Trends-in-Medicine

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By Lynne Peterson

SUMMARY

Percutaneous heart valves may be the technology of the future, but it's not the near future. Cardiothoracic surgeons are convinced these devices are 5-10 years away. ♦ Edwards Lifesciences appears to have the lead in aortic valves, but 3F Therapeutics could be the dark horse. ♦ Surgeons were surprisingly positive about Acorn's CorCap CDS ventricular restraint device and Viacor's PTMA. ♦ The market for cardiac assist devices simply hasn't taken off, and doctors don't think it will in the near future. ♦ Axial/ continuous flow left ventricular assist devices are taking the lead from pulsatile devices, and Thoratec's HeartMate-II appears to have the lead in this area, though doctors think it is only an incremental improvement, not a technological leap forward.

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CARDIAC SURGERY UPDATE

New technology was a hot topic at the Society of Thoracic Surgeons (STS) meeting in Tampa FL in January 2005. The STS meeting was preceded by a day and a half Tech-Con conference. Surgeons discussed the latest advances in percutaneous heart valves, ventricular restraint systems, ablation for atrial fibrillation, and cardiac assist devices.

Nearly 1,000 surgeons attended the Tech-Con sessions. Half of them were <age 50, and half have been in practice ≤15 years. An audience survey found (*See page 12 for more results*):

- More than half are slightly (38%) to much more (19%) pessimistic about the future of cardiac surgery than they were last year.
- CABG procedures are not down as much as had been predicted (down ~10%-15%, not 20%).
- Surgeons believe in destination therapy with LVADs – but not for themselves.
- Surgery for heart failure is expected to increase.
- Percutaneous aortic valves are 5-10 years away from use.

Among the growth areas and technologies that were highlighted at this meeting were:

- **ACORN'S CorCap**, a ventricular restraint system.
- **ICDs.** A speaker said, "This is a growth area, period, for electrophysiologists (EPs) and for surgeons…ICDs are not a cure, but they do make a difference… CMS has decided to increase the funding for ICDs, and surgeons can make a contribution here – dealing with all the patients who need ICDs is not easy. There is an increasing need for EPs, a shortage of EPs, and few EP training programs. And interoperative placement of ICDs is efficient – and hospital administrators love that."
- **AF ablation.** A speaker said, "Options for AF have exploded in the last few years, based on new technology that allows procedures to be carried out effectively and rapidly."
- **Percutaneous valve repair.** Currently, 63% of valves in the U.S. are replaced surgically, and 37% repaired surgically, but sources agreed that percutaneous valve repair/replacement will eventually replace a significant share of surgical valve procedures. A speaker said, "Patients live longer with repair than replacement." Another speaker said, "Percutaneous strategies are extremely important, and they are creeping over the horizon…Thought they are not yet ready to have a major impact, the impact is coming."

Dr. Bruce Lytle, Chairman of the Department of Thoracic and Cardiovascular Surgery at the Cleveland Clinic and president-elect of the American Association of Thoracic Surgery, urged surgeons to lead the way into new technologies and procedures, not fight them. He said, "My opinion is that we not only have an opportunity but a responsibility to use these new things…The OR (operating room) environment allows multiple imaging modalities, which is the key to these procedures. We can take it to the hilt. Possession of multiple technologies allows better judgment in their use. We complain that cardiologists make all the judgments on stenting vs. CABG, and that is because they use the technology, and they are good at it…Until we have technologies and are good at them, we will not make the decisions…My judgment is that this is the way to go."

Dr. Lytle predicted these new technologies will change: surgeon training, ORs, hospital investments in technology, and the organization of surgeon practices. He said, "We have to support people who go off for six to 12 months to learn new technologies."

A Belgian surgeon, Dr. Hugo Vanermen, also urged cardiothoracic surgeons to become involved in percutaneous valve technology and not just concede the field to interventional cardiologists. He said, "I think cardiac surgeons are entering turbulent times. The message is a serious and maybe dreadful one. The percutaneous approach is a very disruptive strategy, but not enough surgeons are performing the endoscopic approach that produces the same results…A lot of people are saying the aortic valve can't be safely stented, but the interventional cardiology R&D investments are five times that being invested in cardiac surgery. The interventional cardiologists are thriving on piles of dollars. Percutaneous valve therapy will be a $1.4 billion business within a couple of years. Cardiac surgeons need to invest in our future. We need to:

- Build operative suites with 2D imaging where percutaneous procedures can be done in absolute safety.
- Consider less invasive procedures.
- Develop our own percutaneous system and interventional suite to be able to offer off-pump treatment to elderly patients with a lot of comorbidities through a painless port.
- Embrace advances in technology.
- Partner with industry to develop new tools.
- Work with industry to ensure training in new procedures and products.
- Track and benchmark our data.
- Drive reimbursement.

A Texas doctor explained how his cardiac surgeons have approached this issue: "We started with an endovascular program…We found cardiologists willing to partner with us… We went looking for them and found agreeable cardiologists…We found that most will respond very well if you shine a little attention on them and show you want to learn what they do. The first thing is to make up your mind that you are interested in learning something that will be difficult. The first few times you won't be comfortable with guidewires, etc. …but you can do percutaneous valve implantation." Another speaker added, "It is easier for a surgeon to learn endovascular techniques than for an interventional cardiologist to learn surgery."

PERCUTANEOUS VALVES

Can a catheter lab procedure eventually take the place of major heart surgery on diseased valves? Cardiothoracic surgeons are, as would be expected, less enthusiastic about percutaneous valves than interventional cardiologists, but they do see a role for percutaneous valve repair – in the future. Most sources believe it will be at least three to five years, and more likely five years, before a percutaneous valve is approved by the FDA, and they predicted it will be close to 10 years before these valves are commonplace. An expert said, "Even once percutaneous valves are approved, they will be used in tertiary centers for a long, long time. Percutaneous aortic valves will be applicable only to very sick patients for a long time…But several valves are ready for clinical trials." Another expert said, "My bet is that the percutaneous valve that gets approved – and used – will not be any of the current approaches…I think the first viable clinical approach will be replacement of a homograft valve…Animal models are not good, and that is one reason why aortic valves are not approvable in the next couple of years."

Every surgeon at the meeting was aware of the patient who died in conjunction with a live percutaneous valve repair case with an Edwards Lifesciences's aortic valve on the first day of the 2004 TCT meeting. If a noted interventional cardiologist such as Dr. Antonio Colombo has outcomes like that, percutaneous valves are far from ready for prime time, surgeons insisted. They dismissed a suggestion by an Edwards official that the problem was not the valve but the cardiologist. However, sources also did not believe the TCT death is a major setback for percutaneous valves. An Ohio surgeon said, "No one expected this (percutaneous valves) to be a walk in the park."

