The next-generation self-expanding transcatheter device: 30-day outcomes from the TVT-Registry

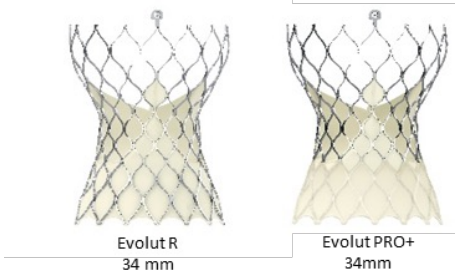
Tanvir Bajwa, MD; Chad Rammohan, MD; Rishi Puri, MD, PhD; Bruce Rutkin, MD; Blake Gardner, MD; James E. Harvey, MD; Carlos Sanchez, MD; Azeem Latib, MB Bch

Background

- Transcatheter aortic valve replacement (TAVR) continues to develop and expand into lower-risk patients and new indications.
- TAVR devices continue to evolve to include lower-profile delivery systems and expanded sizing availability.
- This analysis examines outcomes from the next-generation Evolut PRO+ system compared to the Evolut R system.

Methods

- Patients who underwent TAVR for treatment of native aortic valve stenosis between January 2020 and June 2020 using an Evolut R or Evolut PRO+ self-expanding prosthesis (Medtronic, Minneapolis, MN) were included in this analysis.
- This analysis included patients with native tricuspid aortic stenosis and excluded any valve-in-valve or previously failed bioprosthesis.
- Site-reported events for in-hospital, and 30-days outcomes as reported in the STS/ACC TVT Registry™ were examined.
- Site-reported echocardiographic data for post procedure and 30 days were analyzed.
- Comparisons of outcomes were performed by valve type (Evolut R TAV or Evolut PRO+) and Evolut R 34 mm vs Evolut PRO+ 34 mm valve size.



Baseline characteristics

Mean ± standard deviation or %	EVR (N=525)	PRO+ (N=3963)
Age[1]	78.2 ± 8.1	78.9 ± 7.9
Body surface area (m^2)	1.9 ± 0.3	1.9 ± 0.3
BMI < 21 kg/m^2	7.1%	6.4%
Albumin < 3.3 g/dL	15.4%	12.2%
Male	64.4%	50.4%
NYHA Class		
I	4.0%	4.3%
II	28.1%	30.2%
III	55.4%	56.8%
IV	12.4%	8.7%
STS Score %	4.8 ± 4.1	4.6 ± 4.0
Diabetes mellitus	42.7%	39.1%
Prior stroke	10.1%	10.2%
Annular calcification[2]	81.3%	81.7%
Chronic lung disease/COPD	40.6%	32.6%
Peripheral vascular disease	37.0%	23.6%
5-Meter gait speed (seconds)	7.7 ± 4.0	8.0 ± 13.3
Aortic valve annulus size (mm)	25.3 ± 3.5	24.4 ± 3.0

