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Cardioversion of atrial fibrillation in obese patients: Results from the Cardioversion-BMI randomized controlled trial

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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 the 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 one of four arms by modality (adhesive patches or handheld paddles) and shock vector (anteroposterior [AP] or anteroapical [AA]). If the first two shocks (100 and 200 J) failed, then patients received a 200-J shock using the alternative modality (patch or paddle). Shock vector remained unchanged. In an observational substudy, 20 patients with BMI of 35 or more, and who failed ECV at 200 J using both patches/paddles underwent a trial of MPA.

Results: In total, 125 patients were randomized between July 2016 and March 2018. First or second shock success was 43 of 63 (68.2%) for patches and 56 of 62 (90.3%) for paddles ($P = 0.002$). There were 20 crossovers from patches to paddles (12 of 20 third shock success with paddles) and six crossovers from paddles to patches (three of six third shock success with patches). Paddles successfully cardioverted 68 of 82 patients compared with 46 of 69 using patches (82.9% vs 66.7%; $P = 0.02$). Shock vector did not influence first or second shock success rates (82.0% AP vs 76.6% AA; $P = 0.46$). MPA was successful in 16 of 20 (80%) who failed in both (patches/paddles), with 360 J required in six of seven cases.

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

KEYWORDS
atrial fibrillation, direct current cardioversion, left atrium, obesity, transthoracic impedance

1 | INTRODUCTION

With burgeoning rates of both obesity and atrial fibrillation (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 to 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 [AP] vs anteroapical [AA]) in most patients.[4] However, this did not specifically examine electrode positions in obese patients. Moreover, the modality used appears to be an important factor. In a randomized trial of 201 patients, handheld 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 handheld paddles and, hence, more efficient energy delivery to the left atrium.[6,7] Again, this study did not prespecify the impact of the 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 safety, many centers routinely use patches for ECV with a reduction in the availability of handheld 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 handheld paddles would be more effective than adhesive patches. We also performed an additional observational substudy in morbidly obese patients to test the safety and efficacy of Manual Pressure Augmentation (MPA) in those with refractory ECV to 200 J.

2 | MATERIALS AND METHODS

2.1 | Cardioversion-BMI randomized controlled trial

We prospectively recruited 125 patients between July 2016 and March 2018 at four hospitals in Melbourne, Australia. Patients were included if they were undergoing a clinically indicated external cardioversion for persistent atrial fibrillation (PeAF) and had a BMI of 30 or more. Atrial flutter was an exclusion criterion.

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

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

For 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 midaxillary line with the patient supine. For 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 the 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 the use of inbuilt sensors to assess paddle-to-patient contact was also 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 first or second shock (ie, up to 200 J biphasic) and (2) rate of successful cardioversion by modality (ie, 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 first shock (100 J).

2.2 | Statistics analysis

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 (ie, paddle/patch) to provide a power of 0.8 at an α value of 0.05.

