Maximum-fixed energy shocks for cardioverting atrial fibrillation

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ESC Congress Paris 2019
Together with World Congress of Cardiology

Declaration of interest

- I have nothing to declare

Cardioversion of atrial fibrillation

- Commonly performed clinical procedure
- Energy selection – an everyday clinical question

2016 ESC Guidelines on the management of AF

- No recommendations on energy levels

Low-escalating energy shocks

- Suggested to avoid harm (monophasic shocks)

Biphasic shocks

- Effective and safer than monophasic shocks
- Advantage of low-escalating biphasic shocks is less clear

Aim

Maximum-fixed versus low-escalating energy shocks for cardioverting atrial fibrillation

Study design

Cardioversion
Sample size = 276

Low-escalating (125-150-200 J)

Maximum-fixed (360-360-360 J)

Setting

Randers Regional Hospital, Denmark

Inclusion

- Elective cardioversion of atrial fibrillation, age ≥18 years, able to sign informed consent

Exclusions

- Non-AF arrhythmias, hemodynamically unstable AF, untreated hyperthyroidism, pregnancy, previously enrolled in the trial

Endpoints

Primary Endpoint
Sinus rhythm 1 min after cardioversion

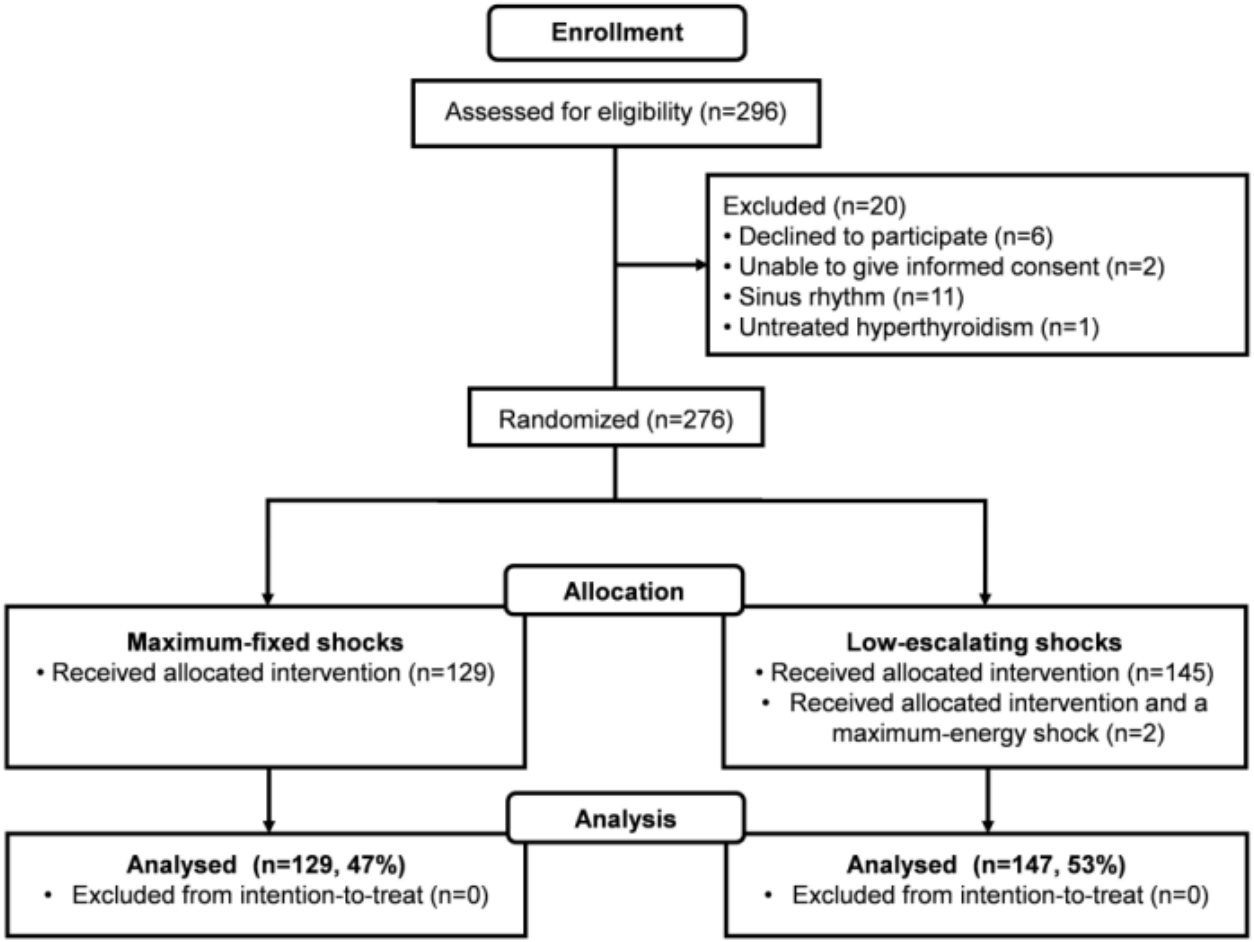
Safety endpoints

- Cases of arrhythmias
- Myocardial Injury (troponin I (HS) changes)
- Skin redness or burns
- Patient-reported discomfort or pain (Visual Analog Scale)

