

Operator Experience and Procedural Results of Transcatheter Mitral Valve Repair with Mitraclip: *Insights from the STS/ACC TVT Registry*

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Background



- **TMVr with Mitraclip is a relatively new and complex procedure approved in the U.S. in 2013**
- **It requires a unique operator skillset and navigation of the right and left atria, mitral valve apparatus, and left ventricle**
- **The relationship between operator experience and procedural outcomes has not been fully characterized**

Methods

- **Mitraclip procedures from the STS/ACC TVT Registry were analyzed categorically according to operator case number**
 - **1-25, 26-50, and >50 cases**
- **Operator case number was also analyzed as a continuous variable to allow for visual estimation of the ‘learning curve’**
- **In the case of two operators with different levels of case experience performing a procedure together, the case was categorized based on the higher case number**

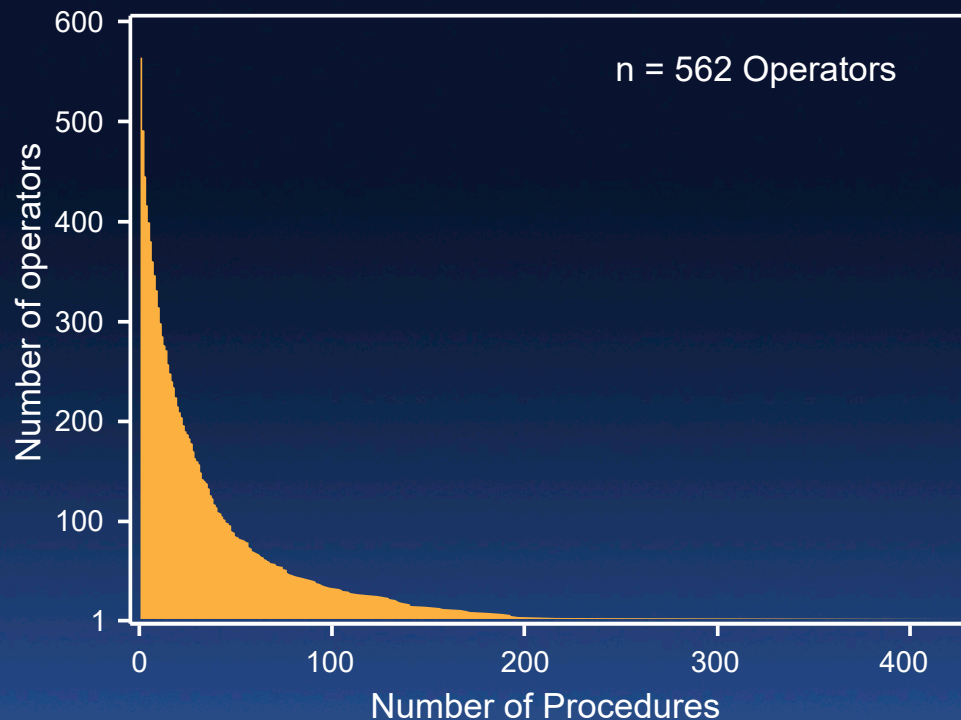
Outcomes

- The primary outcomes were procedural success, procedure time, and in-hospital procedural complications
- Two definitions of procedural success were utilized
 - ‘Acceptable’ – moderate or less residual MR, no death or urgent surgery
 - ‘Optimal’ – mild or less residual MR, no death or urgent surgery
- In-hospital complications were analyzed individually and as a composite endpoint

Statistical Analysis

- Generalized linear mixed models were used to examine the relationship between operator case number and outcomes while adjusting for baseline clinical variables.
- A hierarchical structure was adopted, with random intercepts at the **operator and site levels**

Results: Mitraclip Volume



- **14,923 cases performed by 562 operators at 290 sites between 2013 and 2018**
- **230 operators with case experience between 26-50**
- **116 operators with case experience > 50**

Patient Characteristics (i)

	1-25 cases (n=6,431)	26-50 cases (n=3,467)	>50 cases (n=5,025)	p-value
Age, Median (IQR)	82 (74,86)	80 (73,86)	81 (73,86)	<0.01
NYHA Class				<0.01
III	63.8%	63.6%	62.9%	
IV	21.7%	21.4%	19.9%	
LV ejection fraction (median, IQR)	55 (40,60)	55 (40,60)	55 (40,60)	<0.01
Prior Stroke or Transient Ischemic Attack	16.6%	17.8%	15.7%	0.04
Severe Chronic Lung Disease	11.0%	11.9%	10.6%	0.21
Prior MV Repair	0.01%	0.01%	0.02%	0.54
Prior MV Ring	0.01%	0.01%	0.01%	0.89

