Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Cardiothoracic surgeons believe that the SYNTAX trial comparing PCI and CABG will boost CABG volume. ♦ In the current economic environment, hospitals – and surgeons – have pretty much lost interest in expensive technology such as Intuitive Surgical's da Vinci robot. ♦ Surgeons are worried about reimbursement cuts and too few new surgeons getting trained, but they are upbeat and optimistic about percutaneous valves, viewing them as an opportunity, not a threat. ♦ Within 5 years percutaneous valves are expected to account for 22% of aortic valves, mostly through market expansion, even if the price is $20,000+ each. ♦ Earlier concerns about transapical valve performance have been resolved. ♦ Enthusiasm has waned for Abiomed's Impella, and surgeons were negative about Evalve's MitraClip. ♦ Atrial fibrillation ablation is growing, despite the Justice Department investigation of AtriCure.

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SOCIETY OF THORACIC SURGEONS

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The mood at this year's Society of Thoracic Surgeons (STS) meeting was surprisingly upbeat in a down economy. Cardiothoracic surgeons said the economy has had little impact on them personally or their cardiac surgery departments except that hospital budgets have been severely restricted. However, they said most big purchases have been on hold. Getting expensive new devices approved is very difficult, though not impossible, and new hospital construction that was already underway is continuing.

This is bad news for companies selling big-ticket items, like Intuitive Surgical's da Vinci robot, and it means that expensive new technology – like Impella's Recover ventricular assist device is getting more careful scrutiny. Yet, surgeons are seeing a continuing increase in atrial fibrillation ablations, the decline in CABG surgery has stopped and perhaps starting to pick back up a little, and surgeons have embraced percutaneous aortic valves that they once saw as a threat.

Comments included:

- *Dr. Douglas Johnston of the Cleveland Clinic:* "Everyone thinks the winds of change are blowing, and there have to be hard national decisions on some things. It is imperative to look at outcomes and benefits of some things, like robotic mitral repair, etc. The benefits of some things are hard to demonstrate. No one in the U.S. wants to think about things like dollar costs vs. medical benefit, but we may need to think about them, especially if there are equivalent but less desirable options out there. We spent $100,000 on cannulas for robotic surgeries last year. We do a lot of cases, but that is a giant healthcare expense."
- *New Mexico:* "We are trying to be prudent in new decisions. We want to be absolutely sure when we go to the well that we need something. People need to be very pragmatic and understand the difference between 'want' and 'need' …We play nicely with the interventional cardiologists, and we need to figure out where the dollars are best spent. Evidence-based medicine should dictate where we go, and I think cardiovascular surgery will come out looking pretty good."
- *Kentucky:* "New equipment is hard to get now, and no one is getting trained. In five years, there will be a crisis (shortage of cardiac surgeons), and the public won't get heart surgery in a timely fashion."

THE BUSINESS OF CARDIOTHORACIC SURGERY – Facing many challenges

Cardiothoracic (CT) surgeons face a number of business challenges over and above the general economic downturn, including competition from other specialties, changing reimbursement, plus a shortage of residents that is likely to result in a severe shortage of CT surgeons in a few years.

"Your profession is at a major crossroads," Dr. James Field, general manager, The Advisory Board Company, a think tank that advises hospitals and medical practices, told surgeons, adding, "This is not business as usual. This is something fundamentally different…In the previous model, it was okay to come to work and focus on patients, clinical outcomes, and technologies. I think that is completely inadequate for the future. Heart surgeons need to become business people. They need to be leaders and direct this (change)…If you don't do this, the chances of you not prospering in the future are very high."

Dr. Field pointed to several negative forces affecting cardiothoracic surgeons:

- **A downturn in surgical volume**.
- **An increasingly co-morbid population**.
- **Regulatory mandates**.
- **Decreased physician reimbursement**. A bundled payment demonstration for cardiac surgery is "around the bend," with a bundled payment for Medicare Part A and Part B, "This will start next year. The hospital will get one fee, and you will have to work with the hospital to come up with the most effective treatment, and you will have to lead the way to do this correctly and efficiently."
- **Greater quality scrutiny**. With a spotlight on quality performance – and new quality metrics being introduced for cardiac procedures – he called for a "revolution in CT surgery quality management."
- **Procedural migration/cannibalization**.
- **Increased competition and product commoditization**. "With more competition for fewer cases, the average volume per hospital is going down. The average number of CABG cases per hospital was 297 in 2001 and 211 in 2007. You will see programs actually fail going forward. You need to think about what to do in your hospital and market to achieve sustainability over time…What will you do to capture and sustain 200 open heart cases over time?"
- **A focus on cost**. He predicted that payors will shop around, and a lot of people won't get elective procedures because they can't pay for them.

Dr. Field warned that the specialty's future prospects are tied to innovation across three fronts:

1. **Specialty remodeling.**
2. **Innovation "beyond the fringe."** He noted that "surgeons are not paving the way on new technology and in making decisions on what new technology is coming into the hospital."
3. **Care delivery reform.** He urged surgeons to think collectively about the CV universe, to integrate into a multidisciplinary center – medical cardiology, electrophysiology, interventional cardiology, cardiothoracic surgery, and vascular surgery – into a broad Cardiovascular Service, "Cardiovascular Service is the new world order. You need to be sitting at the table, to be represented…Form a valve center with one-stop-shopping, bundled services, and multidisciplinary action… Take a page from the oncology playbook with weekly multidisciplinary CV conferences, co-located services, adapted care pathways, etc."

There are growth areas for CT surgeons. Dr. Field, pointed out that between 2007 and 2012:

- Atrial fibrillation (AFib) surgery (stand-alone) will increase 333%.
- Ventricular assist devices (VADs) will increase 285%.
- Concomitant AFib ablation will increase 73%.

