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FASTTRACK CLINICAL RESEARCH
Atrial fibrillation

Maximum-fixed energy shocks for cardioverting atrial fibrillation

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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 patient-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.[1–3] 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.[7–12]

Different approaches to energy selection have been suggested, e.g. using higher initial energy or higher-fixed energy shocks.[1,5,6,13,14] 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.[1,2,4] Therefore, we compared maximum-fixed with low-escalating energy shocks for cardioverting atrial fibrillation.

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Methods

Study design and setting

The *C*omparison of *H*igh vs. *E*scalating *S*hocks (CHESS) trial was a prospective, randomized, investigator-initiated superiority trial. We assigned patients to biphasic cardioversion of atrial fibrillation using maximum-fixed or low-escalating energy shocks. Patients were recruited in an outpatient clinic at Randers Regional Hospital, Denmark at the pre-cardioversion consultation.

The trial protocol was approved by the Danish Research Ethical Committee for the Central Denmark Region and the Danish Data Protection Agency. The trial was conducted in accordance with the principles of the Declaration of Helsinki. All patients provided written informed consent. Staff members from the Clinical Research Unit, Randers Regional Hospital, Denmark and care providers from Department of Internal Medicine and Department of Anesthesiology, Randers Regional Hospital, Denmark collected the data in collaboration with the investigators. The investigators designed the trial; monitored and managed the data, performed the statistical analyses, and wrote the manuscript. The trial is registered at clinicaltrials.gov (NCT02923414).

Patients

All patients with persistent atrial fibrillation scheduled for elective direct-current cardioversion were eligible for participation in the study. We defined persistent atrial fibrillation in accordance with the 2016 ESC guidelines on the management of atrial fibrillation.[2] The inclusion criteria were an electrocardiogram (ECG) documenting atrial fibrillation, age ≥18 years, and ability to sign the informed consent. Exclusion criteria were patients with haemodynamic unstable atrial fibrillation, untreated hyperthyroidism, pregnancy, and previous enrolment in the study. Patients were required to receive sufficient anticoagulation or alternatively a transoesophageal echocardiogram documenting the absence of intracardiac thrombi according to guidelines.[2]

Randomization and treatment

Randomization was performed using simple randomization (1:1 ratio, no blocks) assigning patients using computer-generated random numbers.[15] The numbers were placed in consecutive numbered, sealed, opaque envelopes. The envelopes were opened by the treating physician immediately prior to cardioversion.

Patients were randomized to cardioversion with maximum-fixed (360-360-360 J) or low-escalating (125-150-200 J) energy shocks. Patients were anaesthetized using 1 mg intravenous propofol per kilogram body weight to a maximum dose of patient's height in centimetres minus 100 cm. Subsequent boluses of 20 mg were administered if required. Synchronized shocks were delivered until sinus rhythm or to a maximum of three shocks. All shocks were delivered using Lifepak 20, Stryker/Physio-Control Inc., Redmond, WA, USA, through self-adhesive electrodes. All shocks were administered with the electrodes placed in anterior-posterior position.[4] The patients and care providers were blinded to the intervention but due to the nature of the study, the physician delivering the shocks was not blinded. The nurse measuring the skin redness and the investigator analysing ECGs were both blinded to the intervention. Baseline variables were collected before randomization during the pre-cardioversion consultation.

Endpoints

The primary endpoint was presence of sinus rhythm on a 12-lead ECG recorded 1 min after cardioversion.[16,17] Secondary efficacy endpoint was first shock efficacy, i.e. cardioversion efficacy using 360 vs. 125 J.

Secondary safety endpoints were defined as: any cases of arrhythmia detected on 4 h ECG-surveillance [sinus node dysfunction (atrioventricular blocks, asystole, or transient bradycardia), ventricular arrhythmia, or premature ventricular complexes]; myocardial injury measured by high-sensitive troponin I; skin discomfort or pain on a visual analog scale (VAS) 2 h after cardioversion, and degree of skin redness after removal of electrodes.

Blood sampling and biochemical analysis

We measured high-sensitive cardiac troponin I at baseline before cardioversion (1–2 days before cardioversion was accepted) and 4 h after cardioversion. The analyses were performed immediately after blood sampling in a central clinical biochemistry DANAK ISO 15189 accredited laboratory. The measurements were performed using SIEMENS ADVIA Centaur troponin I assays, Siemens Healthcare GmbH, Erlangen, Germany [Troponin-Ultra: 10% coefficient of variation at 30 ng/L, Troponin-HS (TNIH): 10% coefficient of variation at 4.46 ng/L].