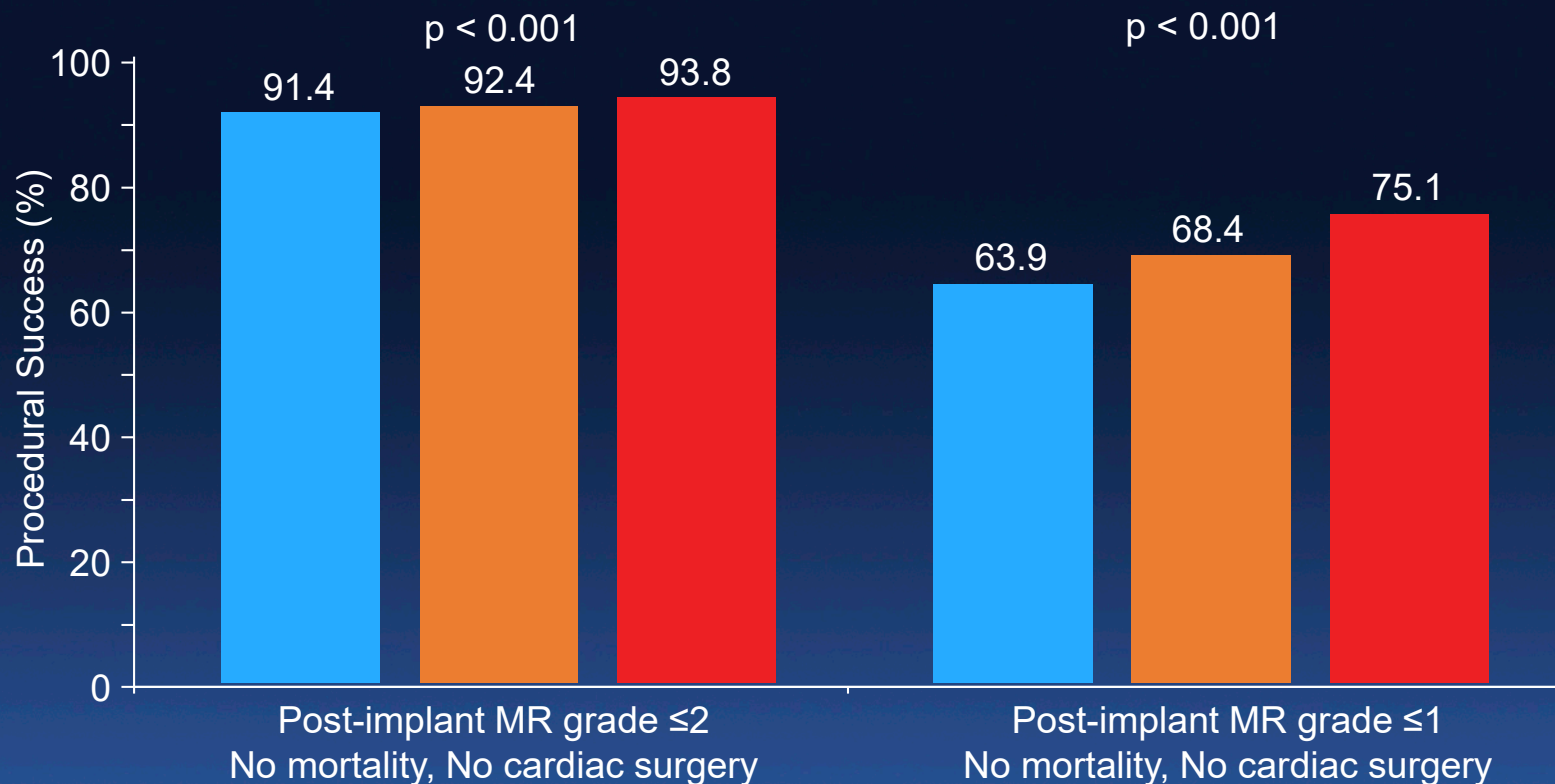
Patient Characteristics (ii)

