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External Defibrillation/Cardioversion Protocol in Patients with an Implanted Cardioverter Defibrillator or Pacemaker: Systematic Review and Meta-analysis

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ABSTRACT

Introduction: The use of cardiac implantable electronic devices (CIED) is increasing, and implanted patients require more often interventional procedures such as external defibrillation (ED) and electrical cardioversion (ECV). The creation of periprocedural care algorithms for patients with CIED is complex: the different programming capabilities of currently manufactured devices, confusion regarding the differences between pacemakers (PM) and implanted cardiac defibrillator (ICD), the use of old devices in some patients and lastly the continuous evolution in CIED technology with the introduction of leadless PM and subcutaneous implanted cardioverter defibrillators (S-ICD). Procedural advisories have been developed by professional societies, but the recommendations of these societies differ regarding to ED and ECV use. **Methods:** We performed a systematic database search of studies published between January 2000 and October 2021 assessing ED and ECV by the selection process (PRISMA) and identified 5 prospective eligible articles. Two meta-analyses assessed the proportion of patients whith complications and the proportion of patients with no clinicallly relevant parameter modifications, respectively.**Results:** The final population for the meta-analysis included 2077 patients. The meta-analysis showed a weighted random pooled effect size of 0.55% (95% CI = 0.04% − 1.06 %) for complications, and of 22.4% (95% CI = 2.03% – 42.7%) for no clinically relevant modification parameters. **Conclusions:** Our review indicates that few dysfunctions are detectable in patients with chest implanted CIED treated with ECV or ED. When an impanted patient undergoes ECV or ED procedures, caution is needed including CIED interrogation before and after the procedure.

Keywords: external defibrillation, electrical cardioversion, pacemaker, implanted cardioverter defibrillator, cardiac implanted electrical devices, emergency electrophysiology procedures

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Introduction

Atrial tachyarrhythmia (AT) is a common comorbidity in patients with pacemaker (PM) or implanted cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT). More than 50% of patients with a dual chamber PM had AT in the published in RATE (Registry of Atrial Tachyarrhythmia/Atrial Fibrillation) registry [1-5]. Furthermore, in a meta-analysis of primary and secondary prevention ICD trials, the prevalence of AT was up to 25% [6,7]. Numerous case reports on direct external cardioversion (ECV) associated complications in PM patients exist, with many of them occurring in older devices and unipolar leads after monophasic shocks with an antero-lateral shock orientation [8-10]. Only few prospective reports with a small number of patients have been published, revealing no relevant adverse events in patients with contemporary leads and devices after ECV [11-15]. In this study we performed a systematic review and meta-analysis on the occurrence of complications of ECV and external defibrillation (ED) in patients with cardiac implanted electrical devices (CIED) implanted from 2000 to 2021. A further purpose was to evaluate the guidance of patients with CIED during the pre-procedural, intra-procedural, and immediate post-procedural periods.

Cardiac Implanted Electrical Devices and External defibrillators

PM is a well-established therapeutic tool primarily implanted in patients older than 60 years, but also used in children, including infants. Depending upon the pacing modality, a lead is placed with the electrode at its tip positioned against the endocardium of the right atrium for atrial sensing and stimulation and/or near the apex of the right ventricle for stimulation. Alternatively, the electrodes may be attached to the epicardial surface via the subxyfoid route. The energy required to stimulate the heart in PM is on the order of 1 to 10 μJ over a time frame of 1 msec or less [16]. CRT with a PM (CRT-P), used for cardiac resynchronization therapy, has three leads that connect the PM to the right upper chamber of right atria and both ventricles.

ICD are available, using the same technology and implantation techniques used for PM. ICD deliver up to 40 Joule (J) of energy to the heart within 10 seconds after ventricular fibrillation or ventricular tachycardia is detected. The ICD is placed subcutaneously or submuscolar on the chest in the left or right deltopectoral region of the superior thorax, and the lead is tunneled through subcutaneous tissue to the subclavian vein, passing along its lumen to the heart. CRT with an ICD (CRT-D) may be recommended for people with heart failure who also have a risk of sudden cardiac death.