Statistical analysis

We assumed an efficacy of 85% in the low-escalating energy group and 95% in the maximum-fixed energy group. To achieve a power of 80% to detect this 10% difference a total sample size of 276 patients was needed assuming no attrition. The analysis of outcomes was performed as intention-to-treat. Categorical outcomes are compared using the χ^2 test. To compare the changes in high-sensitive troponin I changes we analysed the data for normality by performing histogram analysis and quantile–quantile plots. The appropriate tests (Student's *t*-test or Wilcoxon rank-sum test) were used for comparison. The statistical analysis was performed using R version 3.4.2.[18]

Results

Patients

Patients were enrolled from September 2016 to March 2019. In total, 296 patients were screened for participation (*Figure 1*). Of the 276 patients randomized, 129 patients (47%) were allocated to maximum-fixed energy shocks and 147 patients (53%) to low-escalating energy shocks. The baseline variables were balanced between groups (*Table 1*). There were no missing data on the primary endpoint, and no patients were excluded from the intention-to-treat analysis.

Endpoints

The primary endpoint, i.e. sinus rhythm 1 min after cardioversion, occurred in 114 of 129 patients (88%) in the maximum-fixed energy group compared to 97 of 147 patients (66%) in the low-escalating energy group (between-group difference of 22 percentage points; 95% confidence interval 13–32, $P < 0.001$). The relative difference in presence of sinus rhythm between groups, using the low-escalating energy group as reference, was 1.3 (95% confidence interval 1.2–1.5) corresponding to a number needed to treat of 5 (95% confidence interval 3–8) (*Figure 2*). When comparing maximum-fixed and low-escalating shocks in patients with persistent or long-term (>1 year) persistent atrial fibrillation the between-group differences on the primary outcome remained unchanged (Supplementary material online).

The secondary efficacy endpoint, i.e. sinus rhythm after first shock, occurred in 97 of 129 patients (75%) in the maximum-fixed energy

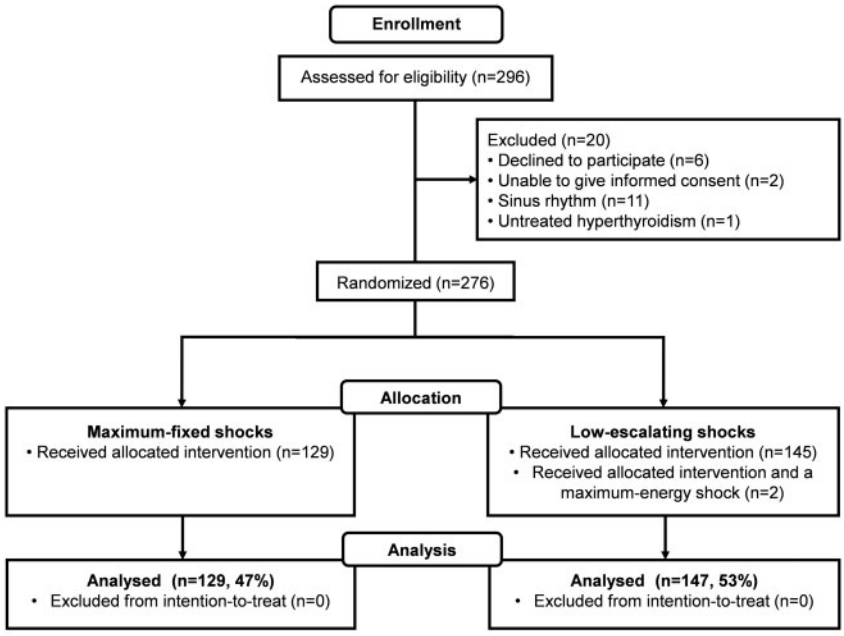

Figure 1 Study participant flow chart.

group compared to 50 of 147 patients (34%) in the low-escalating energy group (between-group difference of 41 percentage points; 95% confidence interval 30–51, relative difference 2.6; 95% confidence interval 1.9–3.6) (*Figure 2*). Sinus rhythm at discharge, i.e. 4 h after cardioversion was achieved in 110 of 129 patients (85%) in the maximum-fixed energy group, and in 93 of 147 patients (63%) in the low-escalating energy group (between-group difference of 22 percentage points; 95% confidence interval 12–32, relative difference 1.4; 95% confidence interval 1.2–1.6). Summarized data on cardioversion procedure characteristics for comparison between groups are provided in *Table 2*. All patients were anaesthetized using propofol as pre-defined and no concomitant antiarrhythmic drugs were used prior to or during cardioversion. The use of maximum-fixed energy shocks reduced the total number of shocks delivered and resulted in a small decrease in median procedure time when compared to low-escalating energy shocks (*Table 2*).