Dr. Randolph Chitwood Jr. of East Carolina Heart Institute, the 2008 STS president, exhorted thoracic surgeons to focus on five areas over the next few years, predicting that the practice model for cardiothoracic surgeons will be "entirely different' in the future than it is today:

1. Discovery and innovation – to guide technology and operational changes in the specialty.
2. Professional synergy – working closer with the American Association for Thoracic Surgery (AATS).
3. Service integration – to integrate cardiologists, vascular surgeons, and cardiac surgeons into a single department with a new business model.
4. Education reform – to change the way residents are trained and improve postgraduate education.
5. Winds of change – to know and understand governmental health plans that are being proposed so they can either be supported or challenged, as needed.

Shortage of future surgeons

Dr. Edward Verrier of the University of Washington, surgical director of the Joint Council on Thoracic Surgery Education, warned that there could be a looming manpower issue in the next five years in thoracic surgery. He pointed out that 51% of active surgeons are age ≥51 and likely to retire in the next 15 years, yet 10% of residency programs have gone unfilled over the past three years. He said, "Supply will soon fall behind demand as the population ages…Women are underrepresented (<5% of current trainees), and current skills are not being properly taught. There is a 18% board failure rate…

New skill sets (catheter and imaging) are not being taught. Proper skills are not being taught in medical schools – imaging, endoscopy, robotics, minimally invasive surgery… Length of training and lifestyle concerns make the specialty less attractive, and postgraduate training is woefully inadequate."

He suggested a new training program be developed with vascular surgery that would lead to board certification in both specialties, "The old system of apprenticeship is no longer viable. We have to change the way we teach, and we need to develop alternative training algorithms to attract more women."

He recommended:

- Expanding simulation and e-learning tools.
- Expanding new skill sets in education.
- Providing faculty education in "adult learning."
- Developing new supporting relationships with industry, philanthropy, and extramural education research funding sources based on educational priorities.

CORONARY ARTERY BYPASS GRAFTING (CABG) – Likely to pick up post-SYNTAX

The results of the SYNTAX trial comparing drug-eluting stents (Boston Scientific's Taxus) and CABG have been presented several times in the past year, and Dr. Michael Mack of Dallas briefly reviewed the results again at STS. In SYNTAX, PCI (percutaneous coronary intervention) – stenting – was ***inferior*** to CABG in SYNAX. To be non-inferior, PCI would have had to have a MACCE (all-cause death, CVA/stroke, MI, and repeat revascularization) rate within 6.6% of the rate for CABG, and the actual difference, when adjusted for the confidence interval, was 8.3%.

SYNTAX, sponsored by Boston Scientific, was a randomized comparison of CABG and PCI in an all-comers population of 3,075 patients with *de novo* left main or 3-vessel coronary disease at 62 European and 23 U.S. sites. The SYNTAX patients were complex. On average, they had 3.6 lesions, received 4.6 stents, with a total length of 86.1 mm. One-third of patients got ≥100 mm stents. The excess MACCE in the PCI arm was due primarily to revascularization, and some experts argue that the bleeding risk with CABG outweighed the increase in PCI revascularization. However, other experts pointed out that CABG has a durability advantage, that over time PCI is expected to compare even less favorably to CABG.

Surgeons interviewed at STS said SYNTAX either has had no impact on CABG volume, has already resulted in an ***increase*** in CABG, or is likely to increase CABG volume in the future. Some, but not most, surgeons said isolated left main disease is increasingly being treated with stents as a result of SYNTAX, but even when those patients are going to interventional cardiologists, that does not appear to be negatively impacting CABG volume.

- *Dr. Mack:* "It hasn't been long enough to say. I think we will get a truer sense once the primary endpoint trial is published, but there is a strong sense from what we've seen already that CABG is no longer declining and may be increasing. Whether that is due to SYNTAX, appropriateness criteria, or to concerns about the hazards with stenting, dual antiplatelet therapy may need to be lifetime therapy in drug-eluting stent patients, and we need more awareness of who the patients are where that is not possible due to co-morbid disease or an inability to pay for the drugs."
- *Texas:* "I haven't seen any change as a result of SYNTAX yet, but the question is what happens in 2-3-4 years…MACCE was lower with PCI in isolated left main disease patients, so we might find them going to PCI, but everyone else benefits from bypass, and that can't be discounted."
- *Illinois #1:* "It's too early to tell, but I do expect SYNTAX to have an impact, increasing CABG. Patients will think more about their choices. And differences in follow-up occur at Years 5-7. This is the first time that, even for a short time, there is an advantage for grafting over DES."
- *New York:* "I don't know why there is so much debate on what is right. Since SYNTAX started, there is more debate/discussion, and that was not happening before. The reality is doing what's right for the patient. I believe SYNTAX will eventually increase CABG."
- *Illinois #2:* "CABG has increased. The gatekeepers are re-evaluating (CABG vs. PCI). We are getting calls before interventions, and the patient is given options now."
- *New Mexico:* "I haven't seen a change in CABG volume yet, but we will see an impact – an increase in CABG. Evidence-based medicine will dictate – as long as patients are educated about the results of the trial…And I don't think most cardiologists will do even left main percutaneously unless they are forced to do so as a bailout."

Dr. Mack reminded surgeons that not all the results in SYNTAX were positive for CABG:

- **Stroke** at 1 year was 3.5 times higher with CABG. He said, "Stroke in the CABG arm continues to be a concern, and we can't ignore it."
- The **symptomatic graft occlusion rate** with CABG was the same as the stent thrombosis rate with PCI (3.4% each). However, he said the two complications are not really comparable, "It looks like mortality with graft occlusion is not as high as with stent thrombosis."

