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Cardioversion of Atrial Fibrillation in Obese Patients: Results from the Cardioversion-BMI Randomized Controlled Trial

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This is the author manuscript accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jce.13786.

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Funding support:

Dr Voskoboinik is supported by co-funded NHMRC / NHF post-graduate scholarships & Baker IDI Bright Sparks scholarships. Prof Kalman is supported by a NHMRC practitioner fellowship. This research is supported in part by the Victorian Government's Operational Infrastructure Funding.

Disclosures: None

Abstract

Aims: Obesity is associated with higher electrical cardioversion (ECV) failure in persistent atrial fibrillation (PeAF). For ease-of-use many centers prefer patches over paddles. We assessed the optimum modality and shock vector, as well as safety and efficacy of the Manual Pressure Augmentation (MPA) technique.

Methods: Patients with obesity (BMI≥30) and PeAF undergoing ECV using a biphasic defibrillator were randomized into 1 of 4 arms by modality (adhesive patches or hand-held paddles) and shock vector (anteroposterior [AP] or anteroapical [AA]). If the first two shocks (100J, 200J) failed, then patients received a 200J shock using the alternative modality (patch or paddle). Shock vector remained unchanged. In an observational sub-study, 20 patients with BMI≥35 who failed ECV at 200J using both patches/paddles underwent a trial of MPA.

Results: In total, 125 patients were randomized between 7/2016–3/2018. First or second shock success was 43/63 (68.2%) for patches & 56/62 (90.3%) for paddles (p=0.002). There were 20 crossovers from patches to paddles (12/20 3rd shock success with paddles) and 6 crossovers from paddles to patches (3/6 3rd shock success with patches). Paddles successfully cardioverted 68/82 patients compared with 46/69 using patches (82.9% vs 66.7%; p=0.02). Shock vector did not influence 1st or 2nd shock success rates (82.0% AP vs 76.6% AA; p=0.46). MPA was successful in 16/20 (80%) who failed both patches/paddles, with 360J required in 6/7 cases.

Conclusion: Routine use of adhesive patches at 200J is inadequate in obesity. Strategies that improve success include use of paddles, MPA and escalation to 360J.

Keywords:

Atrial fibrillation; Direct current cardioversion; Obesity; Transthoracic impedance; Left atrium

Abbreviations:

AF – Atrial Fibrillation;

BMI – Body Mass Index;

ECV – Electrical Cardioversion;

AA – Anteroapical;

AP – Anteroposterior;

LA – Left atrium;

LVEF – Left Ventricular Ejection Fraction;

SD – Standard Deviation

Introduction

With burgeoning rates of both obesity and AF in Western countries, increasing numbers of patients are being referred for direct electrical cardioversion (ECV) as part of a rhythm control strategy. Success rates range from 50 – 93%[1-2] and depend on several factors including left atrial size, AF duration and transthoracic impedance (TTI). Body mass index (BMI) is a key determinant of TTI, and therefore cardioversion failure is more frequent in obese patients[3].

A recent large meta-analysis did not demonstrate a difference in cardioversion success rates for different electrode positions (anteroposterior vs anteroapical) in most patients[4]; however, this did not specifically electrode positions in obese patients. Moreover, the modality used appears to be an important factor. In a randomized trial of 201 patients, hand-held paddles successfully cardioverted 98% of patients, compared with 86% with adhesive patches ($p = 0.001$)[5]. This is likely explained by a lower TTI conveyed by hand-held paddles and hence more efficient energy delivery to the left atrium[6-7]. Again this study did not prespecify the impact of intervention in obese patients. We hypothesized that an even greater difference would be observed with paddles in obese patients.