Randomized clinical trials are needed, and some of the problems include trial endpoint definitions, duration of follow-up, agreement on clinical indications, control group, and device durability. Even Dr. Marty Leon of Columbia University – one of the interventionalists helping to push these procedures – admitted at TCT, "When we talk about a clinical trial paradigm, we're looking at five to 10 years before we can get in a commercial paradigm." Interventional cardiologist Dr. Donald Baim of Harvard Medical School/Brigham & Women's Hospital described percutaneous valves as a compelling interventional opportunity, saying, "There are at least 150,000-200,000 patients who are either too sick for

AVR (aortic valve replacement) or not sick enough for MV (mitral valve) repair. We could enhance their quality of life substantially if we could offer safe and effective percutaneous aortic valve replacement or MV repair (annuloplasty and/or edge-to-edge)."

Cardiologists, surgeons, and the FDA met last year and agreed on guidelines for percutaneous valve trials. Those guidelines will be released in April 2005. Surgeons believe these guidelines are "putting the brakes on" percutaneous valves. Reportedly the guidelines will require:

- 30-day safety endpoints, which are MACE+device failure.
- One-year ***and*** two-year follow-up for efficacy.
- Randomized trials are required. The comparator could be medical therapy only if the patient couldn't go to surgery – by a surgeon's decision.

Several sources said they believe the FDA has gotten tougher on devices recently. "The FDA and other regulatory bodies are under intense pressure by industry," a speaker said, adding, "IRBs are inundated with applications. But with the Vioxx (Merck, rofecoxib), abdominal aortic endograft, and Cypher (Johnson & Johnson, sirolimus-eluting stent) debacles – and fiscal considerations – regulatory agencies are not moving quickly. And percutaneous carotid coverage is still being debated by CMS." Another expert said, "I think before the meeting last year, industry thought percutaneous valves would be like stents, but the FDA tone is different. There has been a shift in surgical influence…And enrollment in trials will take longer than for stents…The first percutaneous aortic valve approval is more than three and perhaps five years away …Mitral valves will be even tougher."

The audience at a Tech-Con session offered a prediction as to which valves are most likely to be successful percutaneously:

Valves Most Likely to be Successful by Percutaneous Techniques

Aortic	Mitral	Pulmonary	All	None
15%	10%	55%	16%	5%

Edwards appeared to have the lead with its percutaneous aortic valve, but the company's timeline for FDA approval recently was revised, and 3F Therapeutics and Medtronic's pulmonary valve are close behind. Edwards is now predicting PMA approval in 2008 or 2009. Edwards also dropped plans to seek a humanitarian device exemption (HDE) in 2005. Several sources predicted that Viacor's rod system could get FDA approval sooner than Edwards aortic valve.

European approval of percutaneous valves may not be much quicker than U.S. approval. A U.K. doctor said, "Right now, it is American companies, not European companies, so the U.S. is the focus."

If a percutaneous valve is approved sooner, it may not find widespread use. The situation could be like what happened with LVADs – slow to take-off as doctors wait for better technology.

There are four key areas of valve repair/replacement being investigated percutaneously.

1. Pulmonary valves

About 3,000 pulmonary valves are replaced each year in the U.S. The market could be three or four times that number with valve modifications, an expert predicted.

Medtronic is working a so-far unnamed percutaneous version of its Contegra valve, and it appears to have the lead in the pulmonary valve area. The valve, which was developed by Dr. Philip Bonhoeffer in the U.K., consists of a bovine jugular venous valve mounted on a platinum iridium stent (Numed). It can be collapsed on a balloon and inserted.

Dr. Bonhoeffer said, "No percutaneous valve is ready for prime time…Pulmonary valves are an easier site than aortic valves, so this is an important first-step into percutaneous treatment." He has done 10 patients in Paris, seven in London, and 50 under a revised protocol in London, for a total of 67 patients to date. In the beginning, there was a significant problem with a hammock effect, occurring in 7 of 17 patients, but he believes that issue has been solved. There was no mortality. Delivery time improved from 120 to 80 minutes. Complications in the last 50 patients included:

- Procedural homograft rupture, which he attributed to operator error.
- 2 device dislodgments, and he noted that "imaging is the clue here."
- 3 patients (8.3%) had to be explanted by one year: 1 for a stent fracture, 1 hemolysis in the context of residual stenosis, and 1 stenosis in the small Hancock tube.
- 2 cases of endocarditis.
- 3 stent fractures: 1 treated with a second device, and 2 that are being watched.

Dr. Bonhoeffer hopes that U.S. implantations will be able to start in late 2005. He said, "This modified stent approach is safe, we know the (pulmonary) anatomy exactly, and there is very little anatomic variation (from patient to patient). Patients have already gone through an operation, and re-operations are more difficult, so surgeon acceptance will be much higher. I have the firm belief that this is the safest approach to a complex problem…The technique is not difficult."

What is the trial design for pulmonary valves likely to be? Dr. Bonhoeffer said, "We might not need long-term follow-up if we compare it to prolongation of conduit. My patients have had a median of three previous operations, and I'm very reluctant to go into the chest a fourth time, so we might offer this approach sooner with those patients. Dying patients also

might be in favor of a make or break procedure, but we, as doctors, can't take that approach."

2. Aortic valves

An industry source said the market for these devices is small and far away, "If percutaneous aortic valves were approved today, only 4% of patients would get them. Aortic valves are 10 years away." A Texas surgeon commented, "The majority of patients with aortic stenosis never get to see a cardio-thoracic surgeon. At Loma Linda University researchers identified 740 patients with severe aortic stenosis between 1993-2003. Only 283 patients received AVR (38%); 62% were treated medically. The reasons given were: AVR was not offered or performed, lack of symptoms, or not good surgical candidates. Survival with medical management was 60% at one year, 32% at five years, and 18% at 10 years."

➢ **EDWARDS' Cribier-Edwards Aortic Percutaneous Heart Valve (PHV).** This is a proprietary balloon-expandable stent technology integrated with a percutaneously delivered equine pericardium tissue heart valve that Edwards got with the purchase in 2004 of Percutaneous Valve Technologies (PVT). Dr. Alain Cribier of the University of Rouen, France, who developed this valve, performed the first clinical percutaneous aortic valve replacement with good results.

The Edwards device involves crimping a balloon on a stainless stent, and then inserting it into the aortic valve up to the heart. The crimped device is expanded in the aortic valve. The device is held in place by an absorbable suture that, as it dissolves, cinches slowly down. This was described as a technically difficult procedure, and placement needs to be extremely precise. If the balloon is inflated too low or too high in the aorta, there will be problems. Another concern is that if the stent is not fully apposed to the wall of the aorta, the calcium deposits can be a problem if they are not uniform.

Dr. Cribier used the valve in 24 patients in the RECAST trial, which started in December 2004. Those patients had a mean age of 82, and all were NYHA Class IV – all with end-stage disease and life-threatening comorbidities. There were some paravalvular leaks post-op, and Dr. Cribier said this will be solved with larger stents – up to 26 mm for males.