Why should the stroke rate be higher with CABG than PCI? Dr. Mack suggested it is because most PCI patients got longer

dual antiplatelet therapy than CABG patients (12 months vs. 3 months), saying it raises questions about whether CABG patients would also benefit from extended dual antiplatelet therapy, "The only difference between the CABG and PCI patients was that the PCI patients were getting dual antiplatelet therapy almost across the board, and the CABG patients weren't, raising the question of whether there is a protective effect to dual antiplatelet therapy after coronary revascularization. There is no proof, but we are having trouble coming up with another explanation why stroke should be any higher with one vs. the other."

Indeed, one of the surprise results of SYNTAX may be that surgeons will start prescribing long-term dual antiplatelet therapy for CABG patients. Dr. Mack said, "There isn't any strong evidence, but that is the thought…Obviously, we need to drill down on the CABG stroke patients and find the particulars. Were they on or off pump? Did they have known cerebrovascular disease, etc.?...In the meantime, I'm going to use dual antiplatelet therapy more (in CABG patients). We do all CABG off-pump, and we routinely have been using dual antiplatelet therapy for three months, and I will probably treat longer – probably a year." Dr. Chitwood said he also is considering extending dual antiplatelet therapy in his CABG patients, "I might do that. I picked up on that (at the meeting). We are not doing it yet. I wonder if you should put someone on Plavix full-time forever as with some drug-eluting stent."

Dr. Mack said he has been strongly criticized by some surgeons for participating in SYNTAX, and he defended his decision, "We felt some pressure that we had sold out the surgical community by agreeing to participate in this trial," with some surgeons suggesting the trial was not ethical. He explained, "We agreed to the trial because at the time of the trial design we did a run-in at 104 centers of more than 12,000 patients with left main and 3-vessel disease, and we found that already one-third were getting PCI, so we felt we were already losing the game without a fair, balanced trail, and SYNTAX was an attempt to provide an evidence-based approach."

While emphasizing that post hoc stratification of a failed trial is only hypothesis-generating, Dr. Mack pointed out that there still are some interesting data from the trial.

SYNTAX Post Hoc Analysis

Measurement	CABG	PCI
MACCE in all left main patients	13.7%	15.8%
MACCE in isolated left main patients	8.5%	7.1%
MACCE in left main + 1 vessel disease	13.2%	7.5%
Death/CVA/MI to 12 months in left main patients	9.1%	7.0%
MACCE in diabetics	14.2%	26.0%
MACCE in non-diabetics	Nss difference	

Will SYNTAX change guidelines? Dr. Mack doesn't think so. He said, "Nothing in SYNTAX would change the appropriateness criteria" in the new ACCF/SCAI/STS/AATS/AHA/ASNC guidelines or the ACC/AHA guidelines.

More data from SYNTAX will be available at the European Society of Cardiology meeting in September 2009.

PERCUTANEOUS VALVES – An opportunity more than a threat

The hot topic at this year's Society of Thoracic Surgeons meeting was percutaneous aortic valves, which are now viewed as an ***opportunity***. That's a big change from three years ago, when cardiac surgeons were worried about how to save their profession from the ***threat*** of interventional cardiologists doing percutaneous valves. Now, they are anxious to be at the forefront of this new technology. Comments included:

- *Dr. Johnston:* "They are only a threat as far as they are applied before there is adequate data to evaluation in which patients they should be most appropriately used and before we have long-term durability data. Most of us are enthusiastic about the potential to help patients with percutaneous valves and the potential to help patients not now referred (to surgeons for valve replacement)…We need to focus on cost, safety, and efficacy, not just on perceived degree of invasiveness."
- *New York:* "I'm getting trained in percutaneous valves."
- *Illinois:* "I'm getting trained in percutaneous valves."
- *Canada:* "It is a huge opportunity for patients and for doctors. There definitely will be a group of patients who will benefit. There is still a fundamental problem with percutaneous valves because they leave the damaged valve in place. They are good for very sick patients but not for conventional patients."
- *South Dakota:* "We will do percutaneous valves whether we agree with it or not. They are an opportunity for both patients and doctors. Surgeons are now at the mercy of cardiologists."
- *Kentucky:* "Percutaneous valves are the hottest things on the horizon. Everything else on the horizon is fancy marketing…We have a hybrid operating room, so we will be positioned to do them when they are approved…I will go to Europe later this year to see Edwards' valves)."
- *Florida:* "Younger surgeons want to get involved. I'll take the company (Edwards) course. It's an opportunity – a new market."
- *Texas:* "We aren't doing percutaneous valves yet, but the technology certainly will find a niche. There are some early promising results in selected patients…I'm hesitant to counsel a patient that this is the way to go."

Aortic valves

U.S. surgeons have been getting trained in percutaneous procedures, and more are planning to get trained this year. In five years, percutaneous aortic valves are expected to have FDA approval and to account for an average of 22% of all aortic valve patients in the U.S., but the market is also expected to expand by about the same amount, so percutaneous valves are not predicted to cut into use of tissue or mechanical valve procedures. Comments included:

- *Dr. Johnston:* "In five years more than 20% of aortic valve patients will be getting a percutaneous valve, and I would hope that is mostly patients not now being operated on. Two recent studies demonstrated very well that aortic stenosis is a hugely under-rated problem, that patients are under-referred. One of the most valuable lessons from percutaneous valve research is that the current scoring systems don't reflect risk of aortic stenosis in the 21st century…We've gotten much better taking care of patients with the currently available techniques…We need to decide which patients really benefit best from transcatheter valves and which are not good patients for them."
- *Dr. Mack:* "Percutaneous valves will expand the market and eat into some current high risk surgical patients. Five years from now (two years after commercialization), percutaneous valves will be 20% of procedures, and in 10 years they will eclipse surgical valves, assuming they get approved in three years and are reimbursed."
- *Canada:* "Percutaneous valves will expand the market, mostly with new patients who would never have conventional surgery."

