

Observations on Cardiology Technology and Devices

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Table of Contents

Introduction.....	1
Background.....	1
Cardiac catheterization.....	1
Nuclear cardiology.....	2
Electrophysiology.....	3
Echocardiography.....	4
Cardiothoracic surgery.....	5
Technology Issues.....	6
Outdated Computer Equipment.....	6
Large Patient Issues.....	9
New Device Recommendations.....	9
Acoustic Device.....	10
Ultrasonic Device.....	11
Other Device Needs.....	12
Conclusions and Recommendations.....	13
References.....	13

Introduction

The purpose of the clinical practicum course was to provide an opportunity for biomedical engineering students to see clinical application of technology. The Fall 2006 section was run by Dr. Peter B. Kurnik, and hence focused on cardiology. The cardiology specialties observed included:

- Cardiac catheterization
- Nuclear cardiology
- Electrophysiology
- Echocardiography
- Cardiothoracic surgery

This paper summarizes some of the key trends and needs observed, and elaborates on possible avenues for further investigation, such as to produce a device to help find the femoral artery.

Background

This section summarizes the typical activities for each of the cardiology specialties observed. There are no outside references cited in this section because it is based on first hand observations, and discussions with various doctors, nurses, technicians, product reps, etc.

Cardiac catheterization

Cardiac catheterization uses catheters (hollow flexible tubes) which are fed through the vascular system from the femoral artery or vein into the aorta and left ventricle, or into the right atrium and right ventricle, respectively. (The left atrium is hard to get into, since it would require going backward across the mitral valve, or entering from the pulmonary veins.)

Once in or near the heart, via various types of catheter it is possible to perform many tasks.

- Visualize blood flow into the coronary arteries, using a contrast agent or “dye” which is opaque to X-ray. This is mainly done to assess the presence and extent of stenosis in those arteries.
 - The amount of dye used is based in part on the patient’s hepatic capacity, since removal of the dye from the blood is done by the liver.
- Estimate pressures in and near the heart. This can be used to estimate cardiac output.

- Use the dye to visualize the extent of regurgitation across the heart valves. Large amounts of regurgitation could indicate, for example, aortic valve insufficiency.
- Take biopsies of the myocardium, often to assess whether there is rejection of a transplanted heart. A very long sheath is used for biopsy catheters, to protect the patient from the metal biopsy head.

In a very compromised heart, a balloon pump can help maintain circulation. A balloon pump being placed in the descending aorta was observed in a patient. The balloon pump inflates during diastole to provide increased backpressure and fill the coronary arteries, then deflates during systole to allow full systemic blood flow. The balloon pump is installed using a catheter which remains in place for the day or two the pump is being used, then is removed with the pump.

Nuclear cardiology

Nuclear cardiology examines the movement of the myocardium, typically under both normal (at rest) and stressed conditions. The patient is given a radioactive tracer substance intravenously, which attaches well to receptors in the myocardium. The heart's movement is recorded by scintillation detection cameras, using a methodology which allows cross sectional views to be made. Analysis of these images allows doctors to:

- Assess whether the heart is beating evenly, or some portions of the myocardium are unresponsive.
- Assess whether the heart is normal size or enlarged (cardiomegaly).
- Look for defects in the heart, such as a patent foramen ovale (PFO) or atrial septal defect (ASD).
- Assess whether parts of the heart are ischemic (since they will glow less brightly from absorbing less tracer).

The patient may be stressed before a test by having them walk on a treadmill, or if that's too stressful, they might be stressed chemically using intravenous adenosine or dipyridamole, for example.

Interpreting the results of nuclear testing can be made difficult if there are image artifacts (such as shadows) due to interference by other body parts – for example, large breast mass and/or the

nearby abdominal wall can provide false indications of diminished cardiac muscle circulation. Subcutaneous fat deposits can also produce image artifacts.

