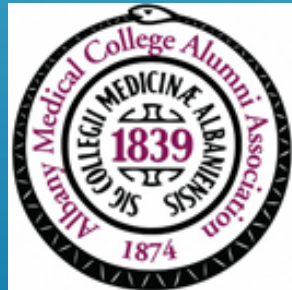


Outcomes of Defibrillator Lead Implants Performed by High Volume Operators vs. Low Volume Operators:

Results from the Pacemaker and
Implantable Defibrillator Leads Survival
Study (“PAIDLESS”)




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What is the original PAIDLESS study?

- ▶ Retrospective analysis at a large-volume implanting hospital
- ▶ Includes all patients at Winthrop University Hospital that underwent defibrillator lead implantation between February 1, 1996 and December 31, 2011
 - ▶ A total of 4078 leads were implanted in 3802 patients
- ▶ The study compared patient characteristics, implant approach, lead construction, recall status, lead survival, and patient mortality

Lead failure

- ▶ Defined by the Medtronic System Longevity Study:
 - ▶ Failure to capture
 - ▶ Failure to sense
 - ▶ Abnormal pacing impedance (< 400 ohms or > 2000 ohms)
 - ▶ Abnormal defibrillation impedance (< 20 ohms or > 200 ohms)
 - ▶ Insulation defect
 - ▶ Lead fracture
 - ▶ Extracardiac stimulation
 - ▶ Cardiac perforation
 - ▶ Tricuspid valve entrapment
 - ▶ Lead tip fracture
 - ▶ Lead dislodgement
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- A decorative graphic consisting of several parallel white lines of varying lengths, slanted diagonally from the bottom right towards the top right, set against a blue background.

Recall status

- ▶ Three lead manufacturers: Boston Scientific (537), Medtronic (1834), St. Jude Medical (1707)
 - ▶ October 2007: Medtronic Sprint Fidelis was recalled due to lead fracture (801 PAIDLESS leads)
 - ▶ November 2011: St. Jude Medical Riata and Riata ST were recalled due to insulation failure (703 PAIDLESS leads)
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PAIDLESS results

- ▶ Boston Scientific and St. Jude leads performed better than Medtronic leads ($p < 0.001$ and $p = 0.01$, respectively)
- ▶ Recalled leads were associated with earlier lead failure ($p = 0.0126$) and more patient mortality ($p = 0.006$)
- ▶ Multivariable Cox regression model: factors contributing to lead failure
 - ▶ Younger age
 - ▶ History of percutaneous coronary intervention
 - ▶ Baseline rhythm (sinus vs. atrial fibrillation vs. flutter)
 - ▶ Lead insulation coating (combination vs. silicone)
 - ▶ Number of coils (one vs two)
 - ▶ Recalled lead status

Purpose of this sub-study:

- ▶ To investigate the effects of operator volume on defibrillator lead failure

Methods

- ▶ Between February 1, 1996 and December 31, 2011 at Winthrop University Hospital:
 - ▶ High volume operators: performed ≥ 500 implants
 - ▶ Low volume operators: performed < 500 implants
 - ▶ These two groups were analyzed based on patient characteristics and lead failure
 - ▶ Statistical analyses included: T-tests, Chi-Square tests, and Kaplan-Meier analysis
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Results

Operator group	Number of operators	Type of operator	Number of patients N=3802 (%)	Number of implants N=4078 (%)
High	4	Electrophysiologists	3150 (83)	3375 (83)
Low	4	Electrophysiologists and a cardiothoracic surgeon	652 (17)	703 (17)

Results

- ▶ Patient characteristics:
 - ▶ High volume operators group
 - ▶ More men (75% versus 69%; $p=0.0006$)
 - ▶ Older patients (71 ± 12 years versus 68 ± 13 years; $p<0.0001$)
 - ▶ Longer follow up (4 ± 3 years versus 2 ± 2 years; $p<0.0001$)
 - ▶ Implanted mostly with Medtronic leads (52% versus 10%)
 - ▶ Implanted more with recalled leads (42% versus 12%; $p<0.0001$)

Results

- ▶ Lead failure:
 - ▶ More lead failures occurred in patients operated on by high versus low volume operators (136 failures (4%) versus 17 failures (2%); $p=0.0408$)
 - ▶ Kaplan Meier analysis: time to lead failure was not significant ($p=0.0806$)
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Conclusions

- ▶ Contrary to previous studies, high volume operators used more recalled leads and had more lead failures than low volume operators
 - ▶ This may be attributed to lead selection and differences in patient characteristics
 - ▶ Further research is needed to better understand the impact of operator volume on lead failure and patient outcomes
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