



Pacemaker implantations and new left bundle branch block

- a SCOPE 2 sub-analysis -

Potential conflicts of interest

Speaker's name : Costanza Pellegrini

I do not have any potential conflict of interest to declare

Speaker's name : Michael Joner

Dr. Joner reports personal fees from Abbott, Astra Zeneca, Biotronik, Boston Scientific, Edwards, Orbus Neich, ReCor, Shockwave and grants from Boston Scientific, Cardiac Dimensions, Edwards, Infraredx

The ACURATE *neo*TM and *neo2*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
© 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

Why this study?

- incidences of left bundle branch block (LBBB) and permanent pacemaker implantation (PPI) vary considerably across different valve types

Boston Scientific - ACURATE neo



LBBB: 10.3 - 13%
PPI: 3.8 - 21%

Medtronic - Evolut R



LBBB: 12.8 - 25-9%
PPI: 11.8 - 25%

Edwards - SAPIEN 3



LBBB: 7.5 - 20.5%
PPI: 4.5 - 31%

- increased 1 year mortality for LBBB and PPI

Study or Subgroup	NOP-LBBB		No NOP-LBBB	
	Events	Total	Events	Total
Franzoni et al. 2013	8	63	26	175
Nazif et al. 2014	21	121	190	1030
Testa et al. 2013	42	224	117	594
Carrabba et al. 2015	4	34	7	58
Urena et al. 2014	22	79	167	589
Chamandi et al. 2019	42	212	114	808
Lopez Aguilera et al. 2016	5	80	3	73
Houthuizen et al. 2012	62	233	78	446
Nazif et al. 2019	19	179	69	1000
Schymik et al. 2015	41	197	57	437
Houthuizen et al. 2014	30	111	56	365
Jorgensen et al. 2019	30	237	22	447

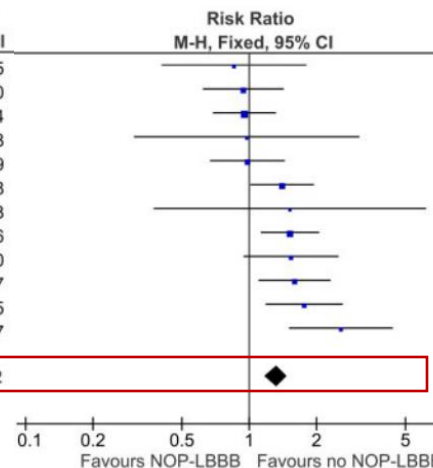
Total (95% CI) 1770 6022

Total events 326 906

Heterogeneity: $\text{Chi}^2 = 21.43$, $\text{df} = 11$ ($P = 0.03$); $I^2 = 49\%$

Test for overall effect: $Z = 4.57$ ($P < 0.00001$)

Farouq et al. 2020 Eur Heart J, Auffret et al. 2017 Circulation



Study or Subgroup	PPI		No PPI	
	Events	Total	Events	Total
Engborg et al. 2017	1	41	12	87
Walther et al. 2018	2	29	20	164
Houthuizen et al. 2012	20	118	140	679
D'Ancona et al. 2011	3	20	51	302
Urena et al. 2014	46	239	272	1317
Mouillet et al. 2015	41	252	98	581
Gonska et al. 2018	18	147	48	385
Biner et al. 2014	6	58	18	172
Jorgensen et al. 2019	17	210	63	798
Fadahunsi et al. 2016	114	651	1536	9134
De Carlo et al. 2012	6	44	16	125
Pereira et al. 2013	5	19	9	37
Buellesfeld et al. 2012	19	98	37	207
Chamandi et al. 2018	57	322	197	1307
Kawaguchi et al. 2015	10	28	40	132
Fujita et al. 2019	601	3459	2421	17413
Nazif et al. 2015	45	173	374	1800
Schymik et al. 2015	13	69	85	565
Nadeem et al. 2018	32	146	81	526
Lopez Aguilera et al. 2018	8	39	22	178
Marzahn et al. 2018	36	145	96	711