Safety and harms

Cases of any arrhythmia following cardioversion occurred in 7 of 129 patients (5%) in the maximum-fixed energy group and in 7 of 147 patients (5%) in the low-escalating energy group. There was no difference between groups on the degree of skin redness or patient-reported post-procedural pain or discomfort (*Table 3*).

Overall, we did not detect any myocardial injury in either of the two treatment groups measured by changes in high-sensitive troponin I levels. The median (25 percentile–75 percentile) change in high-sensitive troponin I was in the maximum-fixed energy group 0 ng/L (0–0) and in the low-escalating group 0 ng/L (-1 to 0). Additional details on the troponin measurements are provided in the Supplementary material online.

Discussion

Maximum-fixed energy shocks were more efficient compared with low-escalating energy shocks in cardioverting atrial fibrillation. We found no difference between groups on cases of post-shock arrhythmia, no myocardial injury measured by changes in high-sensitive troponin I and, skin burns, patient-reported post-procedural pain or discomfort.

Choosing the optimal energy setting for initial and subsequent shocks in cardioverting atrial fibrillation is an everyday question in clinical practice. The current study provides warranted evidence in favour of maximum-fixed energy biphasic shocks.

There are several advantages of using maximum-fixed energy shocks compared to low-escalating energy shocks. First, we found a substantially greater efficacy in the maximum-fixed energy group. This may result in more patients experiencing symptom relief, less need for up-stream medical therapy (e.g. antiarrhythmic drugs with possible side-effects/harm), and a possibly reduced number of hospital contacts for additional costly cardioversion attempts. Second, we found procedural advantages of maximum-fixed shocks resulting in fewer total shocks delivered and a slightly shorter procedural duration. Third, there may be a further advantage of using higher energy shocks as they exceed the upper-limit of vulnerability for ventricular fibrillation induction in humans.[19,20] This is supported by clinical data only reporting ventricular fibrillation after cardioversion using energies below 200 J (5 of 2959 shocks <200 J vs. 0 of 3439 shocks ≥200 J).[21]

The only previously randomized data on energy selections using biphasic shocks are reported in the BEST-AF trial.[22] The study compared fixed energy (200-200-200 J) and low-escalating (100-150-200-200 J) energy shocks but did not find a difference in cardioversion

Table 1 Baseline characteristics

Characteristics[a]	Maximum-fixed energy (*N* = 129)	Low-escalating energy (*N* = 147)	Standardized mean difference
Age (years)	68 ± 9	68 ± 8	0.04
Male sex, *n* (%)	90 (70)	109 (74)	0.10
Body mass index (kg/m^2)	30 ± 6	29 ± 6	0.14
Left atrial indexed volume (mL/m^2)	37 ± 13	39 ± 13	0.09
Atrial fibrillation duration, *n* (%)			0.05
<1 month	14 (11)	17 (12)	
1–12 months	77 (60)	85 (58)	
>12 months	37 (29)	45 (31)	
Medical history, *n* (%)			
Hypertension	84 (65)	81 (55)	0.19
Congestive heart failure	39 (30)	36 (25)	0.15
Valvular heart disease	9 (7)	17 (12)	0.13
Ischaemic heart disease	9 (7)	16 (11)	0.14
Diabetes mellitus	11 (9)	13 (9)	0.01
Stroke or transient ischaemic attack	15 (12)	11 (7)	0.14
Pacemaker[b]	1 (1)	2 (1)	0.06
CHA_2DS_2-VASc score, *n* (%)[c]			0.17
0	7 (5)	11 (7)	
1	21 (16)	32 (22)	
≥2	101 (78)	104 (71)	
Medication use, *n* (%)[d]			
Amiodarone	10 (8)	12 (8)	0.02
Vitamin K antagonist	27 (21)	26 (18)	0.10
Non-vitamin K oral anticoagulant	95 (74)	115 (78)	0.16

