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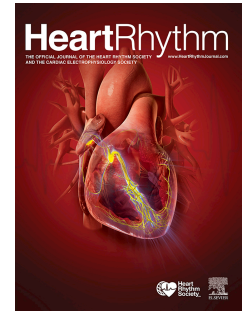
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Competitive Athletes with Implantable Cardioverter Defibrillators - How to Program?

Data from the Implantable Cardioverter Defibrillator Sports Registry

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Abstract

Background: Athletes with ICDs may require unique optimal device-based tachycardia programming.

Objective: To assess the association of tachycardia programming characteristics of ICDs with occurrence of shocks, transient loss-of-consciousness, and death among athletes.

Methods: A sub-analysis of a prospective, observational, international registry of 440 athletes with ICDs followed 44 months (median) was performed. Programming characteristics were divided into groups for rate cut-off, very high, high, and low and for detection, long-detection intervals (>nominal) or nominal. Endpoints included total, appropriate, and inappropriate shocks, transient loss-of-consciousness and mortality.

Results: In this cohort, 62% were programmed with high-rate cutoff and 30% with long detection. No athlete died from an arrhythmia, related or unrelated, to ICD shocks. Three patients had sustained ventricular tachycardia below programmed detection rate, presenting as palpitations and/or dizziness. ICD shocks were received by 98 athletes, of which, 64 were appropriate, 32 were inappropriate; 2 patients received both. Programming a high-rate cutoff was associated with decreased risk of total ($P=0.01$) and inappropriate ($P=0.04$) shocks overall and during competition or practice. Programming long detection intervals was associated with fewer total shocks. Single vs. dual chamber devices, and the number of zones were unrelated to risk of shock. Transient loss-of-consciousness, associated with 27 appropriate shocks, was not related to programming characteristics.

Conclusion: High-rate cut-off and long detection duration programming of ICDs in athletes at risk of sudden death can reduce total and inappropriate ICD shocks without affecting survival or the incidence of transient loss-of-consciousness.

Introduction

Until recently, athletes who required an implantable cardioverter defibrillator (ICD) were restricted by professional societies' consensus statements from continued competition¹. However, the prospective, international, observational, ICD Sports Registry^{2 3} of athletes participating in sports with ICDs, indicated no sports-related deaths, failures to defibrillate, or injuries, suggesting that many athletes with ICDs can safely participate in sports. Now, as stated in a recent ACC/AHA scientific statement, sports participation with an ICD "may be considered" ("IIB" classification)⁴.

While ICDs can save lives, appropriate and inappropriate shocks affect quality-of-life and have devastating consequences^{5-7 8 9}. For athletes with ICDs, it is critical to know how to program the ICD optimally to minimize shocks, while continuing to prevent death, hemodynamic collapse, or transient loss-of-consciousness, due to a life-threatening arrhythmia.

Present data¹⁰⁻¹⁵ provide guidance regarding complexities of ICD programming in primary and secondary prevention circumstances for older patients with impaired ventricular function but recommendations may not apply to athletes, who are younger, more active and with difference disease conditions. Based on these trials and collaborative opinion, a recent consensus document¹⁶ has provided guidance regarding appropriate ICD programming. The class I recommendation to program the tachycardia rate detection zone to 185-200 bpm to reduce total therapies may not apply to athletes.

This investigation assessed the association of ICD tachycardia detection programming with the occurrence of ICD shocks (appropriate and inappropriate), transient loss-of-consciousness and death in athletes

Methods

We performed a sub-analysis of the ICD Sports Registry (described elsewhere²) including 440 athletes receiving ICDs for primary and secondary prevention indications. Athletes were followed a median of 44 months^{2,3}. This study was approved by the Yale Human Investigation Committee and by Institutional Review Boards of participating sites; all patients signed an informed consent.

Patients were asked to call the central site if they received an ICD shock; they were queried about preceding activity and any sequelae. Patients were also contacted every six months about shocks received and changes in medical status or sports participation. Medical records were obtained from sites or patients' treating physicians or facilities and reviewed by study personnel for shocks or changes in health or ICD status (e.g., lead replacement, death). Stored ICD electrograms and event detail data were reviewed for rhythm diagnosis and shock outcome by two electrophysiologists (R.L., B.O., H.H.).