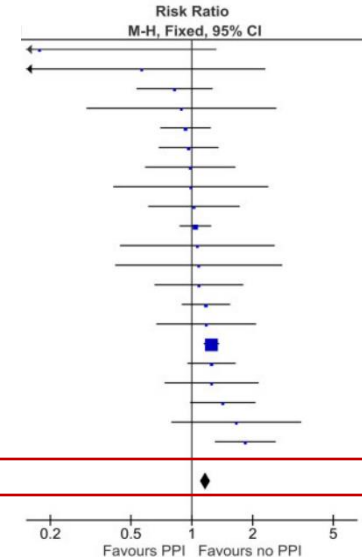
Total (95% CI) 6307 36620

Total events 1100 5636

Heterogeneity: $\text{Chi}^2 = 25.47$, $\text{df} = 20$ ($P = 0.18$); $I^2 = 21\%$

Test for overall effect: $Z = 5.27$ ($P < 0.00001$)

Test for overall effect: $Z = 5.27$ ($P < 0.00001$)



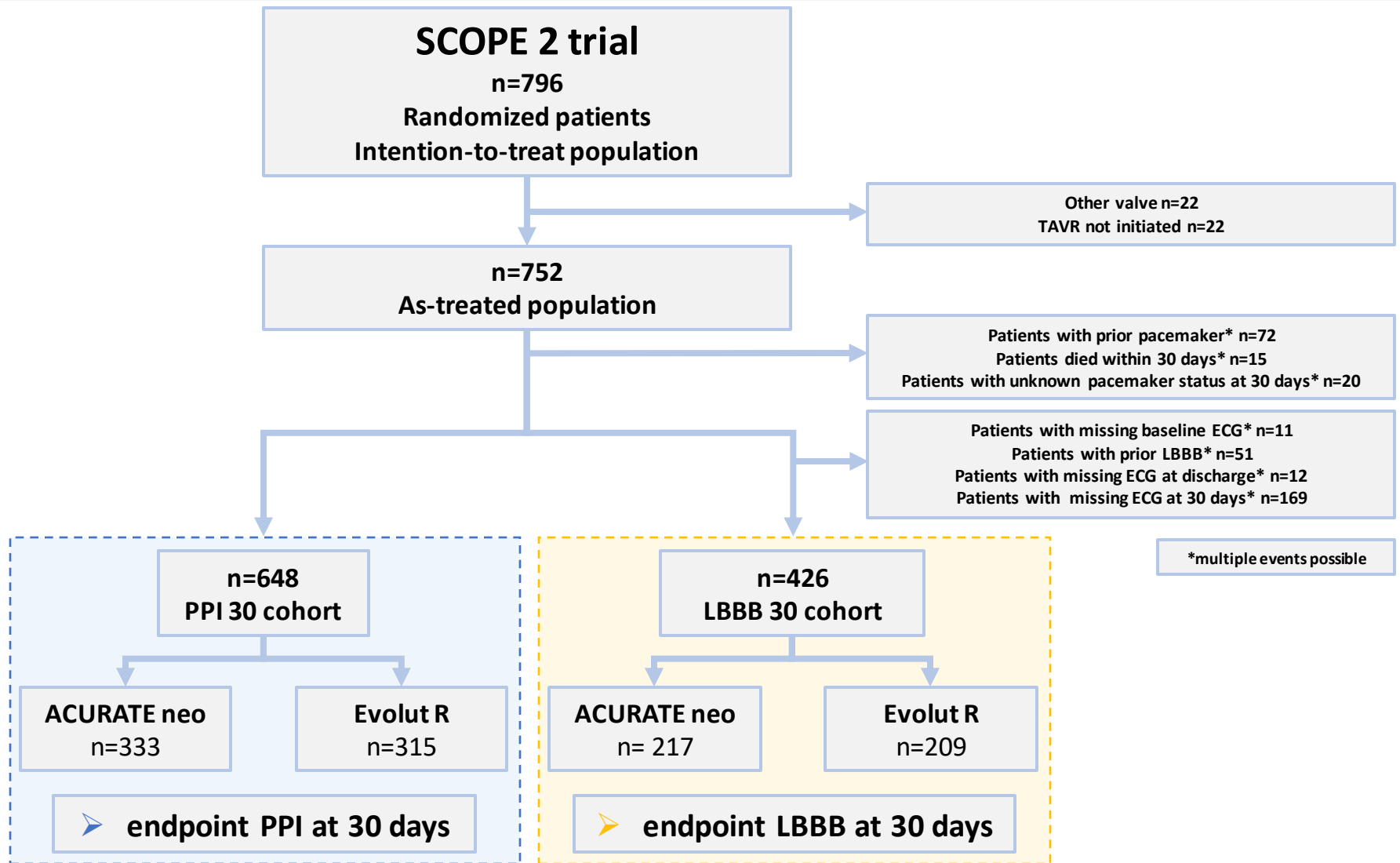
What did we study?