Electrophysiology

Cardiac electrophysiology focuses on the electrical signals of the heart – not just through electrocardiograms (EKGs), but also includes “mapping” the heart’s internal conduction system for anomalies such as irritable foci or extraneous conduction pathways that can cause arrhythmias, the ablation of such extra tissue if needed, and the implantation of pacemakers and/or defibrillators. Pacemakers speed up a heart rate that is too slow naturally. Defibrillators shock the heart when it’s beating too fast (tachycardia), goes into ventricular fibrillation (Vfib), or stops completely. Implantable devices were observed which can do both functions, depending on the patient’s needs at the time.

The device is implanted in the upper chest, and uses a permanent catheter in the subclavian vein or artery to allow the electrical leads to follow into the heart. The leads are screwed into the wall of the heart – in an atrium and/or ventricle, again depending on the patient’s needs.

In rare cases, leads might need to be implanted outside the heart, but it’s much easier surgically if internal leads can be used.

The device is calibrated by measuring key voltages of the native heart, and finding the minimum amount of help needed to achieve good cardiac performance. Parameters for each pacing lead include:

- 1) the P wave amplitude in mV from the body,
- 2) the R wave peak voltage (V) needed, and
- 3) the amount of resistance (typically 100-200 ohms) in the body.

When a device is tested for defibrillation ability, key measurements may include

- 1) how long it took for the device to detect a Vfib condition (~3 seconds), and
- 2) how much voltage was needed to get the heart restarted. Excess voltage damages the heart, so it’s good to use as little as possible.

Even after the device is implanted, it can be calibrated via wireless connection, referred to as telemetry. Accordingly, the patient is monitored post-operatively in a special ‘telemetry room’ where the device’s settings can be monitored and changed quickly if needed.

Echocardiography

Echocardiography uses ultrasound to observe the structure of the heart, and Doppler ultrasound to measure the speed of movement of the heart and/or blood. Good echocardiography equipment can use all of these modes.

- Normal ultrasound uses pulses in the 2-5 MHz frequency range (7 MHz for pediatric use) to observe structure. Higher frequencies produce better resolution of small objects, but at the cost of less depth of penetration into the body.
- Doppler ultrasound measures the speed of blood flow, such as through a valve. Typical flow speeds are on the order of 1 to 3 m/s. Excessively high flow speeds can indicate constriction of the valve's opening, among other possible problems.
- Tissue Doppler measures the speed of myocardium movement, typically around 0.2 to 0.4 m/s.

Ultrasound uses several kinds of transducers.

- The most common is one about two inches wide for transthoracic use. Transthoracic use views the heart from outside the chest, typically peeking between the ribs near the sternum, below the sternum, or from the lower left side of the chest (the Four Chamber View, looking down the apex of the heart).
- Smaller, high frequency transducers exist for pediatric use (e.g. to find congenital defects).
- Transesophageal transducers go down the esophagus to view the heart from posterior.
- Very small transducers (5-10 mm?) are also used directly on the heart during cardiothoracic surgery.

Normal ultrasound produces images or movies of the heart, which can be used for many purposes.

- Estimate ejection fraction of the left ventricle.
- Measure the thickness of the myocardium, the septa, valves, or any other structure.
- Determine if the heart is hyperkinetic or hyperdynamic.
- Determine if the heart valves are moving normally, or are stiff (valvular stenosis).
- Identify the presence of excess fluid around the heart (pericardial effusion).
- Identify inflammation of heart valves (endocarditis) or of the myocardium (myocarditis).

Doppler ultrasound can help find other conditions.

- Assess the extent of regurgitation through any of the heart valves.
- Identify defects in the heart, such as a patent foramen ovale (PFO) or atrial septal defect (ASD).
- Determine the velocity of blood flow through the valves as a function of time.
- Tissue Doppler can determine the velocity of the myocardium as a function of time. The ratio of velocities $V_{\text{blood}}/V_{\text{tissue}} > 15$ can be a sign of improper valve function.

Effective use of ultrasound depends on excellent quality people to operate it. If poor images are obtained, the only conclusion might be a part is “not well visualized,” and other techniques will be needed to assess that part.

