

MEXICO CITY

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GLOBAL EXPERTS, LOCAL LEARNING





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CoreValve SURTAVI Trial Clinical Sites



The clinical outcomes in 1746 intermediate-risk patients with severe, symptomatic aortic stenosis were investigated in a randomized fashion comparing TAVR (performed with the use of a self-expanding prosthesis) with surgical aortic-valve replacement.



TRIAL Timeline



2012 2013 2014 2014 2015 2016

Entry STS 4-10%

Risk Based Entry Heart Team ≥3% to < 15%

June 2012, 1ST EU Pt

Evolut R

Nov 2012 First US Pt

Activation of 40
Sites from US
High and Extreme
Risk Trials

Activation of ~30 Additional Sites

Randomized Enrollment Concluded May 2016



The NEW ENGLAND JOURNAL of MEDICINE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

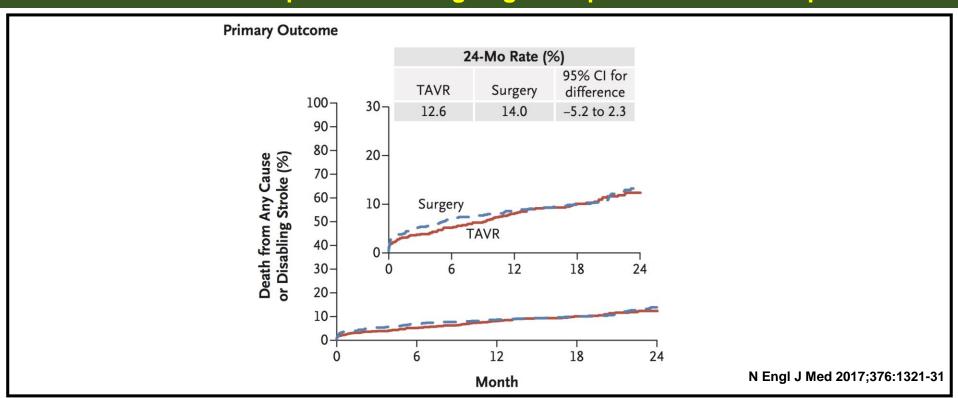


N Engl J Med 2017;376:1321-31



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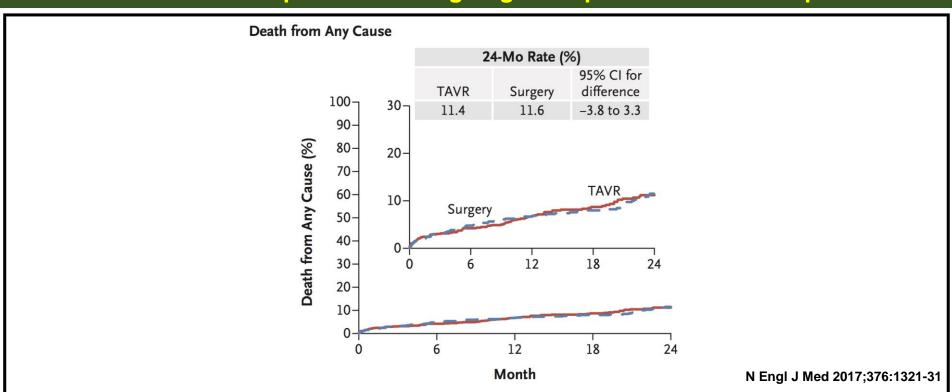
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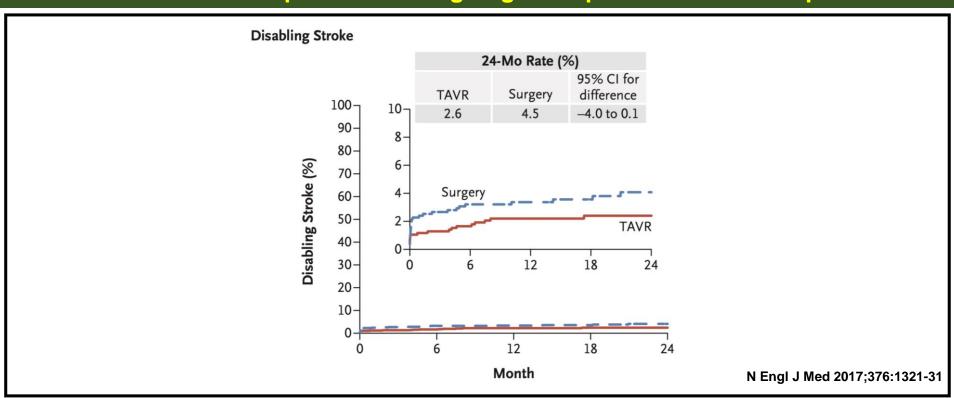
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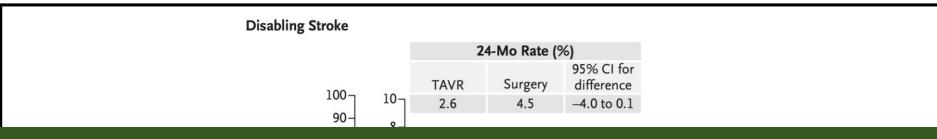
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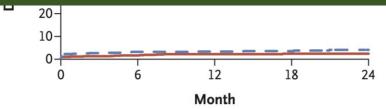
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Conclusion:

TAVR was a noninferior alternative to surgery in patients with severe aortic steno- sis at intermediate surgical risk, with a different pattern of adverse events associated with each procedure.

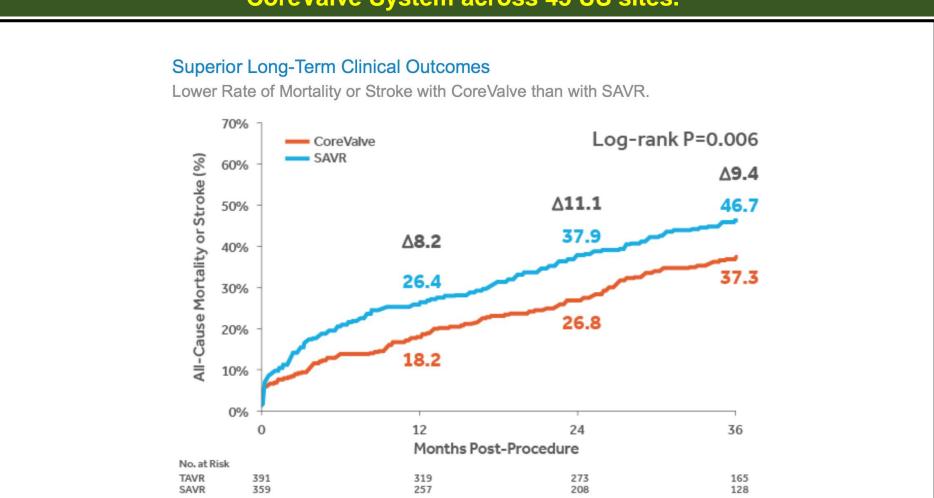


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CoreValve US Pivotal Trial High Risk Study



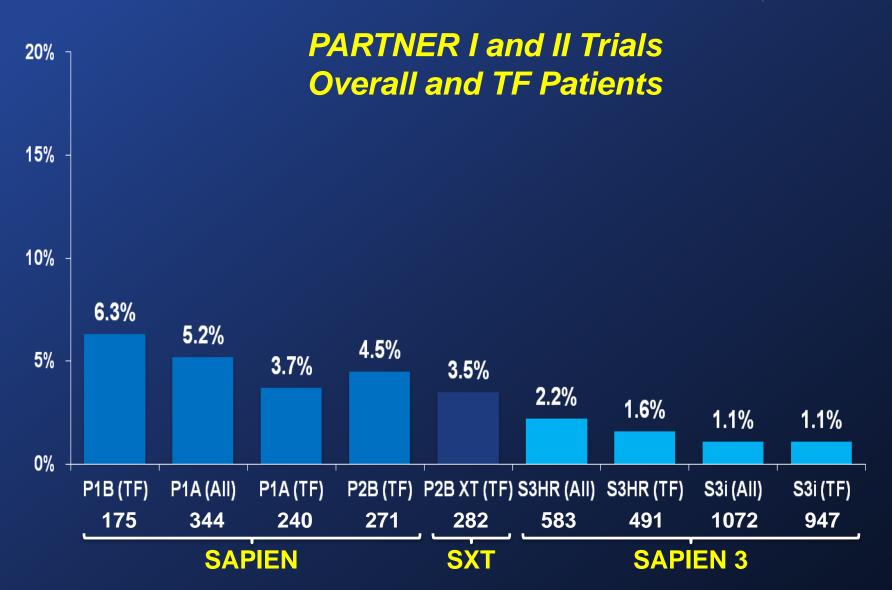
795 patients between surgical aortic valve replacement (SAVR) and TAVI with the CoreValve System across 45 US sites.



All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)









Thank you