Preliminary results on 20 patients in the I-REVIVE trial found:

- One death before implantation.
- 1 VF during pre-balloon aortic valvuloplasty (BAV).
- 3 technical failures.
- 1 death after implantation.
- 12 patients were discharged from the cath lab – one of which had a stroke, and one had a tamponade.
- At 3 months, 7 were alive, and at 6 months, 4 were alive.

Dr. Cribier concluded, "Percutaneous aortic valve implantation might become – in the near future – a very realistic way of treating a selected population." However, another expert warned, "The Cribier valve won't happen. I'm very dubious." In Europe, compassionate cases are being done, and three patients have reached the 12-month mark. Edwards officials said they have received approval for the first of multiple centers in a non-randomized, revised study that will allow the company to start enrolling high-risk patients. The first patients are expected to be enrolled by the end of 2Q05 and lead to a CE Mark in 2006.

The day after the STS meeting, Edwards announced that the FDA granted "conditional" approval of its IDE and will allow a single-center, randomized feasibility trial of 20 patients to begin, probably before the end of 1Q05. The trial will compare 10 patients getting percutaneous valves with 10 patients getting balloon aortic valvuloplasty. Once that trial is completed, the company will be allowed to start a second phase study with another 40 patients at two centers. This is fewer sites than had been expected; an expert had indicated that two trials would start with four sites and be expanded to 10 sites, so it appears the FDA is being very careful with these trials.

After both these trials (all 60 patients) are completed, Edwards will be allowed to start the one-year, randomized, multicenter, pivotal REVIVAL trial of <400 high risk patients who are not surgical candidates (on a scoring system on which both Edwards and the FDA reportedly both agreed), using a 1:1 randomization. The primary endpoint will be a composite score that includes mortality. Again, sources predicted that enrollment "will not be as quick as in stent trials."

An Edwards official said investigators have performed the first procedure using a retrograde delivery system. He said the company has approval to use both antegrade and retrograde approaches in the U.S. studies.

➢ **COREVALVE'S Percutaneous ReValving System.** CoreValve's self-expanding stented aortic heart valve was implanted successfully in two humans in India in 2004. A balloon is not needed, reducing the risk of balloon-related leaflet trauma, and the valve works on the stent's spring force. The self-expanding stent reduces the risk of paravalvular leaks. CoreValve is still in early stage development and is not yet in clinical trials.

➢ **3F THERAPEUTICS' Entrata.** This device, which takes a very different approach from other aortic valves, uses a valve that is already approved in Europe. It is inserted into the apex of the heart, not through the femoral artery. Thus, unlike femoral access devices (where the size must be ≤25 mm), there is no limit to the size of the Entrata valve. The company believes these valves will not leak the way other percutaneous valves have.

All the animal work is complete, and the first humans will be implanted in Europe in the next three months. The company plans a full PMA in the U.S. and expects to do a 400-patient trial vs. surgery. A Phase I U.S. trial is expected to start by the end of 2005, with 25 patients at four centers enrolled, and then a pivotal trial will be conducted. An official said the company expects it will take about three years for U.S. approval. 3F has plans for aortic, mitral, and tricuspid valves, but it is taking a stepped approach to the market. New data reportedly will be presented at the Society for Heart Valve Disease in Vancouver, Canada, in June 2005, and at the European Association of Cardio-Thoracic Surgery (EACTS) meeting in October 2005 in Barcelona.

The challenges are:

- **Placement** – understanding where to place it with an indirect (not open) view. 3F is working on an IVUS link for the future.
- **Calcification.** An official said understanding how calcified the aortic root is that is being treated is important, "We think treating heavily calcified aortas will be difficult."

Edwards (through PVT) has a very strong patent position in percutaneous valves with the so-called Anderson patent, which has >10 years of protection left. The Anderson patent covers all valve implants on both sides of the heart. However, according to a 3F official, 3F has a contractual agreement with PVT (and thus Edwards) that gives 3F the exclusive right to develop delivery systems ≤80 cm from the heart. This appears to mean that even Edwards can't develop a delivery system to compete with 3F. All this suggests that 3F is a likely acquisition target, and speculation is that Medtronic or St. Jude are potential buyers.

3F also has proven manufacturing capability; it currently manufacturers Edwards valves.

➢ **Paniagua aortic valve.** This is a retrograde implant using a specially-treated pericardium, which allows thin leaflets and simpler retrograde insertions, which are technically less challenging. A catheter transports the replacement valve to the heart, where it expands once it is in place. The valve is between 3 mm and 4 mm in size while in the catheter and can expand to 25 mm. The first human implant was in 2002 in Venezuela.

➢ **Endoluminal aortic stents.** Placement of a lower profile stent-graft through an endoluminal approach is being investigated.

➢ **CORAZON Aortic Valve Demineralization System.** Corazon's technology is a stopped-heart system designed to get rid of calcium by using flushing, dissolution, agitation, and aspiration to dissolve calcium using a proprietary low PH saline demineralization solution. It has been shown to significantly dissolve calcium. The first human experience was presented at TCT 2004. The FDA gave Corazon an IDE for the device in the U.S., and initial human clinical trials showed that patients treated with the system improved aortic valve function with structural preservation.

➢ **TAAP.** A Texas surgeon said, "Percutaneous access to aortic valves is technically challenging and limited by the size of the delivery system…We wanted to avoid the limitations of percutaneous valves and came up with the trans-apical aortic valve implantation (TAAP procedure)…There was valve migration in six (swine) cases (3 distantly, 2 secondary to not unloading the heart, and 1 due to incomplete valve expansion) …We concluded that the apical approach is a reliable method and fluoroscopy provides excellent guidance, but swine are a poor model for aortic stenosis."

Among the challenges remaining for this procedure are:

- Identifying the appropriate population for feasibility studies.
- Defining the characteristic pattern of calcification amenable to – or a contraindication for – this procedure.
- Refining and streamlining the implantation technique.
- Achieving valve performance approximating standard therapy.
- Developing a commercial product.

3. Mitral valves

The mitral valve is a one-way valve between the left atrium and left ventricle. As the left ventricle contracts, the mitral valve closes to prevent blood from flowing backwards into the left atrium. Damage can cause the valve to leak, resulting in mitral regurgitation, or to not open fully, resulting in mitral stenosis. Degenerative aortic stenosis, the narrowing of the aortic valve, is the most frequent valvular dysfunction in adults, and surgical valve replacement is the treatment of choice. Dr. Cribier said, "When thoracic surgery is considered too high a risk or contraindicated, balloon aortic valvuloplasty can be used to palliate the symptoms, but it is associated with a high recurrence rate."