Cardiothoracic surgery

Surgery is the last resort for cardiac care, since it has higher risks of infection and mortality. One open heart surgery was observed, which had several characteristics of note.

- The patient was the same one who had the balloon catheter discussed earlier. The balloon catheter was left running throughout the 7+ hour long procedure; it was to be removed the next day.
- Only arterial segments were used (no veins). Both left and right mammary arteries were used, plus a long segment (about 20 cm) of the patient’s left radial artery.
- The heart wasn’t stopped during surgery as is typical, probably due to the severity of the patient’s condition (no bypass). A U-shaped vacuum device was used to slow local movement of the heart during the procedure, and pressurized saline and CO₂ was used to keep the immediate field clear.

Surgery uses technology from several of the other specialties.

- A cardiac catheter was placed in the right jugular vein to allow pressure monitoring in the right atrium during surgery.
- A small ultrasonic transducer was used to hear blood flow in the newly reassigned coronary arteries.
- The balloon catheter was in the patient’s descending aorta throughout the procedure. Since it depends on an EKG for timing the balloon, it was very confused when the patient’s heart was not in a traditional position, and therefore couldn’t provide a

meaningful EKG signal. During times like that (which lasted for well over an hour), the balloon catheter could only resort to default settings as a best-guess approach for helping the heart.

The anesthesiologist managed the patient's level of sedation during surgery, partly via a Bispectral Index Monitor (BIS). The BIS does spectral analysis of a modified electroencephalogram (EEG) to determine the depth of sedation. A BIS score of 100 is fully awake; the desired range during surgery is 40-60, though prolonged excursions into the 70-80 range were not alarming.

The anesthesiologist also actively managed the patient's blood pressure (BP), to provide low BP when the surgeons were working near the aorta, and high BP to help push blood to more distal parts of the coronary arteries.

Other patient monitoring during surgery included pulse rate, pulse oximetry (oxygen saturation percent of the blood), and the lowest technology measurement but a very critical one, urinary output, which reflects how well circulation to vital organs is being maintained. The pulse rate and BP were monitored via a special catheter in the patient's right arm.

Technology Issues

Across the cardiology specialties, two key technology issues were most prominent – the age of the computer equipment used throughout most of the cardiology area, and the difficulties posed by large patients.

Outdated Computer Equipment

Three different aspects of severely obsolete computer equipment were noted. They are summarized in Tables 1-3, with their impact on patient care, and proposed solutions. While these problems do not appear to have substantial impact on patient care, they tend to affect the productivity of OR staff.

Problem	Old monitors
Specialty affected	All which use X-ray systems
Description	Systems to monitor X-rays are using large, bulky 17-21” CRT-based monitors. Most ORs are small and crowded; working around monitors which are 1.5 to 2 feet deep wastes a lot of valuable space.
Vintage	1995-1996, based on the copyright data on the monitors.
Impact on Patient Care	None directly, though replacing the current monitors would improve workflow and help avoid accidents and contaminated sterile fields.
Solution	Replace existing monitors with ~21” LCD thin panel screens. Should require minimal cost, since monitors are fairly universal in interface.

Table 1. The Old Monitor Problem

Problem	Old computer hardware
Specialty affected	All which use X-ray systems
Description	Systems to monitor X-rays are using 1996-vintage computers, judging from the ‘32 MB RAM’ status messages. Displays often freeze during procedures, forcing everyone to wait for them to refresh before continuing.
Vintage	1996-1999
Impact on Patient Care	Minimal – most of the impact is on the staff, because waiting repeatedly for images to become available slows procedures unnecessarily.
Solution	Upgrade computer system – possibly a major expense since it’s an integral part of the X-ray system. Should probably include use of ECC RAM and robust power supplies due to likely line current variations during operation of other equipment and errant backscatter of gamma rays from X-ray machines.