From the **powered, prospective, randomized SCOPE 2 clinical trial**, comparing the ACURATE neo and the CoreValve Evolut R valves, we performed a sub-analysis to ...

- assess **independent predictors of new PPI** after TAVI, focusing on clinical baseline characteristics, CT-assessed valve morphology and pre-existing electrocardiographic variables
- assess whether newly developed **conduction abnormalities resolve or persist** from discharge to follow-up at 30 days and at 1 year
- confirm from randomized controlled data whether **new LBBB or PPI** after TAVI have an **impact on mortality at 1 year**

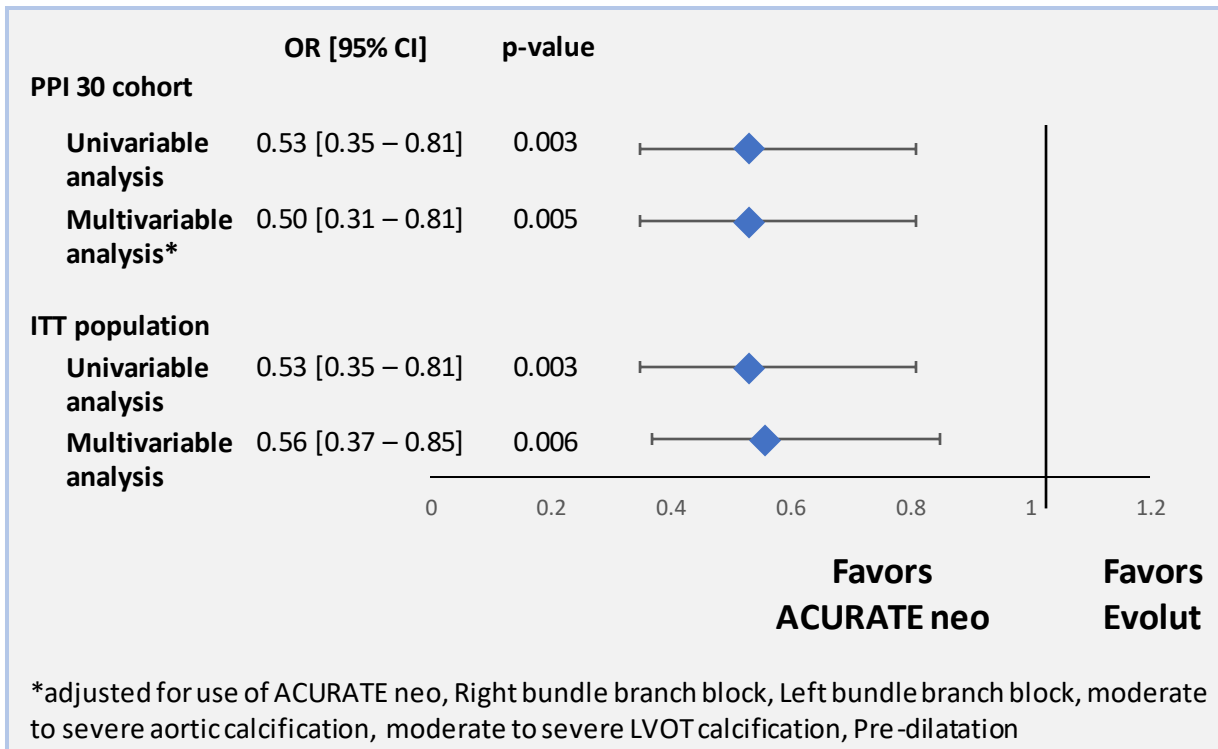
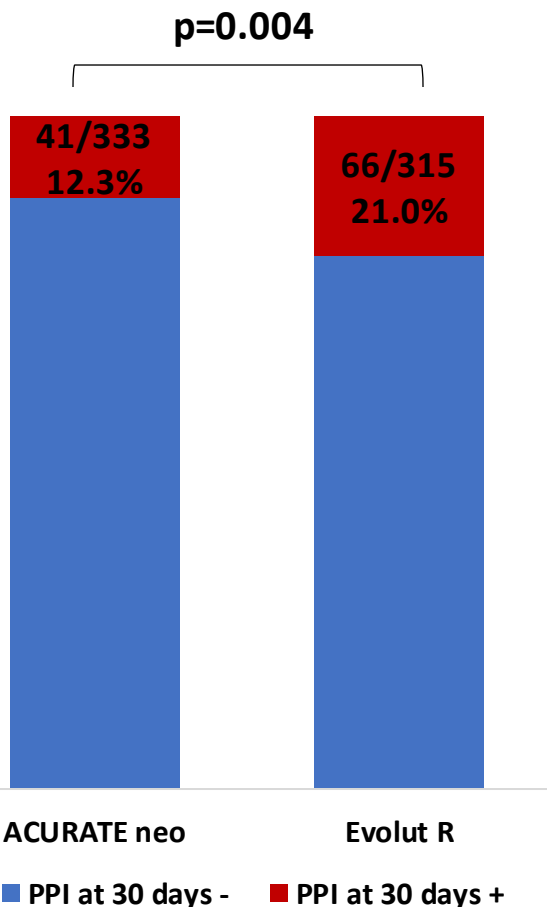
The ACURATE *neo*TM and *neo2*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
© 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

