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Clinical research

A trial of self-adhesive patch electrodes and hand-held paddle electrodes for external cardioversion of atrial fibrillation (MOBIPAPA)

Paulus Kirchhof[1,3]*, Gerold Mönnig[1], Kristina Wasmer[1], Achim Heinecke[2], Günter Breithardt[1,3], Lars Eckardt[1], and Dirk Böcker[1]

[1] *Department of Cardiology and Angiology, Universitätsklinikum Münster, Albert-Schweitzer-Straße 33, D-48149 Münster, Germany;* [2] *Coordinating Centre for Clinical Trials, Hospital of the University of Münster, Münster, Germany; and* [3] *Kompetenznetz Vorhofflimmern (AFNET)*

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Aims External electrical cardioversion is the method of choice to terminate persistent atrial fibrillation. Whether the type of shock electrode affects cardioversion success is not known. We tested whether hand-held steel electrodes improve cardioversion outcome with monophasic or biphasic shocks when compared with adhesive patch electrodes.
Methods and results Two hundred and one consecutive patients with persistent atrial fibrillation (147 male, mean age 63 ± 1 years, duration of atrial fibrillation 6.3 ± 1 months) were randomly assigned to cardioversion using either a sinusoidal monophasic or a truncated exponential biphasic shock wave form. The first half of patients were cardioverted using adhesive patch electrodes, the second half using hand-held steel paddle electrodes, and all patients using an anterior–posterior electrode position. Paddle electrodes successfully cardioverted 100/104 patients (96%) and patch electrodes 85/97 patients (88%, $P = 0.04$). This effect was comparable to that of biphasic shocks: biphasic shocks cardioverted 102/104 patients (98%) and monophasic shocks 83/97 patients (86%, $P = 0.001$). A beneficial effect of paddle electrodes was observed for both shock wave forms. After cross-over from an ineffective monophasic to a biphasic shock, cardioversion was successful in 198/201 (98.5%) patients. Unsuccessful cardioversion after cross-over (3/201 patients) only occurred with patch electrodes ($P = 0.07$).
Conclusion Hand-held paddle electrodes increase success of external cardioversion of atrial fibrillation in this trial. This increase is of similar magnitude as the increase in cardioversion success achieved with biphasic shocks. A combination of biphasic shocks, paddle electrodes, and an anterior–posterior electrode position renders outcome of external cardioversion almost always successful (104/104 patients in this trial).

Introduction

Atrial fibrillation, the most common cardiac arrhythmia, causes important morbidity and mortality in affected patients.[1,2] Many patients experience symptoms ranging from palpitations to fainting due to the arrhythmia, and persistent atrial fibrillation requires continuous oral anticoagulation to prevent thrombo-embolic complications.[3] Although there are currently no sufficient treatment options to prevent recurrent atrial fibrillation over longer periods of time,[4–7] acute restoration of sinus rhythm remains an important treatment goal in patients with atrial fibrillation.[8]

External electrical cardioversion (i.e. trans-thoracic, R-wave synchronized application of a strong electrical shock) is a simple and often successful way to acutely terminate atrial fibrillation.[9,10] The optimal technique for external cardioversion of atrial fibrillation continues to evolve. Biphasic shock wave forms improve the success rate of external cardioversion of atrial fibrillation[11] as well as an anterior–posterior shock electrode position.[12] Still, external cardioversion fails in a relevant proportion of patients.

Hand-held sintered-steel electrode paddles were used in our previous trial (*Figure 1A*) (see Supplementary Material online) and resulted in a relatively high cardioversion success rate,[12] in contrast to most other trials of external cardioversion that used self-adhesive gel-covered patch electrodes (*Figure 1A*),[11,13–15] and reported lower success rates under similar conditions.[11] Hand-held electrodes require manual pressure applied by the operator onto the anterior electrode during the cardioversion shock, which may result in a better and more homogeneous electrode-skin contact.[16] In line with data suggesting that hand-held electrodes convey a lower trans-thoracic shock impedance,[17] such electrodes may deliver shock energy and current flow more efficiently to the left atrium, the putative

* Corresponding author. Tel: +49 251 8345160; fax: +49 251 8347864.
E-mail address: kirchhp@uni-muenster.de