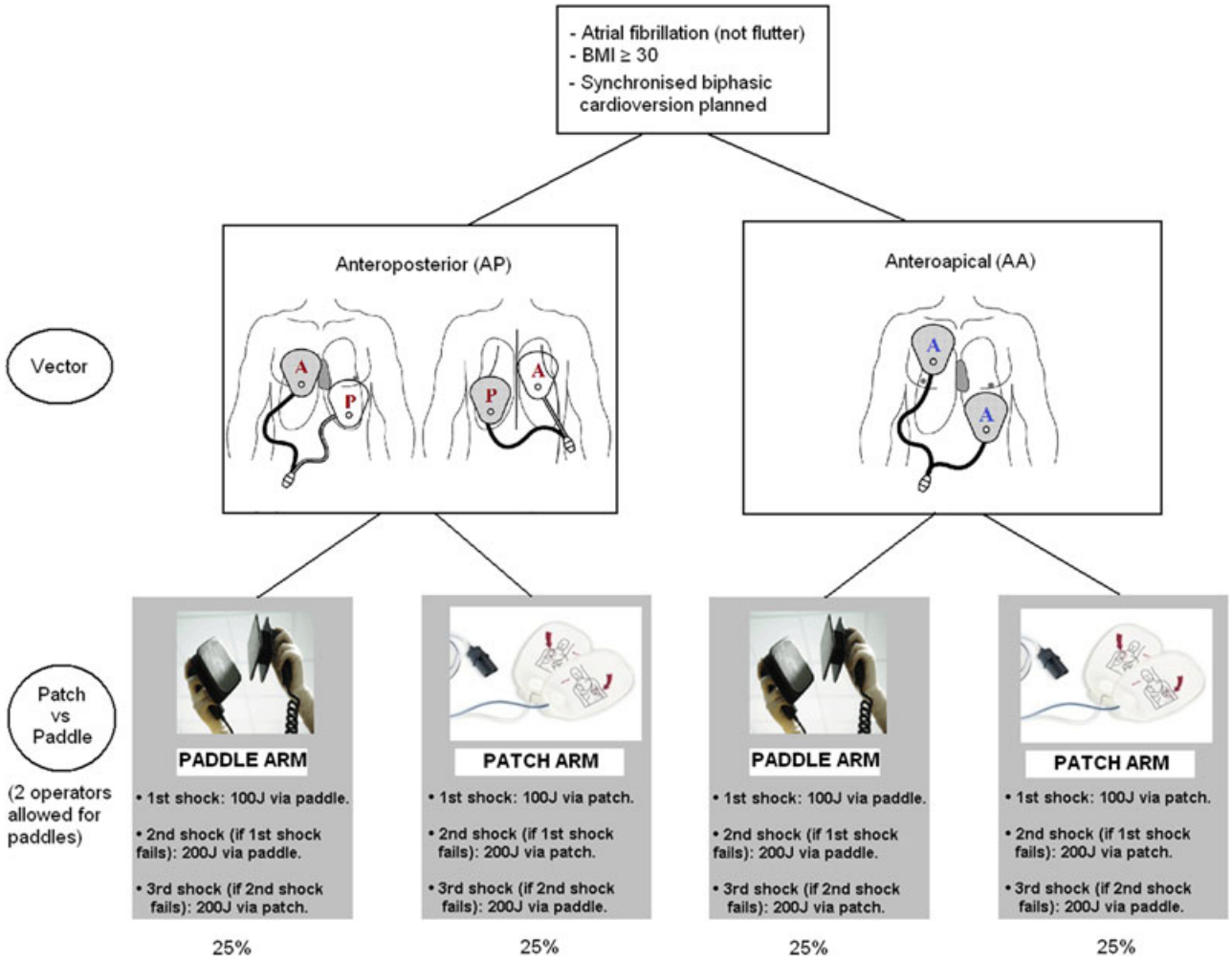

FIGURE 1 Cardioversion-BMI trial protocol including electrode position by shock vector. BMI, body mass index

The primary endpoints were assessed using a 2 × 2 contingency table and χ^2 test. All continuous data are summarized as mean ± SD or median, where appropriate. The Shapiro-Wilk test was performed to confirm normal distribution of data and the Student *t* test then performed. The Mann-Whitney *U* test was used for continuous variables where normal distribution was not present. Comparisons of the clinical characteristics between the 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 (first or second 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, Armonk, NY). $P < 0.05$ 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 complied with the Declaration of Helsinki. The trial (Cardioversion-BMI) was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: 12616000302459).

2.3 | Observational substudy using MPA

During the course of the Cardioversion-BMI randomized trial, we concurrently ran an observational substudy to assess the safety and efficacy of MPA in morbidly obese patients (BMI ≥ 35) with PeAF who failed shocks up to 200 J with both patches and paddles. Patients from the Cardioversion-BMI randomized trial who failed all the 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 MPA 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 200-J biphasic using this approach. However, if a 360-J biphasic defibrillator was available, an additional shock at 360-J using MPA was delivered. Shock vector remained unchanged throughout the study.