➢ **Price.** Price is unlikely to be a barrier to percutaneous aortic valve acceptance in the U.S., even if the valves cost $20,000+. Surgeons pointed out that implantable cardioverter devices (ICDs) cost more than that today. Comments included:

- "Right now the companies can price them where they want because they are in trials. Price will become an issue as it may (also) become an issue with stenting (drug-eluting stents)."
- *Illinois:* "We'll see. It is hard to believe $20,000 will be a viable price. It seems way high."
- *South Dakota:* "$20,000 is less than the $50,000 some ICDs cost."
- *Kentucky:* "Price is not an issue. $20,000 is cheap for the technology."

➢ **Edwards Lifesciences' Sapien vs. CoreValve's ReValving System.** Several surgeons interviewed at STS are participating in the PARTNER trial of Sapien aortic valve, and all have been satisfied with the results so far – with both the transapical and the transfemoral approaches. While European surgeons interviewed in the past tended to prefer CoreValve's ReValving System to Sapien, none of the U.S. surgeons questioned at STS have had any experience with the ReValving System yet. Sources were generally aware that there are advantages to the ReValving System, but they pointed out that Sapien is likely to be available first in the U.S., so that is what they are concentrating on now. And many pointed out that there are better valves further away in development than either Sapien or ReValving System. A few surgeons said they plan to go to Europe this year to get experience with Sapien.

If both CoreValve and Edwards had valves available in the U.S., one expert said cardiologists may prefer CoreValve, "I think the cardiologist's comfort zone will be higher with CoreValve...There is more of a comfort zone with positioning… And CoreValve has been around longer and has a smaller delivery system." Another surgeon said, "The FDA's concern with CoreValve has been nitinol stent fractures in the aortic root. We know nitinol fractures elsewhere in the body. Will that be an issue in the aorta where the stent will move even more? The FDA wanted longer animal data. That being said, the lower 18F delivery system – and not having to deploy immediately – make deployment and delivery so much easier with CoreValve. There is a world of difference between the two (Edwards and CoreValve). At the end of the day, the ballot is still out. Sooner or later, one of the major players will buy CoreValve. It will make it in the U.S., but the problem CoreValve will have is the same Edwards had with the PARTNER trial in Europe. When a device is commercially available, it is hard to put patients in a randomized clinical trial. The same thing will happen to CoreValve; in the middle of its U.S. IDE trial, Edwards will have approval, and who will randomize a patient when they can get a (commercial) valve?"

Dr. Eduardo de Marchena of the University of Miami, who is participating in Edwards' PARTNER trial but who has also tried the CoreValve ReValving System in South America, pointed out that ≥30% of patients with severe aortic stenosis go untreated and the reason for that is not well known, though an Edwards study found 49% are because of major comorbidities. Another expert suggested, "Many patients are being held back by primary care doctors. We see that an awful lot."

He said 30-day mortality and 6-month survival is comparable for Sapien and CoreValve, but aortic regurgitation "seems more prominent' with Sapien, and CoreValve has a smaller (18F) delivery system. He said Sapien is a "bulky and large device."

On the other hand, Dr. de Marchena pointed out that pacemakers have been needed in more CoreValve patients. He said, "From our work in Cali, Colombia, which started March 24, 2008, with CoreValve, we learned patient selection is a critical factor, and a CT scan is very important. Frequently, we see some aortic insufficiency immediately after the procedure, but it goes away with a little time." The results in his first 18 South American CoreValve patients were:

- Very little aortic insufficiency.

- Successful results in 94%.
- Death related to the procedure in 11%; cardiovascular death 5%, vascular death 5%.
- Post-valve dilatation required after valve implantation in 5%.
- No MIs, neurological events, tamponade, or aortic dissections during the procedure.
- Transitory complete AV block in 3%.
- Complete AV block in 22%. He said, "We are very concerned about this."
- Need for permanent pacemaker at 30 days in 33%; by 90 days 38% required a pacemaker.
- At 90 days, 21% any death, 7% CV death, and 7% complete AV block, but still no MIs or neurological events.

➢ **Transapical vs. transfemoral.** Early reports of problems with the transapical approach were blamed on poor U.S. patient selection, which surgeons said has now been resolved. An expert, who has done both transfemoral and transapical valves, said, "The issue (with transapical) has been resolved. The experience in the U.S. was skewed by patient selection. With the European experience, that is resolved. The appropriateness of transapical or transfemoral will sort itself out." For example, he said COPD patients might be better candidates for the transfemoral than the transapical approach.

Prof. Frederich Mohr, chief of cardiovascular surgery in Leipzig, Germany, reported on the experience with transapical implantation (TAVI) of Edwards' Sapien. He pointed out that a recent European consensus paper on TAVI found the procedure feasible and indicted for high risk patients but noted that there are no long-term results and that it should be done with a team approach. Dr. Mohr said TAVI with Sapien currently takes his team, which has done 420 implants, 45 minutes "skin to skin."

At STS he reported on 200 of these elderly patients:

- Stroke 0.5% (1 patient), which he said is lower than for the transfemoral approach.
- Cardiopulmonary bypass not needed after the initial learning curve patients.
- 30-day survival was 77%.
- Valve-in-a-valve in 3 patients (3.7%).
- Reoperation/sternotomy in two patients (2.4%).