What has been the tradition in ED is being replaced with a biphasic waveform. As a result, the standards for ED are changing, with a lower maximum output required to achieve defibrillation. The electrode system is usually bipolar with two equal electrodes of surface about 50 cm^2 in adults. They are positioned so that as much as possible of the current is passing through the heart region. With a more unipolar system with one electrode under the shoulder, the current path is more optimal, and this is used if the defibrillation is planned. Maximum stored energy is usually 360 J in monophasic devices. External shock is given transcutaneously, so the voltage must be high enough to break down the skin even at the lowest dose. To reduce energy, new waveforms have been taken into use: the exponential truncated waveform. It may be monophasic or biphasic. The apllication of the biphasic waveform is that the second pulse shall cancel the net charge caused by the first pulse and thereby reduce the chance of refibrillation [17-20]. Tissue impedance measurements with the defibrillator electrodes are used both in some external and internal defibrillator models. Measuring current and voltage during a shock gives a high current level, minimum value, nonlinear region, peak voltage to peak current ratio. Between shocks, the small signal, linear impedance is also monitored. The measured impedance value is used to customize both waveform and energy level for each shock given. If the patient has a CIED implanted, it will be just below the skin,

usually in the upper left chest. It will be a small bump about two inches long, and you may even see a scar over the area. A CIED keeps the heart beating at the proper rate and from beating too slow. It helps control abnormal heart rhythms, and it will only activate if it is needed. It sends electrical pulses, or shocks, to the heart when it senses any abnormalities in heartbeat, and helps those who have an irregular heartbeat, or are at risk for sudden cardiac arrest. It is always a possibility for both devices to malfunction and fail to deliver the lifesaving intervention a victim needs [21-29]. Although CIED are designed to withstand ED or ECV, the CIED can sustain damage if the electrode pads are placed too close to or directly over the device. In such cases, placing the pad a few inches below where would normally place it is still acceptable.

Methods

Search strategy

A systematic search was limited between January 1, 2000 to October 31, 2021 in the following database: PubMed, Embase.com (Elsevier), the Cochrane Library (Wiley), CRD (centre for Reviews and Dissemination): DARE (Database of Abstracts of Reviews of Effects, HTA (Health Technology Assessment Database). It was performed to identify articles with ED and ECV rates by 3 investigators. The article type was limited to "clinical trial". The following Boolean search terms were utilized: "external defibrillation", "shock", "electrical cardioversion", "cardiac implanted electrical devices" and "emergency electrophysiology procedures". By hand-search records identified through database searching resulting in 148 citations overall.

Studies selection and data extraction

Overall, 110 citations were identified after the removal of duplicates. The references were screened by two independent researchers (AS and FM) and, in case of disagreement, a third researcher (MS) was involved to resolve the differences. The selection process (PRISMA Flow Diagram) is displayed in **Figure 1**.