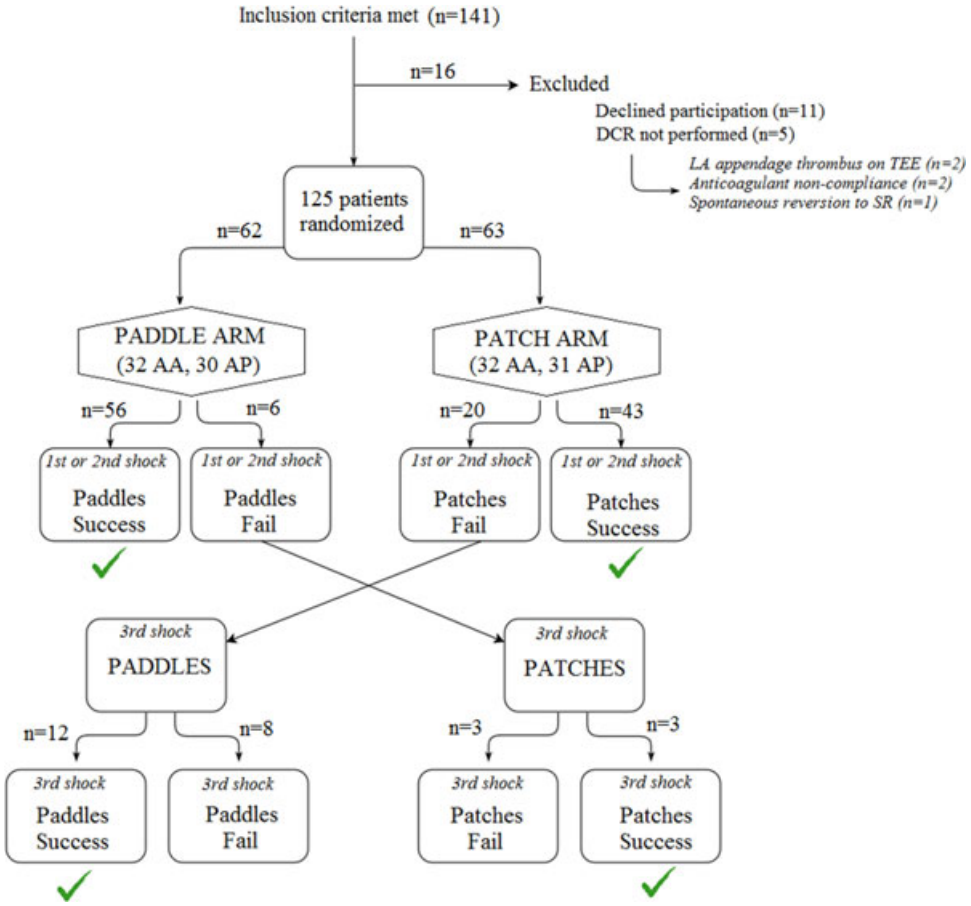

FIGURE 2 Study flow diagram and success rates by modality in the Cardioversion-BMI randomized trial. AA, anteroapical; AP, anteroposterior; BMI, body mass index; DCR, direct cardioversion; LA, left atrial; SR, sinus rhythm; TEE: transesophageal echocardiogram

3 | RESULTS

3.1 | 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 five (4.0%) were acute in patients. 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 first or second shock was 43 of 63 (68.2%) for patches and 56 of 62 (90.3%) for paddles ($P = 0.002$). There were 20 crossovers from patches to paddles (12 of 20 third shock success with paddles) and six crossovers from paddles to patches (three of six third shock success with patches). Paddles successfully cardioverted 68 of 82 patients compared with 46 of 69 using patches (82.9% vs 66.7%; $P = 0.02$).

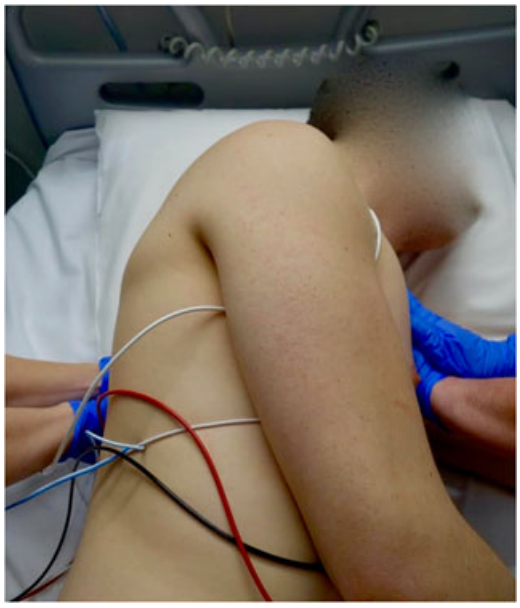

FIGURE 3 Example of MPA using two operators in the anteroposterior position

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
Sex, 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, mo	4 ± 9	5 ± 5	0.61
Antiarrhythmic therapy at, ECV	71	57	0.48
Amiodarone, %	32	23	...
Sotalol, %	21	23	...
Flecainide, %	18	11	...
Echocardiographic data	...	...	...
Left atrial area (cm^2)	28 ± 8	28 ± 9	0.99
LVEF, %	50 ± 12	53 ± 10	0.34
Mean E/E'	9 ± 6	11 ± 3	0.53