For ease of use and workplace safet,y many centers routinely use patches for ECV with a reduction in the availability of hand-held paddles. There are no randomized trials to date looking at cardioversion in obesity. We performed a randomized controlled trial to determine the optimum modality and shock vector for ECV of obese patients (BMI ≥ 30) with persistent AF. In particular, we hypothesized that hand-held paddles would be more effective than adhesive patches. We also performed an additional observational sub-study in morbidly obese patients to test the safety and efficacy of Manual Pressure Augmentation in those with refractory ECV to 200J.

Methods

Cardioversion-BMI randomized controlled trial

We prospectively recruited 125 patients between 7/2016 – 3/2018 at four hospitals in Melbourne, Australia. Patients were included if they were undergoing a clinically-indicated external cardioversion for persistent atrial fibrillation and had a body mass index ≥ 30. Atrial flutter was an exclusion criteria.

A computerized central randomization scheme was generated using block randomization and sets of randomly selected blocks were provided to the investigating sites. Randomization occurred prior to ECV to enable appropriate patient positioning prior to administration of sedation. Thus, operators were not blinded to group allocation.

Patients were randomized in a 1:1:1:1 fashion into 1 of 4 arms based on modality (adhesive patch or hand-held paddles) and shock vector (anteroposterior [AP] or anteroapical [AA]). All shocks were biphasic and synchronized. If the first two shocks (100J, then 200J) failed, then patients crossed over to a 200J shock using the alternative modality (patch or paddle), as shown in Figure 1. Each subsequent shock was delivered at least 3 minutes after the previous failed shock and electrode location and vector remained constant for all three shocks.

For anteroapical (AA) shocks, anterior electrodes (paddle or patch) were placed just to the right of the upper sternal border below the clavicle and the apical electrodes were placed to the left of the nipple with the center of the electrode in the mid-axillary line with the patient supine. For anteroposterior (AP) shocks, the anterior electrode was placed in the right parasternal region, and the posterior electrode was placed in the left infrascapular region with the patient positioned on their side (Figure 1).

To improve efficacy and safety of all cardioversions, body hair was shaved and electrodes were applied to dry, clean skin free of abrasions. For paddle shocks, a coupling agent (defibrillation paste or gel pad) was used to cover the metal electrode surfaces. Firm paddle pressure was encouraged, and use of in-built sensors to assess paddle-to-patient contact were encouraged (if available) to maximize energy delivery. Propofol was the main agent used to provide deep sedation.

Successful cardioversion was defined as two consecutive sinus beats uninterrupted by AF occurring immediately after cardioversion. The prespecified primary endpoints for comparison between the Patch and Paddle arms were (1) rate of successful cardioversion with either 1st or 2nd shock (i.e., up to 200J biphasic) and (2) rate of successful cardioversion by modality (i.e., patch vs paddle). Secondary endpoints were comparisons between AA and AP shock vectors, average energy use (J) by modality and rates of successful cardioversion with 1st shock (100J).

Statistics

A power calculation determined that to detect a minimum absolute difference in the primary endpoint of 20% between both groups, ~58 patients needed to be enrolled in each group (i.e., paddle / patch) to provide a power of 0.8 at an alpha value of 0.05.

The primary endpoints were assessed using a 2 x 2 contingency table and χ^2 test. All continuous data are summarized as mean ± standard deviation or median, where appropriate. The Shapiro-Wilk test was performed to confirm normal distribution of data and a student t-test then performed. Mann-Whitney U test was used for continuous variables where normal distribution was not present. Comparisons of the clinical characteristics between groups were performed using a χ^2 or Fisher exact test. A logistic regression analysis was performed to determine multivariate predictors of successful external cardioversion using the primary endpoint (1^{st} or 2^{nd} shock success) as the dependent variable and BMI, age, ejection fraction, continuous AF duration and LA size as covariates. Data analysis was performed using Statistical Package for the Social Sciences for Windows (SPSS version 23, IBM). P values < 0.05 were considered statistically significant.