Surgical repair or replacement with open, arrested-heart surgery is used for most patients with advanced mitral valve disease, but percutaneous MV repair may be appropriate for patients in which the disease isn't advanced enough. It would be especially beneficial to patients with congestive heart failure (CHF).

The two methods commonly used are:

➢ **Percutaneous heart valves (PHVs).** The appeal of percutaneous heart valve technology is that it can be performed in cath labs using local anesthesia. There are two main approaches to percutaneous valve repair: (1) Direct valve access through a catheter – transventricular or transatrial, and (2) Coronary sinus (CS) access via a catheter, after which devices are used to cinch or reshape the misshapen

valve. Dr. Lytle said, "I think this (coronary sinus approach) will be much harder than people think."

➢ **Balloon aortic valvuloplasty (BAV).** BAV is simple, involving an inflated balloon.

Comparison of Edge-to-Edge and Coronary Sinus Approaches to Mitral Valve Repair

Edge-to-Edge Repair Disadvantages	CS Approach Disadvantages
Large device with transeptal approach	Not truly coplanar with annulus
Complex procedure	Can pinch the LC artery
Valve morph and etiology may influence results	Congested intellectual property space
Unknowns include import of concomitant annuloplasty, durability of repair, and leaflet stress	Unknowns include risks of erosion, long-term benefit of partial circumference ring, and perforation, thrombosis

With PHVs, a stent is implanted so the diseased valve can be kept open without affecting the arteries or the mitral valve. Dr. Cribier said, "We are working on technical refinements of this technique – improvements in delivery systems and, depending on the long term results obtained in the upcoming series of less severely ill patients, I think that percutaneous aortic valve implantation should become, in the near future, a very realistic way of tweaking a selective population of patients with degenerative aortic stenosis."

Options for guidewire delivery of percutaneous aortic valves include the transeptal and retrograde approaches. At TCT, Dr. Cribier said that he will be conducting a feasibility study to determine the best approach for the procedure.

Among the companies with percutaneous mitral valves and devices in development are:

• **CARDIAC DIMENSIONS.** With this early-stage percutaneous approach to annuloplasty, a device is inserted into the coronary sinus to reduce the size of the dilated mitral annulus. Feasibility studies have shown that it can eliminate severe mitral regurgitation reproducibly without adversely affecting cardiac physiology.

• **EDWARDS LIFESCIENCES/JOMED.** Edwards' acquisition of Jomed allows it to develop the coronary sinus (CS) approach. Jomed's device is a complete set including delivery, foreshortening mechanism, and implantable device. Edwards has received regulatory approval in Canada and Sweden to begin a feasibility study of its CS mitral repair procedure, and the first patient has already been treated.

An Edwards official also said the company has completed the preclinical feasibility studies of another mitral valve system. He said this system has demonstrated repeatable procedural and repair performance, procedure times are <60 minutes, and the results mimic the surgical Alfieri repair. First-in-man studies of 10-20 patients are expected to begin in March-April 2005 outside the U.S. An Ohio surgeon commented, "This Alfieri-approach doesn't work in all patients. It scars the flaps, and if it fails, you have to replace the valve. It is surgically easy, but not reproducibly perfect with all doctors."

• **EDWARDS/VIKING Coronary Sinus Approach.** Edwards is working on a competing technique to Evalve, which is percutaneous edge-to-edge suture repair. It uses suction to pull the leaflet into the device, where it can be sutured. Then the device can be turned to grab the other leaflet and the suture can be extended into the tip, tied, and released. It has a similar effect as a surgically placed annuloplasty ring. The patient can go home the same day. This device is now in animal trials and may enter clinical trials in the next six to 12 months. This procedure is considered technically more complex than other procedures, and it is not know whether it works without concomitant annuloplasty.

• **EVALVE'S Cardiovascular Repair System.** This percutaneous MV edge-to-edge repair method uses a tiny metallic clip coated with polyester fabric that can be attached to a telescoping catheter. It imitates the edge-to-edge open surgical technique. Under full anesthesia, a catheter is placed through the skin and guided through the femoral vein to the heart. A smaller delivery catheter guides the clip into place; the clip is opened to grasp the leaflets, and the clip can then be closed and released to create a repair. The hospital stay is usually about two nights, and most patients return to normal activity within one week.

Sources generally were critical of this valve, describing it as "Alfieri-like" and warning that valves tend to become scarred with Alfieri procedures, making revision difficult.

The results of the Phase I safety trial EVEREST-1 were presented at TCT 2004 and showed the clip was successfully deployed in 24 out of 27 patients. Three patients weren't able to benefit from the clip, and it wasn't deployed in them. Adverse events at 30 days, according to the principle investigator, were "what we would expect to see and compare favorably to those observed with traditional mitral valve surgery." The initial procedures took about 2-4 hours in the cath lab. An investigator commented, "Successful placement of the clip with the creation of a double orifice was successful in 24 out of 27 patients. The clip was deployed with resultant MR ≤2+ at discharge in 67% of patients, but notably only 50% of the first 10 procedures, and 76% in the last 17 procedures. The protocol was amended after the first 10 procedures to allow a second clip, and that was used in four patients. One device malfunctioned resulting in removal of the device, and the patient went on to elective repair the next day. NYHA Class improved substantially, with 69% of patients improving from Class III to Class I, and 28% stable.

- **EV3/MITRALIFE.** This is an annular ring implant that is crimped and detached allowing percutaneous mitral annular reshaping (PMAR). The annular ring is placed transvenously into the CS. It allows easy access and is fast to use, but variations in anatomy make the CS location not always close to the mitral valve annular plane. Also, pre-operative or mid-term CS rupture and thrombosis are concerns. Animal work is being done with this device.

- **MITRALIGN.** This suture-based device performs percutaneous mitral annuloplasty using magnetic guidance. A magnetic catheter is guided to the mitral valve. Once it is positioned in the left ventricle via standard retrograde approach, the doctor performs suture-based annuloplasty. This method can be reversed and doesn't leave anything behind. The company is a start-up company and the method has only been done in animals. A speaker commented, "The animal video was very impressive. In early patients, some patients were made ischemic, and the device had to be released."

- **MYOCOR SURGICAL'S Coapsys System.** This is a robotic surgical approach to MR by going through the wall of the heart. A Teflon cord is inserted through the heart and tightened to close the valve's cap. The device then stays anchored on both sides of the heart. It is in a Phase I surgical study in the U.S., expected to be completed in 2005, and it has demonstrated improvement of mitral regurgitation after 12 months. The device has been implanted in about 25 patients in Europe and Asia.

- **ST. JUDE.** Reportedly, St. Jude is working on a percutaneous system, but it is in very, very early stages, and no information was available on it. A St. Jude official said, "We are working on a percutaneous valve, but we don't have a specific project yet. Just don't count us out."

- **3F Therapeutics.** As with aortic valves, this is an apical approach. An official said the company needs to develop a stent for this, but plans to do so.