All shocks delivered using LifePak 20, Physio-Control Inc, USA (truncated exponential waveform)

Results

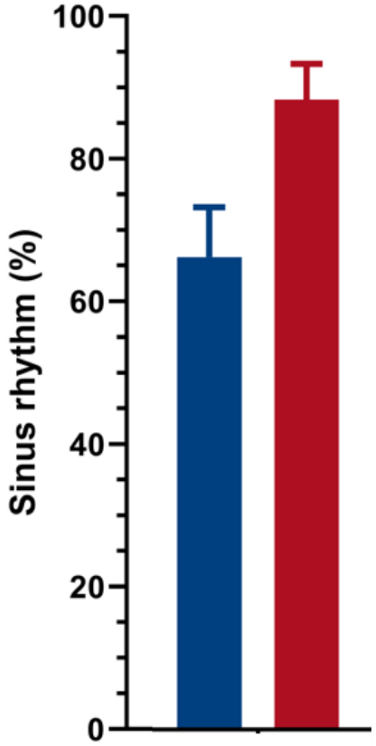
Results


Enrollment
Assessed for eligibility (n=296)
Excluded (n=20)
• Declined to participate (n=6)
• Unable to give informed consent (n=2)
• Sinus rhythm (n=11)
• Untreated hyperthyroidism (n=1)
Randomized (n=276)
Allocation
Maximum-fixed shocks
• Received allocated intervention (n=129)
Low-escalating shocks
• Received allocated intervention (n=145)
• Received allocated intervention and a maximum-energy shock (n=2)
Analysis
Analysed (n=129, 47%)
• Excluded from intention-to-treat (n=0)
Analysed (n=147, 53%)
• Excluded from intention-to-treat (n=0)

Baseline characteristics

Characteristics*	Maximum-fixed energy (N=129)	Low-escalating energy (N=147)
Age – years	68±9	68±8
Male sex - no. (%)	90 (70)	109 (74)
Body mass index - kg/m^2	30±6	29±6
Left atrial indexed volume - mL/m^2	37±13	39±13
Atrial fibrillation duration - no. (%)		
< 1 month	14 (11)	17 (12)
1-12 months	77 (60)	85 (58)
> 12 months	37 (29)	45 (31)
Medical history - no. (%)		
Hypertension	84 (65)	81 (55)
Congestive heart failure	39 (30)	36 (25)
Stroke or transient ischemic attack	15 (12)	11 (7)
Pacemaker	1 (1)	2 (1)
Medication use - no. (%)		
Amiodarone	10 (8)	12 (8)
Vitamin K antagonist	27 (21)	26 (18)
Non-vitamin K oral anticoagulant	95 (74)	115 (78)

Primary endpoint: Sinus rhythm one minute after cardioversion

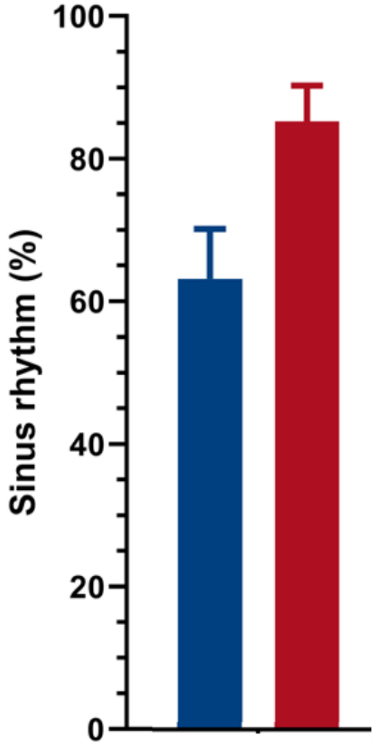


Maximum-fixed (88%)

