SUPPLEMENTAL MATERIAL

Table 1S.
Cox Proportional Hazards Model adjusted for Time of Day

Primary Model without adjustment for AM/PM

	HR	CI	p-value
Main	0.964	0.71-1.32	0.817
< 5 mos	1.72	1.08-2.75	0.0216
≥ 5 mos	0.602	0.39-0.93	0.022

Adjusted for AM/PM

	HR	CI	p-value
Main	0.919	.67-1.26	0.6
< 5mos	1.71	1.06-2.77	0.0287

Although the number of surgeries in the morning (AM) was imbalanced by treatment overall and in the young patients, adjustment for this covariate had no effect on the proportional hazards models.

Cox Proportional Hazard Model: Censoring at 30 days instead of 7 days

	HR	CI	p-value
Main	0.94	.7-1.25	0.658
< 5 mos	1.53	1.004-2.32	0.0481
> 5 mos	0.566	.37-.87	0.0102

Of the 188 patients with observed extubation, 160 were extubated by 7 days, 186 were extubated by 30 days, and two patients (one in each arm) were extubated after 30 days including 1 in the placebo group and 1 in the Triostat group. The main results do not change substantially. For young patients, the effect is slightly diminished, but still significant. For older patients, the hazard ratio is still significant.

Table 2S. Drug Use by Center

		Site 0 (N=106)	Site 1 (N=26)	Site 2, 3&4 (N=35)	Site 5 (N=26)
DRUG	DOBUTAMINE	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	DOPAMINE	50 (47.2%)	19 (73.1%)	23 (65.7%)	16 (61.5%)
	EPINEPHRINE	1 (0.9%)	4 (15.4%)	8 (22.9%)	1 (3.8%)
	MILRINONE	42 (39.6%)	17 (65.4%)	28 (80.0%)	20 (76.9%)
	NITROPRUSSIDE	2 (1.9%)	3 (11.5%)	4 (11.4%)	0 (0.0%)
	NOREPINEPHRINE	0 (0.0%)	2 (7.7%)	0 (0.0%)	0 (0.0%)

Data are shown as percentage of patients receiving a particular drug. Use of individual drugs is similar across most centers, though site 0 shows less use of dopamine, epinephrine, and milrinone than the other centers. Data are pooled for 3 centers with enrollment between 10 and 13 patients.

Table 3S. Summary of Adverse Events from Time of Surgery to the First of Hospital Discharge, 30 Days Post-procedure or Death

	Placebo Total (N=95)	Triostat Total (N=98)	P	Placebo, < 5 months (N=50)	Triostat, < 5 months (N=48)	P	Placebo, >= 5 months (N=45)	Triostat, >= 5 months (N=50)	P
At Least One AE	82 (86.3%)	80 (81.6%)	0.376	45 (90.0%)	42 (87.5%)	0.695	37 (82.2%)	38 (76.0%)	0.458
At Least One Serious AE	12 (12.6%)	14 (14.3%)	0.736	8 (16.0%)	8 (16.7%)	0.929	4 (8.9%)	6 (12.0%)	0.622
At Least One Unexpected AE	40 (42.1%)	40 (40.8%)	0.856	25 (50.0%)	22 (45.8%)	0.680	15 (33.3%)	18 (36.0%)	0.785
At Least One Possibly Treatment-Related AE	45 (47.4%)	57 (58.2%)	0.151	26 (52.0%)	34 (70.8%)	0.065	19 (42.2%)	23 (46.0%)	0.836
Death (any time on study)	5 (5.3%)	3 (3.1%)	0.493	4 (8.0%)	3 (6.3%)	1.000	1 (2.2%)	0 (0.0%)	0.474
Death or Mechanical Life Support	5 (5.3%)	3 (3.1%)	0.493	4 (8.0%)	3 (6.3%)	1.000	1 (2.2%)	0 (0.0%)	0.474
Arrhythmia AE	9 (9.5%)	11 (11.2%)	0.690	7 (14.0%)	7 (14.6%)	0.934	2 (4.4%)	4 (8.0%)	0.477
JET	7 (7.4%)	8 (8.2%)	0.837	5 (10.0%)	5 (10.4%)	0.946	2 (4.4%)	3 (6.0%)	0.735
SVT	2 (2.1%)	3 (3.1%)	1.000	2 (4.0%)	2 (4.2%)	1.000	0 (0.0%)	1 (2.0%)	1.000
VT	1 (1.1%)	0 (0.0%)	0.492	1 (2.0%)	0 (0.0%)	1.000	0 (0.0%)	0 (0.0%)	0.458

Table shows number of patients with adverse events for each treatment category and subgroup. Thus, one patient in placebo group had two types of arrhythmia. There were no significant differences between the placebo and Triostat group. Tachyarrhythmia was the primary safety indicator: JET, junctional ectopic tachycardia; SVT, supraventricular tachycardia; and VT, ventricular tachycardia. There were no significant differences or trends between placebo and treatment for the entire cohort or subgroups.