- **QUANTUMCOR'S Q-Care.** Products in development include computer-controlled single-use catheters for MV access.

- **VIACOR'S Percutaneous Transvenous Mitral Annuloplasty (PTMA).** This device, using telescoping bars, is expected to enter clinical trials in the next few months. A catheter is threaded into the coronary sinus, and three thin but stiff alloy rods are advanced down the catheter. The rod then pushes the posterior portion of the mitral valve anteriorly and straightens the coronary sinus. The procedure is done under echocardiography. The catheter and the three nitinol rods are left in the patient, and they can be accessed in the future if adjustments are necessary.

Several sources suggested this device may get to market ahead of any of the percutaneous valves, and surgeons were relatively positive about the outlook for this device. An expert said, "Technically, this is so easy. That is not the hurdle. We are in negotiations with the FDA, and we hope to start a pivotal trial this year." He couldn't say how long the follow-up is likely to be.

This device was placed in six patients at the Cleveland Clinic, and researchers found the stiffer and longer the rod, the more effect on mitral regurgitation. A speaker said, "It is very easy to use…It was kind of scary. There is a lot of violence involved with the rod going into place. Total procedure time was <1 hour…Once the rods are placed in the best position, we leave the whole catheter in the patient, like a pacemaker. So, if there is not a robust repair (of the valve), we can take the catheter out, remove the cap, and replace the implants (rods) with others that are longer or stiffer." The device was initially a single rod, but it was designed to consist of three nitinol-shaped rods.

One of the concerns with this device is remodeling, and another has been thrombosis. A researcher said, "Thrombosis has not been a problem in animals. Every now and then we have changed French (size) or Dacron and had problems with thrombosis, but not with the current design." Over the next year Viacor plans to start a pivotal human trial, using "people who are not good candidates for surgery." Another expert said, "I suspect the rods will stretch the coronary sinus over time. Maybe this is just a temporary fix." A third expert said, "The question is whether reducing mitral regurgitation is clinically significant."

4. Tricuspid valves. These include self-expending nitinol valves like IVC (inferior vena cava) and SVC (superior vena cava). Among the companies with tricuspid valves in development are Edwards/PVT and 3F.

THE FDA PERSPECTIVE:
Percutaneous Valve Replacement/Repair Devices

About a year ago, the FDA met with officials of the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, the American College of Cardiology, the American Heart Association, and the Society of Cardiovascular Angiography and Interventions to develop an interdisciplinary position statement on the clinical development of percutaneous heart valve technology. That report is expected to be published in April 2005. A participant said the FDA plans to adopt this position statement as its guidelines for percutaneous valve trials. He said the consensus document will call for randomized clinical trials as the most reliable evidence of effectiveness.

Speaking at TCT 2004, Dr. Julie Swain, a cardiothoracic surgeon and FDA consultant, said that a new paradigm is

needed for testing percutaneous valve technologies. She said, "A trial design will likely have to balance less efficacy with safety. A randomized controlled study will be required. The two questions in the trial should be, 'Can you do a percutaneous valve procedure, and should you do it?'"

Among the issues in designing a percutaneous valve trial are:

Patient selection

- **Is a patient a candidate for surgery?** She said if the answer is yes, then surgery is the control group. If the answer is no, then a study is needed to show that an intervention is beneficial versus medical therapy. This might require a five to 10 year study.
- **How is operable defined?** Dr. Swain said it is possible to test inoperable patients, but is inoperable the same as high risk or unacceptable risk? How high is the risk and how is that calculated?
- **Who is the control group?**

Endpoints

A clinical hypothesis might be that percutaneous intervention doesn't relieve stenosis regurgitation but the safety is better. Dr. Swain said, "For effectiveness, a classic non-inferiority trial with a large delta isn't appropriate. Say you do an equivalence trial with the hypothesis that the device you're studying is a certain percentage worse than the open approach, but it's safer. Not p=.05 safer, but some amount safer. That might be a way to test the hypothesis. Then, you need to think about the primary efficacy endpoints. We think that regurgitation should be reduced to 0 or 1+ at one year without stenosis – relief of stenosis without more than 1+ regurgitation."

- **Safety endpoints.** She said, "Possible primary safety endpoints include composite of death, cardiac tamponade, cardiac surgery for a failed procedure, device failure, stroke/neurological deficit, sternal wound reoperation, need for vascular repair, and dialysis. We want a level playing field on the really important safety endpoints…Neurological adverse events – stroke and TIA – should be defined as follows: Stroke is a neurological deficit lasting >24 hours or lasting <24 hours with a brain imaging study showing infarction. TIA is a neurological deficit lasting <24 hours and, if an imaging study is performed, shows no evidence of infarction."

- **Efficacy endpoints.** She said, "Other effectiveness endpoints include LV functions, EF, NYHA class, exercise testing (i.e., six minute walk, $MV0_2$), ventricular dimensions/wall thickness, and technical and procedure success.

Length of trial

Dr. Swain said, "We need to know the durability of the repair, so it will be in the 1-2 year range. A year endpoint with a 5-10 year follow-up is suggested. You should submit feasibility data when all patients have been followed six months, and submit the pivotal data when all patients have been followed one year, and follow all feasibility and pivotal patients yearly for years 5-10…A more expensive and longer study might get you to the goal line quicker. Try to use the same protocol in the U.S. and non-U.S. studies. Use core labs, have an active DSMB, and work early with the FDA."

CARDIAC ASSIST DEVICES

Sales of these devices were expected to take off when bridge-to-transplant was approved, but they didn't. Then, sales were expected to take off when destination therapy was approved, but they didn't. Reimbursement, it was argued, was the barrier, but when CMS upped reimbursement, sales still remained sluggish. Devices are getting better, surgeons said, but they "just aren't there yet," and referrals from cardiologists and primary care doctors are not picking up. Reimbursement isn't great, but it really isn't the problem, they said.

Thus, sources do not expect use of LVADs for either bridge-to-transplant or destination therapy to pick up significantly over the next year or two. Among the comments doctors offered were:

- "The final answer is not in yet, and economic issues also need to be worked out…In most cases, LVADs are the final treatment available – the last resort. They are still not being used early enough."
- "Destination therapy is not there yet. In some centers, transplantation has gotten easier, with waiting lists smaller. For us, for example, the waiting list has dropped from 125 to 25. And there is a high complication rate with destination therapy, limited durability, and patients reject it. If smaller pumps were approved for destination therapy, that might change the market. It would be more like putting in an ICD."
- "The technology is not there for long-term survival. All the devices today are prone to clots and strokes."
- "Destination therapy is limited to transplant centers, and we don't like to refer patients for destination therapy because we can't support them. We can't develop local support systems because we can't put them in."

Total heart replacements. An expert said, "Total artificial hearts as continuous flow devices are being reconsidered after HeartMate-II. We should be able to pursue a totally artificial heart now."

