

#### Successes and Challenges with Transcatheter Valve Therapies in Heart Failure

Anita W. Asgar MD, MSc, FRCPC Montreal Heart Institute

## **Conflict of Interest Disclosures**

- Grants/research support: Abbott
- Consulting fees: Abbott, Medtronic, Edwards Life Sciences, Gore
- Speaker fees: Abbott
- Other:



## **Defining the Problem**

- What is the prevalence of valvular heart disease in the heart failure population?
- What is the prevalence of MR in acute decompensated heart failure?

• What is the prevalence of tricuspid regurgitation?



### **Secondary MR is Common and Predicts Poor Prognosis**





Presence of significant MR has an impact on prognosis regardless of etiology of LV dysfunction



### **Prevalence of MR in ADHF**

- From 2005 to 2014, there were 17,931 weighted ADHF hospitalizations of which 49.2% had an LVEF <50% and 50.8% an LVEF >50%.
- Moderate or severe MR was more frequent in LVEF <50%</li>
- Moderate or severe MR was <u>more likely in</u> <u>females than males</u> regardless of LVEF
- Higher MR severity was independently associated with *increased 1-year mortality* in those with an LVEF <50% (OR: 1.30 [95% CI: 1.16 to 1.45].





## **Tricuspid regurgitation**

- Prevalence of tricuspid regurgitation in the community is largely unknown
- Study performed of community residents in Olmstead county, Minnesota undergoing echo from 1990-2000 (n=16,380)
- Prevalence of TR was found to increase with age
- All-cause TR was frequent (0.55% with 95% • [CI]: 0.50 to 0.60)
- Prevalence was approximately <u>one-fourth</u> of all left-sided valve disease, <u>similar to the</u> prevalence of aortic stenosis.





J Am Coll Cardiol Img2019;12:433-42

## **Tricuspid regurgitation**



Types of TR were divided as follows:

- Congenital: CHD resulting in TR (eg. ASD)
- Organic TR: structural valve disease
- Functional TR associated with Left sided valvular heart disease (including previous valve replacement/repair)
- Functional TR associated with Left sided ventricular dysfunction (LVEF < 50%)</li>
- Isolated TR: pulmonary pressures < 50mmHg</li>
- TR with Pulmonary Hypertension: PASP > 50mmHg



### Epidemiological Study of Tricuspid Regurgitation After Cardiac Transplantation



Transpl Int 35:10197. doi: 10.3389/ti.2022.10197

## **Defining Success and Remaining Challenges**

- What have we learned about the use of transcatheter valve therapies (TEER) in heart failure?
  - MitraClip
  - Procedural success
  - COAPT
- What challenges remain?
- What do we still struggle to understand?



## **Transcatheter Edge-to-Edge Repair (TEER)**

- Over 150,000 implants worldwide of MitraClip device
- Fourth Generation (G4) device currently available with 4 sizes to permit optimal clip selection for patients
- Procedural success defined as reduction in MR to 2+ or less
- Optimal procedural success defined as reduction in MR to 1+ or less
- Edwards Pascal device in IDE trials, currently unavailable and unapproved in Canada INSTITUT DE









## **Contemporary MitraClip™ Outcomes:**

Improvements in MR Reduction with New Generation MitraClip<sup>™</sup> Systems



 $^1\mbox{Kar}$  et al. TCT 2020, Late Breaking Clinical Trial Presentation  $^2\mbox{Lim}$  et al. ACC 2018 Presentation

## **Primary Effectiveness Endpoint** <u>All Hospitalizations for HF within 24 months</u>





### **Mortality benefits of Therapies for HFrEF**



Gountesyre Joann Lindenfeld

VANDERBILT WUNIVERSITY

## **Defining Success and Remaining Challenges**

- What have we learned about the use of transcatheter valve therapies (TEER) in heart failure?
- What challenges remain?
  - Is replacement better than repair?
  - Can we use TEER on the tricuspid valve?
- What do we still struggle to understand?



## **TMVR: Tendyne Mitral Valve**



#### **VALVE DESIGN**

- Tri-leaflet, porcine bioprosthetic valve
- Outer frame contoured to mitral annulus
- Multiple valve sizes and profiles to address broad range of patient anatomies

#### **TETHER DESIGN**

- Separates sealing from securement
- Enables full retrievability

#### APICAL PAD

• Placed over ventricular access site



#### SUMMIT NEW TRIAL DESIGN: AS APPROVED BY THE FDA ON AUGUST 2, 2019



\*2017 ASE Guidelines \*Resulting in severe MR, severe MS, or mixed disease (moderate MR / moderate MS) \*For both Primary and Secondary MR



### **TriClip™ Transcatheter Tricuspid Valve Repair System**

#### **Procedural Information:**

- Performed under General Anesthesia with TEE Guidance
- Femoral venous access
- Specifically designed to treat the tricuspid valve
- Procedural times: 1.5-2.5 hours
- Early discharge the following day

#### Keys to Success:







### **TRILUMINATE** Device Effectiveness

#### TR Reduction Sustained at 1 Year (n=62)



#### 70% Moderate or Less at 1Y



#### 87.1% showed at least 1 grade improvement at 1 Year



### **TRILUMINATE** | Symptomatic Improvements at 1 Year

#### **Sustained Symptomatic Improvement**

**Continued KCCQ Improvement** 





### **TRILUMINATE** 40% Reduced Hospitalization at 1 Year

**Procedural Success Predictive of Mortality and** 

**Reduced Hospitalization Rate** 





## **Defining Success and Remaining Challenges**

 What have we learned about the use of transcatheter valve therapies (TEER) in heart failure?

• What challenges remain?

- What do we still struggle to understand?
  - Which patients will benefit most from mitral and tricuspid therapies?
  - When do we treat?



# COAPT vs. MITRA-FR: 12-MONTH DEATH OR HF HOSP MITRA-FR COAPT



## **Patient Selection and Therapy Decision Making**



European Heart Journal (2020) 41, 1932–1940

CARDIOLOGIE DE MONTRÉAL

## Summary

- Valvular heart disease, particularly mitral and tricuspid regurgitation are common in the general population and in those patients with heart failure.
- Transcatheter valve repair (TEER) for the mitral valve is well-established with good outcomes and excellent safety.
- Tricuspid valve regurgitation is increasingly recognized to have a deleterious outcome on patient survival. Preliminary results with TEER on the tricuspid valve are encouraging.
- Patient selection remains challenging to optimize outcomes.
- New replacement devices beg the question whether replacement will be superior to repair.





## **Backup slides**

## **Tendyne TMVR Procedure**





- Repositionable for optimal valve • placement
- Contoured valve fits securely • within native anatomy
- Apical pad placed over • ventricular access site

## **TRILUMINATE** Reverse RV Remodeling at 1 Year

At 1 Year, the reduction of TR was associated with significantly decreased right atrial and ventricular dimensions demonstrating reverse remodeling, with significant improvement in right ventricular function.