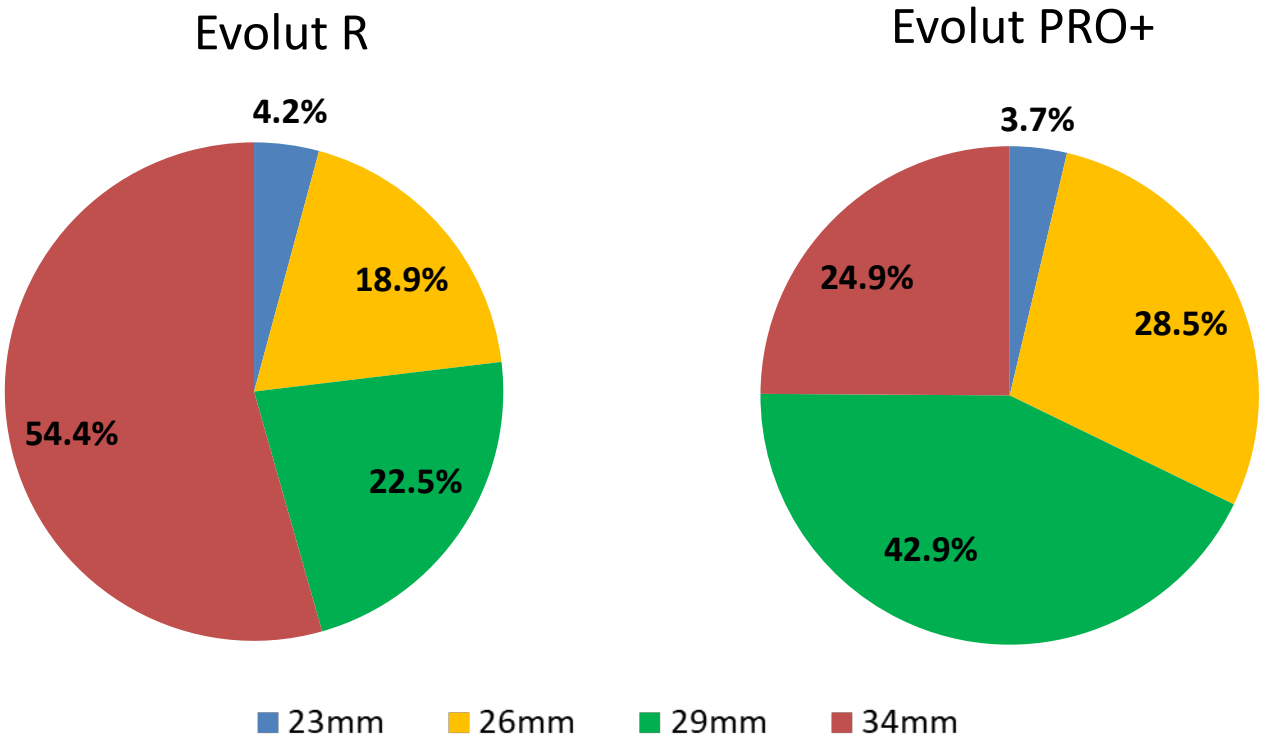
[1]Subjects with age >90 are reported as “90 plus” in the database and for calculation are set to 90

[2]Calcification in the aortic valve leaflets, aorta adjacent to the AV, leaflets or the left ventricular outflow tract (LVOT), or if echo reports document AV calcific degeneration.

Procedural characteristics

% or median	EVR (N=525)	PRO+ (N=3963)
Procedure location – hybrid cath lab or cath lab	45.7%	41.7%
Type of anesthesia - general	47.4%	39.3%
Ilio-femoral access	92.0%	95.5%
More than 1 valve used	0.8%	1.7%
Procedure time (minutes)	89.0	79.0
ICU duration (hours)	18.0	7.5
Total length of hospital stay (days)	2.0	2.0
Length of hospital stay after procedure (days)	2.0	2.0
Annulus rupture	0.0%	0.1%
Discharged - home	89.7%	92.0%