Low-escalating (66%)

22% difference (CI-95%: 13-32), *P*<0.001

Efficacy to discharge: Sinus rhythm four hours after cardioversion



Maximum-fixed (85%)

Low-escalating (63%)

22% difference (CI-95%: 12-32), *P*<0.001

Cardioversion procedure

Characteristics	Maximum-fixed energy (N=129)	Low-escalating energy (N=147)
Median number of shocks delivered (IQR)	1 (1-1)	2 (1-3)
Median cumulative energy (IQR) – Joules	360 (360-360)	275 (125-475)
Median total propofol usage (IQR) – mg	80 (70-90)	80 (70-100)
Median procedure duration (IQR) – minutes	1.9 (1.5-2.7)	2.2 (1.7-3.0)

Safety endpoints

Arrhythmias

Characteristics	Maximum-fixed energy (N=129)	Low-escalating energy (N=147)
Cases of any arrhythmia (%)	7 (5)	7 (5)

Arrhythmias

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Cases of any arrhythmia (%)	7 (5)	7 (5)
Sinus node dysfunction, no. (%)	5 (4)	5 (3)
Asystole (%)	0 (0)	2 (1)
Transient bradycardia (%)	3 (2)	3 (2)
≥2 degree atrioventricular block (%)	2 (2)	0 (0)

Arrhythmias

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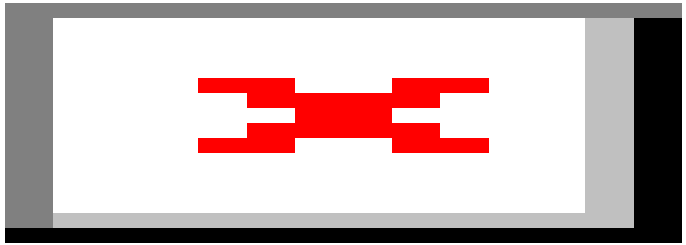
Sinus node dysfunction, no. (%)	5 (4)	5 (3)
Asystole (%)	0 (0)	2 (1)
Transient bradycardia (%)	3 (2)	3 (2)
≥2 degree atrioventricular block (%)	2 (2)	0 (0)
Ventricular tachyarrhythmia (%)	0 (0)	0 (0)
Ventricular premature complexes (%)	2 (1)	2 (1)