The leading devices are:

- **ABIOMED'S AbioCor.** A speaker said, "They did their first series of patients, and soon they hopefully will embark on a more propitious patient group – those who can cautiously survive the procedure."

- **ARROW'S LionHeart.** An expert commented, "Power was never a real problem, but the compliance chamber was. They vented it once or twice a week, and that works pretty well."
- **SYNCARDIA SYSTEM'S CardioWest Total Artificial Heart (TAH).** This is a pneumatic, biventricular, implantable bridge-to-transplant system for full cardiac replacement. It was formerly known as the Jarvik 7.

Pulsatile Devices

There is likely to be a role for pulsatile devices, but pulsatile devices are taking second-seat to continuous/axial flow devices, largely because of their size. An expert commented, "Pulsatile is way too big."

The leading pulsatile devices include:

- **ABIOMED**
  - **BVS.** About 600 of these devices are installed in the U.S., but only about 100 are "very active." A Florida surgeon said, "This is a more short-term device to improve heart function while a patient is getting over surgery. It is not comparable to an LVAD." A New York doctor said, "This is a very reliable device."
  - **AB5000.** An Abiomed source said about half of the sales so far (~50) have been switches from BVS, and the other half are centers getting an AB5000 in addition to a BVS. Another expert said, "This is a beautifully engineered, pulsatile pump. It can be lifesaving, but it is big and hard to get in. I think it has promise to allow patients to be discharged, but there is a lot of hardware with this. Probably people will switch to this when the bugs are out."

Comparison of Abiomed's BVS and AB5000

	BVS	AB5000
Field	Passive	Active
Chambers	2	1
Pump	Semi-ambulatory	Smaller pump
Applicable patients	Same	
Length of support	5-7 days	15-20 days (longest 95 days)
Console	Same console can run both	
Cost	~$18,000	~$45,000

- **WORLDHEART'S Novacor I and II.** A speaker said, "This is a reliable long-term device. It had some problems with strokes because of the inflow cannula, but that has been redesigned. I think this will be a favorable pump."
- **THORATEC'S HeartMate.** This device is FDA-approved for both destination therapy and bridge-to-transplant. The main problem appears to be size. A speaker said, "HeartMate has been very successful as far as thrombo-embolic problems are concerned. The pump works very well, and it is very safe if properly implanted. More than 5,000 have been implanted to date, with >75% survival rate. More than 20% of transplant patients get one of these…Infection has come down a bit, but it is still a big problem." Other issues include elbow angle, torn cusp, and fusion of the aortic valve, which occurs if it is not allowed to open periodically.

Continuous Flow Devices

There are more than 22 continuous/axial flow devices in development.

Continuous Flow Devices in Development

Company	Device	Type of Bearing
Arrow	CorAide	Centrifugal – blood-fed journal bearing
Berlin Heart	Incor	Axial – magnetic bearings
Jarvik	Jarvik 2000	Axial – blood immersed bearings
Micromed	DeBakey	Axial – blood immersed bearings
Terumo	DuraHeart	Centrifugal – magnetic levitated
Thoratec	HeartMate-II	Axial – blood immersed bearings
Ventracor	VentrAssist	Centrifugal – hydrostatic levitated impeller

- **THORATEC'S HeartMate-II.** Thoratec completed its Phase I study of HeartMate-II in August 2004. This included 25 bridge-to-transplant patients at 10 centers, and no serious device-related adverse events or mechanical failures were reported. Another 14 patients have received the HeartMate-II in Europe or in the U.S. through compassionate use.

Thoratec has applied to the FDA for an IDE for a pivotal Phase II trial of HeartMate-II. Recently, the company said discussions with the FDA over the trial's design are continuing, but it expects approval by March 2005. Sources predicted it will be years before HeartMate-II gets FDA approval. An investigator said the protocol has been circulated to centers, but it is not FDA approved – and it may not be for a month or longer; the FDA appears in no hurry. The trial reportedly will enroll 200 patients (vs. 300 for the DeBakey and Novacor trials). This means the three companies are seeking a total of 800 trial patients. An expert pointed out that the HeartMate-I REMATCH-1 trial screened 1,000 patients to find 128 candidates, and there have only been 300 destination therapy devices implanted since CMS approval. One trial advantage that HeartMate-II has is that Thoratec can use its own HeartMate-I data as a control, while the other companies have to use an LVAD competitor (head-to-head) control. An expert said, "This is tough since the rule has been that you can't participate in trials of two different companies." Another expert commented, "The FDA is running these trials like drug trials." Another expert said, "HeartMate-II is the only one with a chance of approval because it can compare to

HeartMate-I. Novacor can't use the HeartMate data to get around a randomized clinical trial."

HeartMate-II was described as better than HeartMate-I or Novacor because it is smaller, but there was no real excitement over HeartMate-II. Sources agreed that HeartMate-II is ***not*** going to suddenly create enthusiasm for LVADs. An expert described it as "not an advance per se – just another axial flow pump – but promising. The clotting issue appears to have been resolved." A Texas surgeon said, "HeartMate-II is a big hemopump that is implantable outside the ventricle. It doesn't unload the ventricle, unlike the Jarvik." An Illinois surgeon said, "HeartMate-II is an incremental improvement, not a 'wow!' improvement." Another Midwest surgeon said, "HeartMate-II is an advance. It had a false start out of the gate, but the more recent results have been better."

Several doctors said they have heard that some surgeons have dropped out of a trial of Micromed's DeBakey device in order to participate in the HeartMate-II trial. A source said, "Micromed only enrolled six of the required 300 patients in a year."

➢ **JARVIK'S Jarvik 2000.** Dr. O.H. ("Bud") Frazier of the Texas Heart Institute said, "You can put it in, so it can move with the ventricle, which is some advantage. There have been no infections of any consequence. The reliability of it has been remarkable – no failures, which were of some concern with HeartMate-I. Early on, there were a lot of deaths because they were implanting it in the same patient groups as HeartMate-I, but it is smaller, and it doesn't work as well in those patients. It is a true assist device…I wouldn't hesitate to recommend this for community hospital use. It is very amenable to a community implant…We are using this routinely in re-do patients. Generally, patients have an easy recovery and normal cardiac output is restored." Another source said, "A bilateral Jarvik heart may obviate the need for an artificial heart."

➢ **TERUMO'S DuraHeart.** An expert warned that this is the device to watch.

PERCUTANEOUS VENTRICULAR ASSIST DEVICES (PVADS)

IMPELLA CARDIOSYSTEM'S Recover LD/LP

This small ventricular unloading catheter, which is placed percutaneously through the femoral artery, is very interesting technology. The device is not implantable; it is external and can provide immediate support and restore hemodynamic stability for up to five days with the small version and about seven days with the larger version as a bridge to give doctors time to develop a definitive treatment strategy. It was developed to address the acute need for ventricular support in patients suffering from cardiogenic shock who have failed standard treatments including pharmacologic therapy. It is inexpensive compared to an LVAD, it is put in with a 13F sheath and a 9F catheter, and the artery is sealed with Abbott's Perclose.