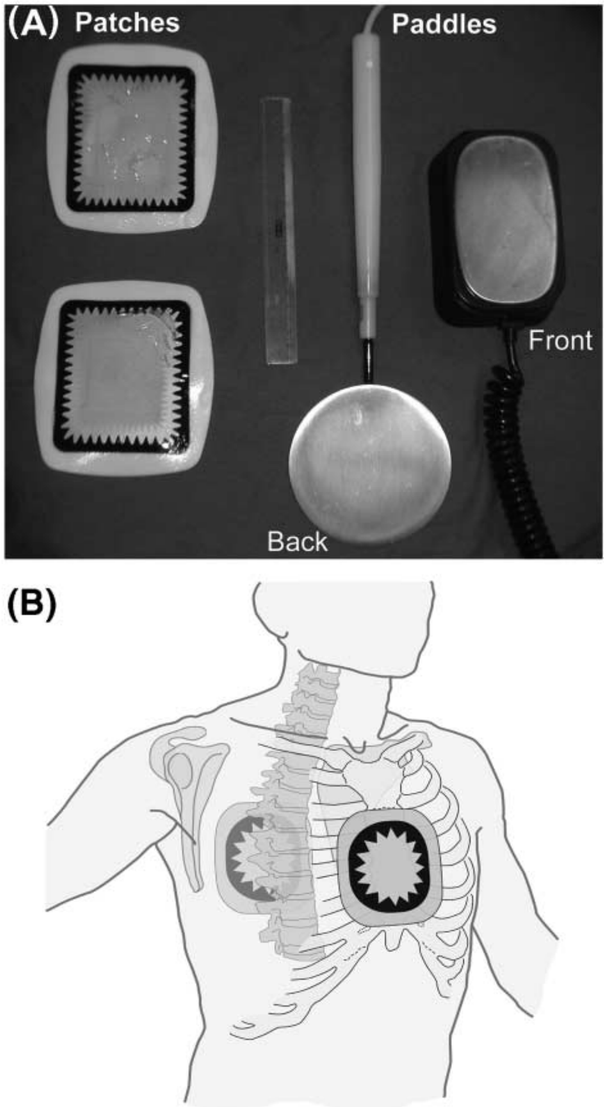

Figure 1 (*A*) Photographs of the shock electrodes used in this trial. Left: A pair of the identical adhesive gel-covered electrode patches. Right: Sintered-steel hand-held paddle electrodes. The circular electrode is placed under the back of the supine patient, the rectangular electrode on the anterior chest. The anterior electrode is held by hand during the cardioversion procedure. (*B*) Schematic drawing of the electrode positions chosen in this trial. The anterior and posterior electrodes are positioned directly opposite each other in a median orientation. The anterior electrode is placed onto the middle portion of the sternum. See online supplementary material for a colour version of this figure.

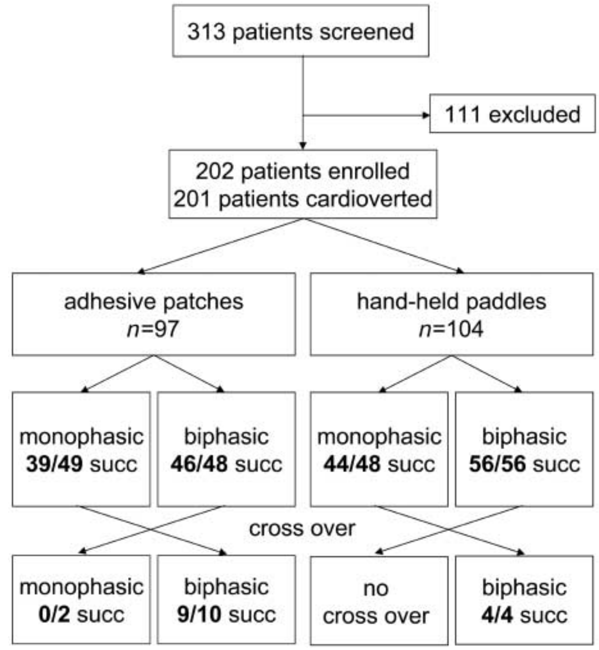

Figure 2 Trial profile. All numbers indicate number of patients.

target area for successful cardioversion.[18] On the basis of these considerations, we tested the effects of hand-held paddle electrodes on cardioversion outcome with either monophasic or biphasic shock wave forms.