Myocardial injury: Changes in high-sensitive troponin I

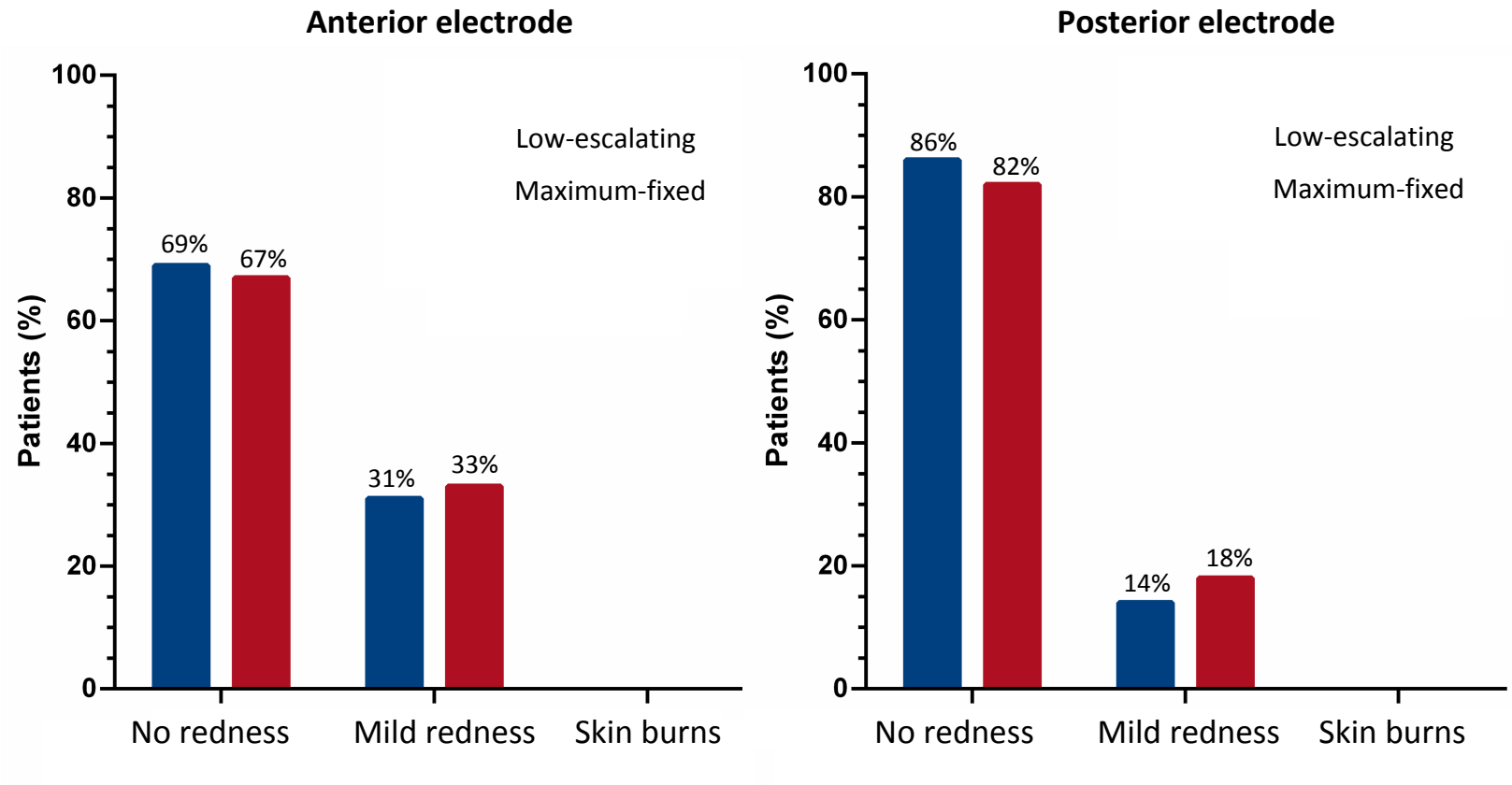
Change in troponin levels, ng/L



	Maximum-fixed	Low-escalating
Median (IQR), ng/L	0 (0-0)	0 (-1-0)

(Three outliers not shown)

Skin redness and burns



Patient-reported discomfort or pain (Visual Analog Scale)

Patients reporting any discomfort or pain (Visual Analog Scale > 0 cm)	**Maximum-fixed energy (N=129)**	**Low-escalating energy (N=147)**
Anterior electrode, no. (%)	30 (23)	35 (24)
Posterior electrode, no. (%)	14 (11)	15 (10)

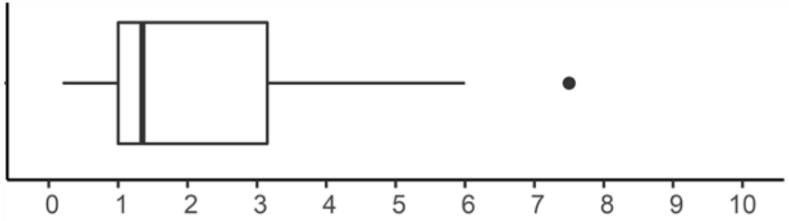
Patient-reported discomfort or pain (Visual Analog Scale)

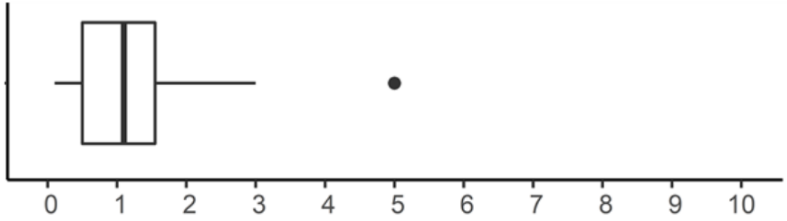
Anterior electrode

Median (IQR)

Maximum-fixed (n=30)
1 (1-3)

Low-escalating (n=35)
1(0.5-2)