All patients provided informed written consent to the study protocol. The trial was approved by the Alfred, Melbourne, Cabrini and Western Health Human Research Ethics Committees and complies with the Declaration of Helsinki. The trial (Cardioversion-BMI) was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: 12616000302459).

Observational sub-study using Manual pressure augmentation

During the course of the Cardioversion-BMI randomized trial, we concurrently ran an observational sub-study to assess the safety and efficacy of Manual Pressure Augmentation (MPA) in morbidly obese patients (BMI $\geq$ 35) with PeAF who failed shocks up to 200J with both patches and paddles. Patients from the Cardioversion-BMI randomized trial who failed all three shocks with patches and paddles were allowed to be included in the study (and enrolled at the time of the initial cardioversion), as were additional patients who were not in the randomized study.

Manual pressure was delivered during the expiratory phase of respiration, with either one or two operators wearing latex gloves providing manual pressure augmentation on each patch with either one or two hands (Figure 3), while another clinician charged and delivered energy through the defibrillator. Initial energy used was mandated at 200J biphasic using this approach; however, if a 360J biphasic defibrillator was available, an additional shock at 360J using MPA was delivered. Shock vector remained unchanged throughout the study.

Results

Cardioversion-BMI Randomized Controlled Trial

In total 125 patients were randomized into either Patch (n=63) or Paddle (n=62) arms, with patients also split between AA (n=64) and AP (n=61) shock vectors. Of these, 120 (96.0%) were recruited from elective ECV lists, while 5 (4.0%) were acute inpatients. A Flow Diagram of the study and success rates by modality are shown in Figure 2. Baseline characteristics of patients in both Paddle and Patch arms are shown in Table 1. Patients were well-matched between the groups and were predominantly male, markedly obese (mean BMI 35) with dilated atria (mean LA area 28 cm^2) and prolonged duration of continuous AF (> 3 months in 55% of patients).

Primary and secondary endpoints are summarized in Table 2. Success from 1st or 2nd shock was 43/63 (68.2%) for patches & 56/62 (90.3%) for paddles (p=0.002). There were 20 crossovers from patches to paddles (12/20 third shock success with paddles) & 6 crossovers from paddles to patches (3/6 third shock success with patches). Paddles successfully cardioverted 68/82 patients compared with 46/69 using patches (82.9% vs 66.7%; p=0.02).

Success with 100J was significantly higher in the Paddle group (50%) compared with the Patch group (27%, p=0.01). Average energy requirement was significantly lower in the Paddle arm (150±50 vs 173±45 J in the Patches group; p=0.01). 1st or 2nd shock success was 27/30 (90%) for AP Paddles, 23/31 (74%) for AP Patches, 29/32 (91%) for AA Paddles, 20/32 (63%) for AA Patches. Shock vector did not influence 1st or 2nd shock success rates (82.0% AP vs 76.6% AA; p=0.46). In the subgroup of 22 patients with morbid obesity (defined as BMI > 40) included in the study (mean BMI 44.5±4.0), 6/22 (27%) were successfully cardioverted with 100J, while 17/22 (77%) were successfully cardioverted with up to 200J. After inclusion of crossovers successful cardioversion was achieved with paddles in 9/16 patients (56%) compared to 8/15 (53%) with patches (p=0.87). Shock vector did not affect final success (AA 75% vs AP 79%; p=0.86) in this subgroup.

Patients who failed all three shocks (n=11) were more likely to be heavier (weight 119±18 vs 106±19kg; p=0.03), have LV dysfunction (LVEF 44.5±11.4 vs

53.0±10.4%; p=0.02) and have a longer continuous AF duration (11.0±12.7 vs 4.8±7.2 months; p=0.04). Antiarrhythmic therapy (82% vs 62%; p=0.20), LA area (30.4±8.1 vs 27.4±7.7 cm2; p=0.27) and previous cardioversion attempts (64 vs 68%; p=0.78) were not significantly different.