Abbreviations: ECV, electrical 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, J	173 ± 45	150 ± 50	0.01
First shock (100 J) success	17/63 (27%)	31/62 (50%)	0.01

Success with 100 J 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; $P = 0.01$), first or second shock success was 27 of 30 (90%) for AP paddles, 23 of 31 (74%) for AP patches, 29 of 32 (91%) for AA paddles, and 20 of 32 (63%) for AA patches. Shock vector did not influence first or second 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 of 22 (27%) were successfully cardioverted with 100 J, while 17 of 22 (77%) were successfully cardioverted with up to 200 J. After inclusion of crossovers, successful cardioversion was achieved with paddles in 9 of 16 patients (56%) compared to 8 of 15 (53%) with patches ($P = 0.87$). Shock vector did not affect the 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 ± 19 kg; $P = 0.03$), 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 cm^2; $P = 0.27$), 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 BMI (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.

3.2 | MPA observational substudy

In total, 20 patients underwent MPA, including 11 patients from the randomized trial who failed all the three shocks (200 J using both patches and paddles). Shock vector remained unchanged for all shocks and was AA in 10 of 20 (50%) and AP in 10 of 20 (50%). Most patients were male (17 of 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 200 J with patches and paddles. MPA at 200 J was successful in 10 of 20 (50%) of these patients and MPA at 360 J was attempted in 7 of 10 remaining patients, with six of seven (86%) being successful. Two operators were used to deliver MPA in five instances. Hence, MPA was successful in 16 of 20 (80%) of patients who failed both patches and paddles at 200 J, despite the shock vector remaining unchanged for all shocks. No complications were reported for patient or operator(s) with this technique.

4 | DISCUSSION

Atrial fibrillation is an emerging epidemic, which is in part related to the increasing prevalence of obesity. ECV 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 handheld 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 200 J capable defibrillators leads to a failure rate of ~30% in obese patients with AF.

(2) Handheld 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 200 J in obese patients is unsuccessful in the majority.
(5) Manual pressure applied over adhesive patches using a gloved hand(s) is likely to improve efficacy further and can be applied safely without risk to patient or operator up to 360-J biphasic.
(6) Availability of 360 J 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 TTI, greater interelectrode distance, and decreased transthoracic current flow due to the 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 the superiority of paddles over adhesive pads in patients with a range of BMIs and included atrial fibrillation and flutter.[9–11] 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 handheld paddles in overweight and obese patients.

Proposed mechanisms for the superiority of paddles include paddle force resulting in lower TTI,[12] more uniform and effective electrode-skin contact,[13] improved emptying of the lungs, and the resultant shorter distance between electrodes and atrium with a higher transthoracic current flow.[14] Excessive current delivery resulting in myocardial necrosis is rare,[15] and the use of 360 J 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.

More important, there is significant heterogeneity between operators with respect to force delivered using paddles, and this may explain the crossover rates observed. In a study of 54 clinicians applying paddle force to mannequins during standard defibrillation, sternal paddle forces ranged from 26.1 to 132.8 N, while apical paddle force ranged from 18.6 to 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 MPA 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 interelectrode distance further and enable more efficient energy transfer accounting for the high efficacy of this technique in the observational substudy.

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 remodeling of AF substrate, and improving long-term outcomes.[19]

4.1 | Clinical implications

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

4.2 | Limitations

There is a learning curve associated with the use of handheld paddles, and we did not assess operator experience or TTI to determine whether this was a significant contributor to unsuccessful paddle shocks. Body fat distribution (ie, 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 the observational nature of the nonrandomized substudy limits the ability to draw definitive conclusions regarding the safety and efficacy of MPA and higher voltages.

5 | CONCLUSION

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

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