Table 2. The Old Computer Hardware Problem

Problem	Software based on obsolete systems
Specialty affected	Echocardiography
Description	The software used to view and analyze ultrasound images in the hospital runs on Windows NT, an operating system made obsolete in 1999.
Vintage	Pre-1999
Impact on Patient Care	May slow analysis of echo data. At present there is a lag of a couple hours between when the images are collected, and when they are reviewed and analyzed. Is part of this delay due to the slowness of the computers doing the analysis? Probably not – review is by humans, but if so, resolving this problem could improve the speed of patient care.
Solution	Upgrade image analysis software, and find something that has at least heard of Windows XP, if not some form of Unix or Linux.

Table 3. The Obsolete Software Problem

All three of these computer technology problems are indicative of a larger scale issue: the lack of a computer technology refresh program. The College of Information Science & Technology, for example, offers new desktop computers to faculty every three years, and typically updates computer lab equipment even more often than that. Since some of the cardiology systems are part of expensive medical systems, perhaps a slower refresh cycle should be considered, such as every five years.

This is not to say *every* computer observed was from the 20th century – a few modern systems were observed, but they were mainly in support roles, such as in the control areas of the cath lab. The ultrasound equipment used by Dr. Robert Foley was especially new – about two weeks old. Unfortunately, such state-of-the-art technology was the exception rather than the rule.

This lack of refresh is both due to budgetary issues and a lack of understanding of clinical environments by business IT personnel traditionally in control of IT in hospitals. Having formally trained medical informatics specialists can help improve understanding between clinical and IT personnel (Silverstein, 2006).

Large Patient Issues

There are several technology issues which were encountered, particularly when dealing with large patients (e.g. 300+ lbs). These issues are described in Table 4. This is a serious problem, since American adults are getting obese very quickly. The percent of extremely obese (BMI > 40) adults in the USA increased from 2.9% to 4.7% during the period 1991-1999¹ (Flegal, 2002).

Area Affected	Problem	Solution
Cath Lab	One challenge for catheterization includes finding the femoral artery and/or vein. In large people, or those with weak pulses (e.g. due to heart failure), it can be difficult and time consuming to find the artery or vein	Create an acoustic or ultrasonic device to help find femoral vessels. See next section.
Cath Lab	The X-ray machine doesn't have a large enough arc span or penetrating ability to handle large patients.	Making the X-ray machine "stronger" (i.e., providing a machine with a higher kV potential) isn't technically difficult. Also need to make the machine larger to accommodate large patients.
Nuclear	1) Large patients won't physically fit in CT or MRI equipment. 2) More tissue to pass through creates artifacts on the images, making accurate diagnosis more difficult.	Making the CT or MRI equipment larger and more powerful is possible (albeit very expensive), but the issue of imaging artifacts is more difficult to address. Perhaps advanced image enhancement algorithms might help.
Echo	More tissue to pass through changes the frequency needed, and impacts the quality of resolution.	New technology might be needed to circumvent or overcome the fundamental frequency/ depth/resolution relationship.

Table 4. Large Patient Issues Summary

New Device Recommendations

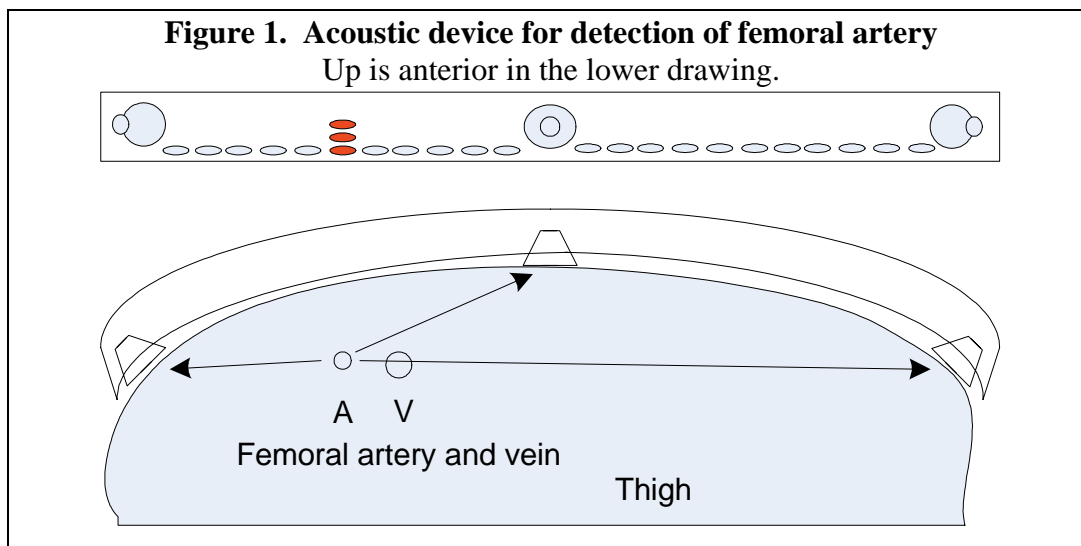
One of the issues identified in the cath lab was the challenge in finding the point of insertion of the catheter. In many patients the femoral artery is easily palpable, but a large patient or one with some extent of heart failure makes this essentially impossible.