Recover received a CE Mark in 2004, and the company launched it in Europe in September 2004. Several renowned interventional cardiologists are currently running their own small trials of the device to test it themselves. A 50-patient U.S. trial is expected to start shortly. The principal investigator will be Dr. William O'Neill of William Beaumont Hospital. This feasibility trial is expected to run just 30 days, and then a pivotal trial will begin.

CARDIACASSIST'S TandemHeart

This device can be inserted either by cardiac surgeons in the operating room or by cardiologists in the cath lab. It has been used in postcardiotomy cardiogenic shock patients and as a bridge-to-transplant or recovery. This continuous flow, external device provides short-term support from a few hours up to 14 days. Currently, it is in use in centers in the U.S. Cannulas are inserted percutaneously through the femoral vein and advanced across the intraatrial septum into the left atrium. The pump withdraws oxygenated blood from the left atrium, propels it by a magnetically driven, six-bladed impeller through the outflow port, and returns it to one or both femoral arteries via arterial cannulas. The pump weighs 8 ounces and is capable of delivering blood flow up to 3.5 liters per minute.

VENTRICULAR RESTRAINT DEVICES

A variety of devices are in development to help treat congestive heart failure (CHF). These include:

MYOCOR'S Myosplint. In human trials in Europe, researchers found that placing the device was safe, but apparently the company is not proceeding with this device, focusing instead on treating the mitral regurgitation aspect of heart failure.

PARACOR SURGICAL. This nitinol device is placed around the heart to provide precise compliance and reduce wall stress without precluding ventricular constriction. It was described as self-anchoring, self-tensioning, reproducible in every patient with every surgeon, and delivered minimally invasively off-pump.

ACORN'S CorCap CDS. CorCap is a proprietary mesh wrap (a multi-filament yarn/knit fabric) that is implanted around the heart to provide support and relieve the wall stress of increased heart size associated LV hypertrophy. It reshapes the heart to an ellipsoid shape. In its pivotal trial, CorCap improved quality of life and slowed worsening of heart failure, but it did not improve survival, increase LVEF, or reduce hospitalizations.

Acorn plans to file CorCap with the FDA in 1Q05 for use during CABG or other open-chest procedures. For the future, the company has been working on a minimally invasive approach. A researcher reported that this has been tried in several different animal models with "significant progress." The first human implant was done in November 2004 in France with a sub-costal incision, and the first robotic implant was done in the U.S. on a cadaver.

The one issue with CorCap is that, in about half of the patients, it gets incorporated into the heart, making transplantation more difficult. A speaker said, "We found mesh incorporated into the ventricle…It was tremendously stuck, and a huge mess getting the heart out…Should we use the constraint device in its present form in someone who might eventually need a transplant or should we wait for better materials or design?" A CorCap investigator, Dr. Mercedes Dullum from the Cleveland Clinic said, "I believe half the people who did have to have the device come out had problems. Currently, I think I would recommend it because you can take it out." Dr. Frazier said, "I think they are tough (to get out)…I guess that is the price you pay. To me, it is worth it if there is a benefit, but the group with the best survival for heart transplants are stable LVAD patients…It is hard to imagine that the restraint devices are taking NYHA Class II patients and making them Class I, so that has to be weighed."

Most surgeons questioned about this device predicted it will find a role. Among their comments were:

- "It's not clear yet that it works. We need long-term follow-up."
- "I wouldn't use this, but I can envision others doing it."
- "I'm really not sure it does anything positive, and it makes transplant more difficult. LVADs also make transplants more difficult, but you get a healthier patient."
- "I would use this if it works. Could this be like TMR? Possibly. There are still a lot of questions about this, especially about who to put it in. It might be reasonable in MR patients, but patients with no reason to go to the operating room are a bigger question."

BACE (Baal annuloplasty of the cardia externally). This polyester strip is an external device, an adjunct to conventional CABG that stabilizes the base of the heart. A strip is anchored posteriorly at the a-v groove with the heart beating. Twelve initial CABG patients were matched to 15 patients, and there were no perioperative deaths. Follow-up to four years found a persistent benefit.

MYOCOR SURGICAL'S Coapsys. This device uses a transventricular band. It is a ventricular and annular remodeling device designed to treat functional ischemic MR. In an animal study, it reduced MR in all animals.

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS)

Cardiac surgeons often implant ICDs when doing open chest procedures, and there was a discussion about how MADIT-II impacts them. One speaker said, "We do an EP (electrophysiology) study, and if it is positive, they get a device…The vast majority get ICDs." Another expert said, "We found that 42% of those with EP studies had positive studies…The problem we are facing is what do you do in the 90 day period that CMS is mandating we wait for payment…The reason for the mandate is CMS wants to see after revascularization that the ejection fraction (EF) remains below 35% for primary prevention...I think over the next few years we will sort out better in terms of primary prevention."

ATRIAL FIBRILLATION (AF)

Several talks reviewed the various approaches to AF ablation.

AF Ablation Techniques

Company	Product	Notes
Unipolar RF		
Osypka	Cobra	Inexpensive, reusable
Medtronic	Cardioblate	Single use
Boston Scientific	Cobra	Single use, flexible tip
Cryoablate		
Erbe	Erbokryo	Reusable, cheap, 2 minutes per segment
CryoCath	Surgifrost	Reusable, inexpensive, argon gas cooled EPI: 2 minutes per segment ENDO: 1 minute per segment
Bipolar RF		
Boston Scientific	Cobra	30 seconds, reusable clamps, single use device
AtriCure	(transpolar)	---
Microwave		
AFX	Flex 4	---
Edwards	Optimaze	---
High Intensity Focused Ultrasound (HIFU)		
St. Jude/Epicor Medical	---	Looks very promising
AtriCure	---	Described as "very good"

One reviewer summed up the various AF ablaton devices this way: "At the end, the message is easy. Epicardial ablation with Flex 4, microwave, and cryoablation was not effect in either acute patients or at two hours…Bipolar RF doesn't harm the esophagus or the cirumflex artery, and unipolar doesn't harm the cirumflex. Microwave causes only esophageal damage. All the others had more or less collateral damage ...Bipolar epicardial ablation is effective and safe; epicardial cryotherapy and microwave ablation are ***not*** effective…Cryo energy produces less thrombus formation." He described Flex 4 and Surgifrost as the worst techniques.