Since nominal programming parameters vary by device type and company, (219 Medtronic, 133 Boston Scientific, 65 St. Jude, 19 Biotronik, 4 other/unknown), we categorized parameters to allow comparisons. Rate was categorized as very high (>240 bpm), high (\geq 200 bpm) or low (<200 bpm) rate and then dichotomized as low or high. Duration was categorized as long (>nominal) or nominal ("out-of-the-box") duration detection (Table 1).

Statistics

Dual versus single-chamber comparison was made for the entire group (440 athletes). Rate cutoff, available in 384, was classified as low, high and very high and low vs high after

combining the latter two groups. Duration programming, available in 178 patients, was classified as long versus nominal.

A sub-analysis compared those with high-rate/long-duration, one or neither in the subgroup in whom both variables were available (N=162). Chi-square tests or Fisher's exact tests compared shock outcomes by rate groups and/or duration groups. Kaplan-Meier analysis compared time to first shock (any, appropriate or inappropriate) across groups using log-rank test. Endpoints evaluated included appropriate shocks (in toto), appropriate shocks during competition or practice, and inappropriate shocks for supraventricular rhythms (in toto) or during competition or practice. Shocks occurring due to lead malfunction and T-wave oversensing were not included, as programming is minimally relevant to shocks for lead malfunction; further, company filtering characteristics for T-wave oversensing vary significantly. Statistical analyses were performed using SAS 9.4 (Cary, NC). Significance was considered $p < 0.05$ (2-sided).

Results

Demographic, clinical, and programming characteristics

Demographics, clinical characteristics and diagnoses are described in Table 2; 25% were \leq age 19; 34% were female and 45% had ICDs for secondary prevention. There were no meaningful differences in clinical or demographic characteristics by subgroups for rate or for duration versus the whole group (not shown). The sports, in which athletes participated, are listed (Table 3).

Regarding ICD programming, while we initially considered high-rate and very high-rate as separate groups, we found no specific differences between the groups and therefore combined them into one group termed "high-rate". Of those, for whom data were available, 62% were

programmed high-rate, 38% were programmed low-rate; 30% were programmed long-detection-duration, and 70% were programmed nominal – with “out-of-the-box” settings. Older patients and those with coronary disease were less likely to be programmed “high-rate”. Other clinical and demographic characteristics were not associated with programming of rate or duration.

Outcomes

Three athletes had sustained ventricular tachycardia below programmed rates (all with high-rate programming) with symptoms including palpitations and/or dizziness but none had transient loss-of-consciousness or died. Two other patients died (reported previously²). One, with coronary artery disease, died at work after multiple shocks while another, with progressive cardiomyopathy, died of heart failure.

High-rate programming was associated with fewer total (19% versus 30%; $P=0.01$) and inappropriate (5% versus 11%; $P=0.04$) shocks, regardless of activity (Table 4). High-rate programming was similarly associated with fewer total (8% vs 17%, $p<0.01$) and inappropriate (5% vs 12%, $p<0.01$) shocks during competition or practice. There was a significant difference in shock-free survival for high-rate versus low-rate programming (Figure 1A) (Log Rank $P=0.01$.)

Programming a long-detection time was associated with fewer total (15% versus 32%; $P=0.02$) and inappropriate shocks (2% vs 9%) (Table 3). Longer detection times, however, were not significantly associated with fewer appropriate shocks (13% vs 23%; $P=0.13$). With long-detection times (versus nominal), there was no significant difference in total, (6% vs 15%, $P=0.07$), appropriate (2% vs 4%, $p=0.47$) or inappropriate shocks (4% vs 11%, $p=0.11$) during competition/practice (Table 3). There was, however, a significant difference in shock-free

survival for greater-than-nominal duration programming versus nominal (Log Rank $P=0.03$, Figure 1B).

Among those ($n=162$) with data available for rate cut-off and duration, 23% were programmed with high-rate and long-duration, 58% with one or the other and 19% with neither. Those with both programmed were less likely to receive shocks than those with one or neither programmed (14% with both, 35% and 28% of those with one, and 45% of those with neither, $p=0.04$), with similar findings for shocks during competition/practice (3% with both, 11% and 14% with one and 25% of those with neither, $p=0.03$).