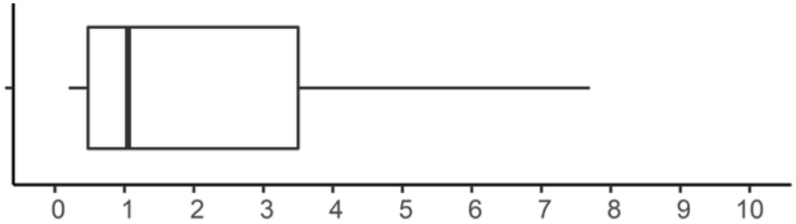


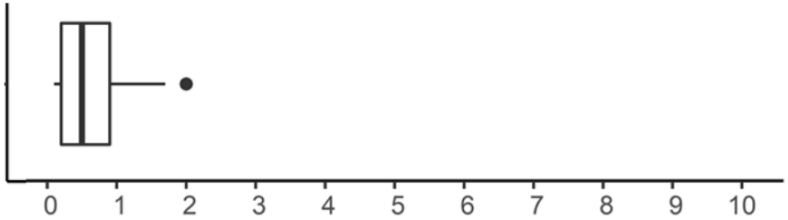
Posterior electrode

Median (IQR)

Maximum-fixed (n=14)
1 (0.5-3)

Low-escalating (n=15)
0.5 (0.2-1)





Limitations

- Single-centre and single-blinded study
- One manufacturer (biphasic truncated exponential shocks)
- Powered for efficacy, not safety endpoints
- Acute cardioversions not included

Conclusion

Maximum-fixed energy shocks were more effective than low-escalating energy shocks for cardioverting atrial fibrillation

We found no difference in any safety endpoint

Investigators

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Lead Investigator: Anders Sjørslev Schmidt, MD, PhD-Student
Co-investigators: Kasper G. Lauridsen, MD; Peter Torp, RN; Leif F. Bach, MD; Hans Rickers, MD

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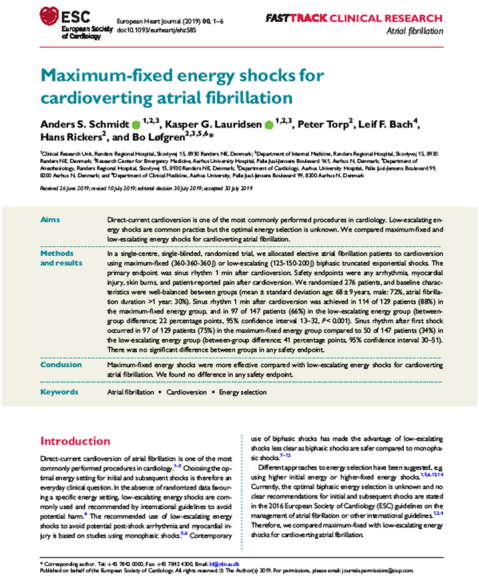
10.1093/eurheartj/ehz585



ESC European Society of Cardiology
European Heart Journal (2019) 00, 1–6
doi:10.1093/eurheartj/ehz585
FASTTRACK CLINICAL RESEARCH
Atrial fibrillation

Maximum-fixed energy shocks for cardioverting atrial fibrillation

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Received 24 June 2019; revised 10 July 2019; editorial decision 30 July 2019; accepted 30 July 2019

Aims Direct-current cardioversion is one of the most commonly performed procedures in cardiology. Low-escalating energy shocks are common practice but the optimal energy selection is unknown. We compared maximum-fixed and low-escalating energy shocks for cardioverting atrial fibrillation.

Methods and results In a single-centre, single-blinded, randomized trial, we allocated elective atrial fibrillation patients to cardioversion using maximum-fixed (360-360-360 J) or low-escalating (125-150-200 J) biphasic truncated exponential shocks. The primary endpoint was sinus rhythm 1 min after cardioversion. Safety endpoints were any arrhythmia, myocardial injury, skin burns, and patients-reported pain after cardioversion. We randomized 276 patients, and baseline characteristics were well-balanced between groups (mean ± standard deviation age: 68 ± 9 years, male: 72%, atrial fibrillation duration >1 year: 30%). Sinus rhythm 1 min after cardioversion was achieved in 114 of 129 patients (88%) in the maximum-fixed energy group, and in 97 of 147 patients (66%) in the low-escalating energy group (between-group difference: 22 percentage points, 95% confidence interval 13–32, $P < 0.001$). Sinus rhythm after first shock occurred in 97 of 129 patients (75%) in the maximum-fixed energy group compared to 50 of 147 patients (34%) in the low-escalating energy group (between-group difference: 41 percentage points, 95% confidence interval 30–51). There was no significant difference between groups in any safety endpoint.