Dr. Nawwar Al-Attar of Paris reported on his hospital's non-randomized experience with TAVI compared to the transfemoral approach, both using Sapien. He said most deaths with TAVI occurred early, "I think this was a reflection of the critical status of these patients. After that, survival was pretty stable compared to transfemoral…TAVI expands the scope of treatment of aortic stenosis in high risk patients. Transfemoral avoids a thoracotomy, but the transapical approach is a mini-thoracotomy, which avoids vascular access complications and is straightforward. Patient selection is crucial for the outcome. Transapical patients had more co-morbidities, and a more critical early postop period."

The discussant, Dr. Todd Dewey of Dallas TX, concluded Dr. Al-Attar's results were worse with transapical than transfemoral, noting that his transapical mortality was 1.5 times what would be predicted by STS historical data. Dr. Dewey added, "Often this relates to clustering of worse patients in the transapical group." He posed several questions for Dr. Al-Attar:

- *Since the populations are intrinsically different, did you look to see if there is a difference in preoperative MR, and did this have an effect on outcomes, particularly post-operatively?* Dr. Al-Attar responded that learning curve and experience have "a crucial and direct influence on clinical outcomes by affecting patient selection, procedural performance, and post-procedure management."
- *Were there any predictors of mortality?* Dr. Al-Attar responded that previous MI was a significant predictor, "We continue to follow patients, and that shows that NYHA Class and LVEF are important contributors to survival."
- *Given time frame of patient accrual, were these patients enrolled in the PARTNER trial? If so, how many and did the trial protocol influence the decision to use the transapical approach?* Dr. Al-Attar said the transapical approach began with the beginning of the PARTNER-EU trial because that is when they got access to TAVI.
- *Besides access, what other variables are important in the choice of transapical or transfemoral? Were you biased against transapical by putting the highest risk patients in the transapical group? If so, why compare them?* Dr.

Dr. Al-Attar's Results with TAVI vs. Transfemoral Implantation of Sapien

Measurement	Transfemoral	Transapical	p-value
Successful implantation	85.7%	100%	Nss, 0.12
Paravalvular leak Grade 3	7%	7%	---
Paravalvular leak Grade 1-2	23%	0	---
Paravalvular leak Grade 0-1	70%	93%	Nss, 0.1288
Procedural death	3%	0	---
MACCE	28%	21%	---
Vascular MACCE	20%	7%	Nss, 0.67
MACCE CVA	5%	0	Nss, 0.30
AV block	3%	7%	Nss, 0.52
Duration of hospital stay	Comparable		---
Peri-procedural mortality	1 patient	1 patient	---
In hospital death	8%	27%	---
In hospital cardiac death	8%	20%	---
Non-cardiac in hospital death	0	7%	---

Al-Attar said, "You might say these populations are not entirely comparable, but TAVI has had bad press so far, and this paper contributes to explaining why. If you take patients denied everything, they are the most ill, the most risky, and you would expect the worst outcomes. But in our data, the transfemoral had more vascular complications, and the strokes were only in transfemoral. So, even though the TAVI patients were high risk, they fared better in terms of complications."

Other physician comments included:

- *Canada:* "I've done transapical with Edwards but no CoreValve. My initial experience with transapical has been fine. The referrals for transapical were patients with bad femoral arteries, which made them worse candidates, and that was the issue with the transapical approach."
- *South Dakota:* "I will learn the transapical approach. It's probably the best approach. That doesn't scare me as a surgeon."

EVALVE's MitraClip

No surgeons questioned had anything very positive to say about this product, and none are using it. Comments included:

- "There is a population of patients for which this is a good solution…2+ MR (mitral regurgitation) at a very short time after surgery is not going out on a limb…There is great technology but applying it to patients with degenerative disease in light of how successful surgery is a little crazy…There are patients who will ask for it, and it will get a certain use…but it is time intensive and difficult to do, so that will limit generalizability for that device…And the patient population is a younger, healthier population that really wants a durable repair…With an elderly patient, it is easier to make an argument for a minimally invasive, less effective procedure."
- "I believe this is going to be good technology for specific patients…I don't think it will dip down into the patient who should have mitral reconstruction…I don't think long-term quality is there with a clip."
- "MitraClip fell off the radar for a while because the company had finished enrolling patients and didn't have anything new for people to do, but interest has picked up again. It is too early to read reaction to it."
- "We've had to fix them (MitraClips). That still has a long way to go. But for sick heart failure patients, it is an option, but not for healthy patients; that would be crazy."
- "MitraClip is still unproven. A percutaneous mitral replacement platform is more interesting – on a beating heart through a small thoracotomy."
- "We use it very selectively at our hospital – just 3 or 4 patients in the EVEREST trial. Some patients refused, and we find many don't meet the criteria or are better candidates for surgery. We were satisfied when we did use it. We haven't used it since the trial, but we will."

Tissue/mechanical heart valves

Surgeons insisted that they have not recently switched valve brands, and none had any plans to change in the near future. An expert said, "There have been small, evolutionary changes in each valve, no revolutionary changes, and there is not that much difference in implantability in most surgeons' hands."

Surgeons said there is nothing new or exciting enough to cause market share shifts. One expert said, "All of the valves went through a recent iteration that supposedly improved durability…As we anticipate a tissue valve will make it 20 years, that is really pushing the patient age for tissue valves lower and lower. And more and more patients are requesting tissue valves because they avoid Coumadin (warfarin) use… The other thing driving tissue valve use is an understanding that the morbidity/mortality of replacement is very low at experienced centers. So thinking is coming around to the idea that valve disease is a lifelong problem that may require multiple surgeries and that a second operation in the future will be safe. An important part of our discussion with patients now is this option, and part of the discussion is the possibility that one of the next options might be a transcatheter valve."