Methods

Trial design

We performed a prospective, randomized, open, mono-centre trial. All patients presenting with persistent atrial fibrillation and an indication for external cardioversion in the Department of Cardiology of the University Hospital Münster, Germany, were consecutively screened for the trial. To be eligible, we required a clinical indication for external cardioversion of atrial fibrillation.[10,19] and documented atrial fibrillation prior to the procedure. To minimize thrombo-embolic complications, documented oral anticoagulation with phenprocoumon (INR 2-3) for 3 weeks or exclusion of left atrial thrombi by trans-oesophageal echocardiography directly prior to the cardioversion procedure was required.[10] Continuation of anticoagulation after cardioversion was recommended for all patients. Care was taken to exclude patients presenting with atrial flutter or atrial tachycardias by examining both the ECG upon admission and the ECG directly prior to the cardioversion shocks.[12,19] All shocks were delivered in an anterior–posterior electrode position (*Figure 1B*).[12] Patients were anaesthetized using standard procedures (either propofol or etomidate in combination with opioid analgetics). The procedural details have been described previously.[12]

Statistical model

The trial was designed to detect an absolute difference in cardioversion success rate of 10% between the two shock wave forms (monophasic/biphasic) and between the two electrode types (hand-held paddle electrodes/adhesive patch electrodes). With an assumed success rate in the patch group of 88%,[11,12] we calculated a group size of 100 patients per group to achieve a statistical power of 0.8 (beta error 0.2) and a two-sided alpha level of 0.05 for each of the two hypotheses. This group size resulted in sufficient statistical power to detect increases in cardioversion success between 9 (90% success rate with standard method) and 13% (79% success rate with standard method).[11,12] Primary end point was successful restoration of sinus rhythm by the cardioversion shock. The primary hypotheses were tested by χ^2 test. Multiple logistic regression was used to test the simultaneous influence of electrode type (patch/paddle) and shock wave form (monophasic/biphasic). Biphasic shock wave forms are increasingly used in clinical practice. We therefore estimated the effect of electrode type with biphasic shocks by analysing cardioversion success after cross-over, when all patients had undergone at least one cardioversion attempt with a biphasic 360 J shock. This was done as an exploratory *post hoc* analysis. Because of technical differences in the defibrillator setup for each electrode type, we chose a sequential design for the comparison of patch and paddle electrodes, whereas the exchange of the monophasic and biphasic defibrillators was tested in a randomized design. The trial was approved by the local ethics committee. All patients gave written informed consent prior to inclusion in the trial.

Protocol

Directly prior to the cardioversion procedure, patients were randomized to cardioversion with either a sinusoidal monophasic or a truncated exponential impedance-controlled biphasic shock wave form. We used the standard shock wave forms of two commercially available external cardioverter/defibrillators (Medtronic Lifepak 9 for monophasic shocks and Medtronic Lifepak 12 for biphasic shocks). Randomization was performed using a computer-read randomization list. This procedure guaranteed complete concealment of the study group from all personnel who participated in the trial. Randomization was in blocks of 100 patients. The first 100 patients were cardioverted using commercially available gel-covered adhesive mesh-wire patch electrodes (Medtronic Physiocontrol Fast-Patches Plus®, Product number 3010188-007), the second half of the patients were cardioverted using sintered-steel hand-held paddle electrodes (*Figure 1A*).[12] The surface area of the electrodes was comparable (*Figure 1A*), and the anatomical position of the electrodes on the thorax was identical between groups (*Figure 1B*). Conductive gel (Spectra360®, Parker Laboratories Inc, Fairfield, NY, USA) was used to cover the steel electrodes prior to their placement onto and below the supine patient.[10]

All cardioversions were performed using a step-up protocol with an initial shock strength of 50 J. Pre-selected shock strengths were equal for both trial groups (50, 100, 200, 300, and 360 J). If all shocks failed, a single shock at 360 J shock energy was delivered using the other shock wave form (cross-over). Successful cardioversion was defined as presence of sinus rhythm immediately after the cardioversion shock as documented in a six-lead ECG written at 50 mm/s paper speed throughout and directly after each cardioversion shock. This definition of successful cardioversion, our primary end point, includes patients with immediate recurrence of atrial fibrillation[12,20] in the successful group. This definition is similar to the end point in other trials of cardioversion[11,12] and was based on the pathophysiological assumption that immediate recurrence of atrial fibrillation is caused by atrial ectopy which is presumably not affected by the cardioversion techniques tested in this trial.

