



Treatment of LVOT Obstruction

“Prevention and management in the context of TMVR”

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

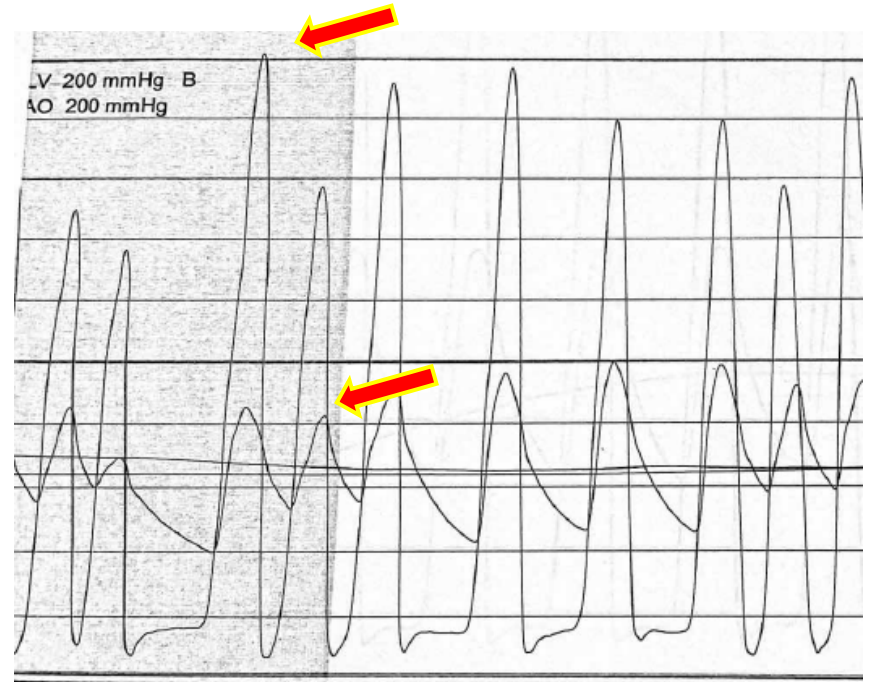
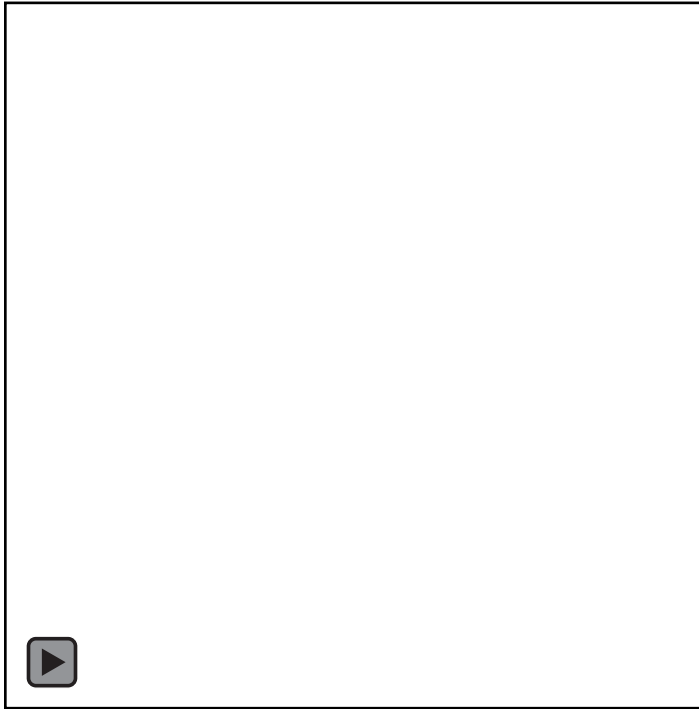
- Institutional Research Grant Support

Company

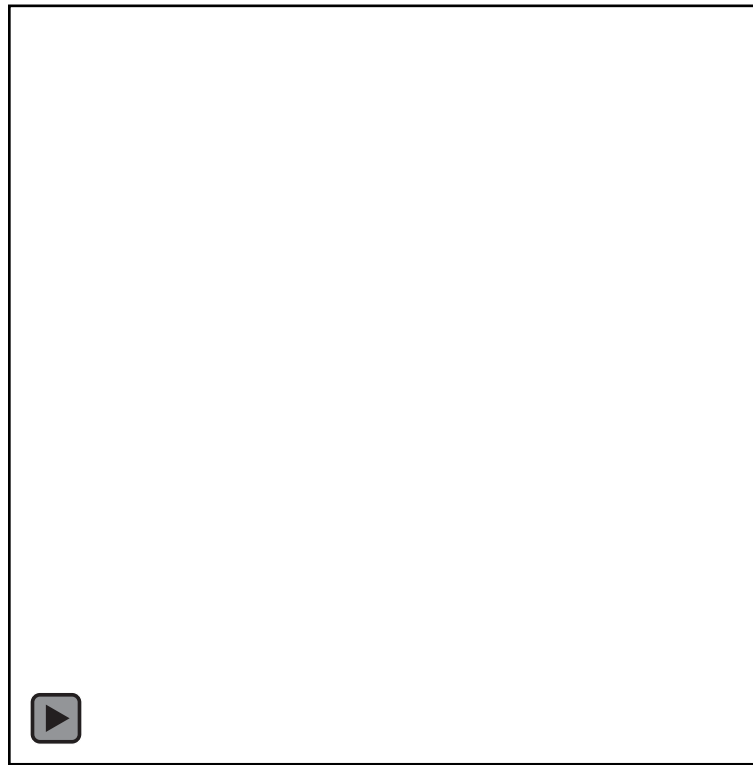
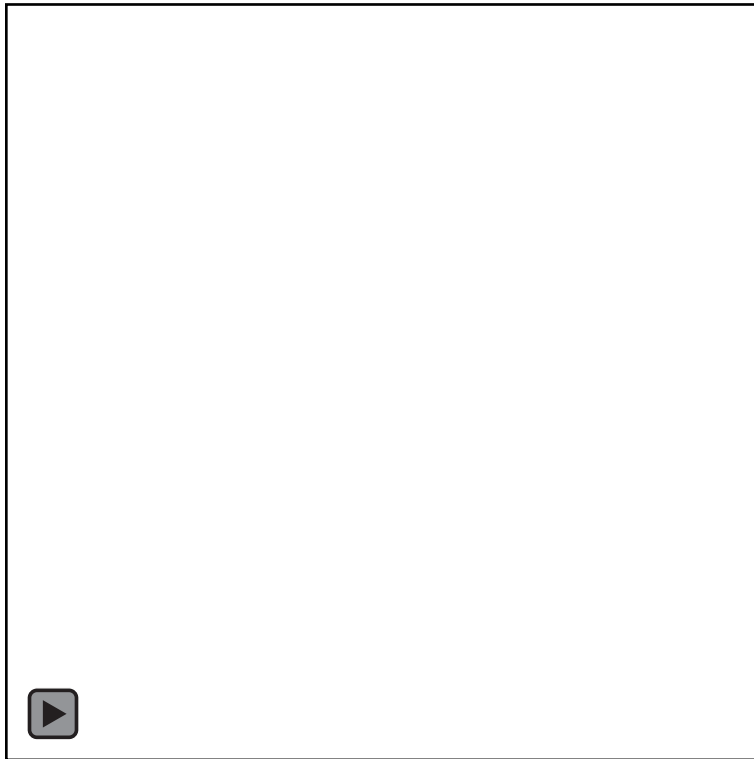
- Edwards Lifesciences

Learning Objectives

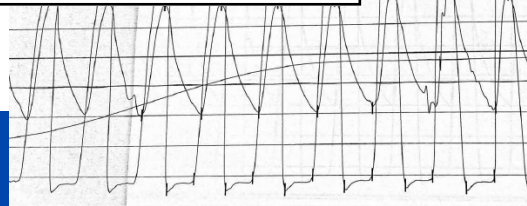
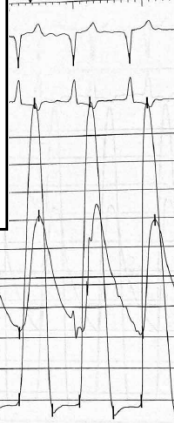
- To illustrate the mechanism of TMVR-induced LVOT obstruction.
- To review outcomes of preemptive septal modification to enable TMVR.
- To describe contemporary strategies to prevent TMVR-induced LVOT obstruction.



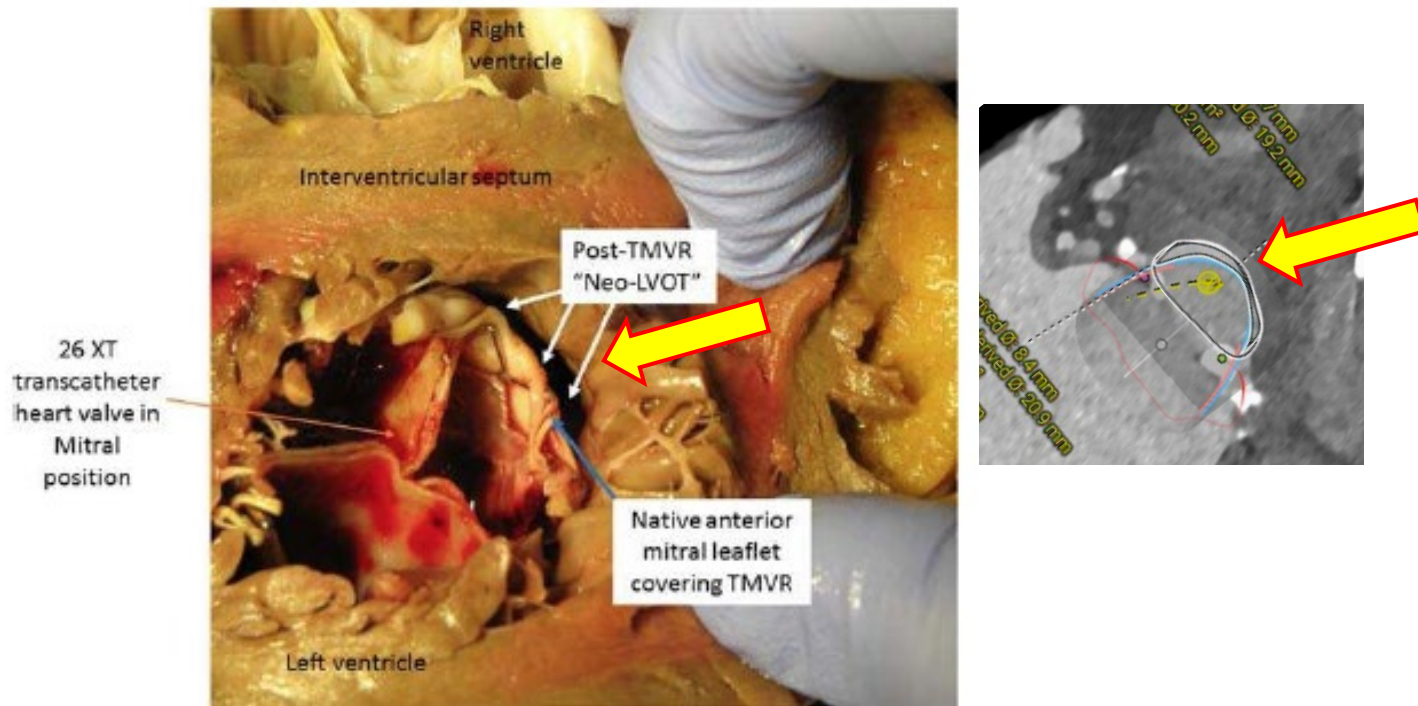
8-7-2014



sure Calculations 1:35:08 PM



LVOT Obstruction



We learned the concept of Neo-LVOT after TMVR the hard way in 2014, before it was defined by CT