The biggest crowd anywhere on the STS exhibit floor – and it was a substantial crowd – was at the Medtronic booth for a live demonstration by California surgeon Dr. Vincent Guadiani of a minimally invasive (MICS) mitral valve replacement in a pig heart. One doctor attending the demonstration said, "Dr. Guadiani is offering practical tips on a procedure we do almost every day."

Dr. Bernard Goldman of North York, Ontario, Canada, said a study by surgeons at his institution found that at one year there was "no difference between stented and stentless (valves), which put a real crimp and damper on stentless use at our hospital. But at 9-12 years, there is improvement with unstented valves…Stentless valves improved long-term hemodynamics both at rest and with stress. However, there was no difference in LV mass at 9 years, and no difference in functional status up to 1 year. (Thus), both valve designs offer acceptable long-term outcomes."

Dr. Goldman said that the suggestion from recent studies is that "stentless valves may be beneficial to patients with more severe LV hypertrophy, impaired LV function, and small aortic roots due to earlier remodeling due to lower trans-valvular gradient and decreased LV systolic wall stress."

ABLATION OF ATRIAL FIBRILLATION – Still a growing area despite government investigation of AtriCure

AFib ablation – both concomitant and minimally invasive (MIS, stand-alone) – is continuing to increase, but few surgeons are doing stand-alone ablations; most are in combination with another procedure such as CABG, but growth of minimally invasive approaches is inching upward.

An AtriCure official estimated that ~80% of surgeon ablations today are concomitant, and 20% are MIS. The growth is not dramatic, according to STS surgeons, but it is steady.

The choice of energy source for ablation is very surgeon-dependent. What is new and exciting for surgeons is left atrial appendage (LAA) ablation – because that is something that, at this time, can't be done by the catheter route. An expert said, "We know that most strokes come from the appendage, and this may change the face of AFib surgery in the future. There are a variety of options, including an LAA clip that is in development (by AtriCure) and which is the best of what I've seen. That has the potential for a safe, quick, thorascopic approach that doesn't disrupt the lumen."

Other general comments included:

- *Dr. Chitwood:* "The concept of bipolar ablation is good. The results in some centers look encouraging. The problem is issues related to conflicts of interest. That does not preclude the technology being efficacious. The problem is can you do a complete Cox-Maze III? I went back to cryotherapy (ATS's CryoCath), which lets me create all the lesion of a Cox-Maze III, and the results are good. We've done 200 patients, and I will report after one year of monitoring (follow-up). We know that if a patient has intermittent AFib, a small atrium, and no regurgitation, we get 95% success, which is comparable to Cox-Maze III. If a patient has long-standing AFib and a big atrium, we are at 55%-60% efficacy. If the patient has mitral regurgitation and developed AFib in the last two years, we get most of those people 90%+…We believe at this point that on-pump total transmural freezing is a good way to do this."
- *Illinois:* "I'm in the camp that favors a less invasive approach than sternotomy, but more invasive than catheter ablation. Our results in paroxysmal and long-standing persistent AFib have been very good, but it is still too invasive. Patients still prefer a catheter approach. So, what will happen is we (surgeons) will get less invasive with better technology, and the other side will get more invasive."
- *Kentucky:* "A Cox-Maze ablation is standard of care. Currently available energy can't repeat that. We do energy ablation, but the results are not as good as a Cox-Maze. I tried cryo ablation and then went to RF and microwave, and then back to cryo."
- *Colorado:* "We are looking at doing more stand-alone AFib ablation and developing that into a program – an AFib center. The question is how to include the EPs (electrophysiologists) in that program."

ATRICURE's Synergy

This should be a great environment for AtriCure, but in October 2008, AtriCure revealed that the Civil Division of the Department of Justice (DOJ) had started an investigation of the company for possible violation of the Medicare False Claims Act relating to (1) off-label marketing of its surgical ablation devices (for atrial fibrillation), and (2) instructing hospitals to bill Medicare using the incorrect billing codes.

However, the DOJ investigation doesn't appear to be impacting use of AtriCure's bipolar radiofrequency (RF) ablation system, Synergy. Surgeons questioned at STS insisted that they haven't switched ablation technology (to cryotherapy, unipolar RF, etc.) because of the ongoing investigation, and new surgeons were visiting the AtriCure booth and signing up to get trained. In addition, attendance was good at a company-sponsored symposium. However, AtriCure had a fairly low key presence at the meeting.

Surgeons also said that recent reductions in the AtriCure sales staff have not affected service.

Surgeon comments about AtriCure included:

- "The DOJ investigation is having no effect. There is still a perception that this is a good device."
- "I wasn't even aware of the Department of Justice investigation of AtriCure."
- "Our use of AtriCure is increasing. The investigation hasn't affected our use. Most of what we do (as cardiac surgeons) is off-label."
- "I'm starting biopolar RF for AFib with Medtronic instead of AtriCure – but not because of the Justice Department investigation."
- "The investigation has not changed our use, which has been flat over the last year. It's found its place for the moment. We've talked about stand-alone procedures, but we are not sure about that yet."
- "I've been using Medtronic's bipolar RF, but I'm thinking of changing because of recommendations from friends using AtriCure. Medtronic's system uses water, which I have been thinking was a better way to go, but AtriCure has a new device to make lesion sets…Ablations will go up over the next year across the country, and I hope in my practice."