Results

Trial patients

From June 2001 until November 2003, 313 consecutive patients underwent external cardioversion at our department. Of these, 111 did not meet the inclusion criteria or did not give informed consent; 202 patients were randomized. One patient was not cardioverted after randomization because of spontaneous termination of atrial fibrillation just prior to cardioversion. The remaining 201 patients were analysed (*Figure 2*).

The patient groups (monophasic shocks vs. biphasic shocks, paddles vs. patches) did not differ in their clinical characteristics (*Table 1*). Cardioversion was more often successful when a biphasic shock was applied (biphasic shocks 102/104 patients vs. monophasic shocks 83/97 patients, *Figure 2*, $P = 0.001$). Successful cardioversion energy could be reliably determined in 193 patients. In the remaining eight patients, the minimal successful shock energy could not be determined because of violations of the shock strength protocol. Biphasic shocks cardioverted at a lower mean pre-selected energy (monophasic shocks 232 ± 10 J vs. biphasic shocks 150 ± 10 J, $P < 0.0001$, all continuous variables given as mean $\pm$ standard error of the mean). Biphasic shocks shifted the success-shock strength relation to lower shock strengths (*Figure 4*).

Cardioversion was more often successful when hand-held paddle electrodes were used (paddles 100/104 patients vs. patches 85/97 patients, $P = 0.04$, *Figure 3*). When paddle electrodes were used, the successful shock energy was not significantly different compared to successful shock energy using patch electrodes (patches 202 ± 11 J vs. paddles 178 ± 10 J, $P = 0.11$). Consistent with this finding, the use of paddle electrodes did not shift the success-shock strength relation towards lower shock energies but rather transferred the curve upwards to higher success rates (*Figure 4*). A beneficial effect of paddle electrodes could be seen for both shock wave forms. This was confirmed by logistic regression with a simple additive model (Pearson's goodness-of-fit statistic $X = 0.8072$, df $= 1$, $P = 0.369$).

To estimate the benefit of paddle electrodes in combination with biphasic shocks, the following analyses were performed. Cardioversion success rate was 100% in the biphasic shock group with paddle electrodes (56/56 patients) but 96% (46/48 patients) when patches were used ($P = 0.07$, *Figure 2*). After cross-over of an ineffective monophasic to a biphasic cardioversion shock, cardioversion was successful in all 104 patients (100%) when paddle electrodes were used but in 94/97 patients (97%) only when patch electrodes were used ($P = 0.07$). Hence, all three patients in whom cardioversion was not successful after cross-over were cardioverted using patch electrodes (*Figure 2*).

A relevant portion of the trial patients could only be cardioverted using high shock energies: 45 patients required shocks above 200 J when the monophasic shock wave form was initially used, and 11 patients required shocks above 200 J when the biphasic shock wave form was used (*Figure 4*). Of these 56 patients (28%), 53 patients (26%) were successfully cardioverted at up to 360 J.

Discussion

Rationale for our trial

Atrial fibrillation is maintained by functional re-entry, mother rotors, or repetitive ectopy in the posterior left atrium or the pulmonary veins.[21,22] Successful cardioversion of atrial fibrillation requires a sufficient shock field gradient, estimated at $\sim$5 V/cm, throughout the left atrium. Two factors were identified that could explain the high success rate with monophasic shocks and an anterior–posterior electrode position in our previous trial.[12] Possibly, the electrode position used in the previous trial was by chance optimized to deliver a maximal shock wave strength to the left atrium. This hypothesis warranted confirmation as it would have allowed to improve cardioversion by educational interventions (training of optimal electrode placement) rather than by changing the equipment used for cardioversion. Another difference between our trial and the majority of published data[11,13–15] was the use of hand-held sintered-steel paddle electrodes as opposed to adhesive electrode patches. The present trial was therefore designed to test whether the use of biphasic shocks and/or hand-held paddle electrodes improved cardioversion outcome when

