were subjected to electroshock with 400 watt seconds defibrillating current.

Eight of the domes were controls. Two domes were subjected to bacterial challenge when it appeared that domes of that lot number become contaminated. The test results follow.

Culture Results of Tests and Controls

On 7-14-80 the first group of six test domes and two control domes were processed. The six test domes were shocked once each at 400 watt seconds. The controls were manipulated in the same manner as the test domes except they were not shocked. The results are described below showing lot number and culture results.

<table>
<thead>
<tr>
<th>Lot No.</th>
<th>C</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>H-P749</td>
<td>H-P795</td>
<td>B33427</td>
<td>H-P732</td>
<td>B28166</td>
<td>H-P749</td>
<td>B7108</td>
<td>B33427</td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td>0</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

C = control dome
T = test dome (shocked)

0 = no growth on culture challenge
+ = growth of E.C. on culture challenge

On 1-17-80 a second group of six test domes and two control domes were processed in identical manner as the first group with two control domes not shocked and six domes shocked at 400 watt seconds each. The results of the second group are described on the following page:
Group 1B: T-shocked once each

<table>
<thead>
<tr>
<th>Lot No.</th>
<th>B33427</th>
<th>B33427</th>
<th>H-P795</th>
<th>B28166</th>
<th>H-P749</th>
<th>B7108</th>
<th>H-P732</th>
<th>H-P795</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>+</td>
</tr>
</tbody>
</table>

Curious as to why a control and a test dome of lot H-P795 showed growth, the remaining two domes of this lot were placed on a wick challenge with E.C. in the same manner as the control group. The domes were filled with sterile broth by aseptic technique and then incubated. Both these domes had E.C. recovered from the dome space.

<table>
<thead>
<tr>
<th>7-23-80</th>
<th>C</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot No.</td>
<td>H-P795</td>
<td>H-P795</td>
</tr>
<tr>
<td>Culture</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

At this point there appeared no significant difference of contamination of dome interspace between control and shocking one time at 400 watt seconds. To provide an adequate number of domes, since the two remaining lot #H-P795 were used up, lot #H-P793 was included. This lot number was chosen from boxes of domes available from the supply department.

On 7-28-80 the final group of domes was processed. There were two control domes which were not shocked, and six domes which were shocked a total of 25 times each at 400 watt seconds. The results of the third group are described on the following page:
**Table 2**

**Manipulation of Domes and Results**

**Group I A. Shocked once - 7/14/80**

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Lot Number</th>
<th>Group</th>
<th>Shock</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>H-P 749</td>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>H-P 795</td>
<td>T</td>
<td>X1</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>B 33427</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>H-P 732</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>B 28166</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>H-P 749</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>B 7108</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>B 33427</td>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Group IB**

**Shocked once - 7/17/80**

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Lot Number</th>
<th>Group</th>
<th>Shock</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>B 33427</td>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>B 33427</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>11</td>
<td>H-P 795</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>12</td>
<td>B 28166</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>13</td>
<td>H-P 749</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>14</td>
<td>B 7108</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>15</td>
<td>H-P 732</td>
<td>T</td>
<td>X1</td>
<td>0</td>
</tr>
<tr>
<td>16</td>
<td>H-P 795</td>
<td>C</td>
<td>0</td>
<td>+</td>
</tr>
</tbody>
</table>

**Domes placed on Wick Challenge - 7/23/80**

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Lot Number</th>
<th>Group</th>
<th>Shock</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>H-P 795</td>
<td>C</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>18</td>
<td>H-P 795</td>
<td>C</td>
<td>0</td>
<td>+</td>
</tr>
</tbody>
</table>

**Group 2. Shocked 25 times - 7/28/80**

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Lot Number</th>
<th>Group</th>
<th>Shock</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>B 28166</td>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>20</td>
<td>B 28166</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>21</td>
<td>H-P 749</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>22</td>
<td>B 33427</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>23</td>
<td>H-P 793</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>24</td>
<td>B 7108</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>25</td>
<td>H-P 732</td>
<td>T</td>
<td>X25</td>
<td>0</td>
</tr>
<tr>
<td>26</td>
<td>H-P 732</td>
<td>C</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Group 2: T-Shocked 25 Times Each

<table>
<thead>
<tr>
<th>C</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>T</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot No.</td>
<td>B28166</td>
<td>B28166</td>
<td>H-P749</td>
<td>B33427</td>
<td>H-P793</td>
<td>B7108</td>
<td>H-P732</td>
<td>H-P732</td>
</tr>
<tr>
<td>Culture</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2 outlines each dome used in the experiment by subject number, lot number, groups, (control or test), manipulation and culture result. The date each group was tested is also included.

