Early Discharge Check List to be Minimalist

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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	Company
Grant/Research Support	Edwards Lifesciences
Grant/Scientific Advisory Board	Medtronic
Executive Physician Council	Boston Scientific Corp

Commercial TAVR case

G.K.

MRN xxxxxxx-x
Proposed Treatment Fast 8/9/2016
Track Eligible: Yes

Referring MD: Mike McConnell, MD
THV MDs: MPF/BF

History: 78 year old male with history of HTN, OSA, and severe, symptomatic AS. History SVT and NSVT on Ziopatch 2013. History of CLL since 2012; Rai stage 0 and no treatment indicated. History of polio at 19 yrs with post-polio syndrome. Currently symptomatic of dizziness associated with nausea, syncope x 2, exertional dyspnea, PND, chest discomfort, and chronic fatigue.

PFTs:

FEV1	2.2 L (83%)
DLCO	-

Anticoagulation History/Regimen:

Aspirin 162 mg daily

Frailty:

BMI	38.3
Serum Albumin	3.5 g/dL (-)
ADLs	4/6 (+)
Grip Strength	13 kg (+)
5m WT	7.8 sec (+)
Score	3/4

STS 2.0%

Age 78, male, Caucasian, 125 kg, 180.7 cm (BSA 2.50), Cr 1.32, HTN, NYHA Class III, EF 62%, AS, trace AI, moderate MR, trace TR, first op, elective

Proposed: Extreme Risk (Frailty) Commercial TAVR, 26 mm Sapien 3, Transfemoral approach, Right side

Echo: **Date** 6/20/2016

AVA	0.72 cm2
AVAI	0.29 cm²/m²
V2 Max	4.0 m/sec
Gradient	41 mmHg
V1/V2	-
EF	62%
RVSP	31 mmHg
AI	trace
MR	mild-moderate
_TR	trace

Notes:

RHC:

RA	2
RV	30/3
PA	33/8
PCW	8
CO	6.95
CI	2.9

Cors:

LM	none
LAD	minor irregularities 10.1
LCX	minor irregularities 7.8
RCA	minor irregularities 8.0
Grafts	-

Coronary heights:

LCA	17.2 mm
RCA	15.9 mm

Vascular access: (in mm)

RCIA	11.2 x 9.2
REIA #1	7.9 x 7.7
REIA #2	8.1 x 7.9
RCFA	8.2 x 7.5
LCIA	11.1 x
LEIA #1	8.3 x
LEIA #2	8.3 x
LCFA	7.9 x 7.7

SOV Diameters:

RCC	34.6 mm
LCC	36.9 mm
NCC	36.5 mm

SOV heights > 15 mm: Yes

Ascending Ao diameter: **Long Axis** 35.5 mm **Short Axis** 35.0 mm

Annulus: **Diameter** ~25.8 mm **Long Axis** 30.1 mm **Short Axis** 21.2 mm
Area 489 mm²
Perimeter 81.6 mm

Summary:

- 78 year old male
- STS 2.0%
- Extreme Risk (Frailty) Commercial TAVR
- 26 mm Sapien 3 THV
- Transfemoral approach
- Right side
- Fast Track eligible
-

Race: 9999

Cardiovascular Med A31

Dept:
()per: 60/JL

HR	64	SINUS RHYTHM
		CONSIDER POSTBRIOR IIIPARCT
PR	200	BORDERLDIE RBPOL ABNORMALITY, ANT- LAT LEADS
aaso	90	
ar	424	
()rcB	438	
QrcF	433	
-- AXIS --		
p	27	
CJIS	7	
'l'	96	