Conclusion Maximum-fixed energy shocks were more effective compared with low-escalating energy shocks for cardioverting atrial fibrillation. We found no difference in any safety endpoint.

Keywords Atrial fibrillation • Cardioversion • Energy selection

Introduction

Direct-current cardioversion of atrial fibrillation is one of the most commonly performed procedures in cardiology.[1,2] Choosing the optimal energy setting for initial and subsequent shocks is therefore an everyday clinical question. In the absence of randomized data favouring a specific energy setting, low-escalating energy shocks are commonly used and recommended by international guidelines to avoid potential harm.[4] The recommended use of low-escalating energy shocks to avoid potential post-shock arrhythmia and myocardial injury is based on studies using monophasic shocks.[5,6] Contemporary use of biphasic shocks has made the advantage of low-escalating shocks less clear as biphasic shocks are safer compared to monophasic shocks.[7–10]

Different approaches to energy selection have been suggested, e.g. using higher initial energy or higher-fixed energy shocks.[5,6,10,11] Currently, the optimal biphasic energy selection is unknown and no clear recommendations for initial and subsequent shocks are stated in the 2016 European Society of Cardiology (ESC) guidelines on the management of atrial fibrillation or other international guidelines.[12,13] Therefore, we compared maximum-fixed with low-escalating energy shocks for cardioverting atrial fibrillation.

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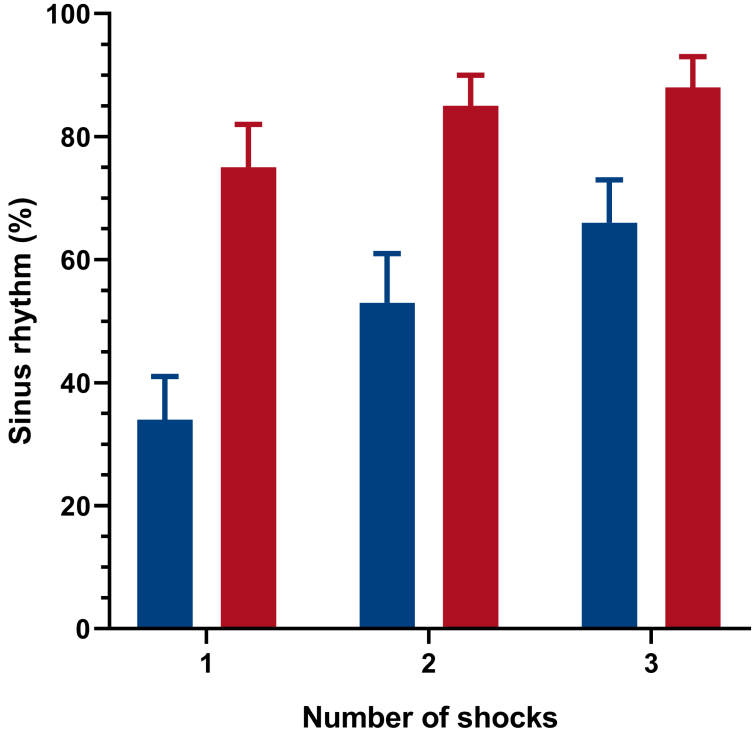
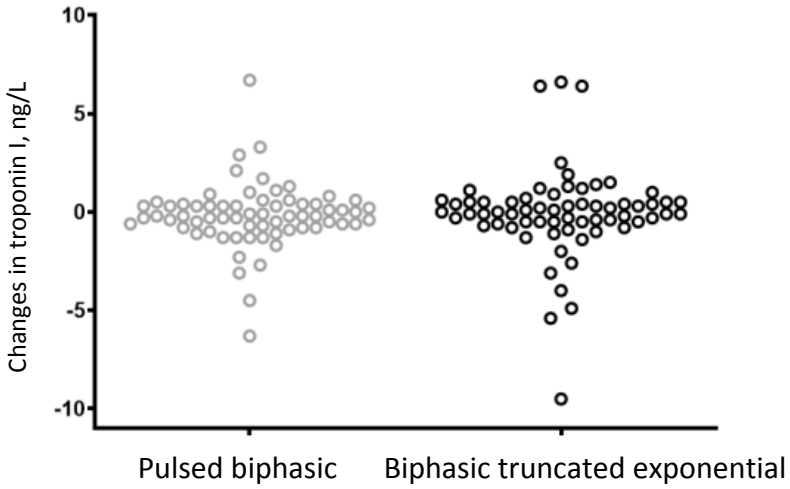