Valve size implanted

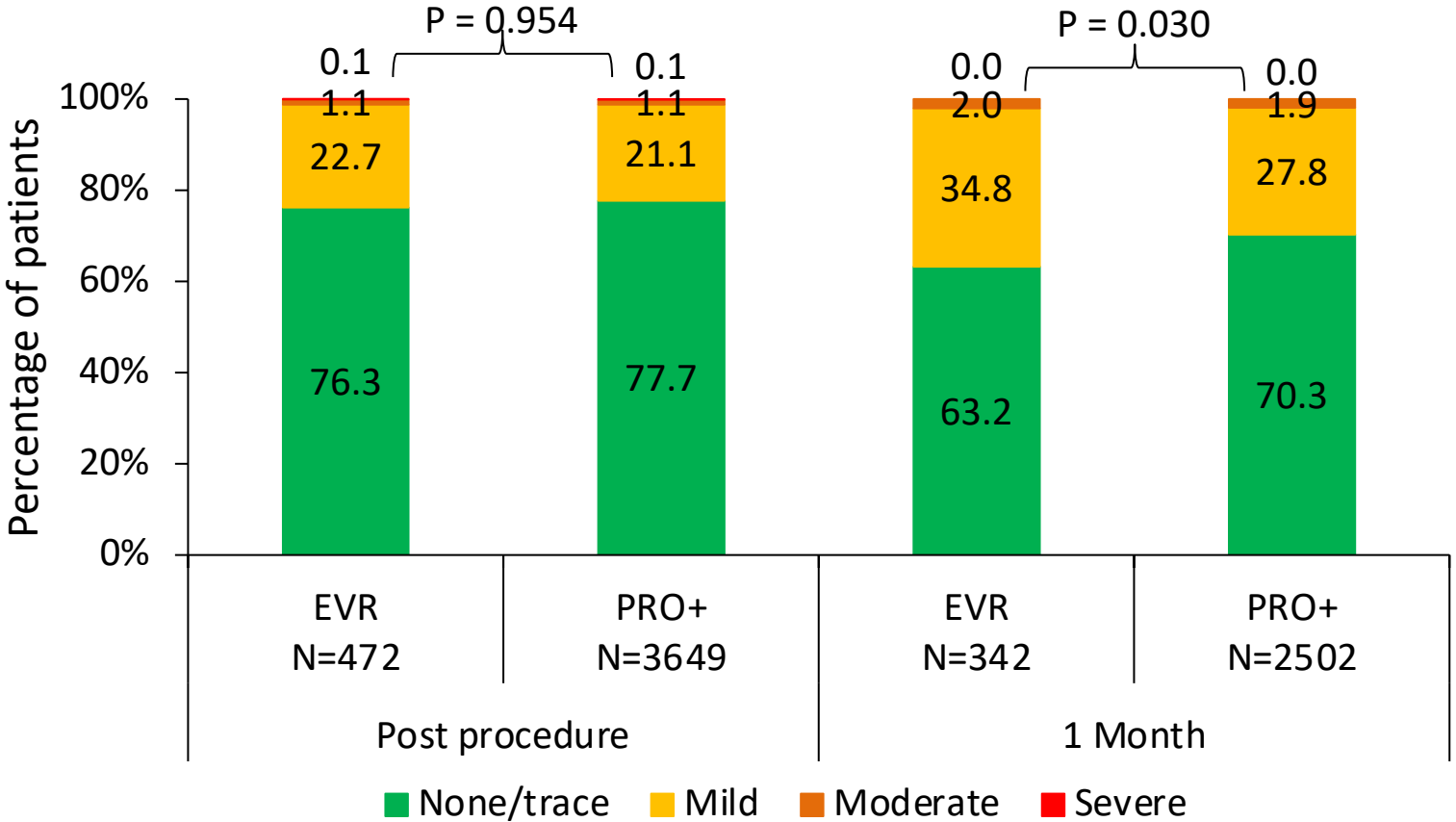


Safety outcomes out to 30 days

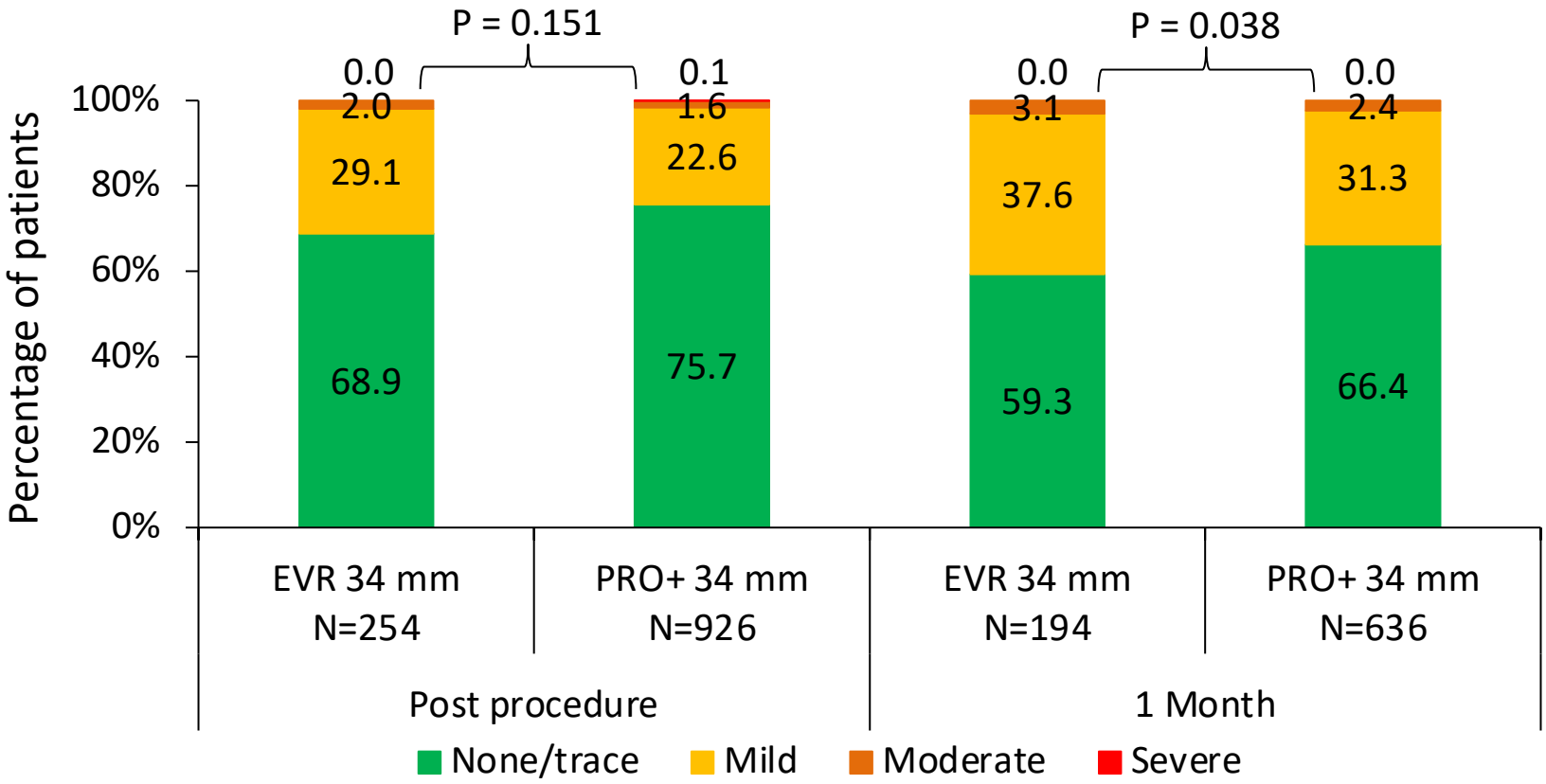
	In-hospital		30 days	
% (n)	EVR (N=525)	PRO+ (N=3963)	EVR (N=525)	PRO+ (N=3963)
All-cause mortality	1.9% (10)	1.2% (48)	3.0% (15)	2.6% (97)
Any stroke	2.5% (13)	2.2% (87)	3.3% (17)	2.9% (111)
Myocardial infarction	0.0% (0)	0.3% (10)	0.0% (0)	0.4% (15)
Major or life-threatening bleeding	4.2% (22)	5.4% (213)	5.5% (28)	6.1% (236)
Major vascular complication	1.1% (6)	1.2% (46)	1.2% (6)	1.3% (52)
Conduction/Native Pacer Disturbance Req Pacer/ICD[1]	10.5% (55)	10.7% (426)	11.9% (61)	12.9% (499)
Conduction/Native Pacer Disturbance Req Pacer/ICD[2]	12.4% (55)	12.5% (423)	14.1% (61)	15.0% (496)
Coronary compression or obstruction	0.2% (1)	0.3% (13)	NA	NA
Device thrombosis	0.0% (0)	<0.1% (1)	0.0% (0)	<0.1% (1)
Aortic valve re-intervention	0.0% (0)	0.3% (11)	0.0% (0)	0.4% (16)

[1]Subjects with pacemaker or ICD at baseline are included.
[2]Subjects with pacemaker or ICD at baseline are not included.