Transient loss-of-consciousness was associated with 27 appropriate shocks in 24 athletes but was not more frequent in those with high-rate or prolonged duration programming, either for appropriate shocks in toto or for those occurring during competition/practice. The mean cycle-length of ventricular tachycardia in transient loss-of-consciousness-associated appropriate shocks was 179 ± 41 (335 bpm), vs 240 ± 43 (250 bpm) milliseconds for non-transient loss-of-consciousness-associated appropriate shocks ($p<0.001$).

The use of single versus dual-chamber devices, and number of programmed tachycardia zones, were not related to ICD shocks overall or during competition/practice.

Discussion

The ICD Sports Registry has demonstrated that many athletes with ICDs can safely participate in sports^{2, 3, 17} but optimal programming has not been established. This sub-analysis of the ICD Sports Registry demonstrates that programming the ICD to a higher rate cut-off (>200 bpm) was associated with fewer inappropriate and total ICD shocks, overall and during competition or practice. Prolonged duration detection reduced total shocks. There were fewer

appropriate and inappropriate shocks overall and during competition/practice although these differences were not significant when outcomes were analyzed separately. Athletes for whom duration data were available was smaller; thus, this analysis may be underpowered to detect differences. Programming at a higher rate or longer duration did not increase the risk of transient loss-of-consciousness before a shock or transient loss-of-consciousness due to untreated ventricular tachycardia below the rate cut-off. There were no deaths due to tachyarrhythmias below the rate-cut-off. Heart-rates during ventricular arrhythmias associated with transient loss-of-consciousness were faster than programmed rate-cut-offs.

Interventions to decrease appropriate and inappropriate shocks are critical to the well-being of patients with ICDs. In randomized trials and registry data from remote-monitoring databases^{18 9, 19}, appropriate and inappropriate shocks are associated with mortality and increased health-care utilization²⁰, although data showing that those with shocks due to lead malfunction or sinus tachycardia do not have higher mortality¹⁹, suggesting shocks may be a marker for conditions increasing mortality. However, the impact of ICD shocks on quality-of-life and psychological well-being is well-documented. Most, although not all, studies⁸, have shown that quality-of-life decreases, and anxiety and depression, can increase after a shock, particularly after multiple shocks⁵⁻⁷. Even following a single shock, quality-of-life can decrease²¹ although the effect decreases over time⁶.

Optimal ICD programming to reduce inappropriate and overall shocks, while still delivering lifesaving therapy and avoiding transient loss-of-consciousness, has been investigated in MADIT RIT, ADVANCE III, PROVIDE, PREPARE, CIDS, French DAI-PP registry, and other trials^{10-15 22}. In MADIT-RIT, high-rate and/or long-detection programming for a primary prevention population reduced the rate of inappropriate and appropriate activations (mostly anti-

tachycardia pacing) by about 79% without adverse effects and, perhaps, with mortality benefit¹² even at a 200 bpm rate cut-off. ICD therapies were reduced by 60% in the French DAI-PP registry when rate cut-off exceeded 220 bpm²³. Other data indicate that additional rounds of anti-tachycardia pacing may reduce the risk of shocks²⁴⁻²⁷. However, these data are based on patients with structural heart disease, ventricular dysfunction, older age (63 years old in MADIT-RIT and 62 years old in the French DAI-PP study) who are not generally athletes.

Nominal (out-of-the-box) settings may not be optimal for any patient^{16, 28} but these data do not apply directly to our population since, for the most part, athletes with ICDs are younger, do not have severe ventricular dysfunction and did not have coronary artery disease. Furthermore, based on the cardiac diagnoses of these athletes, slower ventricular tachycardias (rates <200 bpm) are less likely²⁹.

Similarly, as shown previously^{24, 30}, long-detection intervals reduce the risk of shocks¹⁴ in prolonged episodes of non-sustained ventricular tachycardias, non-sustained supraventricular tachycardia or sinus tachycardia, and in patients with a secondary prevention ICD indication³¹. Other data support prolonged detection intervals even when tachycardia rates are programmed lower than in our patient population¹⁰. In the ventricular fibrillation zone, detection algorithms are generally non-programmable and differ by manufacturer³².

Data regarding use of an atrial lead to help discriminate supraventricular from ventricular tachyarrhythmias has been inconsistent³³ but some data indicate benefit of an atrial lead in dual-chamber devices to decrease appropriate and inappropriate shocks^{34, 35}. We did not find any difference between single and dual-chamber ICDs regarding time to first ICD shock. Dual-chamber devices were not associated with fewer inappropriate shocks in this study.