- ABMJRIIAL ECG -

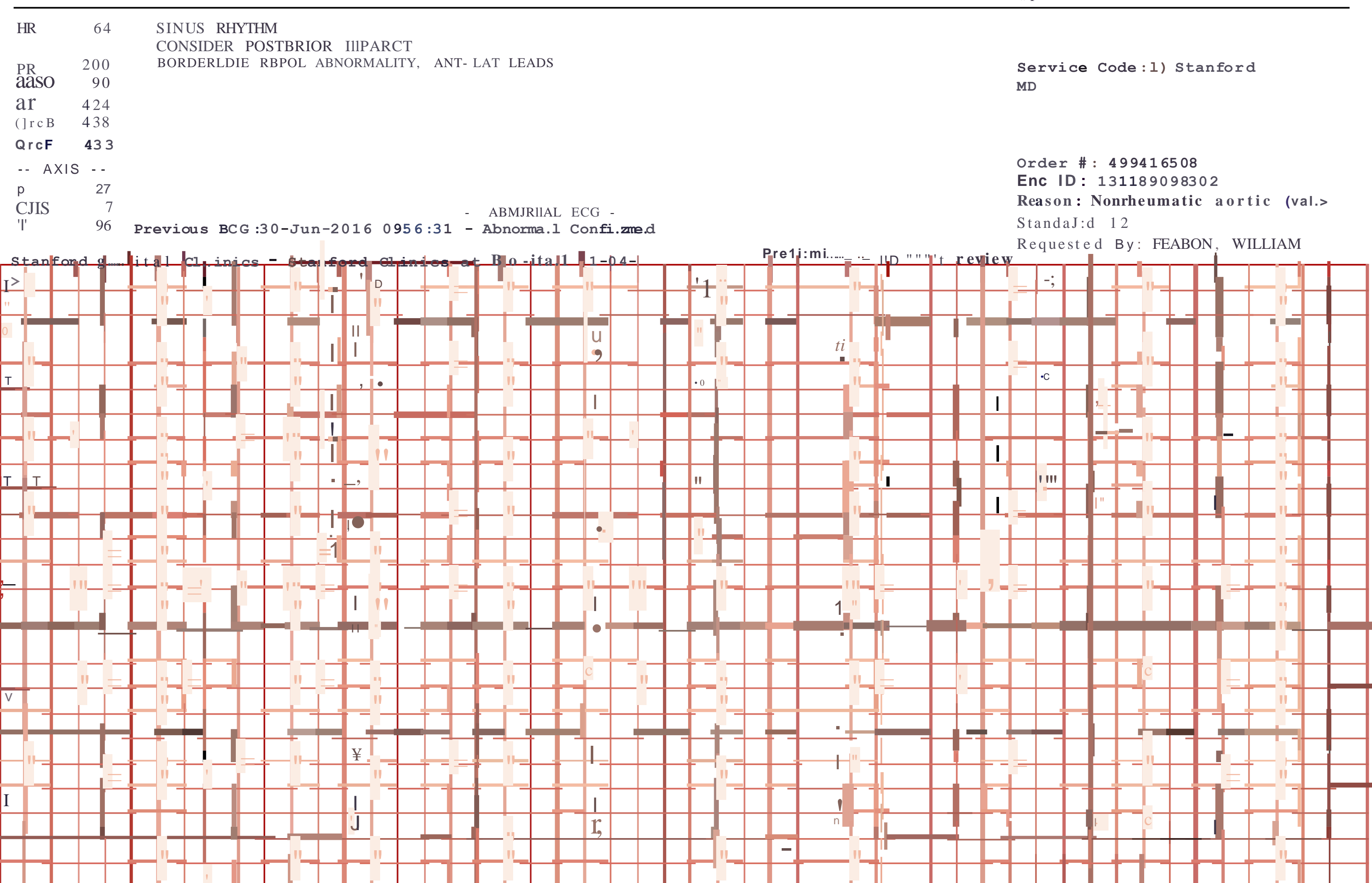
Previous BCG:30-Jun-2016 0956:31 - Abnorma.l Confi.zme.d

Service Code:1) Stanford MD

Order #: 499416508
Enc ID: 131189098302
Reason: Nonrheumatic aortic (val.>
StandaJ:d 12
Requested By: FEABON, WILLIAM

Stanford g... ital Cl.inics - Stanford Clinics at Bo-ita.l 1-04-

Pre1i:mi... review



cc: C\'MIEA31-2 Speed: 25 mm/sec Limb: 10 mm/mV Chest: 10 mm/mV fiO.. 0.5-100 Ela PB090A P?

Patient Flow in HIGH Risk TAVR

* High Risk Factors

HIGH RISK*

Clinic / Friday Conference

ICU Bed Requested

C_1

1st Case → CAPR2

To Follow Cases → Pre – CAPR

1. Anesthesia start A-line
   - Need supplies for starting A-line
   - Need ultrasound
2. Clipping to be done in Pre-CAPR

Cath Lab

ICU Bed Available?