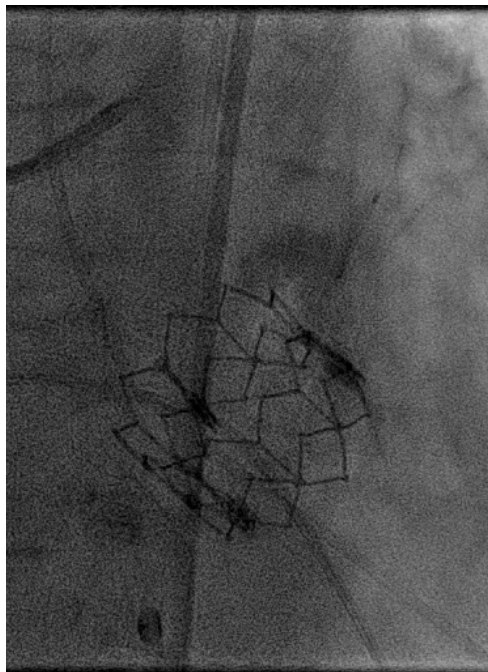
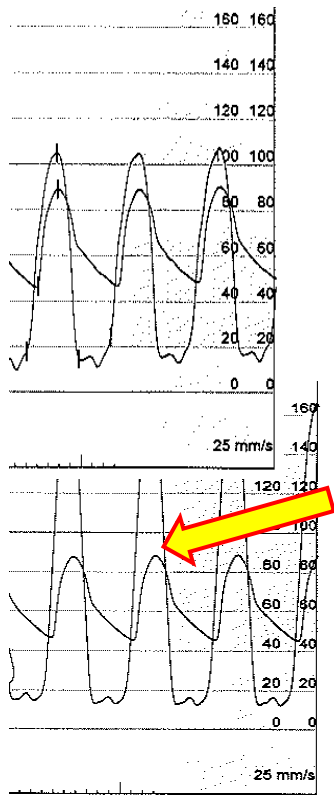
TMVR in MAC Global Registry (n=116)

Multivariate Cox Regression Analysis

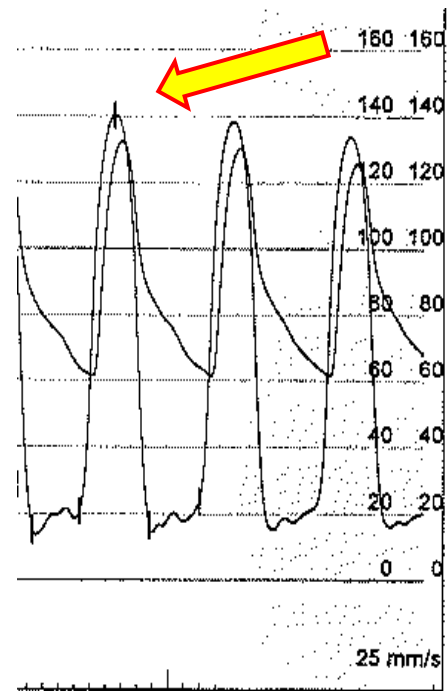
Independent Predictors of 1-Year Mortality

	HR	95% CI	p
Technical success (yes vs no)	0.22	0.09-0.51	0.0005
LVOT obstruction	2.63	1.14-6.06	0.0227

Alcohol Septal Ablation to treat acute LVOTO after ViMAC



Courtesy of Dr. William O'Neill



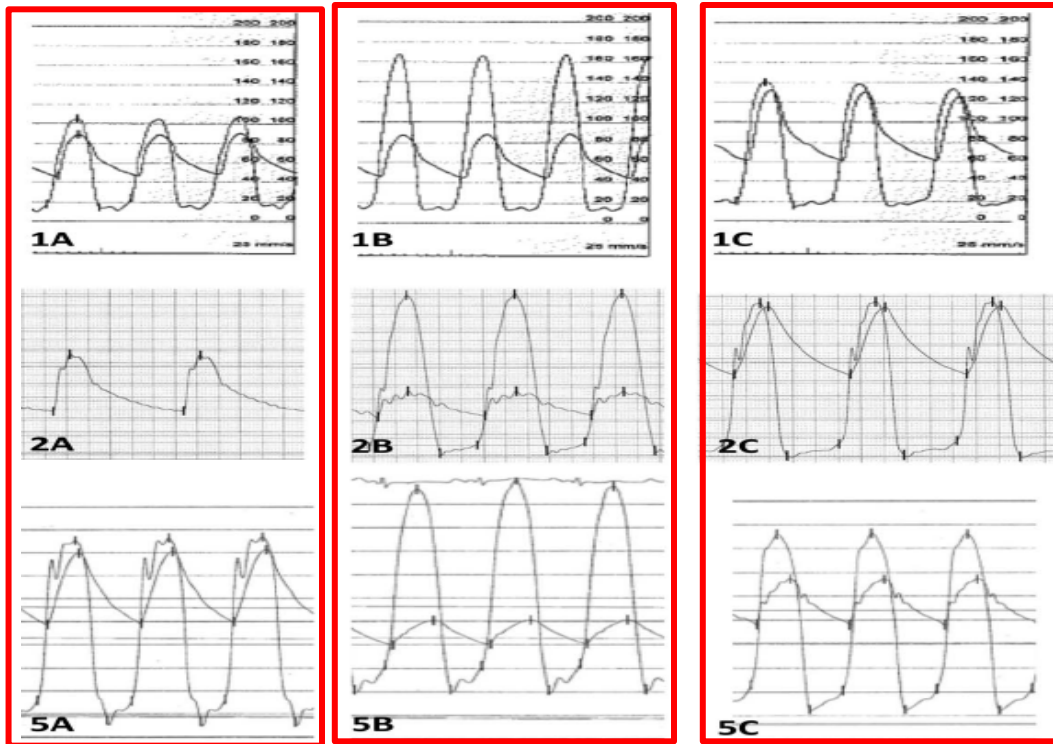
After Alcohol Ablation

Alcohol Septal Ablation as bail out for LVOTO

6 patients treated with alcohol ablation as bail out for LVOTO post TMVR

Reduction in LVOT gradient in all 6 patients

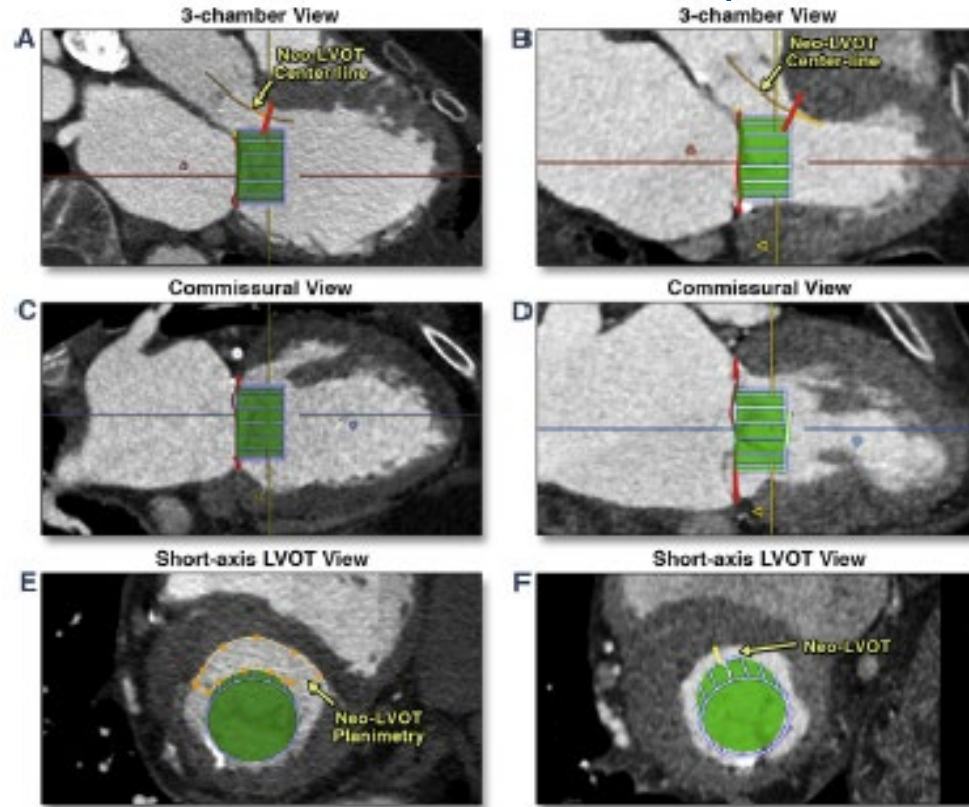
4 were discharged from the hospital after successful rescue