¹ More precisely, the percentage change was between the NHAINES III study from 1988-1994, and the latest NHANES data from 1999-2000.

In visualizing this problem, an odd analogy to an acoustics problem came to mind. In acoustics, the noise from a stream of traffic can be predicted (Menge, 1998) as a function of the amount of traffic, distance from the road, and other parameters. Could the same concept be used to determine the position of the femoral artery? Hence the original concept for this device was purely **acoustic**; a later possible version was to take advantage of **ultrasound** technology to visualize the depth of the femoral artery and vein, and show the direction of blood flow. Both of these approaches are discussed in more detail in the following sections.

Acoustic Device

A conceptual sketch of a purely acoustic device to help guide placement of a catheter is shown in Figure 1. It would listen from three microphones (the trapezoidal shapes), triangulate to determine the position and depth of the femoral artery, and show the user that information graphically somehow (the set of red ovals, for example). Triangulation would be based on the signal intensity from each pulse beat, and the relative timing of arrival at the various microphones. The closer a microphone is to the artery, the louder and sooner the pulse will arrive. The output display would have to be calibrated to quantify depth, e.g. 5 mm depth per oval.



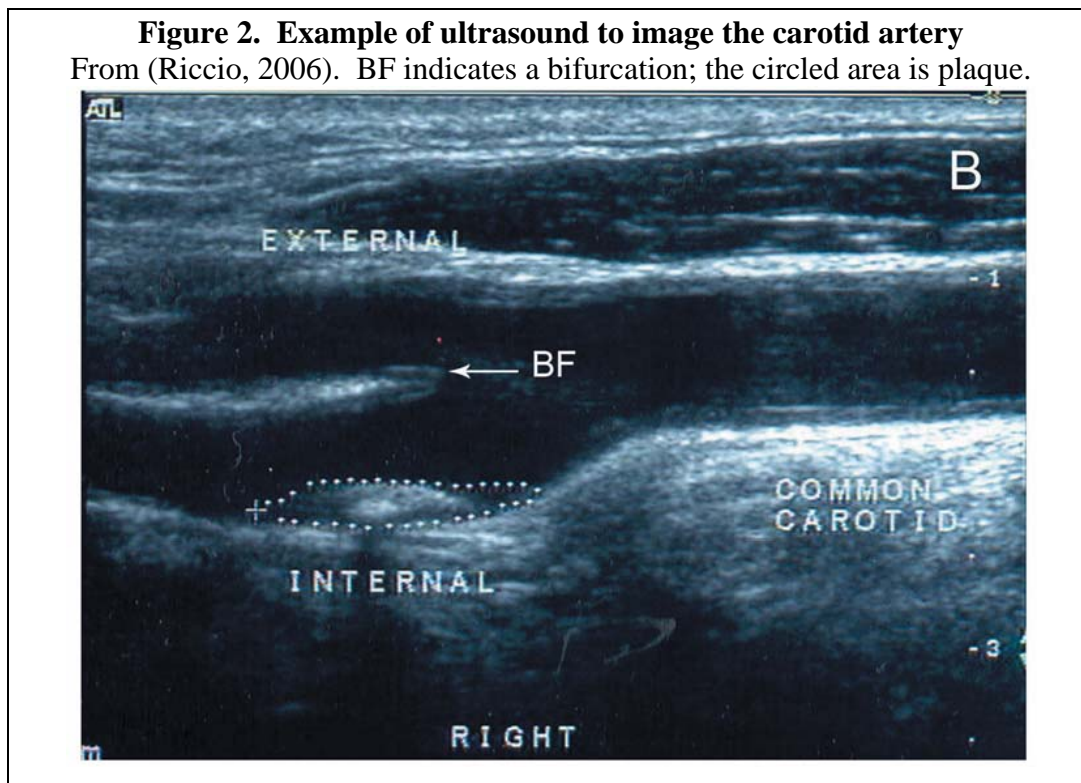
This approach would produce a relatively inexpensive aid, at the expense of providing relatively little information. It would be up to the physician to use the graphic output to guide the catheter sheath to approximately the correct location, and then use other methods to assess exactly where

