

Winter 2014

Dallas-Leipzig Valve 2014

AORTIC STENOSIS

DEGENERATIVE MITRAL
REGURGITATION

FUNCTIONAL MITRAL
REGURGITATION

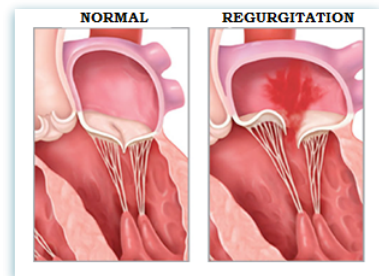
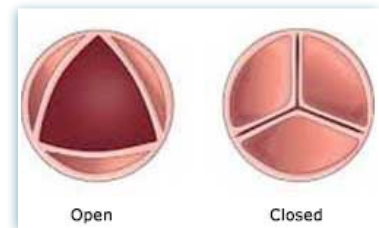
DALLAS-LEIPZIG
ALVE

Westin Galleria, Dallas, Texas • December 10-12, 2014

NEWSLETTER

Dallas-Leipzig Valve Conference - Key Takeaways

- ▶ Trend to reduce cost - move transcatheter valve procedures out of the hybrid OR and under conscious sedation
- ▶ The future of TAVR - improved durability, smaller device profile, new technologies, new indications, cerebral embolic protection, improved imaging, valve-in-valve
- ▶ Mitral is complicated, multidimensional, multicomponent apparatus rather than simply a valve
- ▶ Mitral Regurgitation is recognized to be two types - primary (degenerative, DMR) is a mitral valve issue and secondary (functional, FMR) is a ventricular problem
- ▶ TMVR is coming in the spotlight, yet there is only one mitral solution (the MitraClip from Abbott Vascular) that serves a very small population of DMR patients
- ▶ General anesthesia with TEE will be around for a while
- ▶ 3D Echo is gaining grounds
- ▶ The heart team is recommended under AHA/ACC guidelines and if disregarded, treatment will not get reimbursed



Aortic valves are from
Mars and mitral valves
are from Venus!



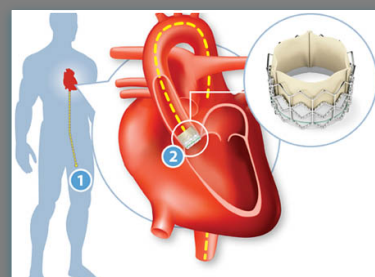
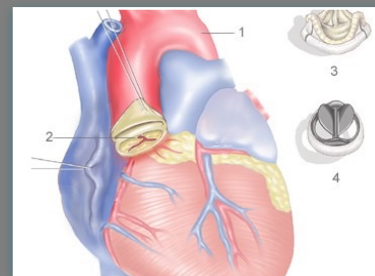
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In Detail

- ▶ Biennial event organized by a core team of doctors at the Heart Hospital Baylor Plano, Plano, TX and the Leipzig Herzzentrum, Leipzig, Germany ¹
- ▶ Hands-on, very educational event with a lot of networking opportunities
- ▶ Three days packed with the most current trends, techniques and technology for heart valves
- ▶ Cardiac surgeons, interventionalists and echocardiographers from US, Germany, Canada, UK and other countries
- ▶ Live cases from both Leipzig Herzzentrum and Baylor Heart Hospital
- ▶ Main topics discussed:
 - ▶ aortic and mitral valves are fundamentally different and thus, different treatment approaches are needed
 - ▶ transcatheter aortic and mitral options
 - ▶ anesthesia options
 - ▶ valve-in-valve
 - ▶ echocardiography choices
 - ▶ the future of the hybrid OR
 - ▶ The Heart Team

Key Takeaways in Pictures



Aortic Stenosis

- ▶ Calcifications visible and valve treatment straightforward
- ▶ Minimal incisions and transapical approaches applied more often

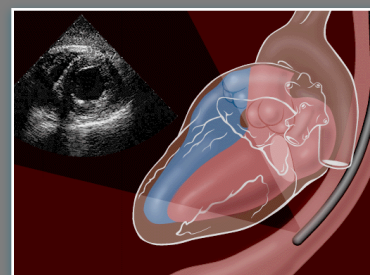
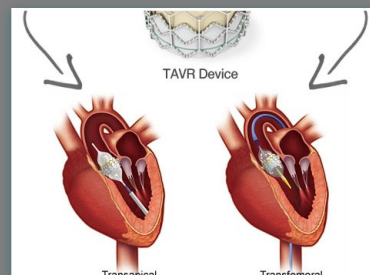
TAVR