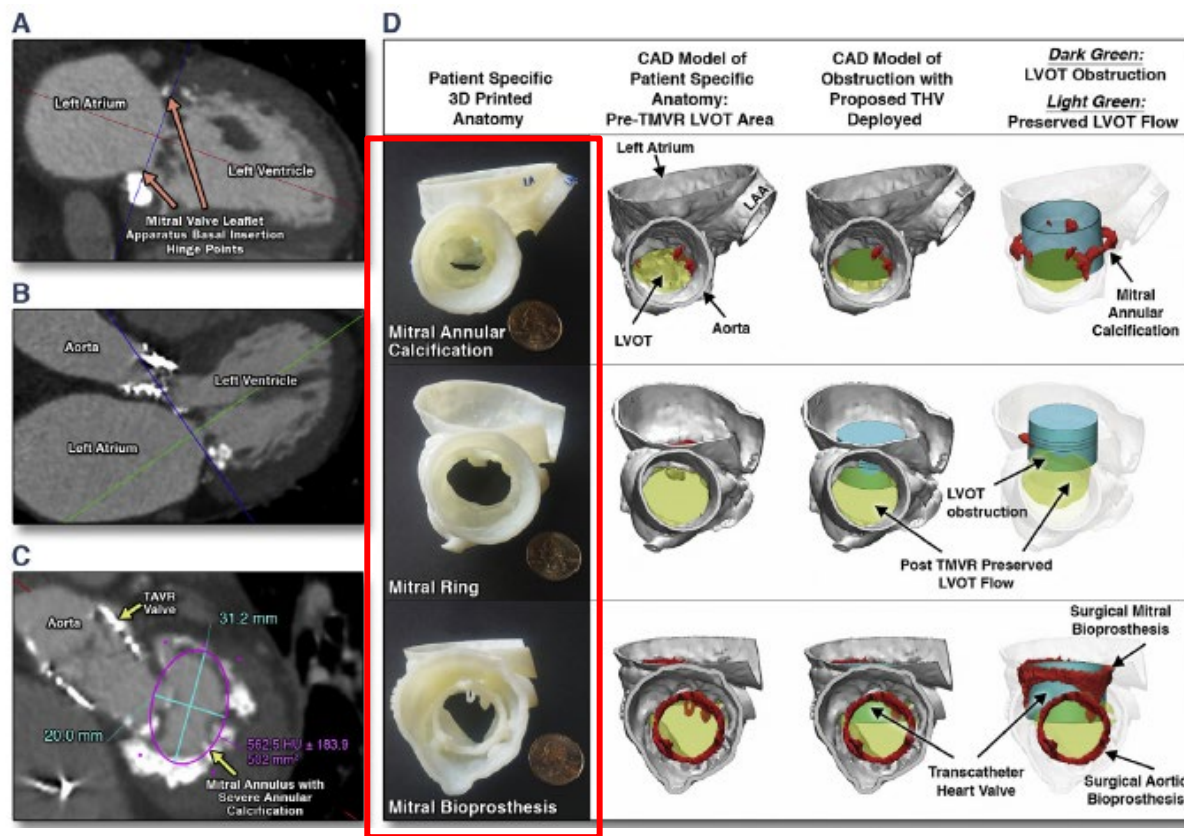
*LVOT gradient recurred the following day due to suspected septal edema

Predicting LVOT Dimensions

“Neo-LVOT concept”

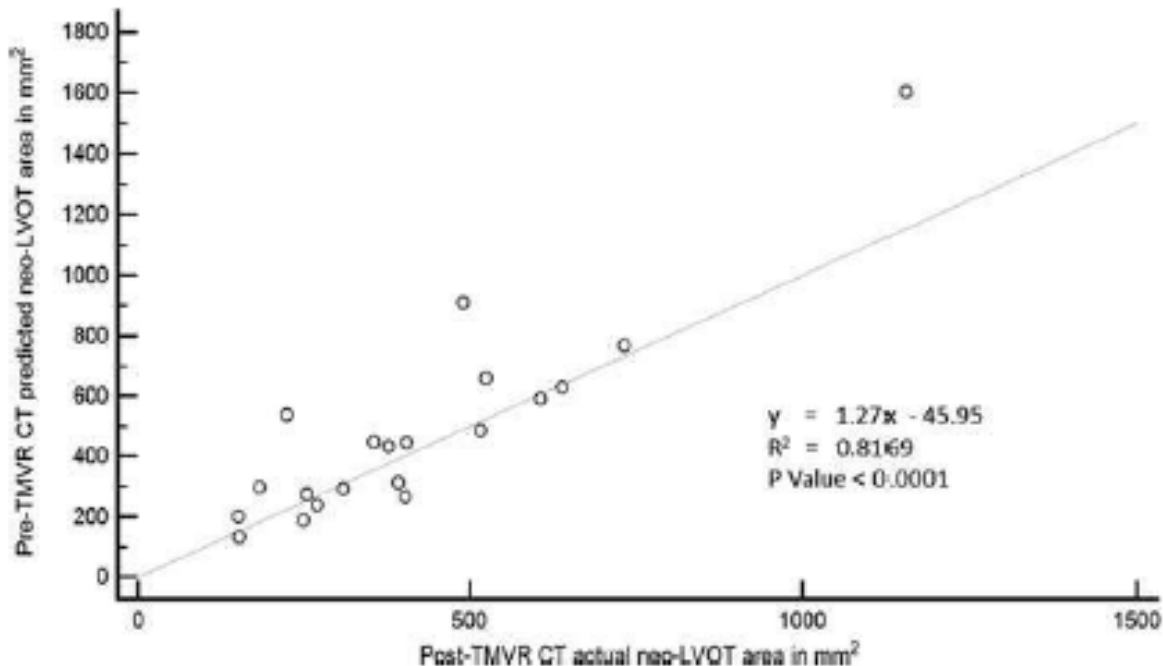


Predicting LVOT Obstruction with Computer-Aided Design & 3D-printing



Predicted vs Actual Neo-LVOT post-TMVR

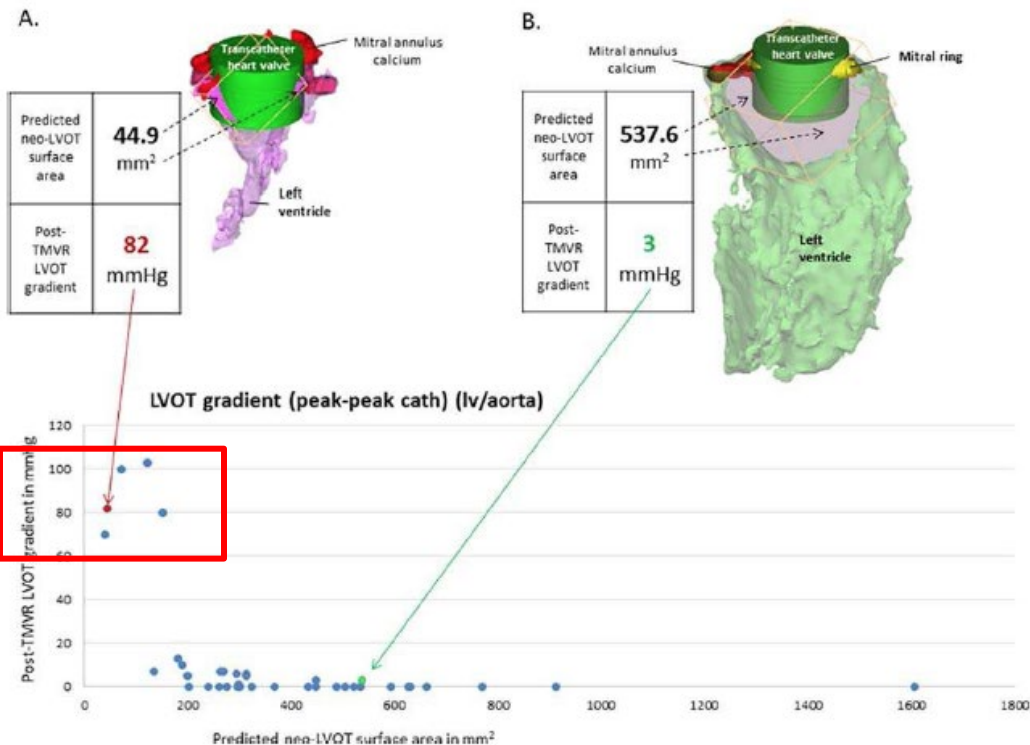
n=38 pts (MViV= 17 ,MViR= 12, ViMAC= 9), 7 had LVOTO.



Depth of implantation and angle may affect actual Neo-LVOT

A Neo-LVOT <189.4 mm² had 100% sensitivity and 96.8% specificity to predict increase in LVOT gradient of ≥10 mmHg

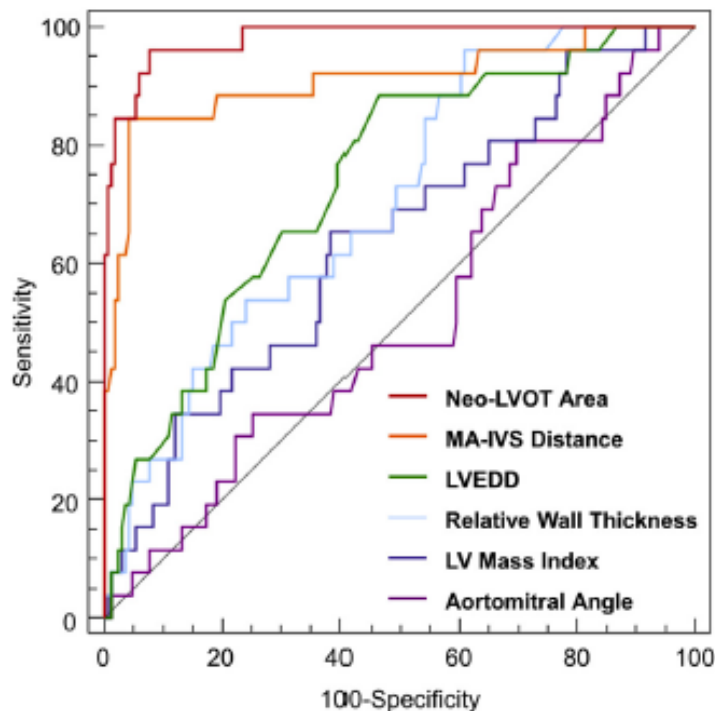
n=38 pts (MVIV= 17 ,MViR= 12, ViMAC= 9), 7 had LVOTO.



Neo-LVOT <189.4 mm²

Predictors of LVOT Obstruction after MViV, MViR and ViMAC

194 patients in the TMVR Registry (MViV=107, MViR=50, ViMAC=37)
Median age 76.(IQR 69-81) years, 54.1% female, 26 of 194 (13.4%) developed LVOTO.