A logistic regression analysis was performed to determine multivariate predictors of successful external cardioversion. Lower body mass index (OR 0.92; 95% CI 0.85-0.98; p=0.025) was a significant predictor of successful ECV. Left ventricular systolic dysfunction (p=0.23), age (p=0.22), LA size (p=0.84) and continuous AF duration (p=0.81) were not statistically significant. There were no safety issues or complications throughout the course of the study.

Manual pressure augmentation observational sub-study

In total, 20 patients underwent MPA, including 11 patients from the randomized trial who failed all three shocks (200J using both patches and paddles). Shock vector remained unchanged for all shocks, and was anteroapical in 10/20 (50%) and anteroposterior in 10/20 (50%). Most patients were male (17/20) and morbidly obese (BMI 39±6). Mean LVEF was 44±12%, LA area 30±8 cm^2 and continuous AF duration was 5.6± 4.4 months.

All patients had failed shocks with 200J with patches and paddles. MPA at 200J was successful in 10/20 (50%) of these patients and MPA at 360J was attempted in 7/10 remaining patients, with 6/7 (86%) being successful. Two operators were used to deliver MPA in 5 instances. Hence, MPA was successful in 16/20 (80%) of patients who failed both patches and paddles at 200J, despite the shock vector remaining unchanged for all shocks. No complications were reported for patient or operator(s) with this technique.

Discussion

Atrial fibrillation is an emerging epidemic, which is in part related to the increasing prevalence of obesity. Electrical cardioversion as a first line rhythm control strategy, however, is less effective in obese patients. A higher failure rate of ECV in an ever-growing obese AF population may in part be explained by the current trend of replacing hand-held paddles with disposable adhesive patches to enable easy-to-use 'hands-free' therapy.

In the first randomized study looking at optimizing ECV success in obesity there were several important findings:

(1) Current standard practice in many centers of using patches with 200J capable defibrillators leads to a failure rate of ~ 30% in obese patients with AF.

(2) Hand-held paddles significantly improve success rates over adhesive patches at the same energy.

(3) Shock vector was not an important factor in determining success rates.

(4) Use of a starting energy below 200J in obese patients is unsuccessful in the majority.

(5) Manual pressure applied over adhesive patches using gloved hand(s) is likely to improve efficacy further, and can be applied safely without risk to patient or operator up to 360J biphasic.

(6) Availability of 360J capable defibrillators may improve success rates in morbidly obese patients, although this was not systematically tested in this study.

Factors that may explain the reduction in the success of ECV for atrial fibrillation in obesity include higher transthoracic impedance, greater inter-electrode distance and decreased transthoracic current flow due to dissipation of current. In addition to greater chest circumference, obese patients have higher volumes of pericardial fat, intrathoracic fat and visceral adipose tissue that may impact ECV success[8].

Several earlier studies suggested superiority of paddles over adhesive pads in patients with a range of BMIs and included atrial fibrillation and flutter[9,10,11]. Many centers (including all four participating sites in the current study) routinely use adhesive pads only for ECV. The present study underscores the importance of maintaining the availability of hand-held paddles in overweight and obese patients.

Proposed mechanisms for superiority of paddles include paddle force resulting in lower transthoracic impedance [12], more uniform and effective electrode-skin contact[13], improved emptying of the lungs and resultant shorter distance between electrodes and atrium with higher transthoracic current flow[14]. Excessive current delivery resulting in myocardial necrosis is rare[15], and the use of 360J biphasic capable defibrillators may improve success further. Internal cardioversion is successful in obese patients who fail ECV [16] with a direct relationship between BMI and defibrillation threshold, but is invasive and more expensive than external cardioversion.