Table 1 Clinical characteristics of the trial patients

	All ($n = 201$)	Biphasic ($n = 104$)	Monophasic ($n = 97$)	Paddle ($n = 104$)	Patch ($n = 97$)
Age (years)	63 ± 1	63 ± 1	63 ± 1	63 ± 1	63 ± 1
Male (*n*)	147 (73%)	79 (76%)	68 (70%)	72 (74%)	75 (72%)
Prior cardioversions (*n*)	1.2 ± 0.1	1.2 ± 0.2	1.3 ± 0.2	1.3 ± 0.2	1.2 ± 0.2
Duration of AFib (months)	6.3 ± 1	5.5 ± 1	7.1 ± 2	8.1 ± 2	4.5 ± 0.2
Body mass index	28 ± 1	27.3 ± 0.4	27.2 ± 0.4	27.4 ± 0.2	27.0 ± 0.5
Cardiac disease					
Coronary artery disease (*n*)	61 (30%)	39 (38%)	22 (23%)	36 (37%)	25 (24%)
Dilative cardiomyopathy (*n*)	24 (12%)	13 (13%)	11 (11%)	13 (13%)	11 (11%)
Valvular heart disease (*n*)	18 (9%)	5 (5%)	13 (13%)	4 (4%)	14 (13%)
Apoplex/TIA (*n*)	10 (5%)	7 (7%)	3 (3%)	4 (4%)	6 (6%)
Sick sinus syndrome (*n*)	2 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)
Sleep apnea syndrome (*n*)	15 (7%)	7 (7%)	8 (8%)	10 (10%)	5 (5%)
Atrial septal defect (*n*)	4 (2%)	3 (3%)	1 (1%)	1 (1%)	3 (3%)
Cardiomyopathy (FHC or ARVCM) (*n*)	10 (5%)	4 (4%)	6 (6%)	4 (4%)	6 (6%)
LV function (available in 194 patients)					
Normal	110 (55%)	59 (57%)	51 (53%)	57 (59%)	53 (50%)
Slightly depressed	37 (18%)	16 (15%)	21 (22%)	18 (19%)	19 (18%)
Moderately depressed	25 (12%)	12 (12%)	13 (13%)	10 (10%)	15 (14%)
Severely depressed	22 (11%)	15 (14%)	7 (7%)	14 (14%)	8 (8%)
Median	Normal	Normal	Normal	Normal	Normal
Antiarrhythmic drugs at cardioversion					
Amiodarone (*n*)	46 (23%)	26 (25%)	20 (21%)	22 (23%)	24 (23%)
Flecainide (*n*)	30 (15%)	15 (14%)	15 (15%)	19 (20%)	11 (11%)
Other sodium channel blocker (*n*)	4 (2%)	3 (3%)	1 (1%)	0 (0%)	4 (4%)
Sotalol (*n*)	28 (14%)	11 (11%)	17 (18%)	14 (14%)	14 (14%)

There were no significant differences in the clinical characteristics between the groups. All continuous variables are given as mean ± standard error of the mean.

an effective anterior–posterior electrode position[12] was used.

Effect of hand-held sintered-steel electrodes

The use of hand-held sintered-steel paddle electrodes improved cardioversion success when compared with adhesive electrode patches in this trial. The position of adhesive patch electrodes can probably more easily be standardized, especially in multi-centre trials, resulting in the use of patch electrodes in almost all published studies.[11,13–15] The result of the present trial is concordant with the high success rate using monophasic shocks and hand-held paddle electrodes in our previous report (95% after cross-over[12]). Of note, another trial that also used paddle electrodes, although in an anterior–lateral electrode position, also reported relatively high success rates of external cardioversion.[23] When patients with restoration of sinus rhythm but immediate re-initiation of atrial fibrillation were counted as successful cardioversion, monophasic 360 J shocks yielded a success rate of 93% (101/109 patients), and biphasic 200 J shocks a success rate of 96% (113/118 patients). When the effects of different shock wave forms (monophasic/biphasic) and the effects of electrode position are considered, published trials using patch electrodes reported comparably lower cardioversion success rates.[11,13–15] Within the limitations of such an informal meta-analysis, published data are therefore concordant with the result of our trial.