There were no statistically significant differences between groups.
[a]Data reported as mean ± standard deviation for continuous variables and counts (percentages) for categorical variables.
[b]Pacemakers were tested after cardioversion without any reports of malfunction.
[c]The CHA_2DS_2-VASc score is a measure of the risk of stroke in atrial fibrillation patients (congestive heart failure, hypertension, an age of 65–74 years, diabetes, and vascular disease are assigned one point; previous stroke or transient ischaemic attack, and an age of ≥75 years are assigned two points).
[d]Additional data on the baseline characteristics (e.g. medications and dosages) are provided in the Supplementary material online, *Table S1*.

success between groups. We used 360 J which is the maximal possible energy setting in any biphasic defibrillator. In the absence of recommendations in the 2016 ESC guidelines on the management of atrial fibrillation we defined the low-escalating energy shocks in accordance with national Danish guidelines recommending escalating shocks to 200 J.[2,23] In addition, the final shock of 200 J was similar to the energy settings in the BEST-AF trial being the only previous randomized trial investigating biphasic shock energy settings.[22] The BEST-AF trial used biphasic truncated exponential shocks similar to our study however from a different manufacturer using impedance compensation.

Several defibrillators are used in clinical practice using different maximum energy settings, waveforms (e.g. truncated exponential, rectilinear biphasic, and pulsed biphasic), and impedance compensation.[7,16,17,24] To our knowledge, the defibrillator used in our study (and other LIFEPAK series defibrillators) are the only devices capable of delivering 360 J. Comparing biphasic truncated exponential and pulsed biphasic shocks resulted in a difference in cardioversion efficacy.[7] In contrast, shock efficacy of biphasic truncated exponential and biphasic rectilinear shocks were not different despite using different maximum energy shocks.[16,17,24] Accordingly, the benefit of using maximum-fixed shocks may also apply to other biphasic defibrillators than the one used in the current study.

Between-study comparisons of cardioversion success-rates are difficult. Previous cardioversion studies have reported success-rates between 66% and 98% depending on the types of patients included; the cardioversion protocol (e.g. energy selection, maximum number of shocks in protocol, waveform, and electrode position), and choice of primary endpoint (e.g. one sinus beat present; sinus rhythm for 1 min, or sinus rhythm to discharge).[5–7,9–13,17,22,24,25] Cardioversion efficacy depends on atrial fibrillation duration with greater efficacy for shorter duration of atrial fibrillation.[14] Our study population consisted mainly of patients with longer-duration atrial fibrillation (30% >1 year duration) which may explain the cardioversion success-rates in the current study. Some cardioversion trials reported success-rates of 90–98% and included recent-onset atrial fibrillation (duration < 48 h) and some specifically excluded patients with long-term atrial fibrillation.[9–11,16,17,24,25]

This study included a number of safety endpoints to provide insights on the safety of using maximum-fixed energy biphasic shocks. We measured high-sensitive troponin I before and after cardioversion to ensure that cardioversion can be performed without causing

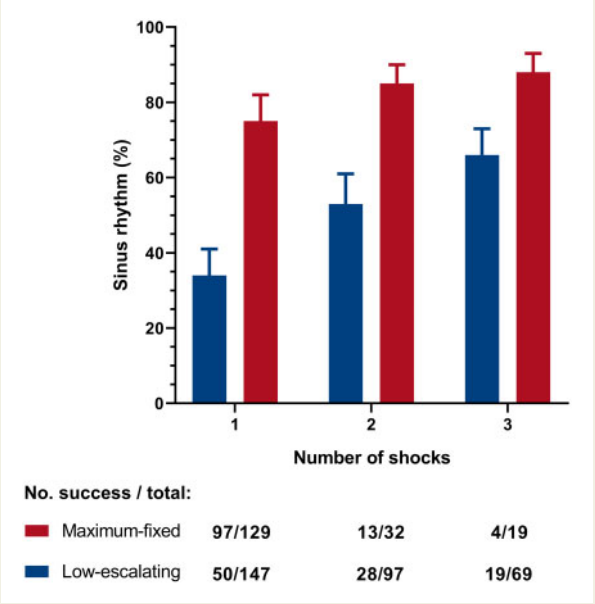

Figure 2 Cumulative cardioversion success of the two treatment groups. The bars represent the cumulative cardioversion success of maximum-fixed and low-escalating energy shocks. The error bar illustrates the upper limit of the 95% confidence interval for the proportions. The table below the figure shows the number of patients cardioverted at different number of shocks (no. successfully cardioverted/no. of patients attempted cardioverted).

