was 27 ± 10 months (<1–114 months). In all pts, driving habits, ICD discharges and accident occurrence were evaluated, all pts were seen in the outpatient clinic every two months.

Results: No change in driving habits after ICD implantation was reported by 140 pts (86%) group 1 (G1), while the remaining 22 pts (14%) group 2 (G2) showed modifications. During the follow-up ICD-discharges (D) occurred in 99/162 pts (61%), in 84 pts (63%) in G1 and in 15 pts (70%) in G2. There was a mean incidence of 18 ICD-discharges per pt in G1 and 20 ICD-D/pt in G2. ICD-D occurred in 8 pts (5%) whilst driving a motor vehicle. 4 pts (2%) reported on accident occurrence.

Conclusions: The incidence of ICD-D during driving is low and the majority of pts do not modify their driving habits. An accident resulting from an arrhythmic event appears to be rare and therefore, restriction of drivers' licenses after ICD implantation is not considered mandatory.

9:00

736-3 Costs and Complications of Non-thoracotomy Defibrillator Systems: Impact of Health Care Financing Administration Guidelines

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Non-thoracotomy implantable defibrillator (ICD) systems have been shown to have lower costs and fewer complications than thoracotomy systems. Recent interpretation of Health Care Financing Administration regulations has challenged reimbursement for investigational devices or combinations of components not approved by the Food and Drug Administration ("off-label"). We compared the costs and complications associated with approved pulse generator/lead systems (CPI 1600/Endotak, CPI 1705/Endotak and Medtronic 7217/Transvene, n = 136) with investigational and "off-label" systems (CPI 1625/Endotak, CPI 1715/Endotak, Medtronic 7219/Transvene and Ventritex V100 or V110/TVL and V100/Endotak, n = 79). Age [63 ± 12 years versus 63 ± 11 years (mean ± SD)] and ejection fraction (31 ± 15% versus 31 ± 11%) were similar for patients with approved and investigational systems, respectively. However, total hospital charges including preoperative care and evaluation, implant procedure and hardware, postoperative testing and revisions were $64 ± 19,000 for approved devices versus $57 ± 16,000 for non-approved devices (p = 0.02) despite higher overall costs of newer pulse generators and leads. Total length of stay was 17 ± 10 days versus 14 ± 8 days (p = 0.03) and complications including lead dislodgement, increased defibrillation threshold, hematoma and infection were 25/136 versus 4/77 (p < 0.005) for approved and investigational or "off-label" systems, respectively. Based on data provided by the manufacturers, anticipated average battery longevity is 3.8 years for approved systems and 5.5 years for investigational or "off-label" systems.

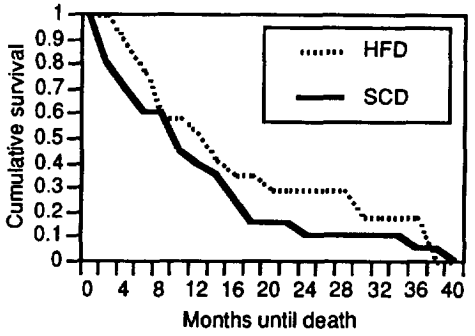
Conclusions: The prudent use of current investigational or "off-label" non-thoracotomy ICD systems is more cost-effective and is associated with fewer complications than approved ICD systems. When increased battery longevity is considered, long term costs of non-thoracotomy ICD therapy may be improved dramatically with the use of investigational or "off-label" systems. Review of reimbursement regulations may be warranted.

9:15

736-4 Time Course of Sudden Death and Heart Failure Death in Patients with Third Generation Implantable Cardioverter-Defibrillators

Michael O. Sweeney, Mary L. Guy, Hasan Garan, Brian McGovern, Jeremy Ruskin. *Massachusetts General Hospital, Boston, MA*

Thirty seven cardiac deaths (12.2%) occurred in 301 pts with third generation implantable cardioverter-defibrillators (ICD) during a mean followup of 26 ± 15 months. There were 17 (5.6%) heart failure deaths (HFD) and 20 (6.6%) sudden cardiac deaths (SCD). Baseline variables including age, gender, cardiac diagnosis, index or induced arrhythmia, and left ventricular ejection fraction were similar for HFD and SCD; mean NYHA class at ICD implant was lower in the SCD group (p = 0.001). Kaplan-Meier survival rates for each group were *not different* (Figure, p = 0.22).



Time-dependent multivariate analysis revealed ejection fraction and NYHA class were the only variables independently related to time until death:

Independent variable	Time-dependent variable	p-value
Ejection fraction	Total cardiac death	0.01
	Heart failure death	0.08
	Sudden cardiac death	0.04
NYHA heart failure class	Total cardiac death	0.10
	Sudden cardiac death	0.10

Conclusions: Sudden death and heart failure death occur at similar rates in ICD pts. Ejection fraction and NYHA heart failure class are the most important baseline determinants of time to death regardless of mechanism.

9:30

736-5 Quality of Life in Patients Receiving Implantable Cardioverter Defibrillators Before Age 40

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As the use of Implantable Cardioverter Defibrillators (ICD) increases, greater numbers of young patients (pts) will receive these devices. Such pts may have different expectations and requirements than older pts who more commonly receive ICDs. We investigated quality of life issues in all 25 pts followed at Yale New Haven Hospital who were under age 40 years (13–40 y, m = 28) at time of ICD placement. Mean time since ICD placement was 3.3 years. Four pts were excluded: 2 had devices explanted, and 2 died (1 from sepsis and 1 from arrhythmia following ICD inactivation). Cardiac diagnoses included: myocardial infarction (7), long QT syndrome (6), cardiomyopathy (6), and other (6).

Each pt received a modification of the New England Medical Center health questionnaire; 16/21 responded (76%). Nine were women, and 10 were married, 3 after ICD implantation. Highest education attained was high school for 6 (37%), college for 7 (44%), and graduate school for 3 (29%). Two pts obtained graduate degrees and 4 women conceived after ICD implantation. All delivered healthy infants including 1 whose ICD discharged during pregnancy. Ten pts were employed; 8 held the same job before and after ICD placement. Two of the employed pts reported work difficulties: both reported that they accomplished less than before, and worked less carefully.

All pts felt their health was good to excellent, with 6 reporting an improvement in health since placement of the ICD, and 1 reporting a moderate decrease in overall health. All felt they were capable of the activities of daily living, while 68% engaged freely in moderate physical activities. Only 31% felt able to fully participate in vigorous activities.

All pts felt they were average to very attractive. However, 63% worried about how their clothes fit with the ICD and 68% worried about wearing bathing suits (89% of the women and 43% of the men). The ICD interfered somewhat with social interactions in 75% of pts, and 50% avoided social functions, while 50% worried about sexual encounters, and 44% avoided these encounters.

Thus, even though these young pts have body image concerns and limit their activities, they are productive, active members of society, justifying aggressive medical therapy and social support.