the artery is located. Femoral vein location would be determined from its typical location lateral from the artery.

A magnetic device for assisting central line placement exists (Bard, 2006a); that's the closest technology to this concept found.

Ultrasonic Device

A second approach would be to use existing ultrasound technology to help find the femoral artery and vein. A similar approach is used for the subclavian vein, jugular vein and carotid artery (Bard, 2006b). An example of ultrasound imaging of the carotid is shown in Figure 2. Special transducers are used to visualize the patient's anatomy, and help guide the sheath needle to the desired vessel. Existing systems are typically limited to 1.5 cm depth for the neck (Central Venous Catheter (CVC)), or 6 cm depth for the subclavian (a Peripherally Inserted Central Catheters (PICCs)). A system for femoral use would probably need greater depth, perhaps 10 cm, and hence would have to use lower frequency.



According to Bard Access, their products for jugular access are also used for finding femoral vessels, but the 6 cm depth limit restricts the size of patients on whom this can work.

To implement this concept for a femoral-specific device, a probe is needed which will:

- Plug into an existing line of ultrasonic products, such as (Bard, 2006b)
- Meet FDA standards for medical devices (FDA, 2006) and international standards for ultrasonic electrical equipment (IEC, 2005)
- Have sufficient depth to see beyond the femoral vessels of a very large patient (500-600 lb.?)

Other Device Needs

A few other ideas emerged during the course, any of which could be followed up on for creating new or improved devices.

- Pressure measurement in the heart is currently done remotely, via a sensor at the end of a long column of fluid. Internal pressure measuring catheters exist, but are very expensive. It would be nice to have a cheaper way to measure pressures inside the heart directly (and hence more accurately). New nanotechnology-based devices might help in this regard.
- During open heart surgery, the normal pathways for EKGs don't exist. Need a way to monitor heart electrical signals, even when the heart is in an atypical position (such as its apex pointing out of the chest).
- The BIS method for measuring the depth of anesthesia is widely used, but not very sound theoretically. Need a better way to quantify how "far under" a patient is during surgery.

Who doesn't need help? The electrophysiology area probably needs the least improvement of technology. Apparently there's enough profit motive to keep that specialty flowing with innovations. Likewise, the vast range of catheters for every size and shape of patient appears to be exhaustive.

Development of robust information systems with well-defined, comprehensive datasets and resources for data collection and validation to support outcomes research in these specialized environments also needs further work. The national specialty organizations, such as the ACC (American College of Cardiology) and STS (Society for Thoracic Surgery), collect a basic dataset from centers able to provide it, but more comprehensive datasets would help. Medical informaticists are especially helpful in this regard (Gianguzzi, 2002).

Conclusions and Recommendations

Observation of five cardiology specialties has produced two major technology needs: 1) improved computer hardware and software, to improve the workflow and efficiency of surgical procedures, and 2) bigger and better tools for dealing with very large patients. To help address one aspect of the latter need, two variations on a device to help find femoral blood vessels for cardiac catheter placement were described.

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