	1-25 cases (n=6,431)	26-50 cases (n=3,467)	>50 cases (n=5,025)	p-value
MR Severity				0.01
moderate-severe or severe (3+/4+)	93.4%	93.3%	92.0%	
none, trace, mild or moderate (0-2+)	6.1%	6.4%	7.5%	
Mitral Stenosis	5.8%	5.5%	4.2%	<0.01
Mitral Leaflet Calcification	20.2%	19.8%	20.2%	<0.01
Mitral Annular Calcification	36.4%	35.4%	36.0%	<0.01
STS PROM-MV Replacement (median, IQR)	8.9 (5.6,13.6)	8.6 (5.5,13.1)	8.5 (5.3,12.9)	<0.01
STS PROM-Score-MV Repair (median, IQR)	5.8 (3.5,9.5)	5.7 (3.5,9.0)	5.4 (3.3,8.9)	<0.01
Functional MR	15.2%	18.7%	23.7%	<0.01

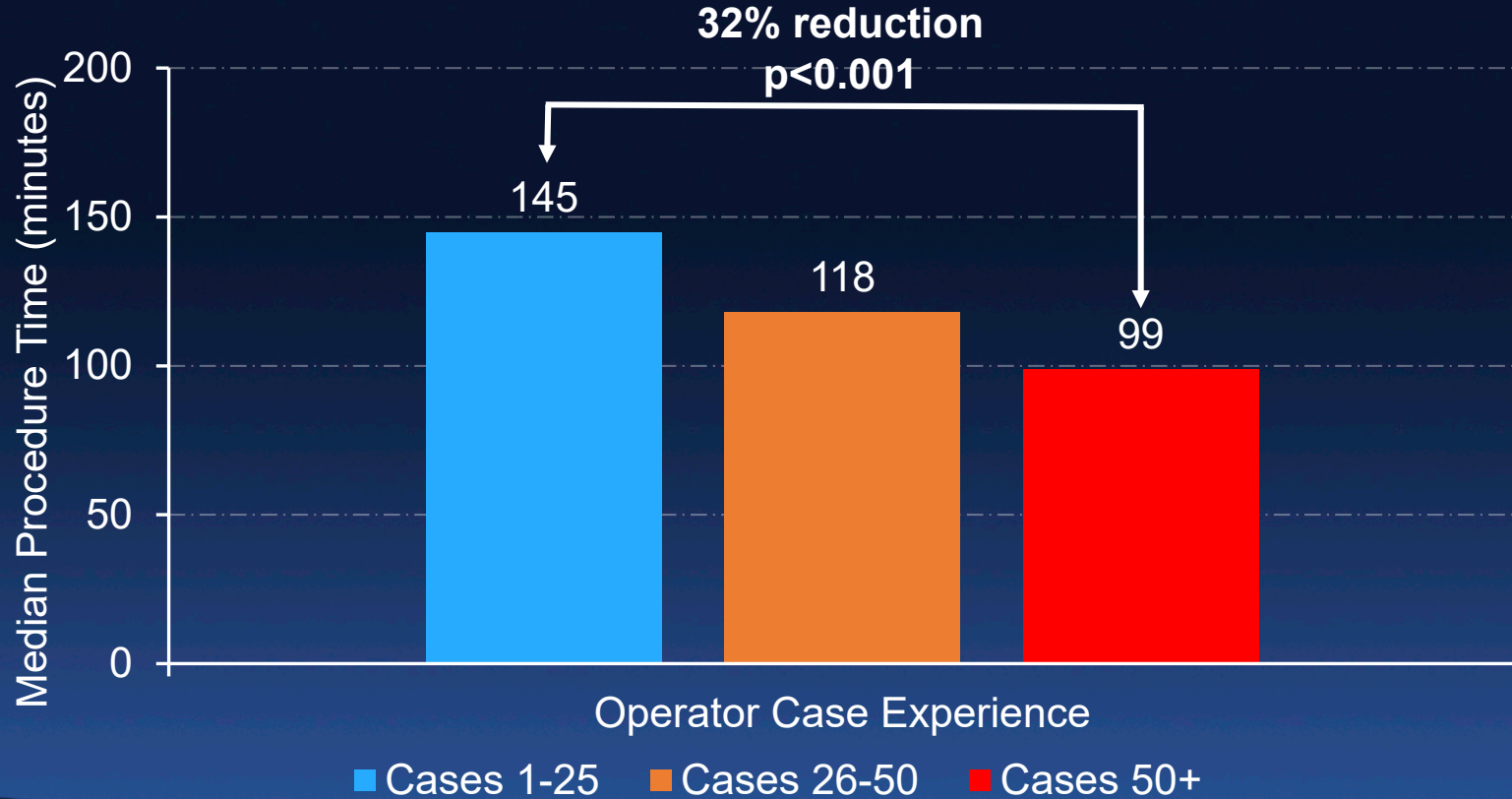
Procedure Characteristics

	1-25 cases (n=6,431)	26-50 cases (n=3,467)	>50 cases (n=5,025)	p-value
Procedure Status				0.01
Elective	88.1	86.4	86.7	
Urgent/Emergent/Salvage	11.9	13.6	13.3	
Number of Leaflet Clips				<0.01
0	2.8%	2.7%	1.6%	
1	56.0%	52.6%	50.4%	
2+	40.1%	44.0%	47.2%	
Clip in A1-P1 Location (lateral)	9.5%	8.9%	8.0%	<0.01
Clip in A2-P2 Location (central)	84.6%	86.3%	88.8%	<0.01
Clip in A3-P3 Location (medial)	10.4%	11.3%	11.1%	0.04
Mean Mitral Valve Gradient (mmHg, median, IQR)	3.0 (2.0,5.0)	3.0 (2.0,5.0)	3.0 (2.0,5.0)	0.20
ASD closure	0.9%	1.4%	2.2%	<0.01