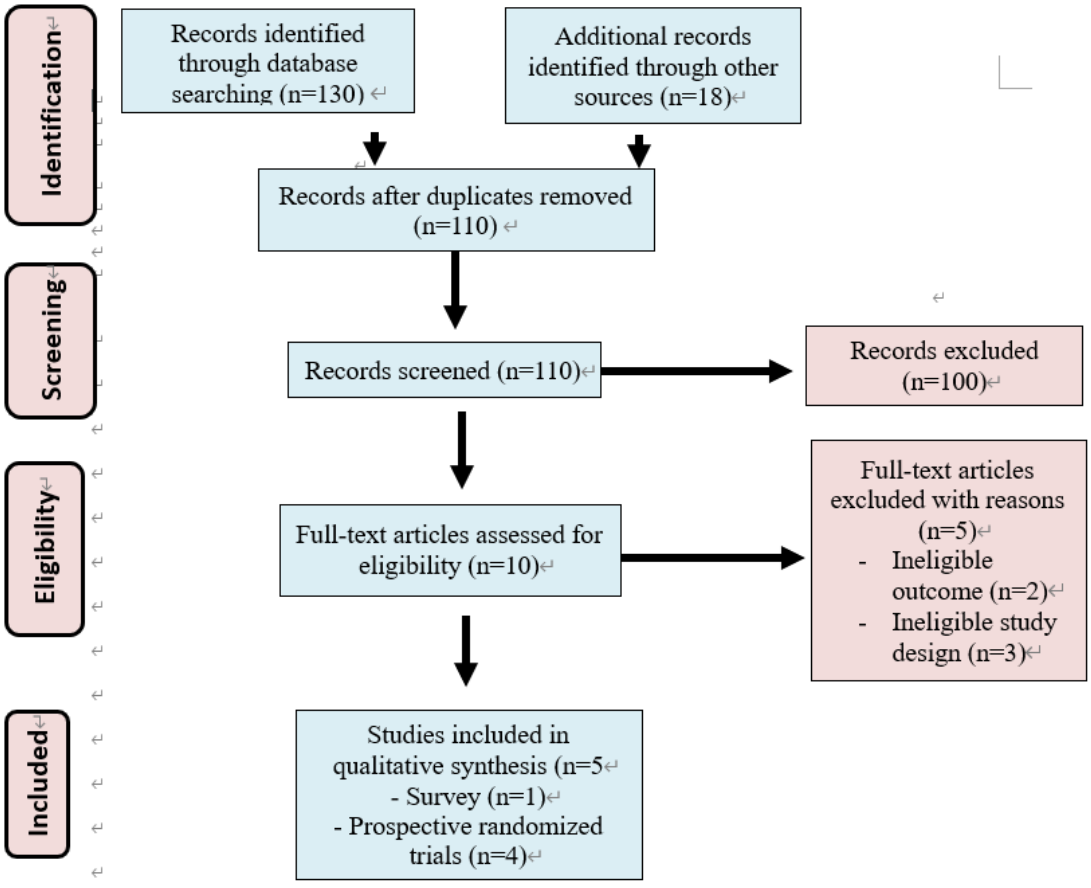


Figure 1:. PRISMA Flow Diagram

Search criteria and methodology were approved by all authors. Titles and abstracts retrieved in the search were reviewed, and observational and comparative studies reporting ED and ECV in CIED patients were selected. For complications analysis case reports, review articles, abstracts, meta-analysis and editorials were excluded. If there were multiple publications from the same study, the latest study with the most complete data available was selected, and the other publications were not used in order to avoid overlapping cohorts. For included studies, only data on ED/ECV in CIED patients were extracted. Extracted data included: namely, ED or ECV, CIED model, patients' mean age, first shock energy delivered, monophasic and biphasic waverform, pads orientation, major complications, no clinical electrical modification parameters. Data were extracted by one author and were reviewed by additional authors.

Table 1: Results of selected studies that investigate the External Cardioversion in CIED patients in chronological order.

Author	# patients	Biphasic Shock	First Shock energy	Antero-Posterior orientation	Complications	No clinically electrical modifications
Botkin et al. 2003 [11]	80 (50 PM, 30 ICD)	none	Not provided	100%	4/80 transient LOPC	none
Manegold et al 2007 [12]	44 (29 PM, 12 ICD, 3 CRT)	52.2%	Monophasic Shock (escalating from 200 J) vs biphasic Shock (escalating from 100 J)	100%	0	acing impedances were reduced trial 402–392 V, P < 0.001; entricular 517–496 V, P < 0.001). entricular sensing was reduced 2.4–11.6 mV, P < 0.004). Patients ith high-impedance leads 3/44(6.8%) emonstrated no significant change of acing impedance
Luker et al 2015 [13]	43 (38 CRT-D, 5 CRT-P)	100%	biphasic Shock (escalating from 100 J)	87%	0	43 (11.6%) crease of pacing threshold, LV lead threshold voltage and drop bipolar LV lead Impedance, 2 RV ad threshold voltage)
Luker et al 2018 [14]	1809 (41 ± 15% ICD, 40 ± 14% PM and 19 ± 10% CRT	96%	biphasic Shock (escalating from 100 J)	71%	11/1809 (0.6%). In 9 a temporary elevation of the pacing threshold, and in 2 a transient exit block	0
Luker et al 2019 [15]	101 (55 ICD, 46 CRT-D)	100%	biphasic Shock (escalating from 100 J)	100%	0	0