Of 26 domes used in the study, 22 were negative and 4 were positive. Only 1 of the 4 positive domes had been shocked, the other 3 were not shocked. Lot No. H-P795 made up 19.2% of the domes used. Of Lot No. H-P795 used, 80% became contaminated. Of the total number of domes, 15.4% showed contamination, all of the same lot number. These results are summarized in Table 3.

**Statistical Analysis**

Statistical analysis of the findings was done using the Chi-Square test. The purpose was to assess the effect of electroshock on bacterial contamination of disposable chamber domes. The experimental group consisted of 18 disposable chamber domes which had undergone electroshock. The control group consisted of six disposable chamber domes which had not undergone electroshock. Both groups were subjected to identical bacterial challenge. Only the control domes which were associated with the experimental group were used in the statistical analysis. This did not include two domes of one lot number which were placed on bacterial challenge when two other domes of lot number H-P 795 deve-
loped contamination. It was felt that inclusion of these domes would bias the data. The Chi-Square test was used to determine if the null hypothesis was correct: that there would be no difference in the proportion of domes having bacterial contamination between the experimental and control groups of domes. The analysis is shown in Table 4.
Table 3
Number of Domes by Lot Number and Culture Results

<table>
<thead>
<tr>
<th>Number</th>
<th>Lot No.</th>
<th>Culture Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 (15.4%)</td>
<td>H-P749</td>
<td>All negative on culture (1 control, 3 test)</td>
</tr>
<tr>
<td>5 (19.2%)</td>
<td>H-P795</td>
<td>4 positive on culture (3 control, 1 test)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 negative</td>
</tr>
<tr>
<td>5 (19.2%)</td>
<td>B33427</td>
<td>All negative on culture (2 controls, 3 test)</td>
</tr>
<tr>
<td>4 (15.4%)</td>
<td>H-P732</td>
<td>All negative on culture (1 control, 3 test)</td>
</tr>
<tr>
<td>4 (15.4%)</td>
<td>B29166</td>
<td>All negative on culture (1 control, 3 test)</td>
</tr>
<tr>
<td>3 (11.5%)</td>
<td>B7108</td>
<td>All negative on culture (3 test)</td>
</tr>
<tr>
<td>1 (3.8%)</td>
<td>H-P793</td>
<td>All negative on culture (1 test)</td>
</tr>
</tbody>
</table>
### Table 4

**Chi-Square Test Analysis**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Shocked</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>A. Observed Frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>Shocked</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Not Contaminated</td>
<td>17</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>B. Expected Frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>Shocked</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>1.5</td>
<td>.5</td>
<td></td>
</tr>
<tr>
<td>Not Contaminated</td>
<td>16.5</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

\[ x^2 = \frac{(-0.5)^2}{1.5} + \frac{0.5^2}{16.5} + \frac{0.5^2}{5.5} + \frac{(-0.5)^2}{5.5} = 0.727 \]

With one degree of freedom the critical value for statistical significance is 3.841. The analysis revealed a result of .727 which indicates that the proportion of contaminated domes for the shocked group was not significantly different than for the control group.

**Problems Encountered**

A major problem encountered was the difficulty in obtaining several different lot numbers for testing. The facility in which the study took place had several older lot numbers in current use with a fairly large
new shipment of a single lot number awaiting use. Several different storage areas in the critical care units and the anesthesiology department had to be checked to get different lot numbers. It would have been most useful to have had access to more of the lot number H-P #795 in order to test more of the domes to determine if all of the tested domes of that lot number demonstrated contamination when subjected to bacterial challenge, thus indicating a possible manufacturer defect in that particular lot number.

A minor problem encountered involved the B domes, which had short arms with leur locks for tubing attachment. A stopcock had to be attached to one arm to assure that there would be no possibility of needle puncture of the dome membrane while it was filled with sterile fluid. Both domes were fitted with sterile stopcock attachments for the electroshock so that there would be no chance of the copper-filled needle touching the membrane and damaging it.

**Summary**

In summary, the data indicated that electroshock was not a predisposing factor to the contamination of sterile chamber dome interspace from bacteria on a contaminated transducer. Those domes which did become contaminated were probably defective because all were of one manufacturer and the same lot number, whereas none of the other domes from the same manufacturer but with different lot number, and none from the other manufacturer became contaminated although subjected to similar handling.
CHAPTER 5
Outcome of the Study

Summary

The purpose of this study was to attempt to identify whether electroshock predisposed to contamination of the intra-arterial hemodynamic monitoring device. Based on the findings recommendations for nursing practices related to the use of the devices could be made.

Infection as a complication of intra-arterial hemodynamic monitoring is a significant problem. In many cases the actual mechanism of bacterial passage into the system remains unknown. This study attempted to identify whether electroshock could be a predisposing factor in the passage of bacteria across the membrane of a presterilized disposable chamber dome. The study addressed two major questions:

1. Could bacteria pass from a contaminated transducer past an unused membrane into a presterilized chamber dome?
2. Could electroshock allow the passage of bacteria from a contaminated transducer past a membrane into a presterilized chamber dome?