Another speaker was critical of all the technologies for AF ablation and left atrial appendage (LAA) removal. He said, "To me, no procedure meets all the criteria so far…We need new approaches. The cardiologists are working on this, and they have some good ideas. The early results with Plaato (Appriva Medical's Left Atrial Appendage Transcatheter Occlusion) look pretty good. And IDX Medical has a new surgical approach – a cloth-coated clip you can place from the epicardial surface. That looks promising." He suggested there are four types of patients who should get AF ablation and/or LAA removal:

1. Cardiac surgery patients with AF. He said, "To me, it makes sense to treat LAA at that time. The MAZE procedure results are excellent; there are almost no strokes."
2. Cardiac surgery patients with isolated AF. He commented, "It could be that appendage management is a stand-alone procedure. That is, patients with AF having only the LAA treated with surgery. A small series of patients has had promising results, with a 60% reduction in late stroke and one thoracotomy for bleeding."
3. Mitral valve surgery patients with no AF. He said, "There are guidelines for this. Excision/exclusion is recommended in the ACC/AHA guidelines, and it is routine practice at many centers."
4. Other cardio surgery with no AF when the appendage is "right there." He said, "This is tougher. A randomized clinical trial would be ***very*** hard to do, requiring 1,500-2,000 patients with clinical follow-up of 5 years. It makes sense, people do it, and it appears safe, but we don't have the data."

ANTICOAGULATION

THE MEDICINE COMPANY'S Angiomax (bivalirudin)

Angiomax is approved for use in lieu of heparin for percutaneous coronary interventions in the cardiac cath lab, and trials are underway to see if Angiomax can also be substituted for heparin during coronary bypass graft surgery (CABG). Fifteen surgeons were asked about off-label use of Angiomax during CABG at their hospitals:

- **9 are not using any Angiomax yet.** One doctor was very negative about Angiomax in CABG patients, "I had a couple of patients who came to the OR already on Angiomax, and they bled their asses off." A Tennessee doctor said, "I don't foresee use in the OR except in isolated cases. Surgeons are slower to change than interventional cardiologists." A Nebraska doctor agreed, "Even if the trials (in CABG) are positive, I think the use will be limited. Cost also is an issue."
- **4 use Angiomax for HIT patients only,** which is <10% of patients. A doctors said, "It might find a role in HIT or heparin antibody-positive patients."
- **2 are participating in CABG trials with Angiomax.** A Georgia doctor said, "I don't see the same role for Angiomax in CABG. It is not reversible. But it is ideal in the cath lab." A Florida doctor said, "I think Angiomax could replace heparin in CABG. It isn't reversible, but it wears off. And it is excreted renally, so there is no issue using it in patients with renal failure. But it would be a slower adoption than in the cath labs."

MISCELLANEOUS TECHNOLOGY TO WATCH

CHF SOLUTIONS' System 100

In 2002, the FDA approved this ultrafiltration device to remove excess fluid from cardiac (CHF) and other patients. The system allows physicians or nurses to extract a targeted volume of fluid from the blood at a controlled rate. A speaker said he had done 11 patients in the last few months, with an average run time of 21.5 hours and an average of 5.5 L removed: Four patients developed clotted filters, and four had adequate volume removal. The researcher commented, "It is safe, effective, and avoids the adverse effects of loop diuretics in CHF patients. It is easy to set up and to initiate treatment. And its small size allows patients to ambulate during treatment."

TECH-CON SURVEY RESULTS

General Topics

CABG procedure volume in the past year	Increased	Same	Down 1%-10%	Down 11%-25%	Down >25%
	17%	28%	28%	19%	7%
Overall cardiac surgery volume in the past year	Increased	Same	Down 1%-10%	Down 11%-25%	Down >25%
	24%	33%	24%	13%	6%
Most important issue in cardiac surgery today	Decreased reimbursement	Declining case volume	Lack of innovation	Medical legal issues	All of these
	21%	10%	10%	7%	52%
Current opinion of drug-eluting stents	Significant advance	Better than I thought but still not as good as cardiologists say they are	All hype	Still too early to tell	---
	21%	32%	8%	38%	---

Congestive Heart Failure and Atrial Fibrillation

The most important criterion for survival after revascularization for cardiomyopathy is	Age of the patient	Status of distant vasculature	Pulmonary artery pressure		Ejection fraction	Male gender
	3%	29%	26%		42%	0
A patient presents with heart failure due to an ischemic cardiomyopathy, 3+MR, anterior akinesia, and a large ventricle. The best approach is	Transplant	CABG	CABG+Dor		CABG+Dor+ Mitral repair	CABG+Dor+ Mitral replacement
	5%	1%	2%		84%	7%
Dor procedures are contraindicated when	EF≤15%	Infarct within 4 weeks	Absence of anterior infarct		Severe MR	More than one infarct zone
	5%	52%	20%		3%	20%
How many patients want and need long-term mechanical device treatment for CHF	100,000	50,000	10,000		<5,000	---
	56%	22%	10%		13%	---
Do you use complete annuloplasty rings or posterior leaflet annuloplasty rings for mitral repair in heart failure patients	Complete annuloplasty rings		Posterior leaflet annuloplasty rings			
	73%		27%			
What is your favorite type of energy source for pulmonary vein ablation for AF	Monopolar RF	Bipolar RF	Cryotherapy	Focused Ultrasound	Microwave	Laser
	10%	59%	14%	1%	15%	1%

Percutaneous Valves

Percutaneous aortic valve implantation is	Intriguing with a role as yet unknown	Likely to have a significant role in the next 10 years	Another cardiology gimmick	Totally ridiculous	---
	44%	46%	4%	7%	---
What specialties should develop percutaneous valves	Cardiac surgeon	Cardiologist	Together	New, specifically trained interventional/surgeon	---
	30%	1%	47%	22%	---
What percent of aortic valve implantation will be performed by the percutaneous approach in the next 5-10 years	0	1%-10%	11%-25%	26%-50%	>50%
	4%	66%	23%	7%	1%
Opinion of mitral valve repair	Edge-to-edge is promising	Coronary sinus is promising	Both promising	Neither likely to work	Percutaneous approach may work but not as well as surgery, yet may still have a role
	2%	6%	25%	3%	64%
Which valve is most likely to be successful by percutaneous techniques	Aortic	Mitral	Pulmonary	All	None
	15%	10%	55%	16%	5%

CHF and AF Procedures

Question	Yes	No
CHF		
Do you see the volume of surgery for heart failure increasing	83%	17%
Do you have a centralized heart failure clinic at your hospital	49%	51%
Would your cardiologist refer a patient for a stand-alone ventricular restraint procedure	30%	70%
Should long-term mechanical device implantation be limited to cardiac transplant centers	41%	59%
Do you believe in destination therapy with a mechanical assist device	73%	27%
If you had end-stage heart failure and transplantation was not an option, would you choose destination therapy for yourself	52%	48%
Do you have personal experience with implanting mechanical assist devices in your current practice (not just in training)	51%	49%
AF		
Do you currently ablate the pulmonary veins when performing CABG on patients with a history of AF	60%	40%

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