Effect of shock wave form on cardioversion success

During the course of this trial, several groups published additional data confirming the effectiveness of biphasic over monophasic shock wave forms.[13–15,23] We could reproduce this finding in our trial and found similar success rates with the use of adhesive patch electrodes when compared with these studies. Specifically, a monophasic shock wave form combined with adhesive electrode patches resulted in a cardioversion failure rate of 20% in this trial (10/49 patients), very close to the failure rate reported in another trial.[11] Most of these failures (9/10 patients in our trial) were overcome by cross-over to a biphasic shock wave form, again similar to previous reports,[11,13–15] and comparable to the effect of biphasic shocks in internal cardioversion of atrial fibrillation.[24] Similar to other studies,[14,23] we also found lower energy needs for biphasic shock wave forms (*Figure 4*).

Optimizing cardioversion success on the basis of anatomy, (electro)physiology, and physics

An anterior–posterior electrode position appears to be superior to an anterior–lateral electrode position for external cardioversion, most likely because of the posterior anatomic location of the left atrium in the thorax.[12] Biphasic shocks also increase cardioversion success.[11,13–15,23] This effect is most likely attributable to the greater chance of exciting the myocardium with a biphasic shock,[25] possibly by increasing local voltage gradients at the point of polarity

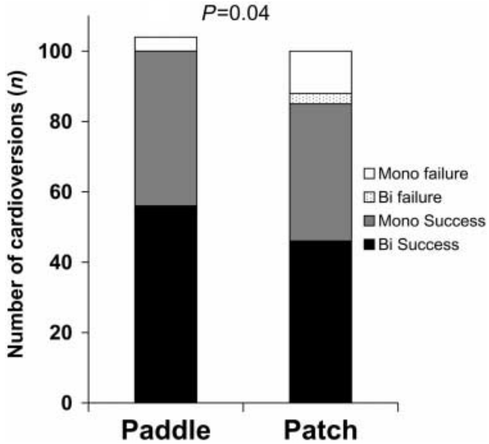

Figure 3 Cardioversion success by electrode type. The number of successful (black and dark grey boxes) and failing (dotted and white boxes) cardioversion attempts are shown split by electrode type (x-axis, paddles, or patches). Cardioversion was more effective with paddle electrodes.

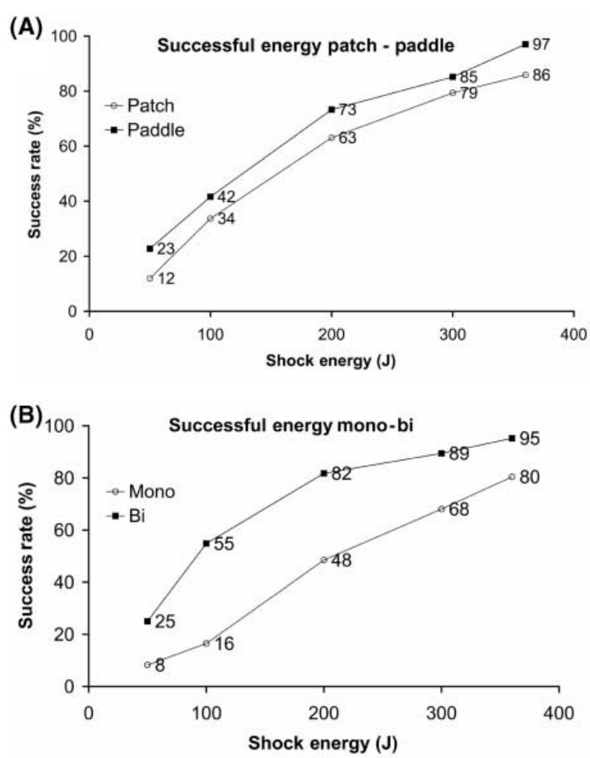

Figure 4 Line plot of cumulative cardioversion success rates (y-axis) at each of the tested shock strengths (x-axis) for paddle electrodes vs. patch electrodes (*A*) and for monophasic vs. biphasic shocks (*B*). Patients who were successfully cardioverted at a given shock strength were considered as successful cardioversions at the higher shock strengths as well. Biphasic shocks shifted the success-shock strength relation upward and towards lower shock energies, paddle electrodes resulted in an upward shift. Data are given for the 193 patients in whom the successful shock energy could be reliably determined. Numbers next to the boxes indicate per cent values for each point.