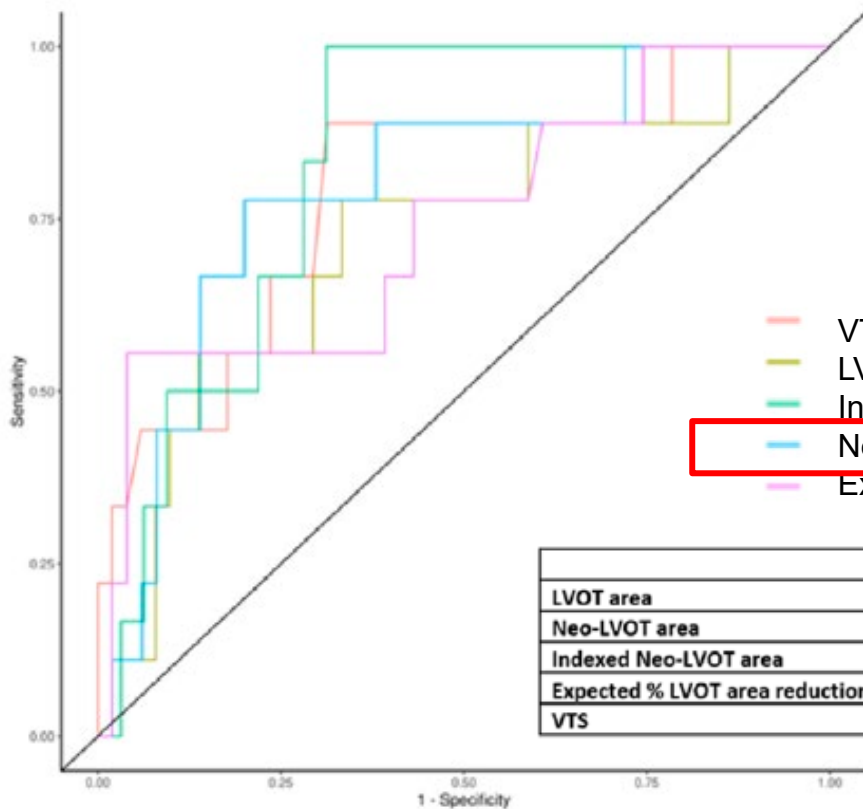


Neo-LVOT Cutoff <170 mm²

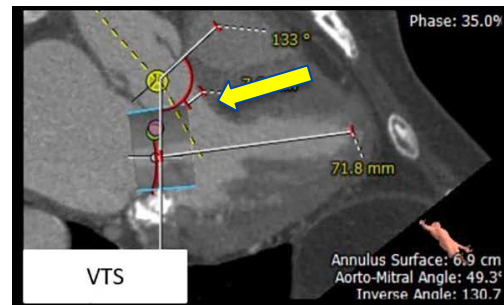
	AUC	Cutoff value	p value	Sensitivity	Specificity
Neo-LVOT Area	0.98	1.7	< 0.001	96.2	92.3
MA-IVS Distance	0.91	17.8	< 0.001	84.6	95.8
LVEDD	0.74	48	< 0.001	88.5	53.3
Relative Wall Thickness	0.70	0.38	0.001	96.2	38.9
LV Mass Index	0.64	105	0.02	65.4	61.1
Aortomitral Angle	0.51	—	0.92	46.2	41.1

Predictors of LVOT Obstruction after ViMAC

116 patients in the TMVR in MAC Global Registry of which 71 had optimal CT quality for analysis



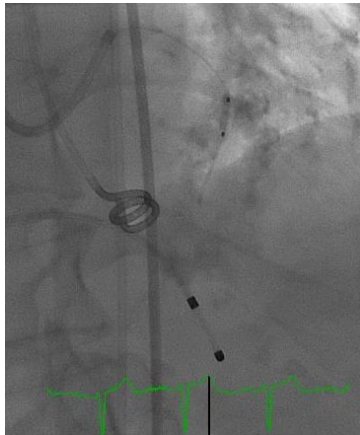
- VTS 5.5mm
- LVOT area 371 mm²
- Indexed Neo-LVOT area 127.5 mm²/m²
- Neo-LVOT area 173.4 mm²
- Expected % LVOT area reduction 63.5%



	AUC	Cutoff Value	Accuracy	Sensitivity	Specificity
LVOT area	0.76	371.5 mm ²	0.54	0.67	0.87
Neo-LVOT area	0.86	173.4 mm ²	0.81	0.8	0.87
Indexed Neo-LVOT area	0.83	127.5 mm ² /m ²	0.73	0.68	1
Expected % LVOT area reduction	0.80	63.5%	0.91	0.62	0.96
VTS	0.86	5.5 mm	0.68	0.72	0.68

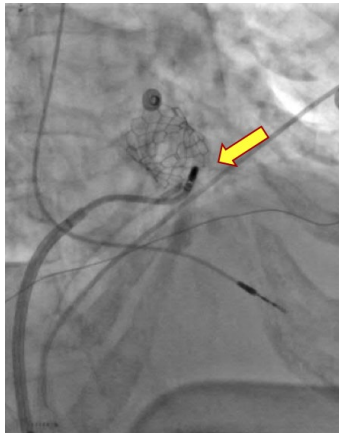
How to Prevent LVOT Obstruction

Septal Reduction Strategies



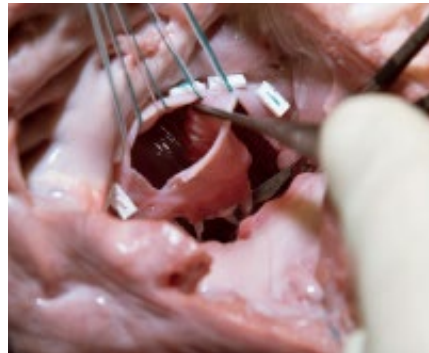
Alcohol
Septal Ablation*

Concept generated in MITRAL trial

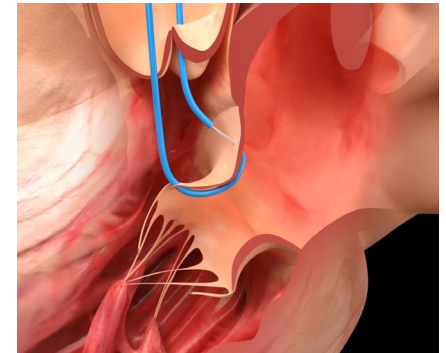


Radiofrequency
Septal Ablation**

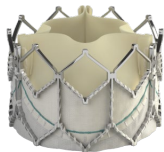
Anterior Leaflet Strategies



Surgical resection
(MITRAL and SITRAL trials)



Percutaneous laceration
(LAMPOON trial)

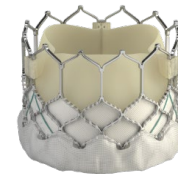


SAPIEN XT

MITRAL Trial

Mitral Impplantation of TRAnscatheter vaLves

91 patients extremely high surgical risk (STS PROM >15% or M&M >50%)



SAPIEN 3

Inclusion Criteria

NYHA II or greater

Valve-in-Valve
n=30

Severe MS (MVA ≤ 1.5 cm²)
At least Moderate-Severe MR

100% Transseptal

Valve-in-Ring
n=30

Severe MS (MVA ≤ 1.5 cm²)
At least Moderate-Severe MR

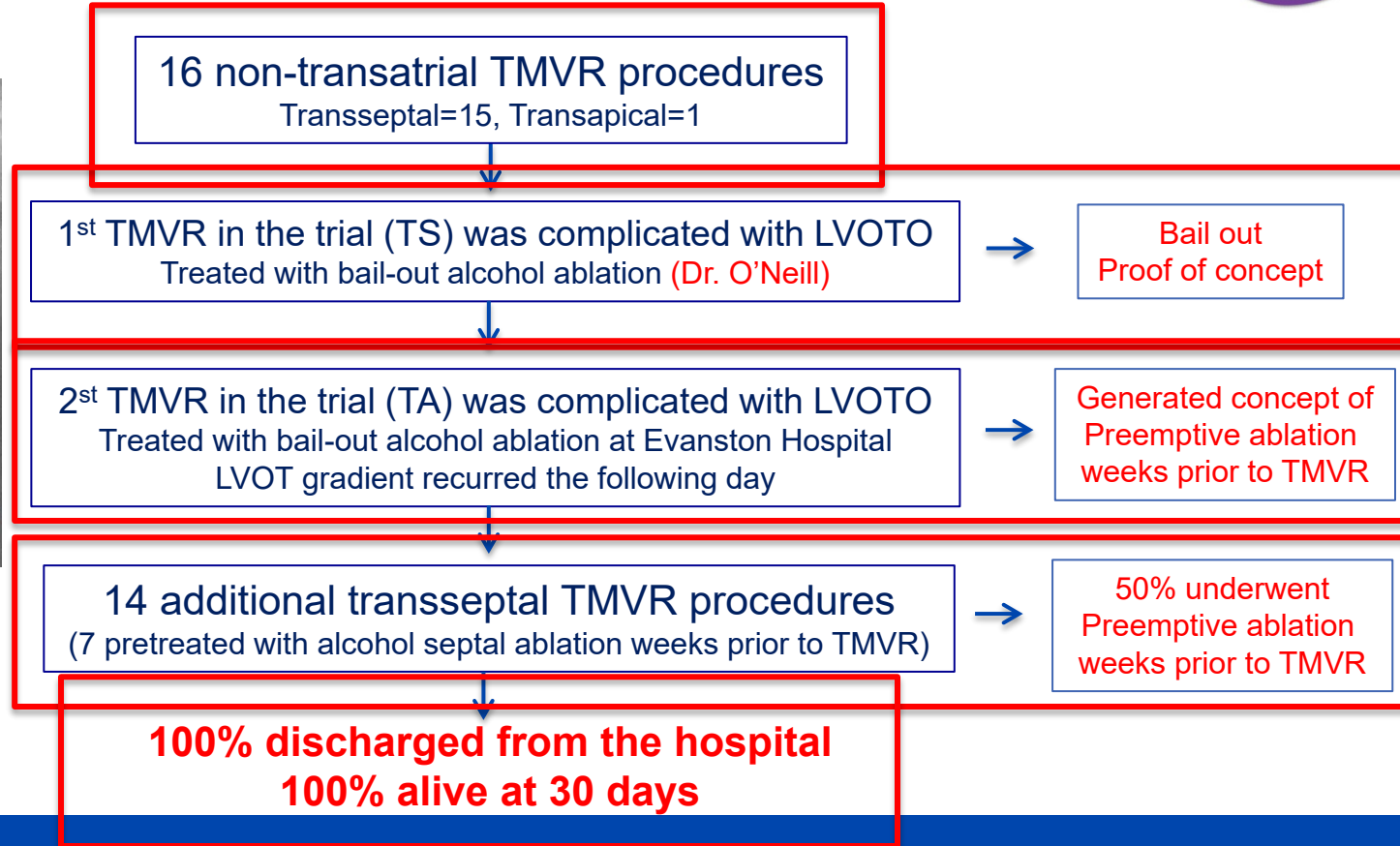
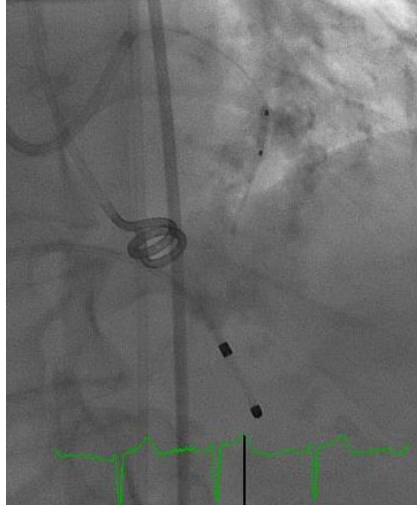
100% Transseptal