Three patients did have a symptomatic ventricular tachycardia below the rate detection raising concern of potential adverse effects of high-rate programming. However, none had transient loss-of-consciousness or other severe symptoms. It is clear that this population of younger athletes with preserved ejection fractions can tolerate slower ventricular tachycardias without hemodynamic instability or potential for sudden cardiac death. These 3 patients with ventricular tachycardia below the detection rate and without hemodynamic instability had ICDs programmed to avoid unnecessary shocks.

Data on exercise testing were not collected. However, exercise testing can likely be helpful to ensure the rate cut-off is above the maximum sinus rate, and to evaluate for T-wave oversensing.

In this study, all participants had transvenous ICDs. Subcutaneous ICDs (SICDs) were not approved during most of the study period. The SICD may require programming different from the transvenous ICD. There are theoretical benefits of the SICD for athletes to potentially reduce lead malfunction due to repetitive motion between the first rib and clavicle. Further data are needed on usage and programming of the SICD in athletes.

Limitations

Whether specific athlete-groups, based on sports, age, cardiac diagnosis, or other features, would benefit from unique programming strategies cannot be determined from our population. Medications, such as, beta-blockers or antiarrhythmic drugs, may affect arrhythmia characteristics and, thus, programming.

Data on duration was not available for all patients, thus, power to see significance of some comparisons may have been lacking. Longer follow-up could additionally reveal differences.

Conclusions

In athletes, high-rate programming is associated with fewer total, and inappropriate shocks, overall and during competition or practice, while long-detection programming is associated with fewer total shocks. High-rate or long-detection duration programming was not associated with increased incidence of transient loss-of-consciousness either prior to shock, or due to ventricular tachyarrhythmias below the rate-cut-off, or with decreased survival.

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Table 1. Programming in Lowest Tachycardia Zone – Nominal Values

	Two-zone programming	One-zone programming
Biotronik	16 beats	8/12 fraction
Boston Scientific	2.5 seconds	1 second
St Jude Medical	19 beats	13 beats
Medtronic	16 beats	18/24 fraction

Table 2. Demographic and Clinical Characteristics

	Entire group N=440	Cut-off subset N=384		P value	Duration subset N=178		P value
		Low N=145	High N=239		Nominal N=125	Long N=53	
Age, years				<.0001			0.67
10-19	111 (25%)	17(11.7%)	74(31.0%)		34(27.2%)	19(35.8%)	
20-29	84 (19%)	11(7.6%)	61(25.5%)		28(22.4%)	10(18.9%)	
30-39	77 (17%)	33(22.8%)	35(14.6%)		19(15.2%)	10(18.9%)	
40-49	84 (19%)	39(26.9%)	39(16.3%)		25(20.0%)	8(15.1%)	
50-60	84 (19%)	45(31.0%)	30(12.6%)		19(15.2%)	6(11.3%)	
Male gender	292 (66%)	99(68.3%)	154(64.4%)	0.44	84(67.2%)	33(62.3%)	0.53
Race				0.72			0.96
Caucasian	410 (93%)	135(93.1%)	226(94.6%)		117(93.6%)	49(92.5%)	
African-American	15 (3%)	5(3.4%)	8(3.3%)		4(3.2%)	2(3.8%)	
Other/unknown	15 (3%)	5(3.4%)	5(2.1%)		4(3.2%)	2(3.8%)	
Cardiac Diagnosis				<.0001			0.06
Long QT Syndrome	87 (20%)	13(9.0%)	61(25.5%)		24(19.2%)	14(26.4%)	
Hypertrophic cardiomyopathy	75 (17%)	12(8.3%)	53(22.2%)		30(24.0%)	9(17.0%)	
Arrhythmogenic right ventricular cardiomyopathy	55 (13%)	33(22.8%)	16(6.7%)		13(10.4%)	6(11.3%)	
Coronary artery disease	45 (10%)	30(20.7%)	13(5.4%)		8(6.4%)	1(1.9%)	
Idiopathic VT/VF (normal heart)	48 (11%)	10(6.9%)	31(13.0%)		14(11.2%)	6(11.3%)	
Dilated cardiomyopathy	35 (8%)	19(13.1%)	13(5.4%)		7(5.6%)	1(1.9%)	
Congenital heart disease	38 (9%)	15(10.3%)	20(8.4%)		14(11.2%)	2(3.8%)	
Catecholaminergic polymorphic VT	12 (3%)	2(1.4%)	8(3.3%)		8(6.4%)	2(3.8%)	
Brugada Syndrome	9 (2%)	1(0.7%)	7(2.9%)		1(0.8%)	1(1.9%)	
Valvular heart disease	8 (2%)	4(2.8%)	3(1.3%)		2(1.6%)	3(5.7%)	
Left ventricular noncompaction	5 (1%)	0(0.0%)	4(1.7%)		1(0.8%)	1(1.9%)	
None, family history	6 (1%)	1(0.7%)	3(1.3%)		2(1.6%)	1(1.9%)	
Other	17 (4%)	5(3.4%)	7(2.9%)		1(0.8%)	6(11.3%)	
ICD indication				<.0001			0.25
Ventricular fibrillation/cardiac arrest	133 (30%)	41(28.3%)	73(30.5%)		38(30.4%)	15(28.3%)	

