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714-5 ICD Device Size can be Reduced by Smaller Capacitors

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Background & Hypothesis: ICDs with smaller capacitors (C) and less maximum energy (E) output than today's ICDs might allow implantation of endocardial lead systems with an acceptable safety margin in some patients. Using small capacitors that deliver shorter duration (SD) waveforms would significantly reduce ICD size.

Methods: Intraoperatively, standard (STD) and SD biphasic (60:40, 80% tilt) waveforms were compared using a cross-over study design:

Waveform	Defibrillator	C [μ F]	E [J]
STD	VENTAK® ECD 2815	125	38 (780 V)
SD	VENTAK® ECD RSD2815	90	20-23 (660 V)

In 30 patients (age: 59 ± 10 ; male: 24, CAD: 22, DCM: 4, EF $42 \pm 15\%$, amiodarone: 8), the defibrillation threshold (DFT) was determined using a step-down protocol (20, 15, 10, 8, 5, 3, 2, 1 J) during ICD implantation. Patients were randomized to receive an endocardial defibrillation lead-alone (TV; Endotak® 0072, n = 15) or in combination with a subcutaneous defibrillation array (SC, Endotak® 0048, n = 15).

Results: The SD waveform defibrillated with energies ≤ 10 J in 67% of the patients with TV and 80% of the patients with SC.

DFT	All [J]	TV [J]	SC [J]	All [V]	TV [V]	SC [V]
STD	9.5 ± 4.9	11.3 ± 4.4	7.7 ± 3.9	322 ± 80	360 ± 74	284 ± 68
SD	10.3 ± 4.1	11.2 ± 4.6	9.4 ± 3.3	411 ± 80	431 ± 92	392 ± 65
p	n.s.	n.s.	n.s.	<0.0001	0.0012	0.0002

The significantly higher voltages of the SD waveform did not significantly reduce the the sensing electrogram amplitude 6 s after a 15 J shock compared to the STD waveform (0.92 ± 0.22 vs. 0.91 ± 0.17).

Conclusions: A shorter duration waveform delivered by smaller capacitors with less maximum energy output yielded a 10 J safety margin for endocardial lead-alone defibrillation in approx. 67% (resp. 80% combined with SC) of the patients tested. Despite higher voltages for the same energy output reductions in post-shock electrogram amplitude were not larger than those seen with standard capacitors.

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714-6 Increased Action Potential Prolongation by Low Voltage Biphasic versus Monophasic Field Stimuli

Robert J. Sweeney, Robert M. Gill, Philip R. Reid. *Eli Lilly and Company, Indianapolis, IN*

In an in-vitro model for defibrillation, we compared action potential prolongation (APP) by monophasic (MONO) and biphasic (BI) field stimulus shocks in epicardial tissue strips from 10 dogs. Strips were paced at one end while cellular impalements were maintained in the center (cell A) to measure APP and at the other end (cell B) to determine if shocks produced propagated activations. Rectangular shocks (0.5 to 10 V/cm) were delivered with MONO (8 ms) or BI (4.8/3.2 ms) waveforms at times ranging from 44% to 112% of the APD90 of cell A. Recordings were made during 3975 shocked and 2578 control action potentials. APP was the % increase in shocked repolarization time relative to the interlaced controls.

While weaker MONO and BI shocks produced propagated activations, the threshold intensity ABOVE which shocks did NOT produce activations was 25.9% lower ($p < 0.0005$) for BI (2.78 V/cm) versus MONO (3.75 V/cm). At most intensities and timings, MONO produced more APP than BI. However, for 2 to 4 V/cm shocks at 90% to 100% of APD90, BI produced more APP than MONO (36.9% versus 17.7%, $p < 0.0001$) shocks.

Thus, increased defibrillation efficacy of BI waveforms may result from a greater APP by BI in the low-voltage gradient regions of the heart during defibrillation.