Native MV (MAC)
n=31*

Severe MS (MVA ≤ 1.5 cm²)
Severe MR + Moderate MS

15 (48.4%) Transseptal
15 (48.4%) Transatrial
1 (3.2%) Transapical

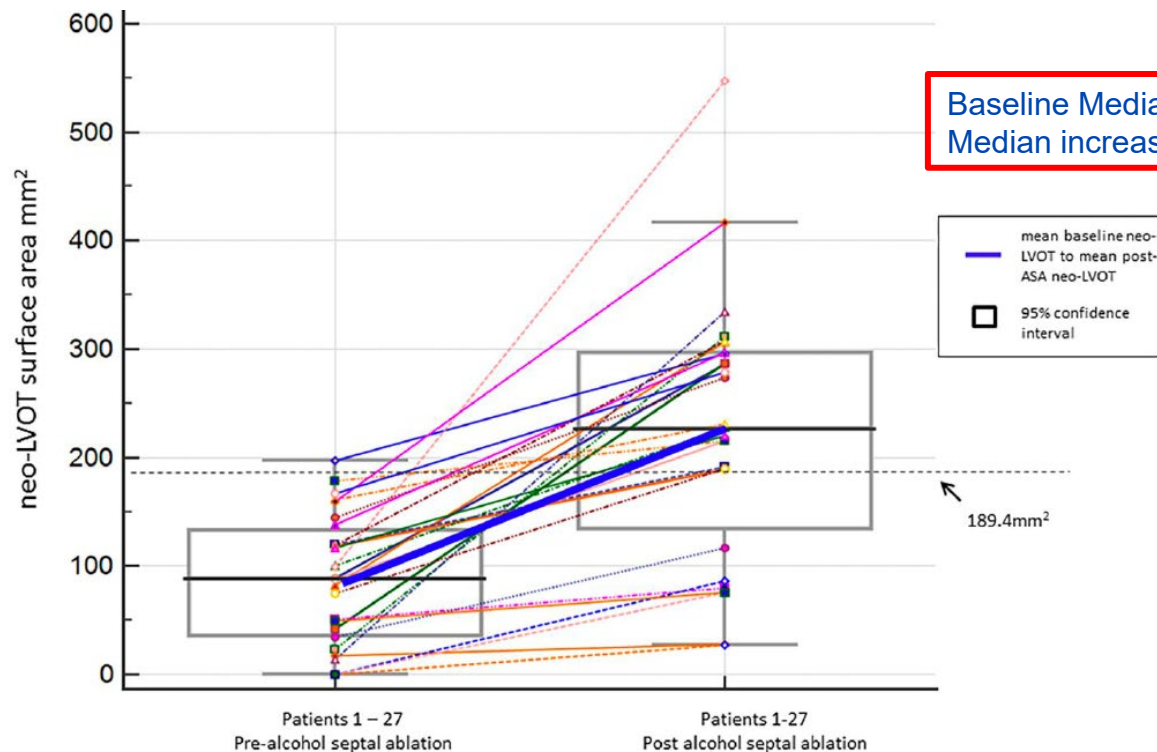
Role of Alcohol Septal Ablation



Pre-emptive Alcohol Ablation to Prevent LVOT Obstruction

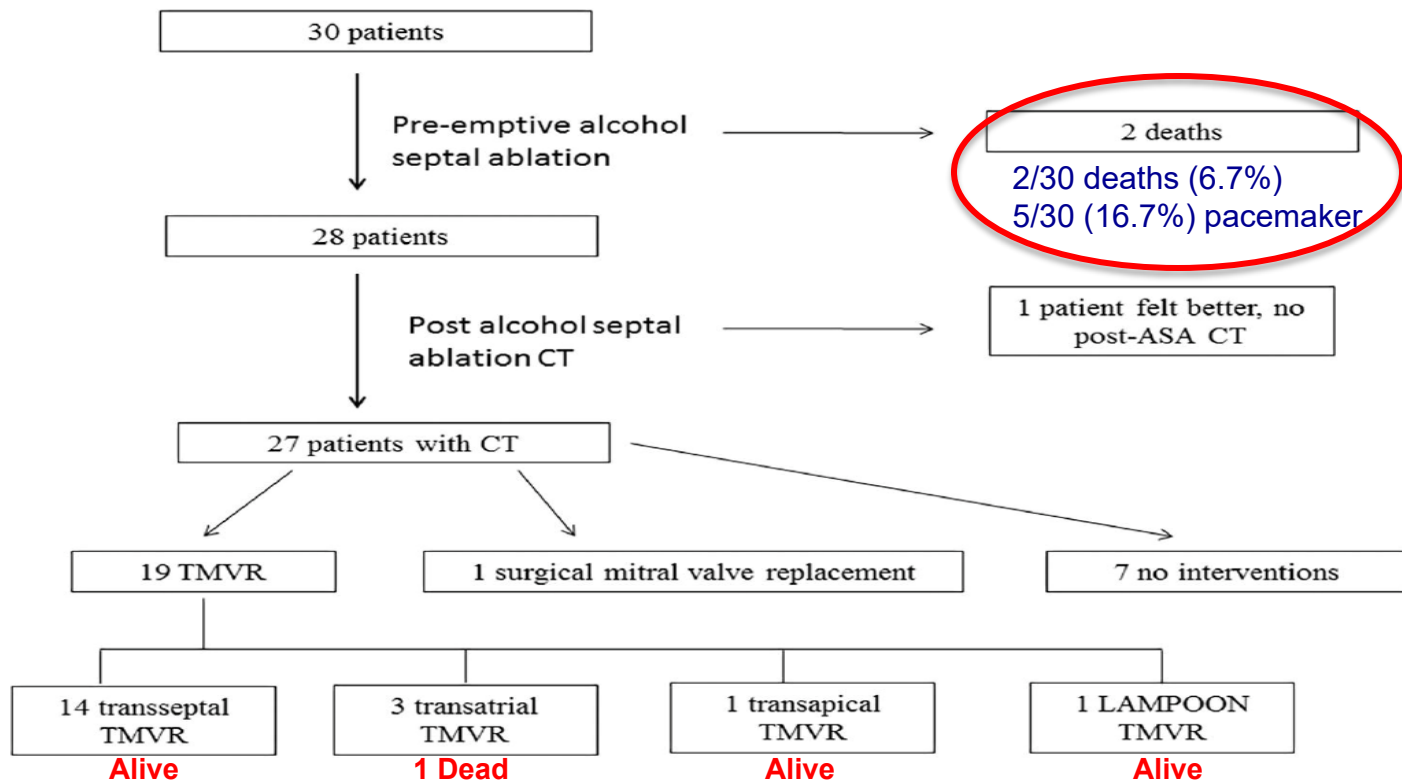
Early Clinical Experience in a Multicenter Observational First-in-Man Study

30 patients STS 7.2%, average 1.6 ± 0.7 ml alcohol, repeat CT 3-4 weeks later



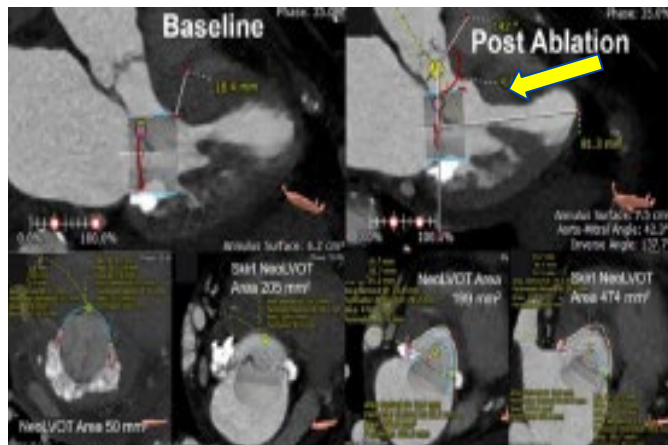
Pre-emptive Alcohol Ablation to Prevent LVOT Obstruction

30 day Outcomes



Pre-emptive Alcohol Ablation to Prevent LVOT Obstruction

22 TMVR patients vs 80 HOCM patients at Mayo Clinic



Septal thickness was less in the TMVR group compared to HCM patients and corresponding lower doses of alcohol were used in this group



Table 4. Computed tomographic characteristics before and after alcohol septal ablation.

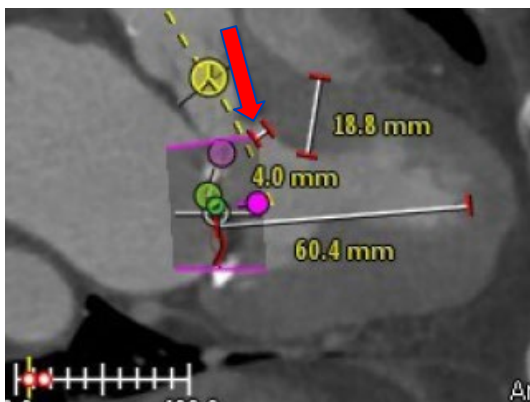
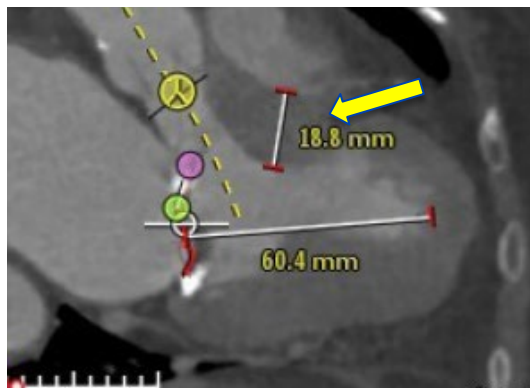
Computed tomography measurements	Before ASA	After ASA	Change	P value
Virtual valve frame to septum distance (mm)	2.8 ± 2.9	6.1 ± 3.2	3.2 ± 2.6	$<.001$
LVOT area (mm^2)	352 ± 79	456 ± 125	98 ± 88	$<.001$
Neo-LVOT area (mm^2)	135 ± 89	233 ± 111	97 ± 60	$<.001$
Dist neo-LVOT area (mm^2)	275 ± 95	357 ± 139	86 ± 109	.095

Table 5. Alcohol septal ablation procedural outcomes.