How was the study executed?



What are the essential results? (1)

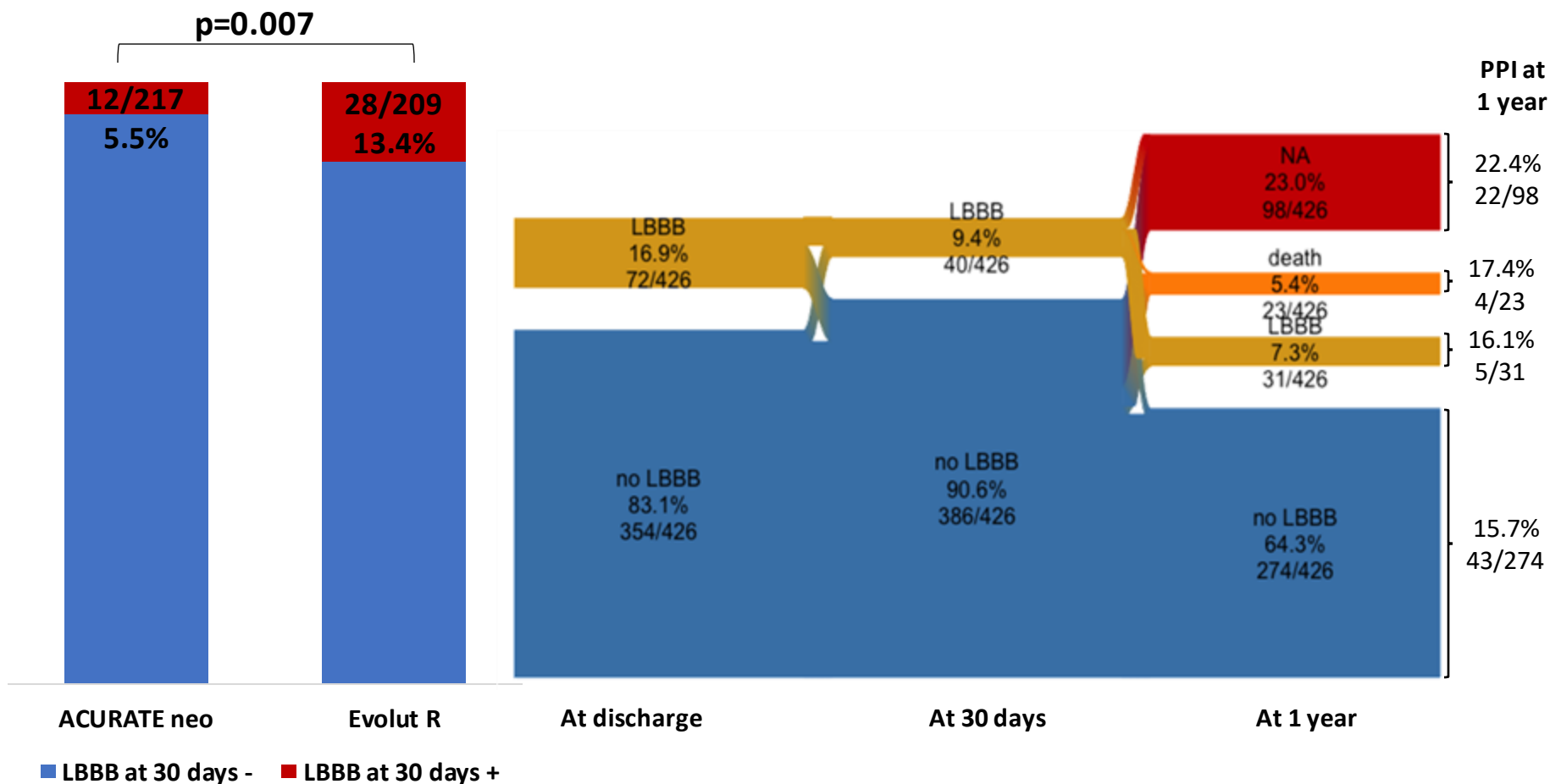
- crude event rates of PPI at 30 days for valve type and multivariable analysis for risk of PPI at 30 days