Total aortic regurgitation by valve type



Total aortic regurgitation in 34 mm valves



Limitations

- Data was not stratified by risk indication and therefore there may be potential for imbalance of risk groups between valve types.
- Changes in patient selection, practice patterns and the potential influence of calcified native valves in device selection are unknown.

Conclusions

- Compared to the earlier device iteration from the Evolut platform, patients treated with PRO+ were discharged home sooner, had shorter procedure times, and less general anesthesia use.
- Rates of annulus rupture in both Evolut R and Evolut PRO+ valves were extremely low.
- Rates of all-cause mortality, major vascular complications and aortic valve reintervention were low for both devices.
- For the 34mm devices, there was a numerical reduction in total aortic regurgitation with the PRO+ valve vs. Evolut R valve at 1 month.
- Further analysis including risk stratification will add to the growing body of knowledge around patient selection and device iteration in this rapidly growing therapy.

The next-generation self-expanding transcatheter device: 30-day outcomes from the TVT-Registry

Tanvir Bajwa, MD; Chad Rammohan, MD; Rishi Puri, MD, PhD; Bruce Rutkin, MD; Blake Gardner, MD; James E. Harvey, MD; Carlos Sanchez, MD; Azeem Latib, MB Bch

Background

- Transcatheter aortic valve replacement (TAVR) continues to develop and expand into lower-risk patients and new indications.
- TAVR devices continue to evolve to include lower-profile delivery systems and expanded sizing availability.
- This analysis examines outcomes from the next-generation Evolut PRO+ system compared to the Evolut R system.

Methods

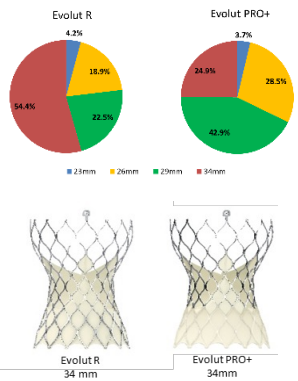
- Patients who underwent TAVR for treatment of native aortic valve stenosis between January 2020 and June 2020 using an Evolut R or Evolut PRO+ self-expanding prosthesis (Medtronic, Minneapolis, MN) were included in this analysis.
- This analysis included patients with native tricuspid aortic stenosis and excluded any valve-in-valve or previously failed bioprosthesis.
- Site-reported events for in-hospital, and 30-days outcomes as reported in the STS/ACC TVT Registry™ were examined.
- Site-reported echocardiographic data for post procedure and 30 days were analyzed.
- Comparisons of outcomes were performed by valve type (Evolut R TAV or Evolut PRO+) and Evolut R 34 mm vs Evolut PRO+ 34 mm valve size.

Table 1. Baseline characteristics

Mean ± standard deviation or %	EVR (N=525)	PRO+ (N=3963)
Age[1]	78.2 ± 8.1	78.9 ± 7.9
Body surface area (m²)	1.9 ± 0.3	1.9 ± 0.3
BMI < 21 kg/m²	7.1%	6.4%
Albumin < 3.3 g/dL	15.4%	12.2%
Male	64.4%	50.4%
NYHA Class		
I	4.0%	4.3%
II	28.1%	30.2%
III	55.4%	56.8%
IV	12.4%	8.7%
STS Score %	4.8 ± 4.1	4.6 ± 4.0
Diabetes mellitus	42.7%	39.1%
Prior stroke	10.1%	10.2%
Annular calcification	81.3%	81.7%
Chronic lung disease/COPD	40.6%	32.6%
Peripheral vascular disease	37.0%	23.6%
5-meter gait speed (seconds)	7.7 ± 4.0	8.0 ± 13.3
Aortic valve annulus size (mm)	25.3 ± 3.5	24.4 ± 3.0

[1]Subjects with age >90 are reported as "90 plus" in the database and for calculation are set to 90
[2]Calcification in the aortic valve leaflets, aorta adjacent to the AV, leaflets or the left ventricular outflow tract (LVOT), or if echo reports document AV calcific degeneration