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Sustained VT	68 (15%)	32(22.1%)	31(13.0%)		22(17.6%)	9(17.0%)	
Transient loss-of-consciousness	110 (25%)	31(21.4%)	70(29.3%)		39(31.2%)	10(18.9%)	
Prophylactic-CAD/CM†	33 (8%)	21(14.5%)	8(3.3%)		4(3.2%)	2(3.8%)	
Prophylactic-other diagnoses**	75 (17%)	11(7.6%)	47(19.7%)		17(13.6%)	15(28.3%)	
Positive electrophysiology study	21 (5%)	9(6.2%)	10(4.2%)		5(4.0%)	2(3.8%)	
Time since initial ICD implantation, months	26 (11-59)	28 (12 – 61)	25 (11 - 58)	0.95	31 (9 – 69)	23 (12 – 47)	0.99
ICD rate cut-off, bpm††	200(188-215)	182 (175 – 188)	210 (200 – 222)	<.0001	206 (195 – 220)	207 (194 – 222)	0.63
Ejection fraction, %	60 (50-65)	55 (40 – 62)	66 (55 – 67)	<.0001	60 (55 – 68)	60 (55 -67)	0.91
Taking beta-blocking drugs	293 (67%)	108(74.5%)	149(64.8%)	0.05	78(62.9%)	39(75.0%)	0.12

Values represent N (%) or as median (interquartile range). ICD, implantable cardioverter-defibrillator; VT, ventricular tachycardia; CAD, coronary artery disease, CM, cardiomyopathy.

*all \leq 21 years old; †as defined by the SCD-HeFT,⁵ MADIT 2,⁷ or MUSTT⁶ trials;

**prophylactic for standard clinical indications; ††lowest zone with treatment programmed, bpm, beats per minute, secondary prevention, VT or VT, primary prevention, other diagnoses.

Table 3. Sports participation

Sports	Total	Pre-High School	High School	College	Post-Graduate
Baseball	23	6	9	6	2
Basketball	71	7	22	17	25
Cycling	56			2	54
Equestrian	3		1		2
Field Hockey	1		1		
Football - Flag	14		3	6	5
Football - Tackle	7		4	1	2
Hockey	7		1		6
Lacrosse	4		2	2	
Racquetball	7			1	6
Rock Climbing†	9		1	1	7
Running					
Track /Field	15	1	13		
Cross Country	8		2	4	2
Marathon	25				25
Running (other)	71		1	5	112
Skiing†	82	1	6	2	72
Snowboarding†	23		4	9	10
Soccer	81	6	118	15	45
Softball	43	2	6	5	30
Squash	6				6
Surfing†	13		1	2	10
Swimming	13		3		10
Tennis	44		7	4	33
Triathlons	30			2	28
Ultimate Frisbee	5			2	2
Volleyball	43	3	11	12	17
Wrestling	1		1		
Other	83	1	21	8	53
Total	814	25	139	110	539

Some subjects participated in more than one sport. All sports meeting criteria for enrollment were tabulated. *defined in text; †potentially dangerous sports