Yet, Medtronic sources said they are seeing surgeons defecting from AtriCure to the Medtronic bipolar RF ablation system, and they said doctors are citing four reasons for switching:

1. They don't want all their eggs in one basket in the admittedly unlikely event that AtriCure should get withdrawn from the market.
2. They are unhappy with service since AtriCure began cutting sales reps.
3. They want to use a product with a more clear FDA indication. Medtronic's indication is for "soft tissue cardiac ablation."

4. They believe irrigation is important. The Medtronic system is irrigated, and the AtriCure system is not.

Dr. James Longoria of Sacramento CA, a consultant to AtriCure, discussed his experience with AtriCure's thoracoscopic bipolar RF ablation system, Synergy, to treat atrial fibrillation (AFib). So far, he has treated 94 patients between March 2006 and May 2008, of which he had data he could present on 61. The mean age was 60.8, mean duration of AF 73.5 months, and 45.9% had persistent AFib. The results, with a mean follow-up of 10.9 months, were:

- No death or complications requiring re-operation.
- 1 patient required a sternotomy for control of bleeding.
- Mean length of stay was 3.8 days.
- 4 developed recurrent AFib, and all of these were corrected with follow-up endocardial ablation.
- 3 required permanent placement of a pacemaker.
- 90.2% were in normal sinus rhythm.

Dr. Ralph Damiano, chief of cardiac surgery at Barnes-Jewish Hospital in St. Louis, was critical of Dr. Longoria's results for several reasons – inflation of success rates, data presentation, over-representation of persistent AFib patients, and a low rate of patients who had exhausted drug therapy.

- **Success rates.** Dr. Damiano said, "The actual guidelines say patients have to have atrial flutter or be off drugs, and you had 10 patients with ablation for atrial flutter and four patients requiring a procedure for AFib. According to the guidelines those patients would have to be listed as failures, and I think you need to report that…If you reported all patients who required an interventional procedure for AFib or atrial flutter, how would that change your numbers?" Dr. Longoria responded, "The success rate would be less...We aren't promising this is an end-all treatment for AFib…Single-procedure efficacy is less than what we reported today…We are not advocating this as a stand-alone procedure."
- **Data format.** Dr. Damiano said, "I would ask you to present this in a standard format…which lowers your success rate to ~50%. If I have a procedure with 90% efficacy and no follow-up procedures are required, that is important."
- **Too few paroxysmal patients.** Dr. Damiano said, "(This is) a very unique series…In almost all series of lone AFib, the paroxysmal population predominates, but paroxysmal is only 15% in your cohort."
- **Most patients had not failed drug therapy first.** Dr. Damiano said, "The present indications for surgical treatment of AFib are patients who failed medical therapy, but according to your presentation, only 40% of your patients failed medical therapy…That would be an unusual occurrence if you advocate ablation before drug treatment." Dr. Longoria responded, "These are all EP (electrophysiology) patients initially…This is the option the patient chose. The option of drug vs. catheter ablation vs. surgical ablation was offered, and all of these patients chose surgical ablation."

JOHNSON & JOHNSON/BIOSENSE WEBSTER's NaviStar ThermoCool Catheter

Shortly after STS, the FDA approved this device, making it the first ablation catheter approved specifically for the treatment of drug-refractory, recurrent, symptomatic, paroxysmal AFib. Other ablation catheters are approved to treat arrhythmias, such as atrial flutter and ventricular tachyarrhythmia, but not atrial fibrillation, though they are widely used off-label for that purpose.

The NaviStar ThermoCool, a saline irrigated, RF ablation catheter, also is approved for the treatment of Type 1 atrial flutter and recurrent drug/device-refractory, sustained, monomorphic ventricular tachycardia due to a prior MI. The FDA approval was based on a randomized, unblinded, 167-patient clinical trial conducted at 19 sites in the U.S., Brazil, Canada, the Czech Republic, and Italy. Data from the study showed:

- The probability of chronic success was 62.7% with NaviStar ThermoCool vs. 17.2% with anti-arrhythmic drug (AAD) therapy at 9 months ($p<0.0001$).
- NaviStar ThermoCool patients have a sharp reduction in symptomatic AFib recurrence vs. AAD patients (75% vs. 21%).
- Good safety, with no device-related serious adverse events at 7 days. At 90 days, serious adverse events were 35.1% with the device and 18.4% with AAD therapy ($p=0.0221$). There was no clinically significant pulmonary vein stenosis at 90 days.

In November 2008, an FDA advisory committee unanimously recommended approval.

The FDA has mandated that J&J establish a physician training program and conduct postmarket a registry and studies to collect data on the long-term safety and effectiveness of the device (including the incidence of stroke, mortality, cardiac arrest, major bleeding, and pulmonary vein stenosis) as well as data on the effect of physician experience in operating the device on procedural safety.

VENTRICULAR ASSIST DEVICES – Enthusiasm has cooled

ABIOMED's Impella Recover 2.5 and 5.0

This minimally invasive, percutaneous left ventricular cardiac assist device was approved by the FDA in June 2008 for use in hemodynamically unstable patients undergoing a percutaneous coronary intervention (PCI) due to an acute myocardial infarction (AMI). It is approved for six days of support and competes with both intra-aortic balloon pumps (IABPs) and

CardiacAssist's TandemHeart. However, enthusiasm appears to have waned.

Impella Recover 2.5 has been described as elegant, easy-to-place, and ingenious. It is inserted via the femoral artery into the left ventricle. Up to 2.5 liters of blood per minute are delivered from the left ventricle into the ascending aorta, providing significant increases in cardiac output and mean arterial pressure with a significant decrease in left ventricular end-diastolic volume (LVED). Despite the increase in systolic pressure, Impella 2.5 decreases diastolic perfusion pressure, improving myocardial supply and demand.