- ▶ Becoming an established treatment option for aortic stenosis
 - ▶ the technology is improving
 - ▶ team training is key
- ▶ Good news - echocardiography data up to 5 years indicate no valve deterioration and excellent hemodynamics
- ▶ It is an alternative procedure for high-risk patients
- ▶ Extensive clinical research - randomized studies and post-market registries
- ▶ Standardized endpoint definition
- ▶ More expensive than conventional valve surgery

¹ 2014 Agenda at <http://www.dallasleipzigvalve.org/agenda-2014>

- ▶ Multiple delivery ways - transfemoral (TF) route; transapical (TA) access; direct aortic (DA) or transaortic; and subclavian or axillary sites ²
- ▶ Predictors of survival:
 - ▶ renal disease, especially, end-stage renal disease, was a good predictor of survival - almost 1/2 of the patients who received TAVR and dialysis, didn't survive to 1 year
- ▶ Para-valvular regurgitation:
 - ▶ improve screening
 - ▶ measurements based on CT alone may not be very accurate
 - ▶ device designs have improved to allow better sizing and more accurate placement
- ▶ Stroke after TAVR - improve patient selection, sizing, filter devices and operator experience
 - ▶ if stroke rates are reduced by using different cerebral protection devices, TAVR for moderate risk patients, younger patients etc. can become an option
 - ▶ is neuroimaging via diffusion-weighted magnetic resonance imaging (DW-MRI) going to become part of the TAVR procedure?
- ▶ The future is improved durability; new technologies; new indications
- ▶ Still not clear if this technology is good for lower risk patients

Key Takeaways in Pictures



Anesthesia

- ▶ The pivotal clinical studies thus far have been conducted with general anesthesia (GA) and transesophageal echocardiography (TEE)
- ▶ Conscious sedation is new with less data:
 - ▶ Pro:
 - ▶ cost - with conscious sedation the procedure costs \$29,000 less
 - ▶ faster discharge
 - ▶ Con:
 - ▶ can't do TEE - less use of contrast for renal dysfunction patients with TEE
 - ▶ less clinical data

Mitral Apparatus

Clearly two different diseases:

- ▶ Primary mitral regurgitation (DMR) - degenerative, diseased valve
 - ▶ if done right, repair is the best treatment option
 - ▶ if repair is done before symptoms, there is a good chance for no further interventions

² M. Mack, 2012, <http://interventions.onlinejacc.org/article.aspx?articleid=1207357>

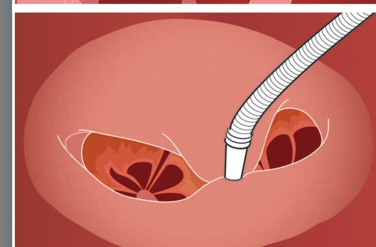
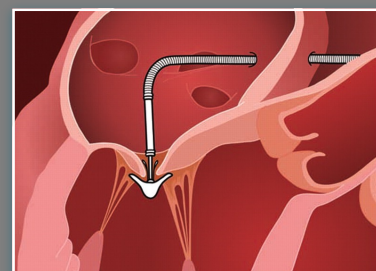
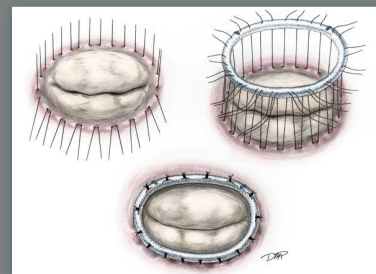
- ▶ the strive should be to leave 0 MR post-operatively
- ▶ 40 cases/year are needed for a surgeon to gain experience in mitral valve surgeries³
- ▶ Secondary mitral regurgitation (FMR) - ventricle issue, usually due to ischemic event
 - ▶ thus far, undersized mitral ring repair was the standard surgical method for FMR, however, it is not addressing the root cause of FMR
 - ▶ repair has recurrence
 - ▶ the end-points cannot be same as for DMR or other cardiac issues; 1-year survival is not indicative - these patients may be alive, but in worsened condition
- ▶ Minimally invasive mitral valve repair is getting more attention - Abbott's MitraClip is still the only mitral transcatheter valve repair approach approved in the US for inoperable DMR patients
 - ▶ MitraClip may also work for FMR, but it is now under clinical investigation to demonstrate safety and effectiveness
- ▶ Other approaches to MR are needed and in development:
 - ▶ due to complexity of the disease many failed, many in early stage, and yet many need to make changes to the first generation devices before further clinical studies
 - ▶ valve replacement other than MitraClip
 - ▶ left ventricle remodeling
 - ▶ chords corrections