No. success / total:

Maximum-fixed	**97/129**	**13/32**	**4/19**
Low-escalating	**50/147**	**28/97**	**19/69**

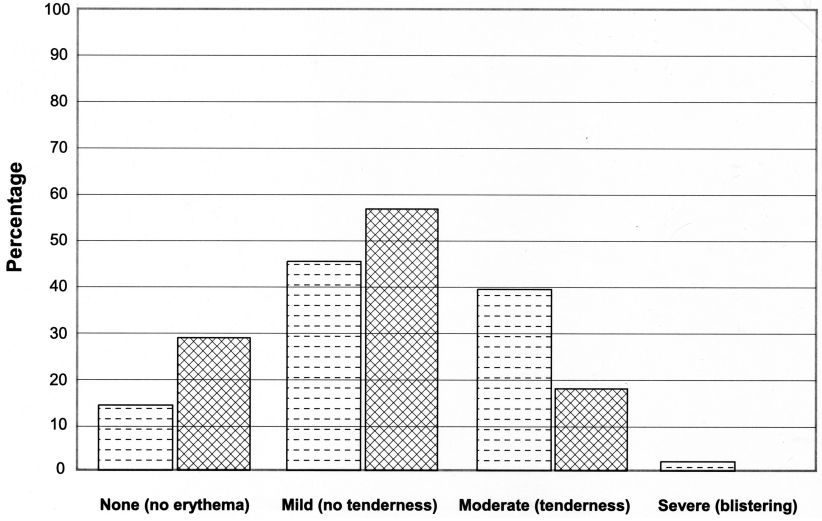
Myocardial injury



Schmidt AS, et al. JAHA, 2017

(& Greves K, *Heart* ,1998; Allan JJ, *JACC 1997)*

Skin redness or burns



Dashed: Monophasic; Hashed: Biphasic

Page RL et al., JACC, 2002

(& Neal S, Am J Cardiol 2003, Schmidt AS, 2017)

Background: Biphasic cardioversion and energy settings

Cardioversion
Sample size = 380

- Low-escalating (100-150-200-200 J) — 90 %
- High-fixed (200-200-200-200 J) — 88 %

Glover BM, *Heart*, 2007

Supplementary baseline characteristics

Characteristic	Maximum-fixed energy (N=129)	Low-escalating energy (N=147)
Antiarrhythmic drugs and dosages		
Amiodarone - no. (%)*	10 (8)	12 (8)
Dosage (mg) - median (IQR)	200 (200-200)	200 (200-325)
Flecainide - no (%)	2 (2)	5 (3)
Dosage (mg) - median (IQR)	250 (225-275)	200 (200-200)
Digoxin - no. (%)	29 (22)	29 (20)
Dosage (mg) - median (IQR)	188 (188-250)	188 (125-250)
Beta blocker	100 (76)	127 (86)
Angiotensin receptor blockers - no. (%)	67 (52)	72 (49)
Calcium channel blockers - no. (%)	34 (26)	40 (27)

Randomization

- **Performed using simple randomization 1:1, without blocks**

Simulation: Randomization of 276 patients 100,000 times

- Treatment 1, median, [IQR], (range): 0.5 [0.48-0.52] (0.36 – 0.63)
- Treatment 2: median, [IQR], (range): 0.5 [0.48-0.52] (0.37 – 0.64)
- A 0.47 / 0.53 split is in the upper/lower quartile but not unusual

Patient-reported discomfort or pain (Visual Analog Scale)

Patients reporting any discomfort or pain (Visual Analog Scale > 0 cm)	**Maximum-fixed energy (N=129)**	**Low-escalating energy (N=147)**
Anterior electrode, no. (%)	30 (23)	35 (24)
VAS score in cm, median (IQR)	1 (1-3)	1 (0.5-2)
Posterior electrode, no. (%)	14 (11)	15 (10)
VAS score in cm, median (IQR)	1 (0.5-3)	0.5 (0.2-1)