Comparison of Impella 2.5 and 5.0

Measurement	Impella 2.5	Impella 5.0
Shape	Same	
Design	Same	
Delivery	Introducer	Femoral cut-down
Flow	≤2.5 L	≤5.0 L
Pressure measure	N/A	Transmitted electronically
Physician	Interventional cardiologist	Surgeons
Status	FDA-approved	U.S. – in clinical trial Canada and Europe – approved

Ongoing Impella trials:

- **2.5 Trial #1:** Impella vs. IABP in high risk PCI patients in the cardiac cath lab. So far, 120 centers have been enrolled, with a goal of 180 sites. Patients have started getting the device, with a total of ~744 patients expected. The company insisted enrollment is going well, but sources described enrollment as going slowly.
- **2.5 Trial #2:** Impella vs. IABP in AMI patients with cardiogenic shock in the cath lab. Abiomed is still recruiting sites for this, with <10 so far.
- **5.0 IDE trial** of ~20 patients that will lead to a pivotal 510(k) trial. Impella 5.0 is still in clinical trials. A company official insisted enrollment is going well, but an investigator said enrollment is going slowly.

Two years ago Impella was described by cardiac surgeons at STS as one of the most exciting technologies on the horizon. This year, STS surgeons had little to no interest in Impella, either the 2.5 or the 5.0, though they said Impella is finding a small niche among interventional cardiologists and cath labs. Comments included:

- "We thought it would be better than it is. A lot of patients we take care of need more support than Impella can do."
- "There is no interest at our hospital, even from the interventional cardiologists. We really don't see that many candidates. When we think we will need an assist, we send the patient to the university hospital."
- "I'm not impressed with Impella."
- "We aren't using Impella. There are so many things out there, and adoption in our practice is slow, especially in cardiac surgery."
- "It will be used by interventional cardiologists. It can be used post-pump for cardiac failure, but it probably won't be used much for that. It will probably be used in the cath lab. I think it is very cool, but what is the indication? A bridge to what? Recovery after MI? After cardiogenic shock? A lot of those patients need longer support… What is exciting is the next generation of miniaturized blood pumps. That is what will revolutionize things… When there is low enough risk with a device that it can be implanted in patients with NYHA Class II heart failure, that is a huge population of patients and will have huge potential impact on society. The devices are not there yet, but they are close."
- "I disagree with how the company is running the trial. It is cumbersome to find a patient for the trial. The device will eventually get through (the FDA approval process), but it is slow. They are excluding too many patients. The company wanted to look good for investors, so they restricted entry to patients not that sick – but it is rescue technology. They've only enrolled mainly at one site so far."
- "In Europe we see that after the initial 10 Impellas, hospitals are not re-ordering. It doesn't give enough support…Impella is not good for cardiogenic shock…And the 5.0 needs a surgical cut-down, so the interventional cardiolo-gist can't use it without a surgeon."

CARDIACASSIST's HeartMate II

Surgeons questioned about LVAD use were primarily using HeartMate II. They described it as an improvement over earlier devices, a more friendly technology, though still not perfect. Today HeartMate II is used in 64 hospitals in the U.S. and more than 2,000 have been implanted.

What's exciting on the horizon? An expert said, "Centrifugal force pumps by HeartWare and Terumo. The problem is that HeartMate II is so successful that it is hard to get anyone to use the other devices."

ROBOTS: INTUITIVE SURGICAL's da Vinci – Too expensive for today's economy and cardiac interest has waned

It's not a good environment for robot sales, with hospital budgets under pressure.

- *Dr. Field, the consultant:* "You (surgeons) ask for a lot of (new technology)…The robot (da Vinci) has no market return whatsoever. They are very, very costly at a time when hospitals have no money."
- *Kentucky:* "We have a robot, but I don't see new buyers getting one now."

- *Dr. Chitwood, who has been a proponent of da Vinci:* "Hospitals on the margin will delay any (large) purchases. Private hospitals are dependent on revenue generated from endowments, stock portfolios, etc. That's what gave them the boost to buy things like a CT scanner or a robot. I think the slope may go lower but not fall off a cliff."
- *Arizona:* "I'm negative on da Vinci. Too much training is required, there are too few applications, and percutaneous valves will replace much of the (cardiac) need…I can't justify buying it just for cardiac surgery, and there is not even enough reason to use urology's robot. But it is interesting."
- *Colorado:* "I trained in cardiac surgery with the da Vinci, but I decided it was a technology looking for a purpose and stopped. Probably cardiac surgery isn't its role. The main reason to have one is to advertise it, but we don't do that. It would be false advertising. But it is excellent for urology."
- *Pennsylvania thoracic surgeon:* "I've removed mediastinal tumors in three patients. Our use is very limited, but thoracic use is increasing. It is good for small spaces, but there is not a big advantage in lung cancer."

In addition, most cardiac surgeons questioned at STS said they are unimpressed with the performance of the robot for cardiac procedures. Dr. Chitwood said there are hospitals in Cleveland, Houston, Atlanta, and Cincinnati doing a lot of procedures with the robot, "We have now gone from pioneers to early adopters…Every month people are getting trained, and it is included in resident training…Cardiac surgery (with the robot) won't take off as it did in prostate surgery…Working in the pelvis is easier than in the heart, and prostate cancer is a more prevalent disease process. I tell people you can start a cardiac program two ways: buy a robot and let it collect dust while you get volume up, or develop a multi-specialty program with urology and gynecology and lay out a plan, with everyone using it so it gets sufficient utilization. Then, eventually get another for each specialty."

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