Unadjusted Outcomes: Procedural Success



Unadjusted Outcomes: Procedure Time

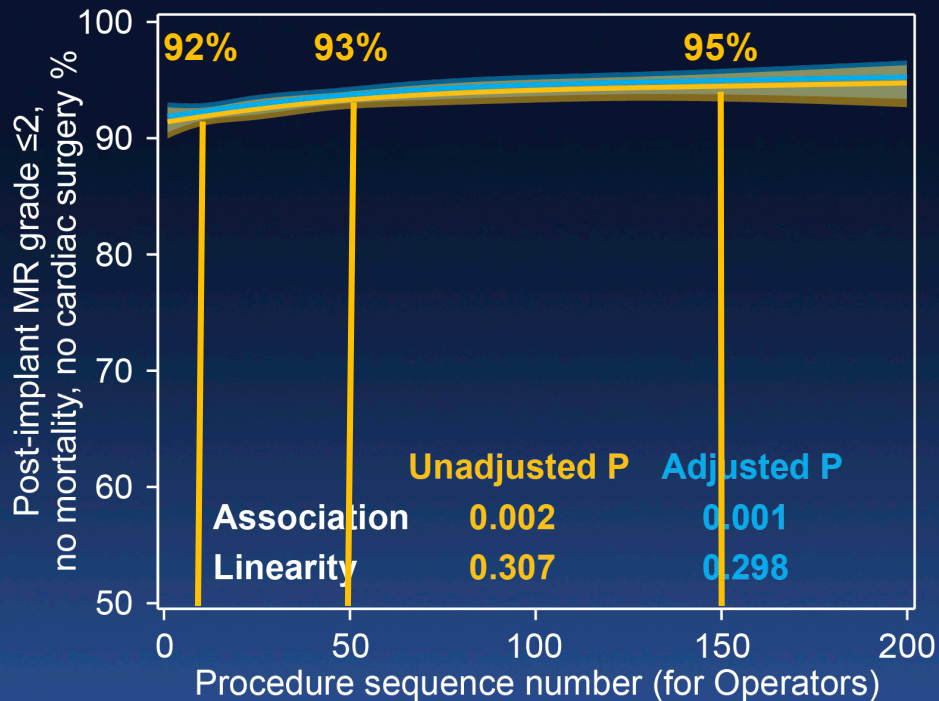


Procedural Complications

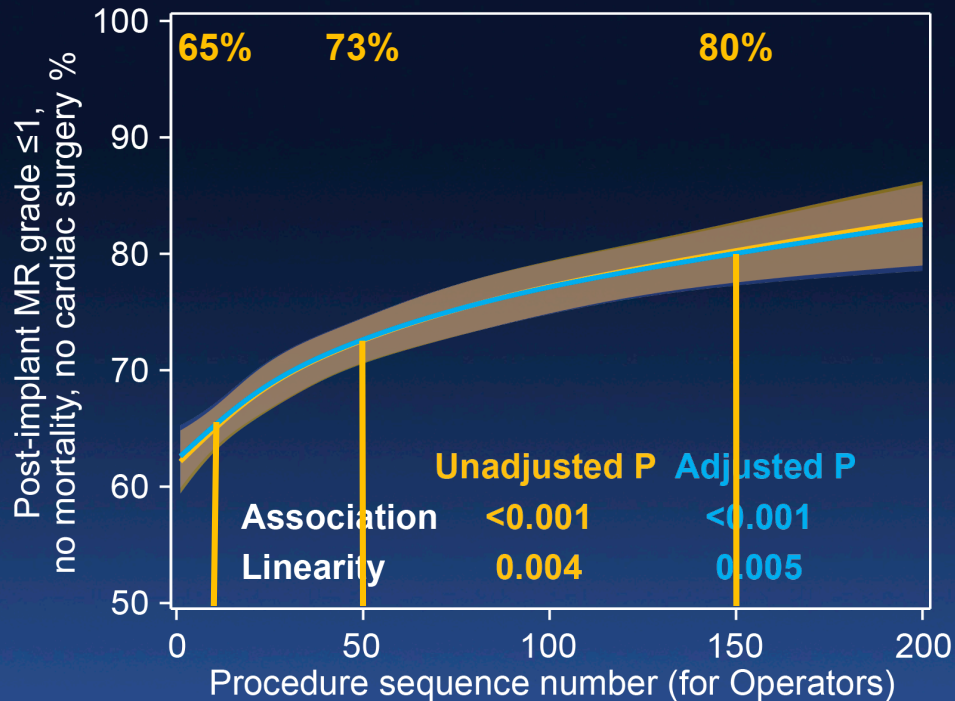
	1-25 cases (n=6,429)	26-50 cases (n=3,466)	>50 cases (n=5,025)	p-value
Composite of Complications	9.7%	8.1%	7.3%	<0.01
In-hospital Death	2.0%	1.9%	1.7%	0.55
Conversion to Surgery	0.5%	0.5%	0.4%	0.42