Table 2 Cardioversion characteristics

Cardioversion procedure characteristics (IQR)	Maximum-fixed energy	Low-escalating energy
Median number of shocks delivered	1 (1–1)	2 (1–3)
Median cumulative energy (J)	360 (360–360)	275 (125–475)
Median total propofol usage (mg)	80 (70–90)	80 (70–100)
Median procedure duration (min)	1.9 (1.5–2.7)	2.2 (1.7–3.0)

IQR, interquartile range.

Table 3 Safety endpoints

Safety endpoints	Maximum-fixed energy	Low-escalating energy
Complications after cardioversion, *n* (%)		
Cases of any arrhythmia (%)	7 (5)	7 (5)
Sinus node dysfunction	5 (4)	5 (3)
Asystole (%)[a]	0 (0)	2 (1)
Transient bradycardia (%)[b]	3 (2)	3 (2)
≥2 degree atrioventricular block (%)[c]	2 (2)	0 (0)
Ventricular tachyarrhythmia (%)	0 (0)	0 (0)
Ventricular premature complexes (%)	2 (1)	2 (1)
Patients reporting any discomfort or pain (VAS >0 cm)[d]		
Anterior electrode, *n* (%)	30 (23)	35 (24)
VAS score in cm, median (IQR)	1 (1–3)	1 (0.5–2)
Posterior electrode, *n* (%)	14 (11)	15 (10)
VAS score in cm, median (IQR)	1 (0.5–3)	0.5 (0.2–1)
Skin redness assessed 2 h after cardioversion		
Anterior electrode, *n* (%)		
No redness	87 (67)	101 (69)
Mild redness	42 (33)	46 (31)
Skin burns	0 (0)	0 (0)
Posterior electrode, *n* (%)		
No redness	106 (82)	126 (86)
Mild redness	23 (18)	21 (14)
Skin burns	0 (0)	0 (0)

[a]The duration of asystole was 7 and 10 s, respectively and did not require intervention.
[b]Transient bradycardia was defined as a heart rate <40 b.p.m. for less than 30 min that did not require intervention, e.g. intravenous atropine or transcutaneous pacing.
[c]One patient had an intermitted second degree atrioventricular block which resolved within 24 h after digoxin discontinuation; one patient with known sinus node dysfunction had a 2:1 atrioventricular block and was discharged after recidivating to atrial fibrillation within 48 h.
[d]VAS score denotes visual analog scale score for pain assessment from 0 to 10 cm where a marker placed at 0 cm denotes no pain and 10 cm is the highest possible pain imaginable.

myocardial injury despite using maximum biphasic energy shocks. This study used high-sensitive troponin measurements and adds to previous studies reporting that biphasic cardioversion is not associated with myocardial injury.[8,24,26–29] Monophasic shocks have been associated with occasional skin burns, while studies on biphasic shocks have reported no or very mild redness and discomfort after the procedure.[24,30] Our study found no skin burns and no difference in the amount of skin redness between groups.

Maximum-fixed energy shocks were not associated with harm and may thus be considered for patients with recent-onset atrial fibrillation and possibly also other arrhythmias. Importantly, haemodynamically unstable patients may especially benefit from maximum-fixed energy shocks to ensure prompt termination of arrhythmia. None of these patients were included in our study, and accordingly, data on maximum-fixed shocks are warranted for these patients.

A number of limitations to our study should be mentioned. First, this is a single-centre study. However, Danish health care and hospitals and are relatively comparable across regions.[31] Second, the physician performing the cardioversion was not blinded to the shock energy used. However, we do not believe this lack of blinding affected cardioversion success and all outcome assessments were blinded. Third, we used biphasic truncated exponential shocks delivered by a defibrillator from one manufacturer only. Fourth, while not powered for safety outcomes, it was reassuring to find no difference on any safety endpoint. Last, we included patients from our out-patient clinic with persistent or long-term persistent atrial fibrillation. We did not include cardioversions of e.g. acute onset atrial fibrillation or other atrial arrhythmias but the high efficacy of using maximum-fixed energy shocks may also apply to these patients.

In conclusion, maximum-fixed energy shocks were more efficient compared with low-escalating energy shocks for cardioversion of atrial fibrillation. We found no difference in any safety endpoint.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

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Conflict of interest: none declared.

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