No

Yes

CAPR1

- Cath procedure room staff call NICU Clerk
- NICU Clerk notifies CVICU team
- Patient goes to CAPR1
- THV/ Fellow writes holding orders for CAPR1
- Anesthesia assumes responsibility for patient care
- Extubation by anesthesia in CAPR1
- CVICU team/ attending evaluates patient

NICU/ CCU?

NICU – CVICU team continues to manage & write full orders

CCU – THV attending calls CCU attending; full orders written by CCU

D3/CSU ?

Home

Care Team:

Clinic / Friday Conference	C_1	CAPR2 / Pre-CAPR	Cath Lab	ICU Bed Available?	NICU/ CCU?	D3/CSU ?	Home
MD+	CVS APP		Cath Lab Team	Anesthesia	NICU Team CCU Team	CVS APP	TAVR NP

*Baseline High Risk Factors:

❑ Cardiac Function
- EF < 30%
- RV dysfunction
- Severe TR
- Severe MR
- RVSP/PAs > 60 mmHg
- At risk for LVOT obstruction
- At risk for SAM

❑ -Respiratory Function
- FEVI < 60% predicted
- On home O_2

❑ Renal Function
- Hemodialysis

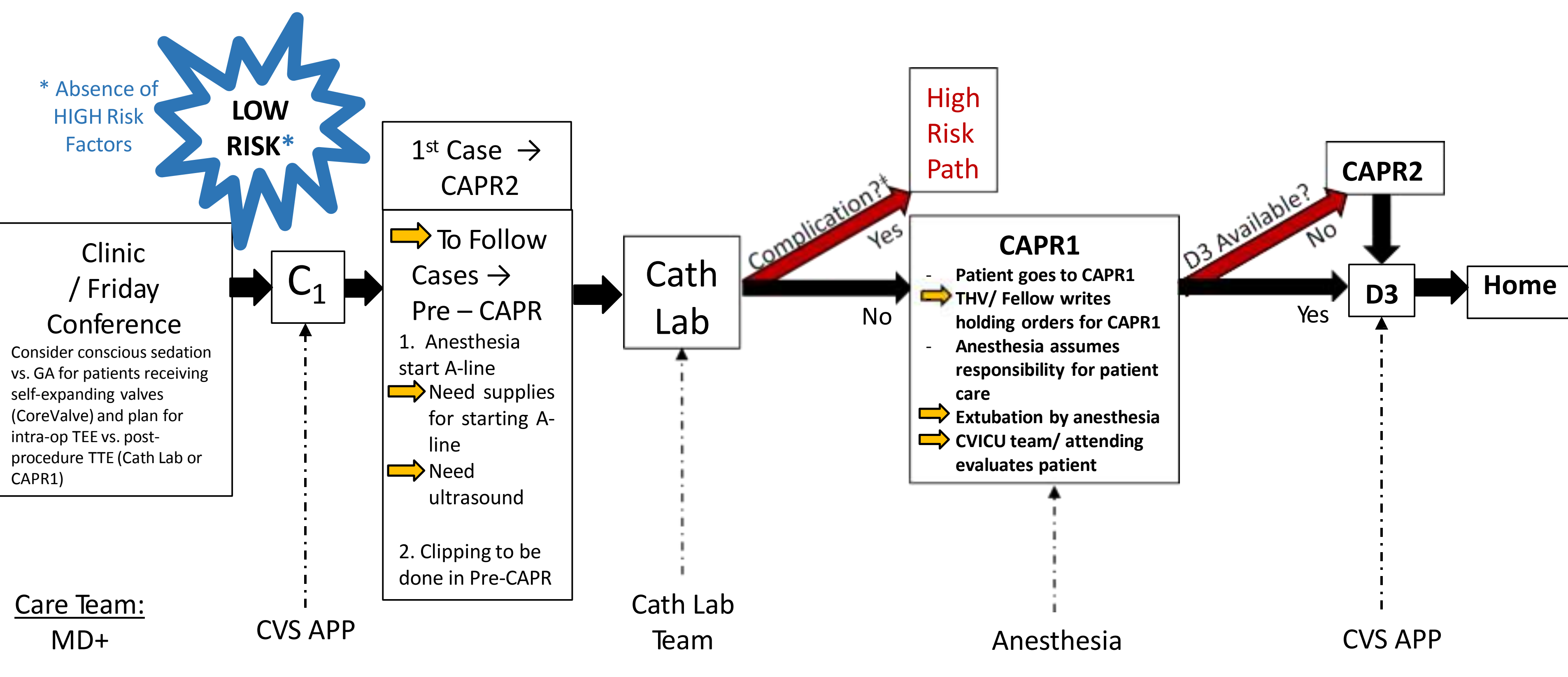
❑ Functional Status
- BMI < 18 or >35

❑ Complex Procedure
- Alternative Access (TA, TAo, SC)
- Concomitant PCI
- Urgent/ Inpatient procedure

