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i2 SUMMIT

LEARNING CURVE IN THE USE OF STARCLOSE VASCULAR CLOSURE DEVICE: AN ANALYSIS OF THE NATIONAL CARDIOVASCULAR DATA REGISTRY

i2 Poster Contributions

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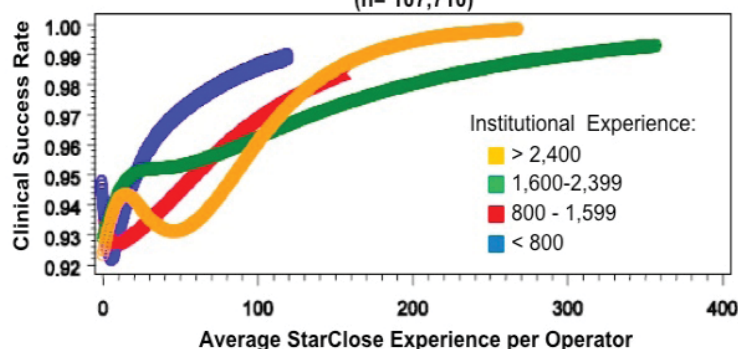
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Background: Understanding rates of learning in the use of medical devices can inform physician training and may help to improve outcomes. However, there has been limited quantification of learning curve effects for medical devices.

Methods: A retrospective analysis of the NCDR CathPCI Registry was performed to assess changes in successful deployment rates with growing institutional experience following the release of the StarClose vascular closure device (VCD). Clinical success (CS) was defined as a procedure with successful deployment and no access site complications.

Results: A total of 107,710 StarClose VCDs deployed between 1/2006 and 12/2007 were analyzed, with overall CS rate increasing from 93% to 97% at 468 institutions. A tri-modal learning pattern emerged, with a rapid initial learning phase, followed by a period of declining success (likely related to adoption of the VCD by new operators at the institutions analyzed), followed by recovery to a steady state of improvement. The rate of learning was found to be influenced positively by diagnostic (vs. interventional) procedures, teaching status and inversely by institutional volume. By Generalized estimating equations modeling, the initial learning phase was characterized by 0.2% improvement in CS with each doubling of experience.

Clinical Success Rates vs. Institutional Experience
Stratified by Institutional Volume
(n= 107,710)



Conclusion: This study shows that national registries can be applied to better understand learning effects after market release of a new VCD.