Figure 1. Valve size implanted



Results

Table 2. Procedural characteristics

% or median	EVR (N=525)	PRO+ (N=3963)
Procedure location – hybrid cath lab or cath lab	45.7%	41.7%
Type of anesthesia - general	47.4%	39.3%
Left/right femoral & iliac	92.0%	95.5%
More than 1 valve used	0.8%	1.7%
Procedure time (minutes)	89.0	79.0
ICU duration (hours)	18.0	7.5
Total length of hospital stay (days)	2.0	2.0
Length of hospital stay after procedure (days)	2.0	2.0
Annulus rupture	0.0%	0.1%
Discharged - home	89.7%	92.0%

Table 3. Safety outcomes

	In-hospital		30 days	
% (n)	EVR (N=525)	PRO+ (N=3963)	EVR (N=525)	PRO+ (N=3963)
All-cause mortality	1.9% (10)	1.2% (48)	3.0% (15)	2.6% (97)
Any stroke	2.5% (13)	2.2% (87)	3.3% (17)	2.9% (111)
Myocardial infarction	0.0% (0)	0.3 (10)	0.0% (0)	0.4% (15)
Major or life-threatening bleeding	4.2% (22)	5.4% (213)	5.5% (28)	6.1% (236)
Major vascular complication	1.1% (6)	1.2% (46)	1.2% (6)	1.3% (52)
Conduction/Native Pacer Disturbance Req Pacer/ICD[1]	10.5% (55)	10.7% (426)	11.9% (61)	12.9% (499)
Conduction/Native Pacer Disturbance Req Pacer/ICD[2]	12.4% (55)	12.5% (423)	14.1% (61)	15.0% (496)
Coronary compression or obstruction	0.2% (1)	0.3% (11)	NA	NA
Device thrombosis	0.0% (0)	<0.1% (1)	0.0% (0)	<0.1% (1)
Aortic valve re-intervention	0.0% (0)	0.3% (11)	0.0% (0)	0.4% (16)

[1]Subjects with pacemaker or ICD at baseline are included.
[2]Subjects with pacemaker or ICD at baseline are not included.

Figure 2. Total aortic regurgitation by valve type

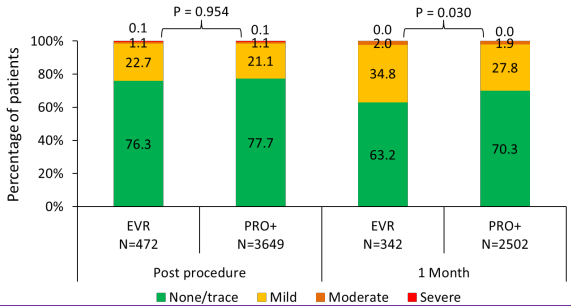
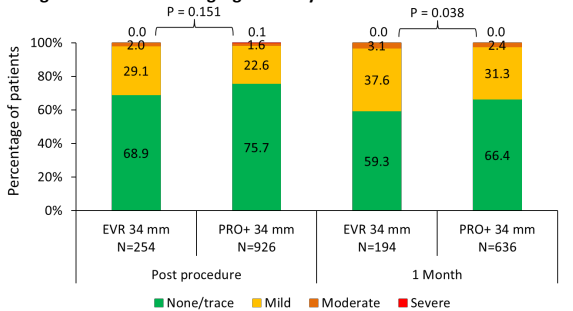


Figure 3. Total aortic regurgitation by 34 mm valves



Limitations

- Data was not stratified by risk indication and therefore there may be potential for imbalance of risk groups between valve types.
- Changes in patient selection, practice patterns and the potential influence of calcified native valves in device selection are unknown.

Conclusions

- Compared to the earlier device iteration from the Evolut platform, patients treated with PRO+ were discharged home sooner, had shorter procedure times, and less general anesthesia use.
- Rates of annulus rupture are extremely low
- Rates of all-cause mortality, major vascular complications and aortic valve reintervention were low for both devices.
- For the 34mm devices, there was a numerical reduction in total aortic regurgitation with the PRO+ vs. Evolut R at 1 month
- Further analysis including risk stratification will add to the growing body of knowledge around patient selection and device iteration in this rapidly growing therapy.