To answer these two questions a number of domes were subjected to electroshock and then challenged with a single strain of bacteria. Cultures were done to assess whether bacterial contamination had occurred within 26 chamber domes. Of the 26 domes, 4 demonstrated bacterial contamination. All of the contaminated domes were of the same manufacturer and lot number. One dome received a single shock, three were handled as controls. This suggests that the contaminated domes
were from a defective lot and that the contamination did not result from manipulation or electroshock.

The data from the study support the research hypothesis stated in Chapter 1: There will be no evidence of bacterial contamination occurring across a disposable dome membrane after electroshock of 400 watt seconds (joules). There was no evidence to support the directional hypothesis that the experimental group would have a significantly higher incidence of bacterial contamination in the presterilized disposable chamber dome after electroshock than would the group not undergoing electroshock.

The answer to the first of the two questions addressed in the study is yes, bacteria can pass from a contaminated transducer past a membrane into a presterilized chamber dome, although in this study the mechanism appears to be membrane defect rather than electroshock. The answer to the second question is no, electroshock does not effect the passage of bacteria through the membrane.

Conclusion

This study provided no evidence that electroshock facilitated bacterial passage from a contaminated transducer past a protective membrane into a presterilized dome chamber. Therefore, based on this data there is no indication that disposable chamber domes need to be changed after a patient has undergone cardiac defibrillation. However, the data resulting from this study indicate that defects do occur in what may have been a defective lot permitting bacterial access to the chamber dome. This problem has a direct implication for the nursing
management of patients with IAHMD's. Nurses set up and maintain the monitoring equipment, and once the IAHMD is in place they maintain the whole system. It is widely assumed that the use of a presterilized disposable chamber dome isolate patients vascular systems from transducer contamination and eliminates the risk of infection at the transducer-dome junction. As a consequence transducers are not routinely decontaminated prior to use. However, if there is a defect in the dome membrane from either manufacturing process or improper handling, there can be direct bacterial access into the chamber dome and from there into the patients vascular system. To protect the patient this potential source of infection should be eliminated by routinely decontaminating all transducers prior to patient use. Transducers should be kept dry, and if used, fluid in the transducer-dome interspace should be sterile.

Review of the nursing literature on the subject leads to the conclusion that nursing as a profession needs to be more actively involved in presenting information on the safe use of invasive devices. Of interest and professional concern was that Centers for Disease Control recommendations on infection control in hemodynamic monitoring were found not to be available in the popular nursing literature. Most information on hemodynamic monitoring and related infection control was found in the medical literature and in specialty literature such as infection control journals aimed at physicians or infection control practitioners (ICP). However, physicians and ICPs are not the primary maintainers or handlers of the system and hence have a smaller impact
than do nurses using IAHMDs in preventing infections. It is recommended that active attempts be made by nursing as a profession to print recommendations from reputable sources, such as from the Centers for Disease Control, in commonly read nursing journals, so more individuals from various nursing disciplines have direct access to the information. Nurses need to develop appropriate procedures for handling the hemodynamic monitoring systems in a safe and protective manner to assist in prevention of patient infections.

In addition to active involvement in providing information and developing appropriate procedures for handling of invasive devices, it is also recommended that the nursing profession should become better trained in the safe use of electrical equipment. As the primary hands-on users nurses can provide valuable support for the maintenance of safe equipment. The goal of eliminating many of the problems which typically are identified only after equipment is put in use on patients could be reached and a significantly lower number of patients with IAHMD-related infections or electrical injury could be achieved.

**Recommendations**

This study tested a small number of domes encompassing only two manufacturers and seven lot numbers.

1. It is recommended that additional manufacturers' domes be tested, including many lot numbers, to determine if there is significant potential for defects to be present.

2. The domes used in this study were made of mylar. Different types of domes are constructed of different materials and the
possibility of electroshock affecting those materials is not known. A larger study is needed to find out if electroshock damages domes of other materials and construction.

3. An epidemiological study comparing the efficacy of specific guidelines of care and handling of IAHMDs on the rate of IAHMD-related infections is needed. Such a study could compare two similar facilities or two units within a facility where different procedures for care and maintenance are in use.

4. Finally, it is recommended that a record of all lot numbers of chamber domes in use and the patients on which they are used be maintained for a set period of time. Any cases of infection could be compared by lot number to see if "bad lots" are a frequent problem or a unique experience associated with this study. Patients infections related to defective domes could be quickly identified, and remaining domes of that lot number could be removed from use and tested, thus preventing further IAHMD-related infections.
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