Cardiac perforation	1.0%	1.1%	0.4%	<0.01
Stroke	0.7%	0.5%	0.8%	0.26
Single Leaflet Device Attachment	1.3%	1.0%	0.9%	0.11
Device Embolization	0.1%	0.0%	0.2%	0.09
Bleeding at Access Site	0.9%	0.9%	0.6%	0.14
Blood Transfusion	9.6%	8.6%	6.5%	<0.01

Procedural Success: Learning Curve Analysis*

Acceptable ($\leq 2+$ residual MR)

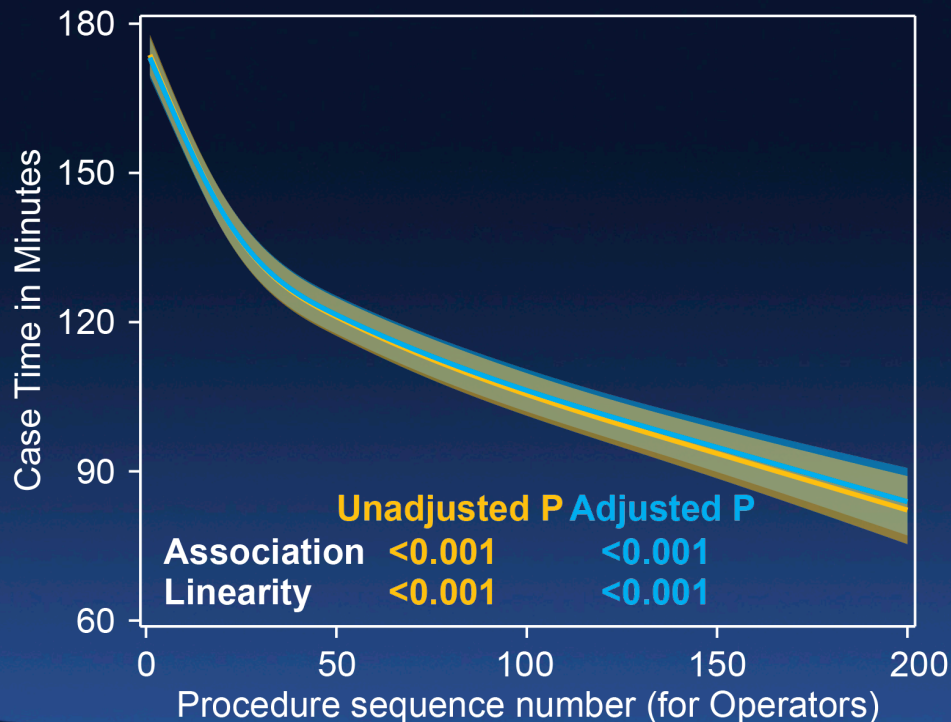


Optimal ($\leq 1+$ residual MR)