715 Cardiogenic Shock, Intra Aortic Balloon Pumping and Thrombolytic Therapy in Acute MI

Monday, March 20, 1995, 2:00 p.m.-3:30 p.m.
Ernest N. Morial Convention Center, Room 103

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715-1 Predictors of Mortality in Cardiogenic Shock: The GUSTO Experience

David R. Holmes, Peter B. Berger, Eric Bates, Lynn Woodlief, Eric J. Topol, Robert Califf, GUSTO Investigators. *Mayo Clinic, Rochester, MN*

Cardiogenic shock during acute myocardial infarction is associated with a marked increase in mortality. In GUSTO I Trial, the mortality in cardiogenic shock patients was 59%. The ability to predict mortality in these patients might help to devise better strategies. Baseline characteristics of 1968 cardiogenic shock patients in GUSTO were assessed in relationship to 30 day outcome:

Characteristics	Alive (N = 1321)	Dead (N = 1647)	χ^2
<i>N (%)</i>			
Age (yrs)	63.4 ± 10.9	69.8 ± 10.4	252.4
Current Smoker	567 (43%)	407 (26%)	92.4
Killip class 1 or 2 on arrival	1140 (87%)	1325 (81%)	67.6
Infarct location anterior	570 (43%)	931 (57%)	57.7
Prior MI	255 (19%)	488 (30%)	44.0
Weight (kg)	78.0 ± 16.2	74.1 ± 15.2	40.0
Height (cm)	170.9 ± 9.9	168.0 ± 9.7	38.4
Admission pulse	79.3 ± 21.1	84.5 ± 22.6	36.9
Diabetes	187 (14%)	369 (23%)	35.4
Time to Rx (hrs)	2.99 ± 1.64	3.32 ± 1.78	33.8
Prior angina	480 (37%)	751 (47%)	29.4

Combining these baseline characteristics in a multivariate model provides very good discrimination of prediction of mortality.

Conclusion: Baseline characteristics can identify patients at high risk of dying associated with cardiogenic shock. Since previous controlled trials have not demonstrated efficacy of thrombolysis in cardiogenic shock, these features may set up preferential triage to primary percutaneous transluminal coronary angioplasty or other aggressive reperfusion strategies.

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715-2 A Prospective, Randomized Trial Evaluating the Prophylactic Use of Balloon Pumping in High Risk Myocardial Infarction Patients: PAMI-2

John Griffin, Cindy L. Grines, Dominic Marsalese, Michael Spain, Bruce Brodie, Bryan Donohue, Thomas Wharton, Jr., Gregg W. Stone, Carlos Balestrini, Costantino Costantini, Thomas Shimshak, Juan Luis Delcan, Denise Jones, Denise Mason, Debra Sachs, William W. O'Neill. *Virginia Beach General Hospital, Virginia Beach, VA; William Beaumont Hospital, Royal Oak, MI*

Myocardial infarction (MI) patients with advanced age, multivessel disease or ventricular dysfunction continue to have a poor prognosis despite reperfusion therapy. Furthermore, the majority of deaths from MI occur within the first 48 hours, thus risk stratification and therapeutic interventions ideally should occur acutely. The PAMI-2 study has prospectively evaluated the hypotheses that 1) emergency catheterization with primary PTCA may allow acute risk stratification and 2) clinical outcome, ventricular function and infarct vessel patency will be improved by balloon pumping in patients identified to be high risk. MI patients who presented 0-12 hrs underwent emergency catheterization and PTCA and were stratified as high risk if one of the following was present: age >70 yrs, vein graft occlusion, 3 vessel disease, ejection fraction $<45\%$, suboptimal PTCA result or if malignant arrhythmias persisted post PTCA. High risk patients were randomized to receive or not receive an intra aortic balloon pump (IABP) for 48 hrs. Catheterization was repeated at day 7 to determine infarct vessel patency and improvement in ventricular function. At 6 weeks a rest and exercise radionuclide ventriculogram was performed. To date, 320 patients have been enrolled, 175 of which have complete data available for analysis. The reasons for high risk status include: advanced age 38%, poor LV function 55%, 3 vessel disease 37%, vein graft occlusion 6%, suboptimal PTCA 9%, and arrhythmias 5%. Despite the high risk status, in-hospital outcomes have been favorable: death 2.9%, recurrent MI 5.8%, stroke 1.2%, angiographic reocclusion 5.8%, heart failure 19.1% and combined events 26.6%. Thus "high risk" patients treated with primary PTCA \pm balloon pumping appear to have a good prognosis. Whether the improved outcome is due to balloon pump support or simply due to aggressive mechanical revascularization will be determined in the entire cohort by March 1995.