ACC.15
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A329
JACC March 17, 2015
Volume 65, Issue 10S

Arrhythmias and Clinical EP

SAFETY OF SPRINT FIDELIS DEFIBRILLATOR LASER LEAD EXTRACTION SEVEN YEARS AFTER FOOD AND DRUG ADMINISTRATION RECALL

Poster Contributions
Poster Hall B1
Saturday, March 14, 2015, 10:00 a.m.-10:45 a.m.

Session Title: Contemporary Challenges in Cardiac Implantable Device Management
Abstract Category: 6. Arrhythmias and Clinical EP: Devices
Presentation Number: 1116-266

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Background: The Medtronic Sprint Fidelis lead was placed under FDA Class I recall due to high lead failure and fracture rates in October 2007.The aim of our study was to determine the safety of Sprint Fidelis laser lead extraction seven years after FDA recall.

Methods: This is a retrospective chart review study of 81 pts who underwent lead extraction of Sprint Fidelis lead (6949 lead) at our center between 2010-14.

Results: The mean age of pts was 61 yrs. Mean LVEF was 33%,there was equal distribution between NICM (52%) and ICM (48%).HTN (75%) followed by DM (42%), AF (33%) CKD (18%) were observed. Prophylactic lead extraction at the time of generator change was the most common indication (56%) followed by lead fracture (27%), infection (15%) and dysfunction (2%). Mean number of leads extracted at time of fidelis removal was 1.44. The average laser sheath size used for the procedure was 14 Fr (12-14) and an outer Visi sheath was used in all cases. Table below compares age of lead and mean laser times.There was statistically no difference by pearson correlation (p - 0.23) in mean laser time and age of leads. One pt had subclavian tear, 2 pts had lead dislodgement and 1 had occlusive thrombosis of the subclavian vein.

Conclusion: Laser extraction of the Sprint fidelis lead is very safe and reliable even after 7 years of recall by FDA. Presence of silicone backfill, inner cable and coil design, and operator experience in a high volume center may be the contributing factors for safe and successful lead extraction of the Sprint Fidelis lead.

Age of leads, number of leads extracted and mean laser time

Age of Lead (yrs)	Number of Fidelis lead extracted (n=81)	Laser Time (sec)
4	10	15
5	14	43
6	31	38
7	18	32
8	5	18
9	3	36