Importantly, there is significant heterogeneity between operators with respect to force delivered using paddles, and this may explain the cross-over rates observed. In a study of 54 clinicians applying paddle force to mannequins during standard defibrillation, sternal paddle forces ranged from 26.1-132.8N, while apical paddle force ranged from 18.6-118.5 N. These findings may explain the variable success in crossovers from paddles to pads, and vice versa, observed in the present study [17]. Moreover, the learning curve associated with using paddles may curtail widespread adoption. In our experience, the Manual Pressure Augmentation technique described (and safely used at our institution for >100 patients to date) is easy to learn and enables consistent application of force. The conformation of the patch to the chest wall while applying pressure (which does not occur with more rigid paddles) and ease-of-use with two operators may shorten inter-electrode distance further and enable more efficient energy transfer accounting for the high efficacy of this technique in the observational sub-study.

The successful defibrillation of AF in obese patients may be of limited durability with each 5 kg/m^2 BMI increase associated with a ~10% higher risk of AF recurrence at follow-up[18]. Achieving weight loss, and addressing associated comorbid conditions such as sleep apnea, hypertension, diabetes and excessive alcohol consumption remain critical. These measures, while difficult to achieve in many, are most likely to be effective at reducing AF recurrence rates, reversing remodelling of AF substrate and improving long-term outcomes[19].

Clinical implications

Cardioversion attempts should not be abandoned in obese AF patients if adhesive patches are unsuccessful at 200J. We propose either the routine use or availability of hand-held paddles to improve the likelihood of successful cardioversion. This may require education of health care workers to ensure cardioversion by hand-held paddles can be delivered safely. Additional strategies that may improve success include Manual Pressure Augmentation and escalation to 360J. These findings may have additional implications for resuscitation of other cardiac arrhythmias, including shock-refractory ventricular tachycardia or fibrillation, particularly in obese patients.

Limitations

There is a learning curve associated with use of hand-held paddles, and we did not assess operator experience or transthoracic impedance to determine whether this was a significant contributor to unsuccessful paddle shocks. Body fat distribution (i.e., chest circumference, abdominal adiposity) rather than BMI may be a predictor of success and was not determined. It is possible that shock efficacy using the AP vector may be different between patients positioned on their side as opposed to supine (not assessed in this study), whereby a morbidly obese patient's weight may exert considerable force on the posterior patch. The relatively small number of patients and observational nature of the non-randomized sub-study limits the ability to draw definitive conclusions regarding safety and efficacy of manual pressure augmentation and higher voltages.

Conclusion

Routine use of adhesive patches with defibrillation up to 200J is inadequate for AF in many obese patients. Hand-held paddles improve ECV success rates and should be considered for electrical cardioversion of atrial fibrillation in obesity. Manual pressure over patches and availability of 360J capable defibrillators may improve success further.

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Table 1: Baseline Characteristics for the Cardioversion-BMI Randomized Trial

Parameter	Patch arm (n=63)	Paddle arm (n=62)	p-value
Age (years)	61±11	60±10	0.76
Gender (% male)	75%	71%	0.65
Weight (kg)	109±20	106±17	0.50
Body mass index (BMI)	35±6	35±5	0.86
Hypertension (%)	41%	50%	0.51

Diabetes mellitus (%)	25%	38%	0.45
Continuous AF duration (months)	4±9	5±5	0.61
Antiarrhythmic therapy at ECV Amiodarone Sotalol Flecainide	71% 32% 21% 18%	57% 23% 23% 11%	0.48
Echocardiographic data Left atrial area (cm^2) LVEF (%) Mean E/E'	 28±8 50±12 9±6	 28±9 53±10 11±3	 0.99 0.34 0.53

Abbreviations: ECV – direct cardioversion, LVEF – Left ventricular ejection fraction.