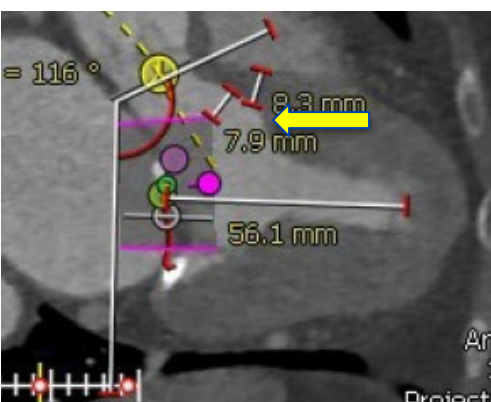
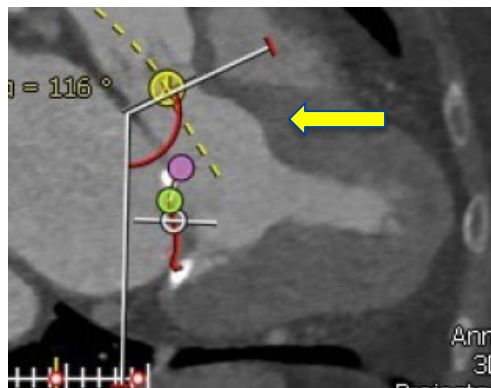
Outcomes at 30 days	HCM group N = 80	TMVR group N = 22	P value ^a
Complete heart block	14 (21)	7 (35)	.195
Major bleeding	3 (4)	0	
Sustained VT	0	0	
Stroke	0	0	
In-hospital mortality	0	0	
30-Day mortality	3 (4) ^b	0 ^c	

30 day Mortality= zero

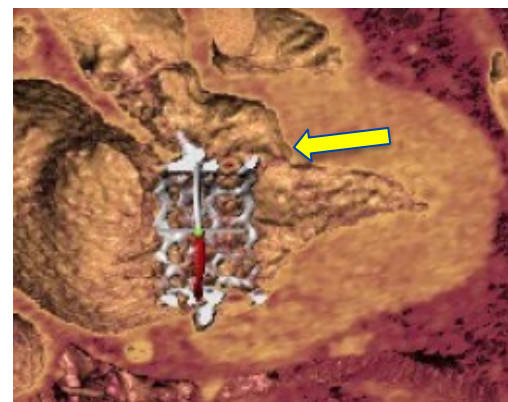
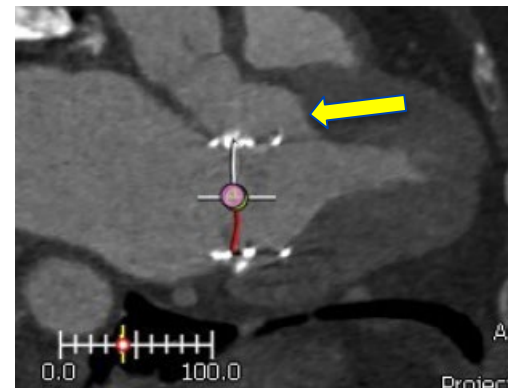
Preventing LVOT Obstruction with Alcohol Ablation



Baseline

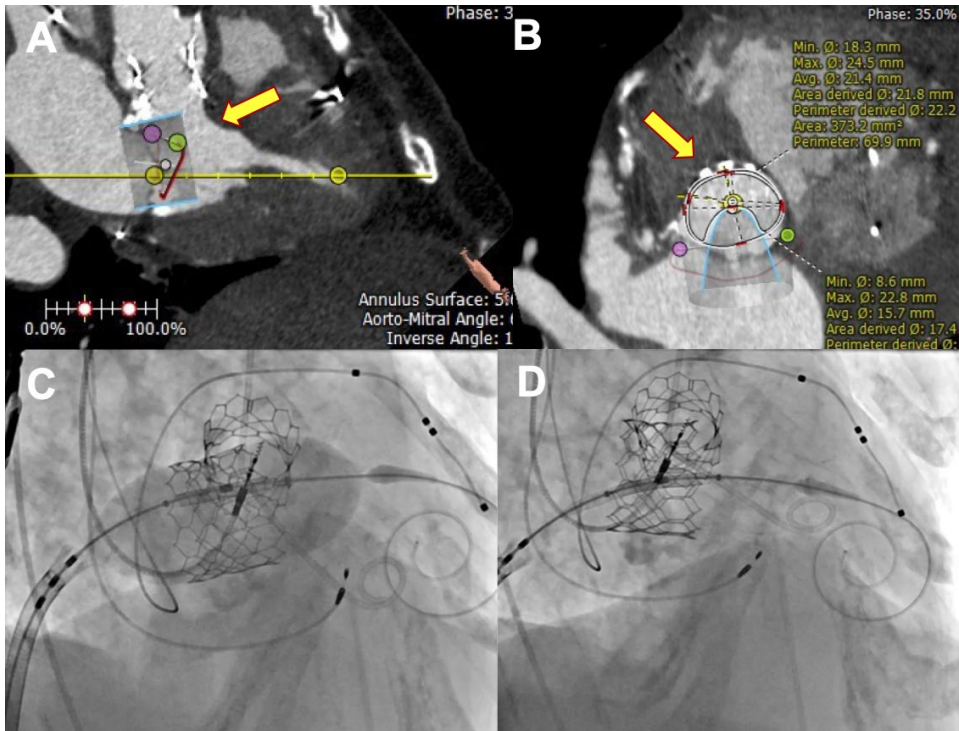
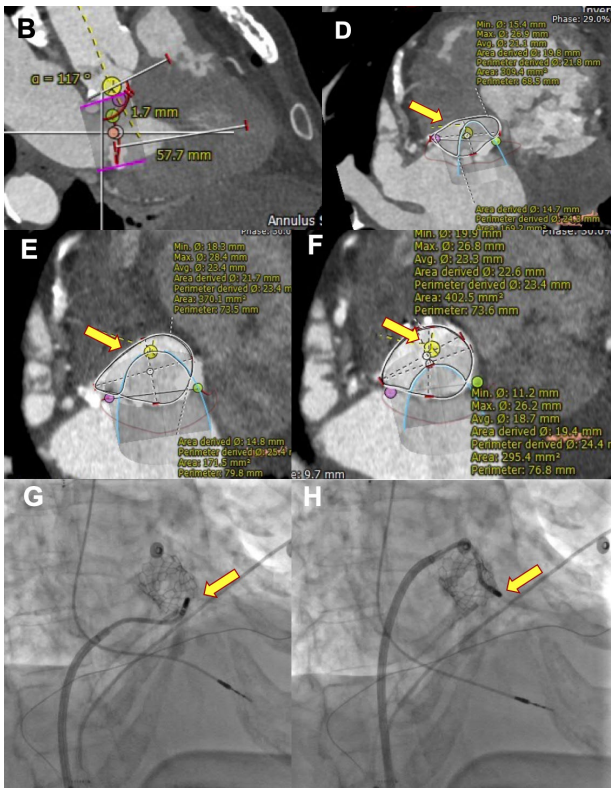


Post-alcohol ablation



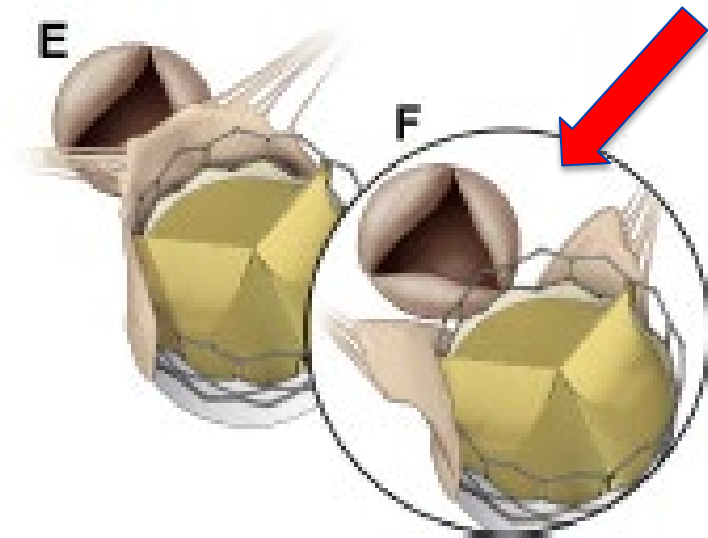
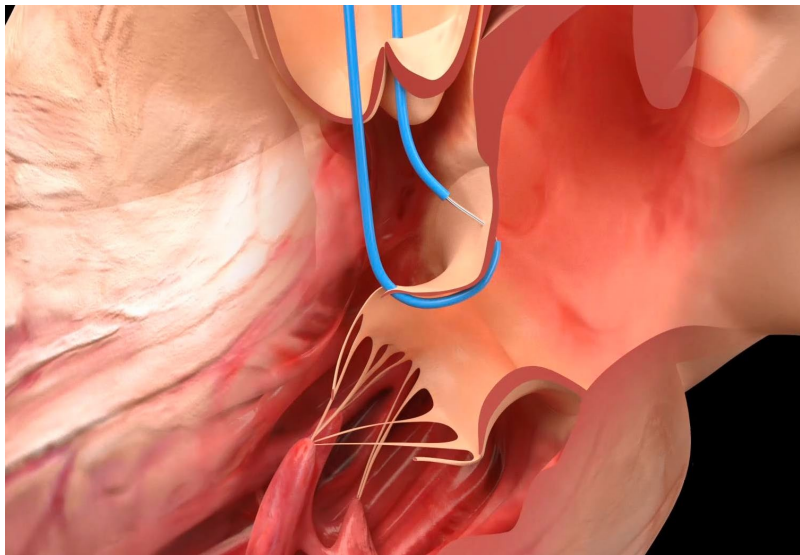
Post-TMVR

Preemptive Radiofrequency Ablation to Decrease risk of LVOTO after ViMAC “RADIO-TMVR”



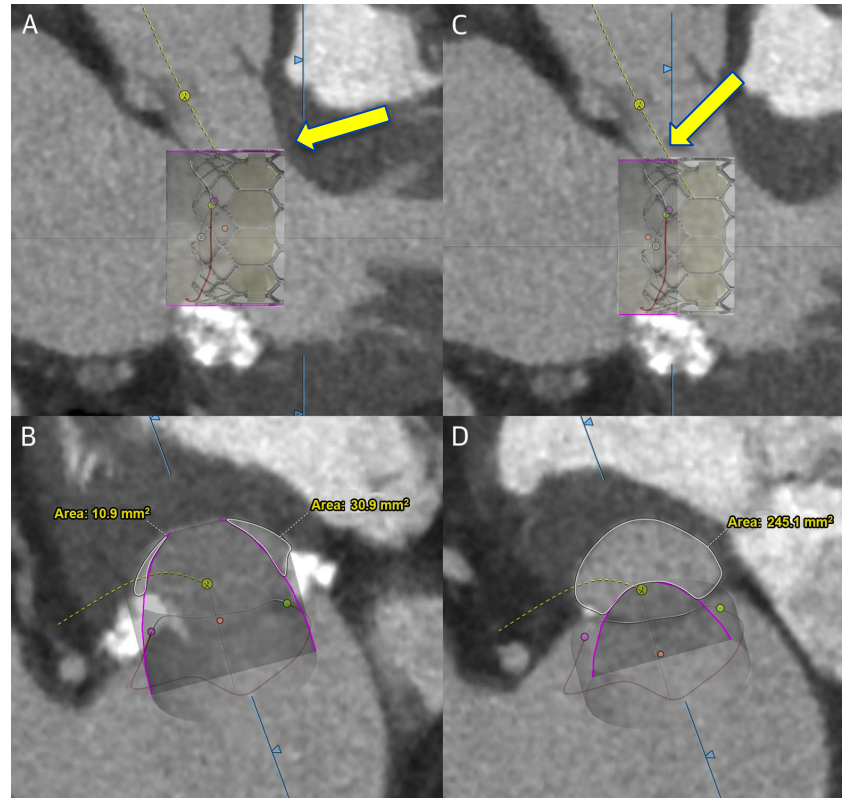
LAMPOON

Laceration of the Anterior Mitral Leaflet to Prevent Outflow ObststructionN



MAC (n=15) and MViR (n=15), STS 10%
30 day mortality 13.3% (2/15) in MAC arm

Neo-LVOT and Skirt Neo-LVOT



How to Prevent LVOT Obstruction

Neo-LVOT <200mm²



Skirt Neo-LVOT <200mm²



Consider septal reduction strategy
Alcohol or RF Ablation
SESAME?