Right bundle branch block OR 6.11 95% C I[3.19 - 11.73] <0.001

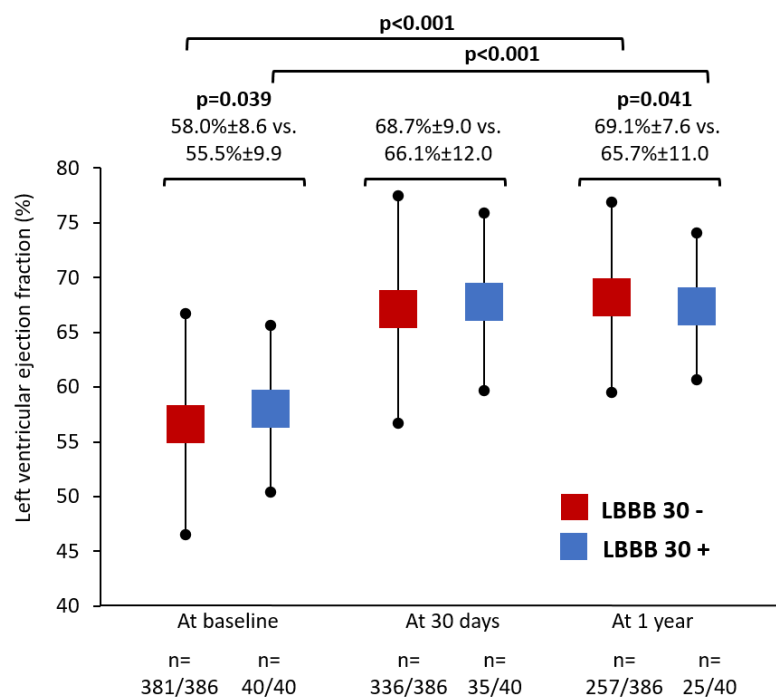
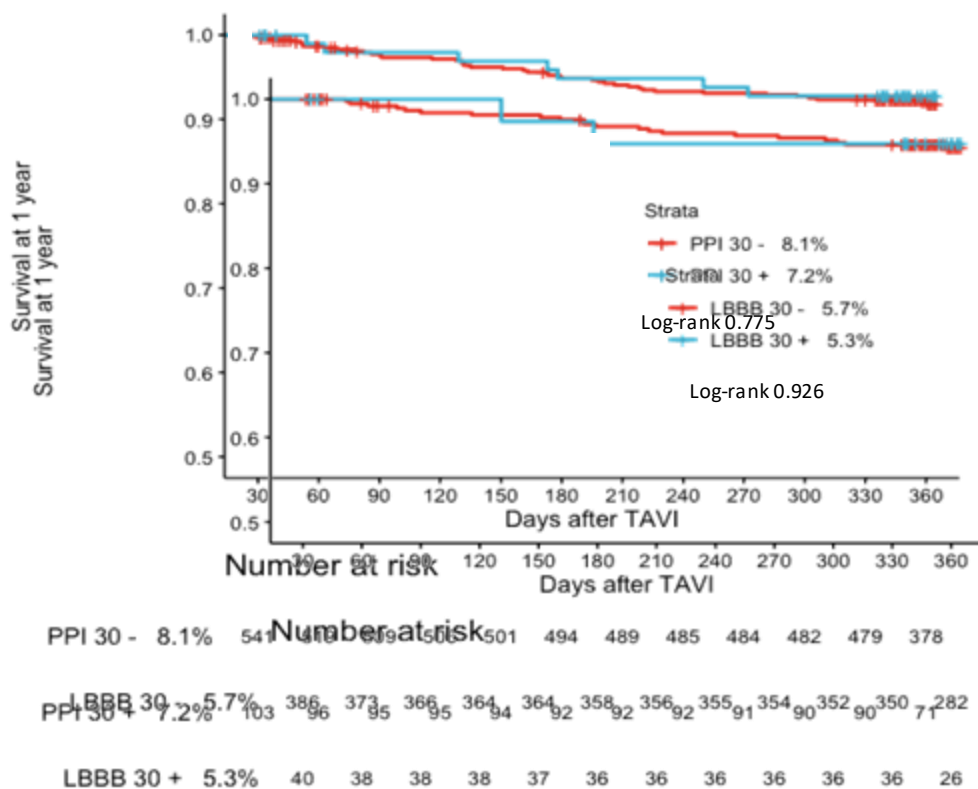
What are the essential results? (2)

- crude event rates of LBBB at 30 days for valve type and evolution of LBBB over time



What are the essential results? (3)

- no impact on 1 year mortality for PPI or LBBB at 30 days
- worse LV function at 1 year for patients with LBBB at 30 days



The ACURATE *neo*TM and *neo*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
 © 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

Why is this important?

- Lack of data on comparison of latest generation heart valves regarding new LBBB and PPI from randomized clinical trials
- by extending TAVI to lower risk and younger patients, it is paramount to reduce post-procedural LBBB and PPI, especially in light of the expected longer survival
- although contemporary metanalysis showed association with increased mortality, the current sub-study could not confirm this finding at 1 year

The ACURATE *neo*TM and *neo2*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
© 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

The essentials to remember

- **why?** Randomized comparative evidence on LBBB and PPI with latest generation valves remain scarce
- **what?** Powered comparison on incidence, predictors and impact of LBBB and PPI at 30 days
- **how?** Sub-analysis from the randomized SCOPE 2 clinical trial
- **what are the results?** LBBB and PPI rates were lower in ACURATE neo compared to Evolut R. Use of the ACURATE neo was associated with decreased risk of PPI.
- **why is this important?** Patient-tailored valve selection should aim to minimize post-procedural complications and these results promote the use of the ACURATE neo in patients at high risk for conduction abnormalities

The ACURATE *neo*TM and *neo2*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
© 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

All trademarks are property of their respective owner.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

©2022 Boston Scientific Corporation or its affiliates. All rights reserved.

The ACURATE *neo*TM and *neo2*TM Valve System are CE-Marked. It is an investigational device in the US and restricted under federal law to investigational use only. Not available for sale.
© 2022 Boston Scientific Corporation or its affiliates. SH-1330206-AA

PCR

PCRonline.com