❑ Demographic Factors
- STS > 15

Action needed

Patient Flow in LOW Risk TAVR

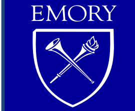


‡ **Procedural Complications:**

- ❑ Rhythm Disturbances
  - Complete Heart Block/ new IVC defects
  - Rhythm requiring defibrillation intraprocedurally
- ❑ Conversion to Open/ Embolization/ More than one valve implanted
- ❑ -Hemodynamic Instability
  - Requiring pressors/IABP
  - ≥ Moderate PLV/AI
  - Cardiac Tamponade
- ❑ Vascular Complication
  - Requiring cutdown
  - Requiring transfusion

➡ Action needed

What’s Next?



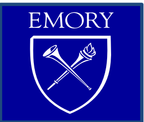
Efficiency and Economics: Minimalist TF TAVR

Sept 2007

May 2015

- Simplify procedure

- No General Anesthesia, No TEE
- Maintain superior outcomes, short and long term
- Decrease resource utilization and cost



Some Data with EW Sapien

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Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach)

CME

Outcomes and Cost Analysis

Vasilis Babaliaros, MD,* Chandan Devireddy, MD,* Stamatios Lerakis, MD,* Robert Leonardi, MD,* Sebastian A. Iturra, MD,† Kreton Mavromatis, MD,* Bradley G. Leshnower, MD,† Robert A. Guyton, MD,† Mihir Kanitkar, MD,* Patricia Keegan, NP,* Amy Simone, PA,† James P. Stewart, MD,* Nima Ghasemzadeh, MD,* Peter Block, MD,* Vinod H. Thourani, MD†

JACC: CARDIOVASCULAR INTERVENTIONS CME

EMORY

Mid-Term Mortality with Minimalist Approach

Minimalist Approach

Standard Approach

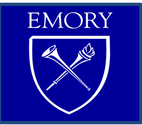
Event-Free Survival

1.0
0.8
0.6
0.4
0.2
0.0

P=0.639

0 100 200 300 400 500 600

Days to Death



Cost Saving with Minimalist Approach

$55,377±22,587

P<0.0001

$45,485 ± 14,397

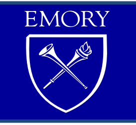
Mean Cost (U.S. Dollars)

80000
75000
70000
65000
60000
55000
50000
45000
40000
35000
30000
25000
20000
15000
10000
5000
0

Minimalist Approach

Standard Approach

Total Experience As of 2015



82
Minimalist
TF-TAVR
DC on POD#1
(7.6%)

417
Minimalist TF-TAVR
(38.6%)

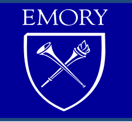
707
TF-TAVR
(65.2%)

1,084
Balloon expandable TAVR
(100%)

2012-Present

2007-Present

Who Is a Minimalist Candidate?



Eligibility confirmed by the Heart Team

Straightforward Vascular Access? STOP

Weight < 100kg? STOP

Coronary arteries acceptable height? STOP

Any barriers to emergent intubation if required? STOP

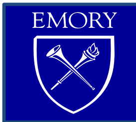
Chronic pain? STOP

Mental status appropriate? STOP

NO → STANDARD TAVR

YES → MINIMALIST TAVR
Conscious sedation

Evolution of TF Minimalist TAVR



80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00

	2012	2013	2014	2015
NONTF-TAVR (%)	40.2%	37.2%	34.3%	20.4%
MA-TF-TAVR (%)	25.7%	54.7%	56.3%	67.9%
SA-TF-TAVR (%)	34.1%	8.2%	9.5%	11.7%

80% Min TF TAVR

NONTF-TAVR (%)
MA-TF-TAVR (%)
SA-TF-TAVR (%)