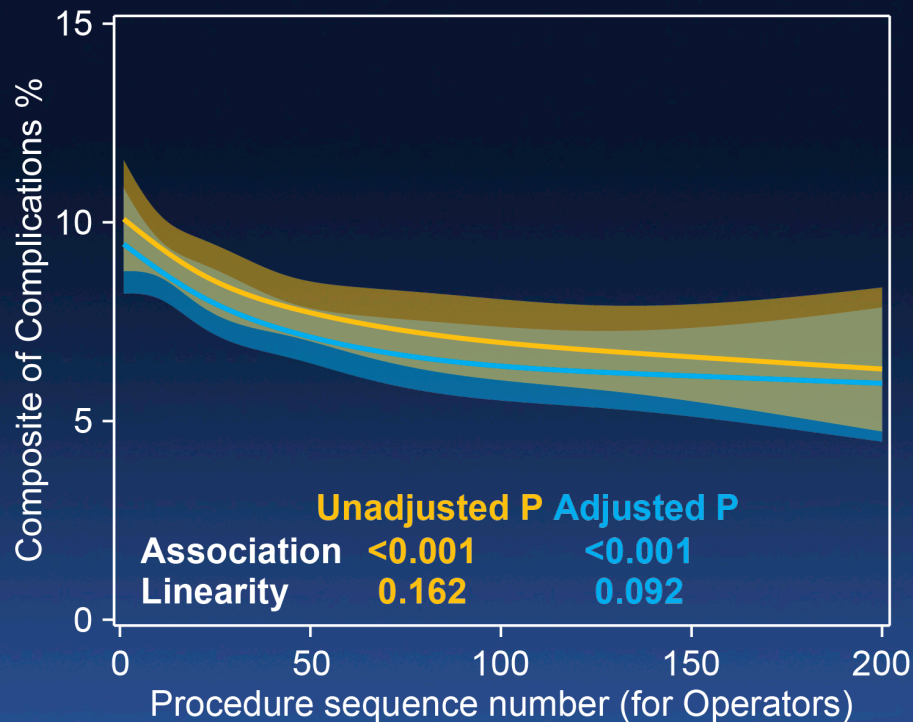


Procedure Time and Procedural Complications*

Procedure Time



Procedural Complications



Secondary Analyses: Mechanism of MR

	Functional vs. Degenerative		Other* vs. Degenerative	
Outcome	Odds Ratio	p-value	Odds Ratio	p-value
Optimal Procedure Success	0.98 (0.88,1.08)	0.632	1.02 (0.86,1.20)	0.834
Acceptable Procedure Success	0.95 (0.81,1.13)	0.585	0.92 (0.71,1.21)	0.556
Composite of Complications	0.94 (0.80,1.10)	0.585	0.93 (0.71,1.21)	0.556
Outcome	Estimate	p-value	Estimate	p-value
Procedure Time	1.36 (-1.1,3.80)	0.274	2.32 (-1.9,6.58)	0.286
* Post-Inflammatory, Endocarditis and Other/Indeterminate Mitral Valve Disease Etiology				

Limitations

- This was a retrospective observational study and despite statistical adjustment, confounders may be present
- Echo data were site-reported and not adjudicated
- Relatively few operators with very high case experience limits ability to fully analyze the duration of the learning curve for TMVr with Mitraclip
- The impact of device design modifications on the learning curve for Mitraclip was not analyzed in this study

Summary

- For TMVr with Mitraclip, procedure success, procedure time and procedural complications improve with increasing operator experience.
- These associations remained statistically significant after adjustment for baseline patient characteristics, indicating that case selection is unlikely to explain these findings.
- The impact of operator experience was greater when considering the goal of 'optimal' MR reduction, i.e., mild or less residual MR.
- The 'learning curve' for Mitraclip appears to flatten after approximately 50 cases; however, the overall duration of the learning curve may exceed 200 cases