Table 2: Comparison between Patch and Paddle arms (first three shocks)

Parameter	Patch arm (n=63)	Paddle arm (n=62)	p-value
Primary endpoint 1: Success (1st or 2nd shock)	43/63 (68.2%)	56/62 (90.3%)	**0.002**
Primary endpoint 2: Success by modality	46/69 (66.7%)	68/82 (82.9%)	**0.02**
Average energy use (Joules)	173±45	150±50	**0.01**
1st shock (100J) success	17/63 (27%)	31/62 (50%)	**0.01**

Figures

Figure 1: Cardioversion-BMI Trial Protocol, including electrode position by shock vector

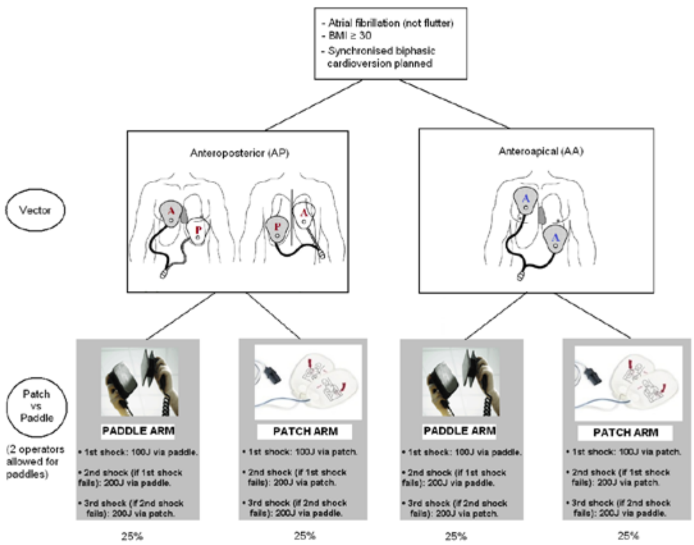

Figure 2: Study Flow Diagram and Success Rates by Modality in the Cardioversion-BMI Randomized Trial. *Figure Legend* – DCR: direct cardioversion, TEE: transesophageal echocardiogram, AA: anteroapical, AP: anteroposterior, SR: sinus rhythm, LA: left atrial.

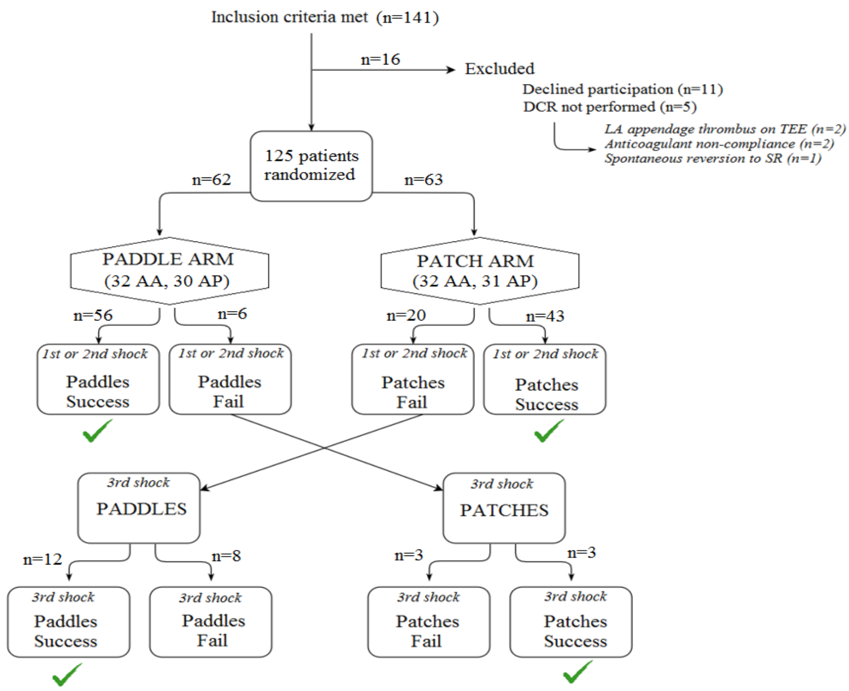

Figure 3: Example of Manual Pressure Augmentation using two operators in the anteroposterior position

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