Valve-in-Valve

Lessons Learned

- ▶ Crucial to determine the true ID of the failing valve
 - ▶ surgical valves are sized differently than transcatheter ones
 - ▶ once leaflets are put in, the true ID is reduced by 1-3 mm
- ▶ Sometimes, it is hard to see the valve on a CT - depends on the current valve materials
- ▶ Global valve-in-valve registry
- ▶ When planning a follow up procedure:
 - ▶ think of possible future interventions - patient age and overall health conditions matter - take into account what will happen in 5-7 years
 - ▶ if the patient is young - leave valve-in-valve option for later

Key Takeaways in Pictures



³ Christina Vassileva 2014 J Thor Cardiovascular Surg 2014 S0022: [http://www.jtcvsonline.org/article/S0022-5223\(14\)01290-2/fulltext](http://www.jtcvsonline.org/article/S0022-5223(14)01290-2/fulltext)

Echocardiography

- ▶ Transesophageal echo (TEE) is a good tool and all TAVR clinical studies were done using it
- ▶ 3D Echo:
 - ▶ new guidelines
 - ▶ is not the new standard, but a great tool to provide better sizing and placement
 - ▶ optimal sizing using 3D echo
 - ▶ since it required general anesthesia, it may be phased out
- ▶ Transthoracic echo (TTE)
 - ▶ gives blurry images, but under conscious sedation

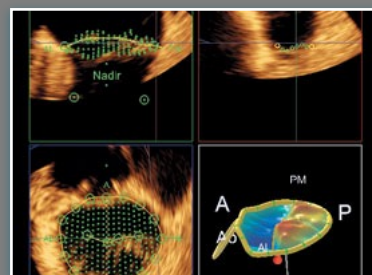
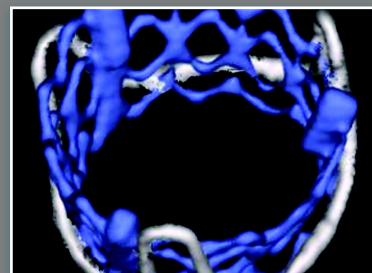
The Future of the Hybrid OR

- ▶ Costly facility - \$3-5 million for hybrid OR
- ▶ Unanimous agreement that TAVR and TMVR should not be done in a catheterization lab.
 - ▶ sterility in the cath lab is lower
 - ▶ generally not equipped with surgical supplies
 - ▶ lighting in cath lab is unacceptable for the surgeons
- ▶ Hybrid OR has established itself as a must till now, but data show that a hybrid cath lab may be a good alternative:
 - ▶ need to have the ventilator, lighting etc.
 - ▶ the ability to transfer to an OR within 20 min is a must
 - ▶ even if it is not hybrid OR, cardiac surgeon must be in the cath lab
- ▶ Currently in the US, 60%/40% in favor of hybrid OR, but the future would likely shift 15%/85% for hybrid cath labs

The Heart Team - new or tried and true?

- ▶ Unanimous - patients with complex heart diseases, especially with diseased valves should be treated by a team of heart specialists: surgeons, interventionalists, echocardiographers, anesthesiologists
- ▶ This was the case in the past and is still the case, but now it is also required as part of reimbursement
 - ▶ AHA/ACC 2014 guidelines ⁴
 - ▶ if you decline the heart team, you will not get reimbursed
- ▶ Shared burden and liability
- ▶ Valve clinic

Key Takeaways in Pictures



⁴ 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: <http://content.onlinejacc.org/article.aspx?articleid=1838843>