Partnership with Nursing and Staff

Nurse and Staff Champions

<u>Cath Lab to Floor protocol:</u>

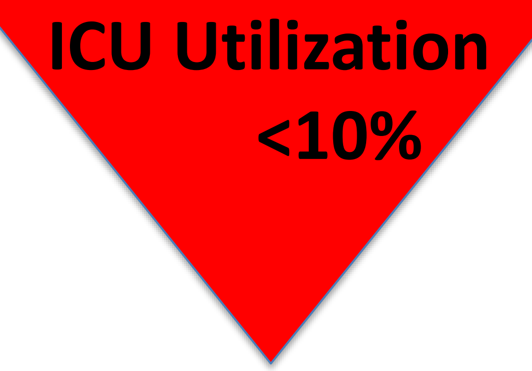
No Neurologic events

No drips

No vascular complications

No heart block

*New LBBB was OK

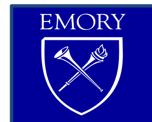


<u>Procedure specific Care Plans:</u>

Early Ambulation Protocol- 4 hrs

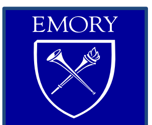
General Diet- immediate

Minimalist Early Discharge POD 1



Procedure Details and Outcomes

	All (N=411)	Early Discharge (N=82)	Standard Discharge (N=329)	P value
Valve type, N (%)				
Sapien	103 (25.1)	4 (4.6)	99 (30.1)	<0.001
Sapien XT	198 (48.2)	39 (47.6)	159 (48.3)	
Sapien 3	110 (26.8)	39 (47.6)	71 (21.6)	
Major vasc complication	13 (3.2)	0 (0.0)	13 (4.0)	0.08
Minor vasc complication	36 (8.8)	3 (3.7)	33 (10.1)	0.08
Pacemaker need	29 (8.4)	0 (0.0)	29 (10.6)	0.001
Major stroke	7 (1.7)	0 (0.0)	7 (2.1)	0.35
30 Day Readmissions	24 (5.8)	4 (4.9)	20 (6.1)	0.80
30 day Mortality	3 (0.7)	1 (1.2)	1 (0.3)	0.36
30 day PVL				
None	232 (58.4)	56 (71.8)	177 (55.1)	0.03
Mild	140 (35.1)	18 (23.1)	122 (38.0)	
Moderate/Severe	26 (6.5)	4 (5.1)	22 (6.9)	



Expedited Minimalist TAVR-
Same Day Admit & Next Day Discharge

80,000
70,000
60,000
50,000
40,000
30,000
20,000
10,000
0

$48,316 ± 10,211

$39,573 ± 10,186

Standard Minimalist-TAVR

Expedited Minimalist-TAVR

DRG 266 - $50,000

DRG 267 - $39,000

Anesthesia Selection Over Time from TVT Registry

100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%

Jan 2012-Jan 2013
Jan 2013- Jan 2014
Jan 2014-Mar 2014
Apr 2014 -Jun 2014
July 2014 -Sep 2014
Oct 2014-Dec 2015
Jan 2015-March 2015
April 2015-June 2015
July 2015-Nov 2015

Moderate Sedation
General Anesthesia

TVTR Procedure start date

Courtesy Jay Giri, MD, MPH UPENN

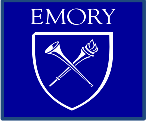
Translating Science to Practice

Analysis Outcomes of Minimalist from TVT registry

Courtesy Jay Giri, UPENN

	Moderate Sedation	General Anesthesia	Odds Ratio	P-value
30-Day Mortality	2.96%	4.01%	0.72	P<0.001
30-Day Death/Stroke	4.80%	6.36%	0.69	P<0.001

Minimalist in Severe COPD: Mortality Benefit?



Cumulative Survival

1.0
0.8
0.6
0.4
0.2
0.0

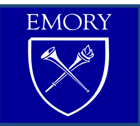
Minimalist TF-TAVR

Standard TF-TAVR

.00 90.00 180.00 270.00 360.00

Follow up (days)

Number at Risk	.00	90.00	180.00	270.00	360.00
Minimalis TF-TAVR	46	43	41	38	33
Standard TF-TAVR	42	34	29	26	25



Conclusions

- Minimalist TAVR is the strategy on which next day discharge and lower costs will be more common.
- Minimalist TAVR may have a mortality benefit in HR patients with significant comorbidities
- Anatomical Risk (not clinical risk) will be the dividing line on whether patients are done Minimalist TAVR (>80%)