Conclusions

A procedural learning curve does exist for transcatheter mitral valve repair with Mitraclip and these findings are independent of mechanism of MR

These findings have important implications as to the level of training and experience necessary to achieve optimal outcomes in this challenging patient population

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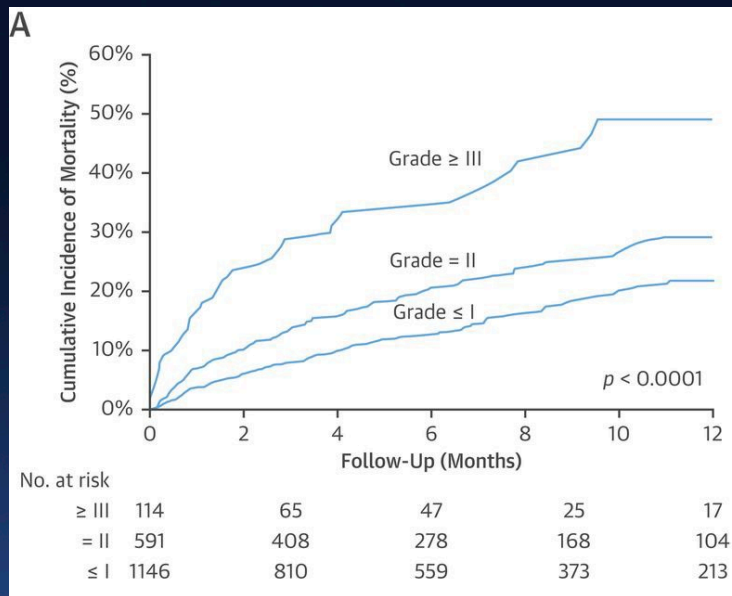
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Thank You