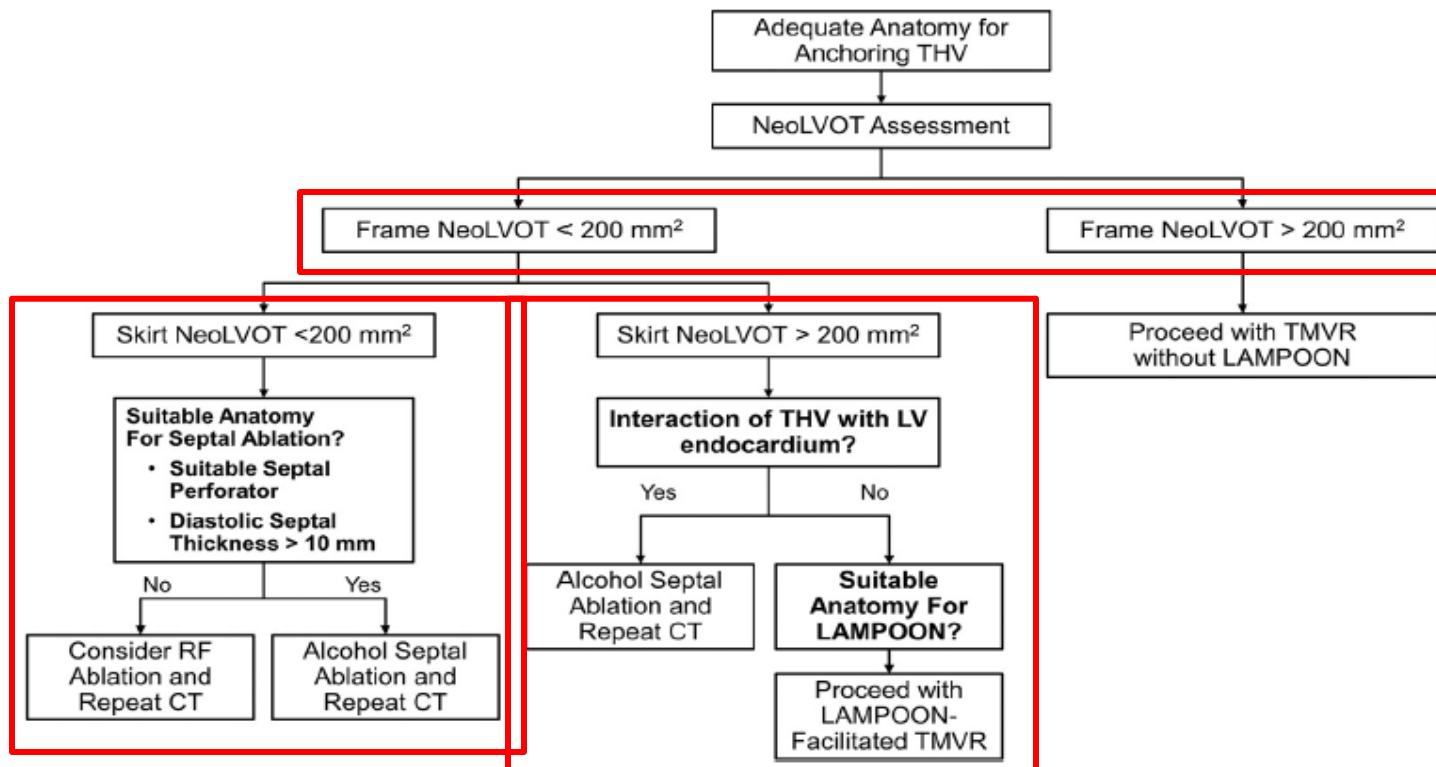
Skirt Neo-LVOT >200mm²



LAMPOON-Facilitated TS ViMAC

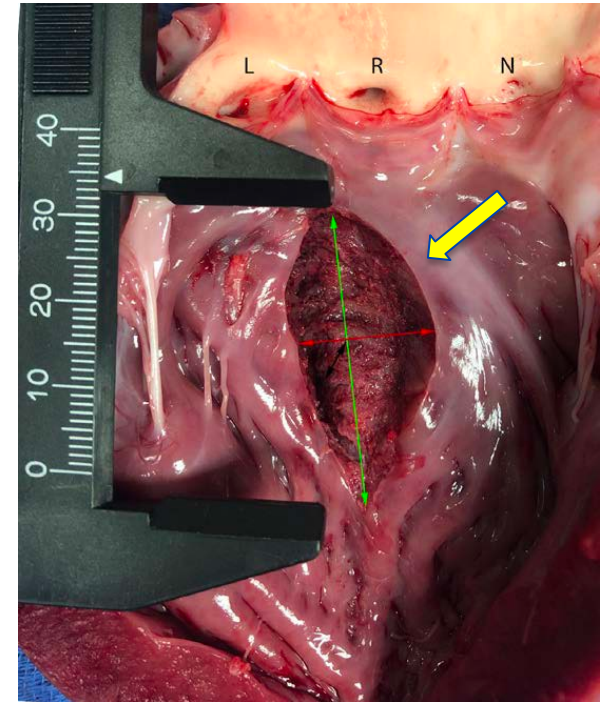
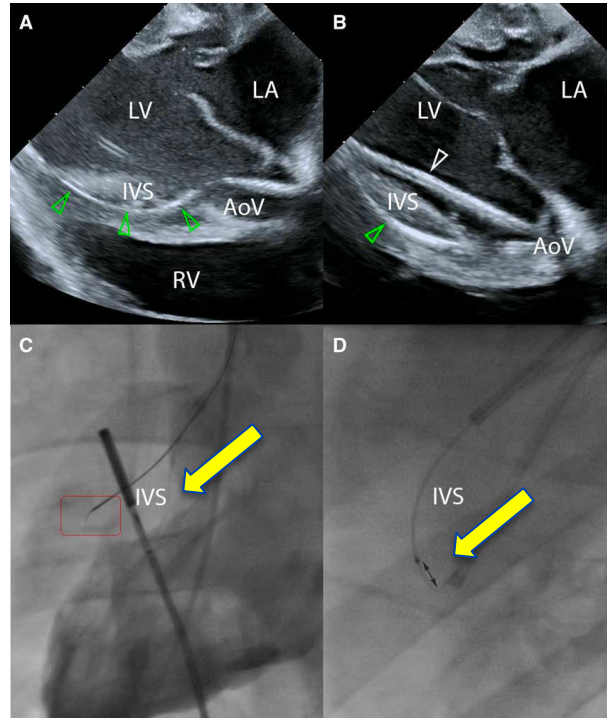
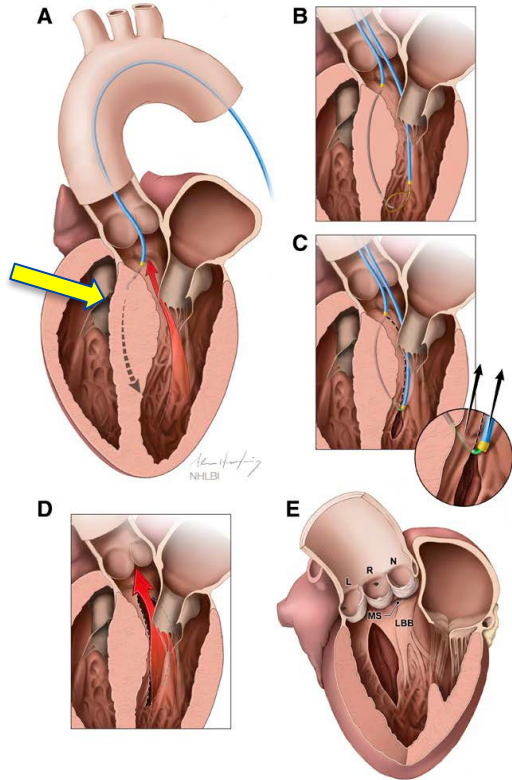
How to Prevent LVOT Obstruction