Table 4: Shock Occurrences Based on Programming Characteristics

	High-rate N=239	Low rate N=145	P	Long- detection N=53	Nominal detection N=125	P
Total shocks (any time)	45 (19%)	43 (30%)	0.01	8 (15%)	40 (32%)	0.02
Appropriate shocks	33 (14%)	28 (19%)	0.15	7 (13%)	29 (23%)	0.13
Inappropriate shocks	13(5%)	16 (11%)	0.04	1 (2%)	11 (9%)	0.09
Shocks (comp/practice)	19 (8%)	25 (17%)	<0.01	3 (6%)	19 (15%)	0.07
Appropriate shocks	7 (3%)	7 (5%)	0.43	1 (2%)	5 (4%)	0.47
Inappropriate shocks	12 (5%)	18 (12%)	<0.01	2 (4%)	14 (11%)	0.11

Differences in N for rate and duration are due to differences in data available for these variables

FIGURE 1. Freedom from shock (including appropriate and inappropriate exclusive of noise/T-wave oversensing)

Figure 1A: Rate Cutoff: Conventional versus high or very high-rate

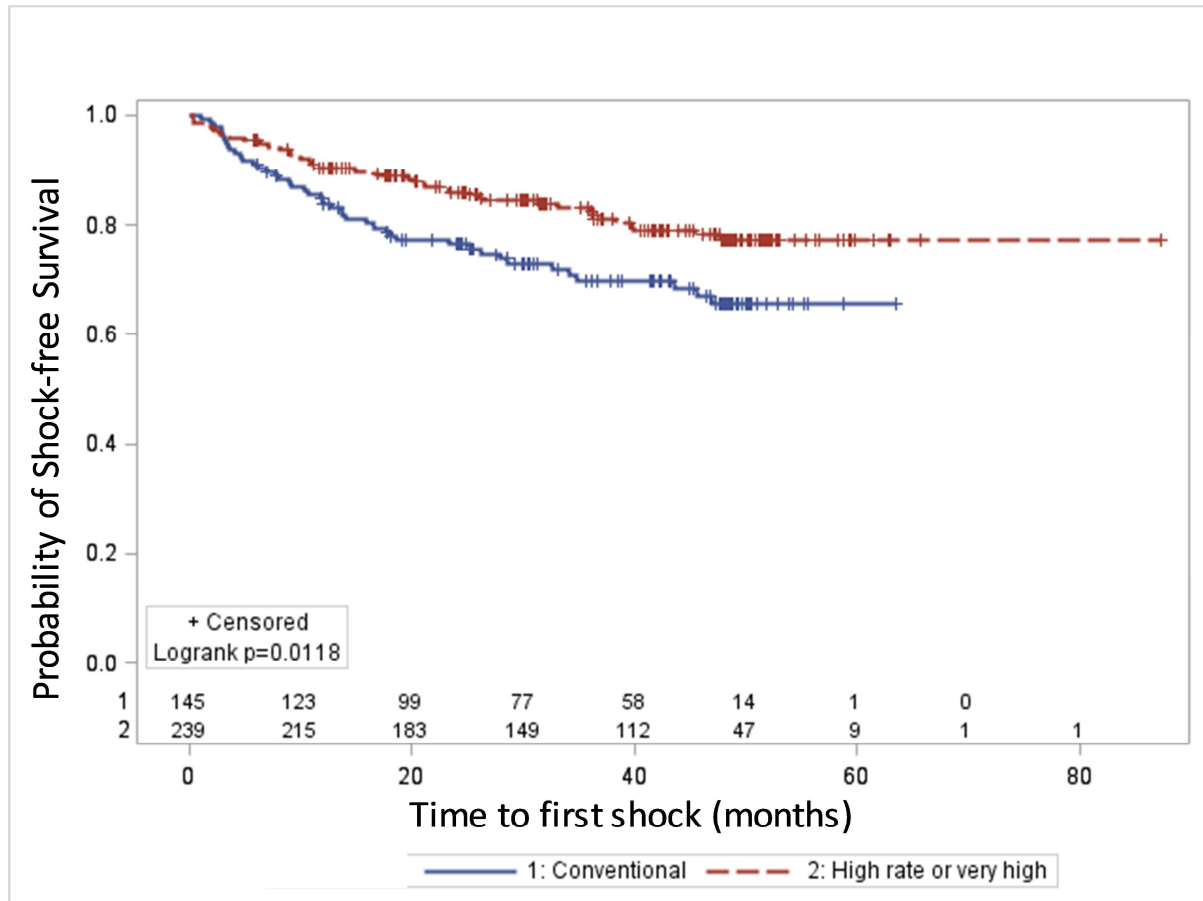


Figure 1B: Duration: nominal versus greater-than-nominal