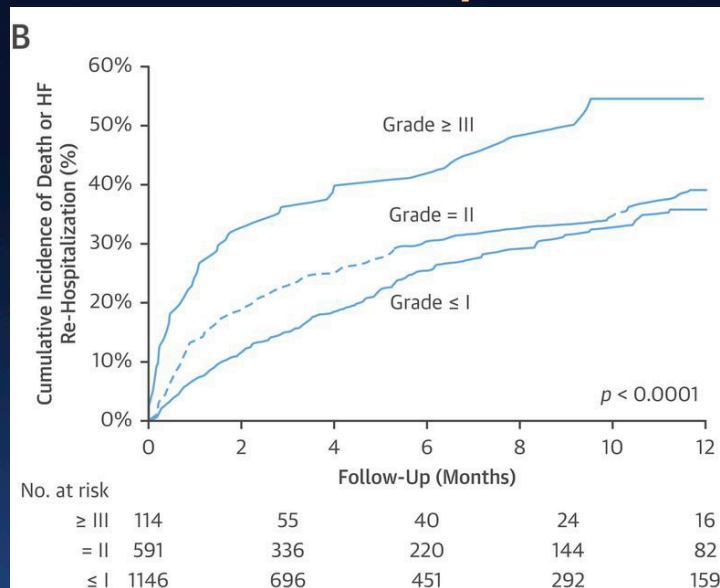


Impact of Residual MR on Outcomes following TMVr

Death

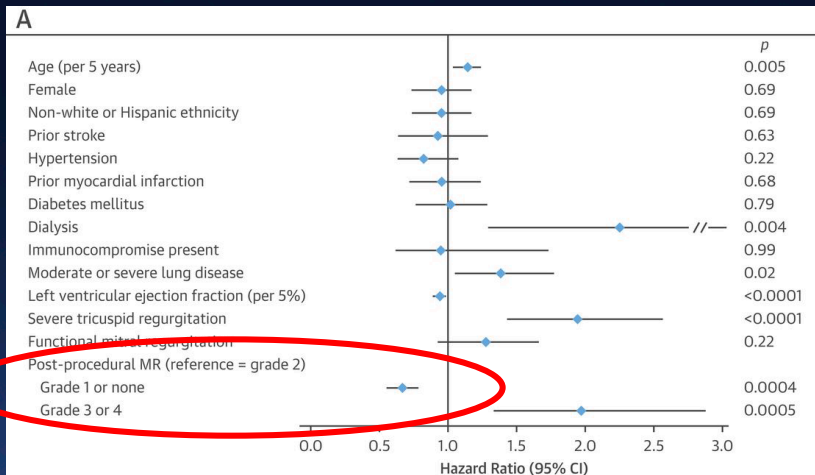


Death or CHF rehospitalization

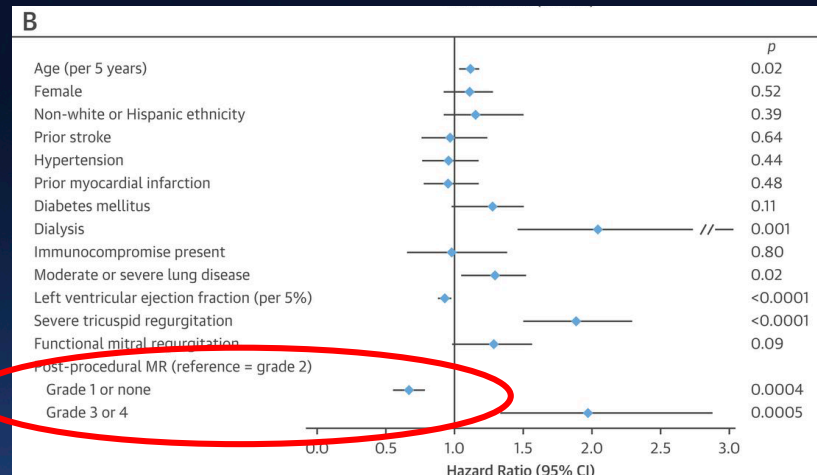


TVT Registry Analysis: 1,851 patients
85.9% DMR 8.6% FMR

Multivariate Predictors of 1-year Outcomes Following TMVr



Death



Death or CHF rehospitalization

Secondary Analyses

Using 3-level hierarchical generalized linear mixed models:

1. To account for site volume: comparison of outcomes with lower-volume operators at lower-volume vs higher-volume sites
 - 25th percentile cutoff
 - 50th percentile cutoff
2. To account for mechanism of MR: comparison of outcomes for degenerative vs functional MR

Secondary Analyses: Site Volume

50th percentile cutoff:

Operators with case experience ≤ 31

Higher volume sites: > 33 total procedures

Lower volume sites: ≤ 33 total procedures

	Higher vs. Lower Volume Sites	
Outcome	Odds Ratio	p-value
Optimal Procedure Success	1.13 (0.95,1.34)	0.174
Acceptable Procedure Success	1.05 (0.86,1.30)	0.613
Composite of Complications	0.99 (0.81,1.20)	0.613
Outcome	Estimate	p-value
Procedure Time	+13.2 (5.82,20.5)	<.001

Results

Case Count	Procedural Success (residual MR grade ≤ 1 , no mortality or need for cardiac surgery)		Procedural Success (residual MR grade ≤ 2 , no mortality or need for cardiac surgery)	
	Unadjusted (% , 95% CI)	Adjusted (% , 95% CI)	Unadjusted (% , 95% CI)	Adjusted (% , 95% CI)
10	64.9 (63.0, 66.8)	65.2 (63.3, 67.1)	91.6 (90.8, 92.3)	92.0 (91.2, 92.7)
25	68.7 (66.6, 70.7)	68.8 (66.8, 70.8)	92.2 (91.3, 93.0)	92.6 (91.8, 93.4)
50	72.6 (70.6, 74.5)	72.6 (70.7, 74.5)	93.0 (92.2, 93.7)	93.4 (92.7, 94.1)
100	77.2 (74.9, 79.4)	77.1 (74.8, 79.3)	93.8 (92.8, 94.7)	94.3 (93.3, 95.1)
150	80.3 (77.5, 82.8)	80.0 (77.3, 82.5)	94.2 (92.9, 95.2)	94.7 (93.5, 95.6)
200	82.9 (79.0, 86.2)	82.5 (78.5, 85.9)	94.4 (92.4, 96.0)	94.9 (93.1, 96.3)

Secondary Analyses: Site Volume

25th percentile cutoff:

Operators with case experience ≤ 13

Higher volume sites: > 15 total procedures

Lower volume sites: ≤ 15 total procedures

	Higher vs. Lower Volume Sites	
Outcome	Odds Ratio	p-value
Optimal Procedure Success	1.06 (0.82,1.39)	0.649
Acceptable Procedure Success	0.96 (0.67,1.37)	0.821
Composite of Complications	1.04 (0.75,1.44)	0.821
Outcome	Estimate	p-value
Procedure Time	9.46 (-.88,19.8)	0.073