FIGURE 7 Algorithm for Management of LVOT Obstruction Risk Before TMVR



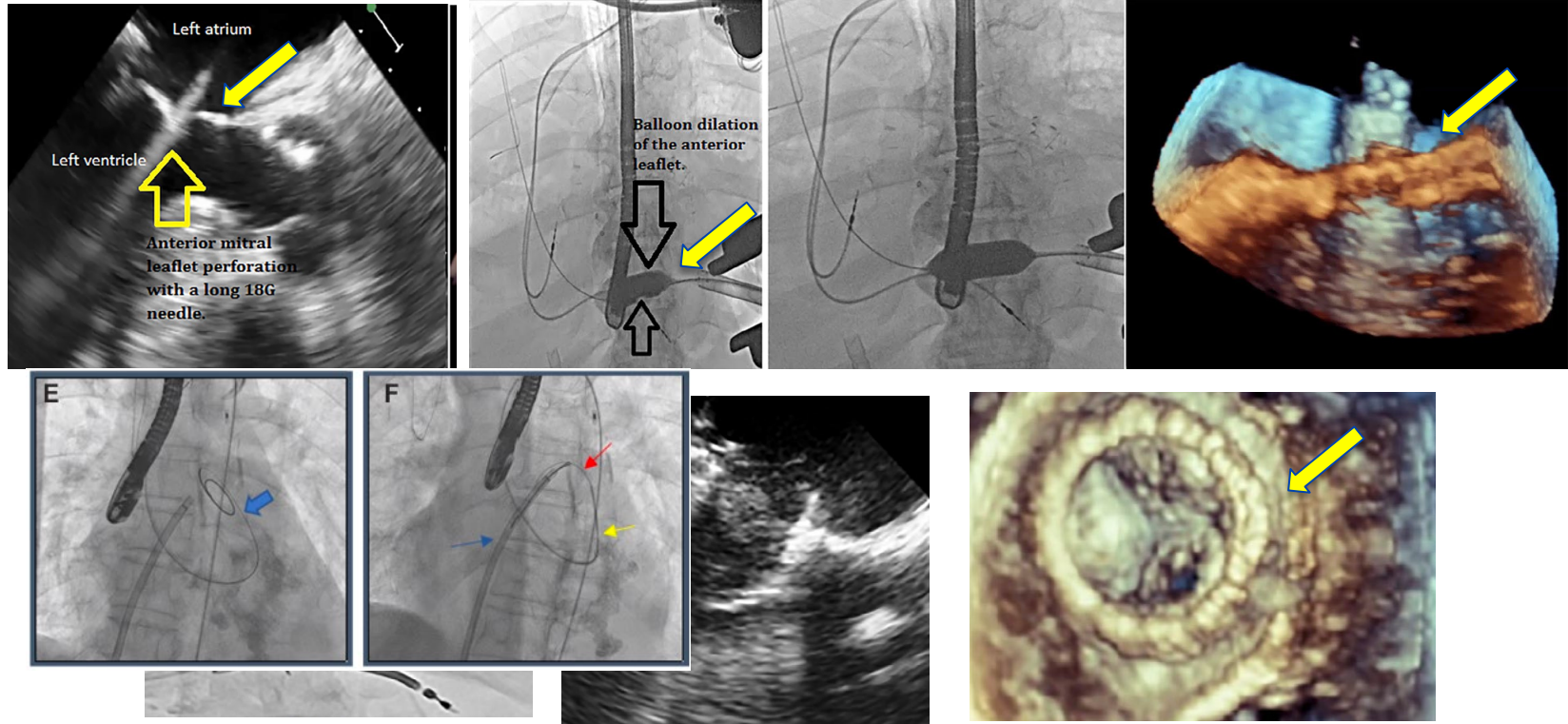
SESAME

SEptal Scoring Along de Midline Endocardium



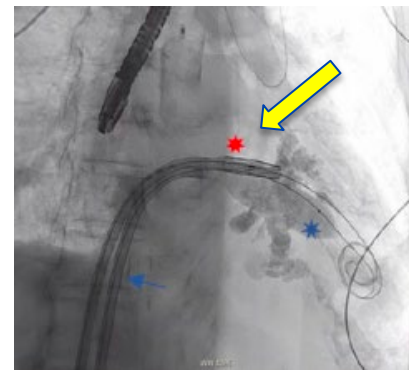
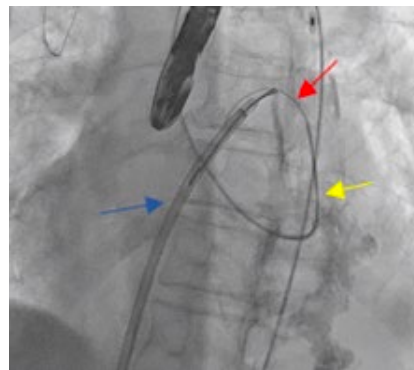
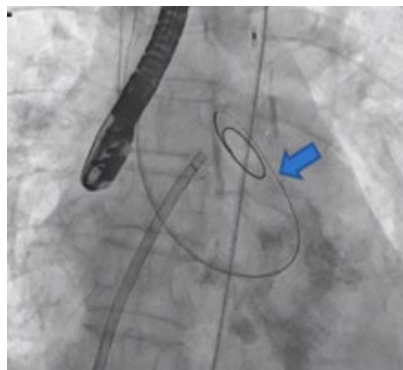
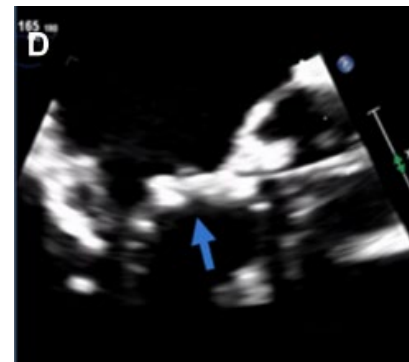
BATMAN

Balloon **A**ssisted **T**ranslocation of the **M**itral **A**nterior Leaflet



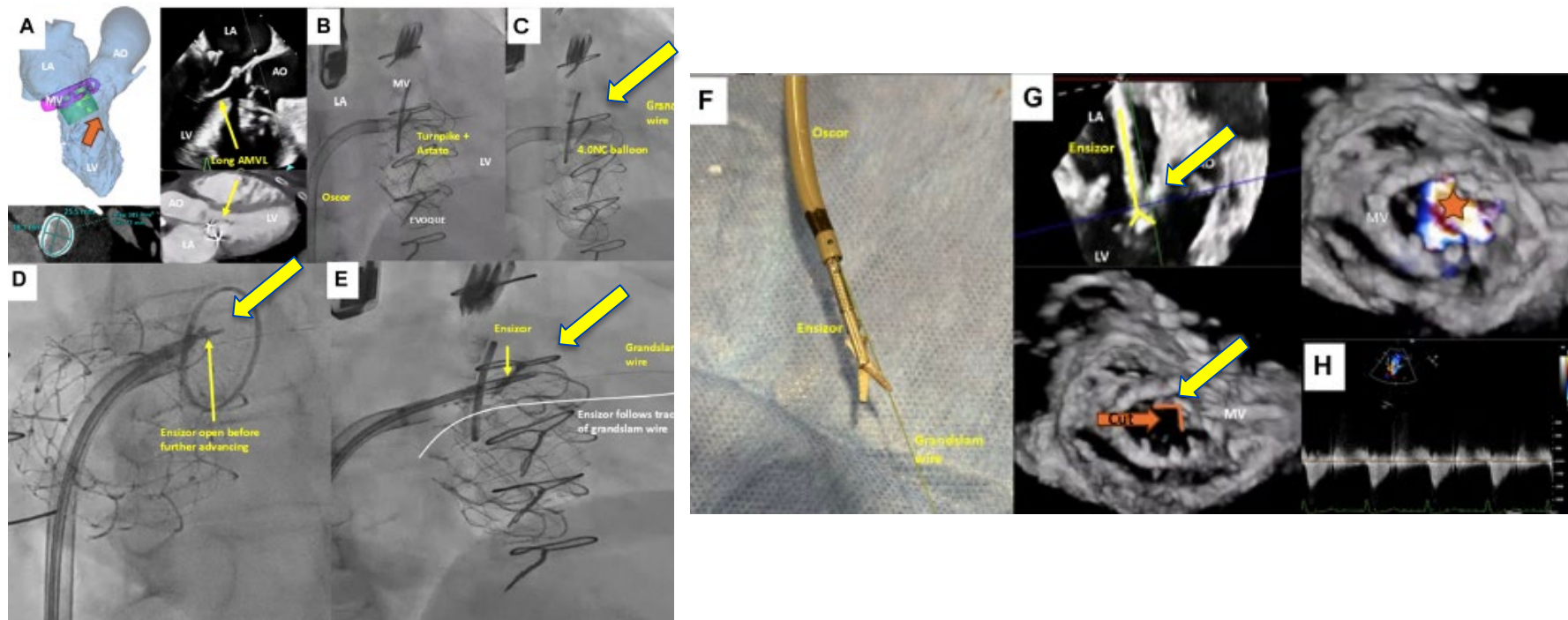
BATMAN & ROBIN

Balloon Assisted Translocation of the Mitral Anterior Leaflet
RetroOgrade Radiofrequency Balloon-Assisted optiMization of Neo-LVOT



WOLVERINE

Wire Landmark-Guided Orientation Controlled Leaflet-Resection to PreVent Left-VentRicular Outflow Tract ObstructionN using Endoscopic-Scissors



Coming next...

El CHAPULIN Colorado ?



Leaflet Cutting Devices

Pi-Cardia

Pi-Cardia completes first-in-human mitral valve splitting with ShortCut

AUGUST 22, 2022 BY SEAN WHOOLEY



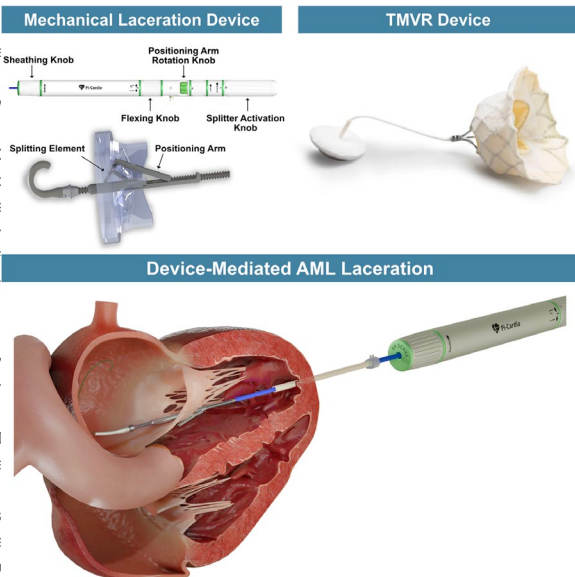
Pi-Cardia announced today its successful first-in-human valve with its ShortCut device.

Rehovot, Israel-based Pi-Cardia announced today its successful first-in-human valve with its ShortCut device to split the leaflets prior to treatment in patients at risk of obstruction after transcatheter aortic valve replacement (TAVR) or left ventricular outflow tract (LVOT) obstruction after transcatheter mitral valve replacement (TMVR).

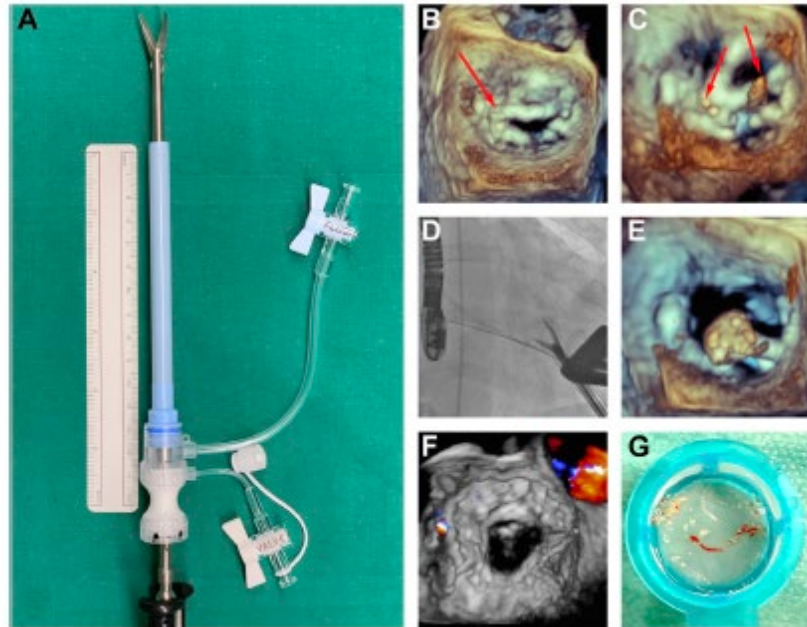
The company said in a news release that the device is designed to split the leaflets.

Prof. Lenard Conradi and I presented the ShortCut Mitral component at the ESC Congress.

"We were able to successfully split the anterior leaflet in patients with mitral valve disease who otherwise have no other option."



MitraCut



Summary

- LVOT obstruction is the Achilles' Heel of TMVR
- TMVR-induced LVOT Obstruction can be predicted with Cardiac CT
Neo-LVOT area, Neo-LVOT Area Index, VTS, Skirt Neo-LVOT Area.
- Percutaneous septal and leaflet strategies to decrease the risk of LVOTO
include: Alcohol or RF septal ablation, LAMPOON, SESAME, BATMAN,
BATMAN & ROBIN, WOLVERINE.
- New transcatheter devices are being developed to cut anterior MV leaflet
prior to TMVR to decrease the risk of TMVR-induced LVOTO



Thank You

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