switch—an electrophysiological effect.[26] In the present trial, the use of hand-held sintered-steel electrodes improved cardioversion outcome to a similar extent as the use of a biphasic shock wave form (*Figures 2* and *3*), although hand-held paddle electrodes did not reduce successful cardioversion energy to the same extent as biphasic shocks (*Figure 4*). This effect may rather be based on the physics of the interface between the electrode and the patient's skin (i.e. a better and more homogeneous electrode-skin contact and reduced trans-thoracic shock impedance).[16,17] A combination of such anatomical, electrophysiological, and physical improvements appears to render external cardioversion virtually always successful (100% or 104/104 patients in this trial, *Figure 2*).

Economical aspects

The practice of medicine is increasingly constrained by economical considerations. Therefore, even small economical savings may give doctors leeway to improve patient care. Although we did not plan a formal cost-effectiveness analysis in this trial, we estimated the cost difference between hand-held paddle electrodes and single-use adhesive patch electrodes in our institution on the basis of the unit price for adhesive electrode pairs and the price of the conductive gel used to cover the paddle electrodes. Replacing adhesive gel electrodes with hand-held paddle electrodes requires a moderate investment (~500 € in Germany for the posterior electrode) and may even assist in reducing cardioversion-related cost because the disposable adhesive gel patches are no longer needed. The use of paddle electrodes was associated with reduced procedure cost of 20 € per cardioversion. The total reduction will be less because of the need to clean the paddle electrodes after each cardioversion, usually with wiping tissue. Changing the wave form for cardioversion from monophasic to biphasic, in contrast, does in itself not alter the procedure cost but often requires a one-time investment for a new external defibrillator. Given the reports that biphasic shock wave forms may cause less side effects, especially skin burns,[14,15] and the additive effects of biphasic shocks and paddle electrodes on the success rate of cardioversion and defibrillation, such an investment may derive clinical benefit beyond increasing cardioversion success rate.

Limitations

This trial was performed at a single tertiary care centre with a long-standing experience in cardiac electrophysiology. Local factors, such as specific techniques for position of the paddle electrodes, the amount of pressure applied onto the anterior paddle, or other unidentified factors, may have influenced the result of this trial. A medial anterior–posterior position of the shock electrodes was used in this trial (*Figure 1B*) and in our previous trial[12] and resulted in high overall success rates for cardioversion (98.5% after cross-over to biphasic electrode position). There are no systematic data on the exact position of cardioversion electrodes, and the guidelines do not specify an 'ideal' anterior–posterior electrode position in detail.[10] Some, however, recommend slightly different electrode positions (e.g. no placement onto the sternum), and the specific electrode position could have contributed to the higher efficacy of paddle electrodes. Furthermore, the type of electrodes (patches or paddles) was not randomized in this trial. Hence, although some published data—analysed across studies—indirectly indicate that paddle electrodes may improve cardioversion outcome, the effect of electrode type on cardioversion outcome needs to be confirmed in other randomized and ideally multi-centre trials.

Because of the high cardioversion success rate achieved with biphasic shocks (98.5% overall success rate after cross-over), this study did not include sufficient patients to demonstrate that the use of paddle electrodes improves cardioversion when biphasic shocks are used. Nonetheless, there was a trend towards better cardioversion success rates with paddle electrodes ($P = 0.07$). Further studies that include a larger number of patients are needed to formally test the effect of paddle electrodes on cardioversion success with biphasic shocks.

Conclusion

The use of reusable hand-held sintered-steel paddle electrodes including a back paddle electrode instead of adhesive gel-covered patch electrodes can improve cardioversion success to a similar extent as the switch from a defibrillator with a monophasic shock wave form to a device that delivers a biphasic wave form. When confirmed in other studies, these data encourage the use of hand-held sintered-steel electrodes for external cardioversion of atrial fibrillation.

Supplementary material

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

Acknowledgements

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