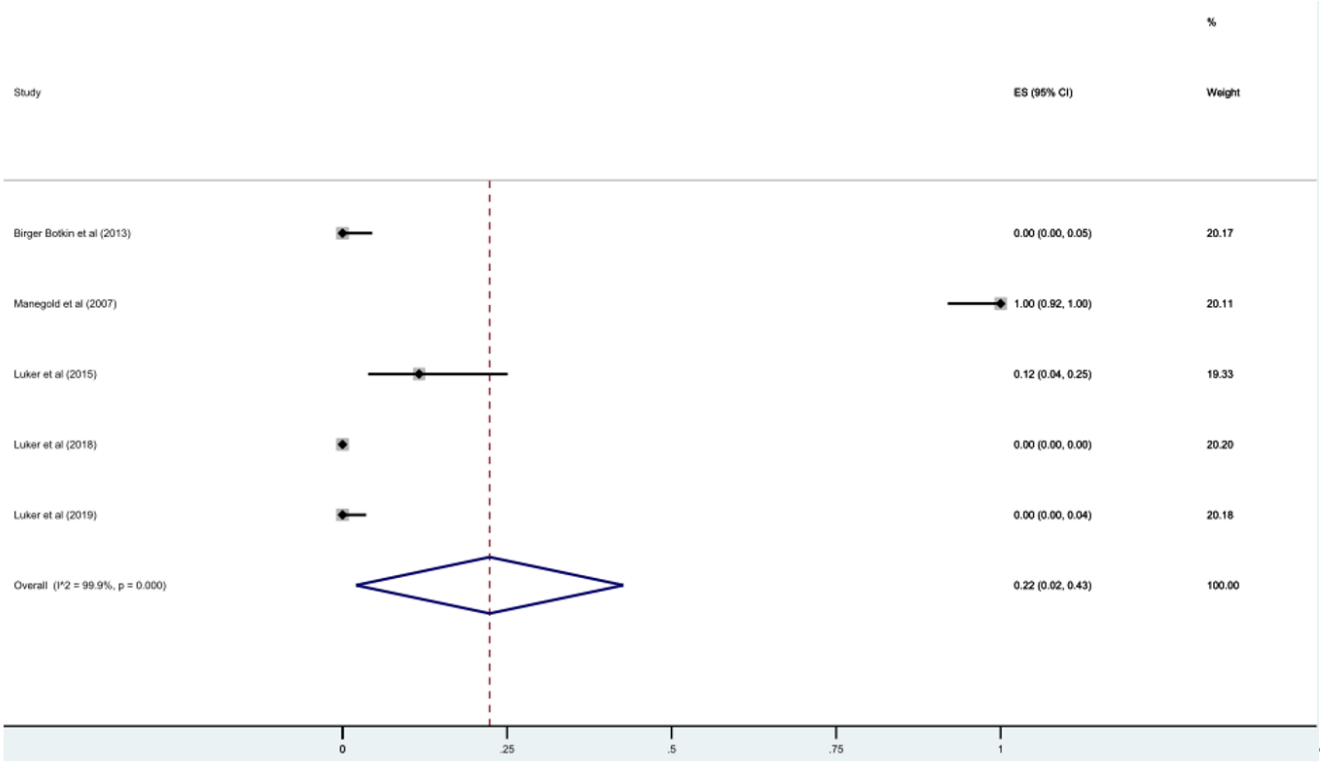


Figure 2: Meta-analysis of the proportion of patients with complications in the selected studies.

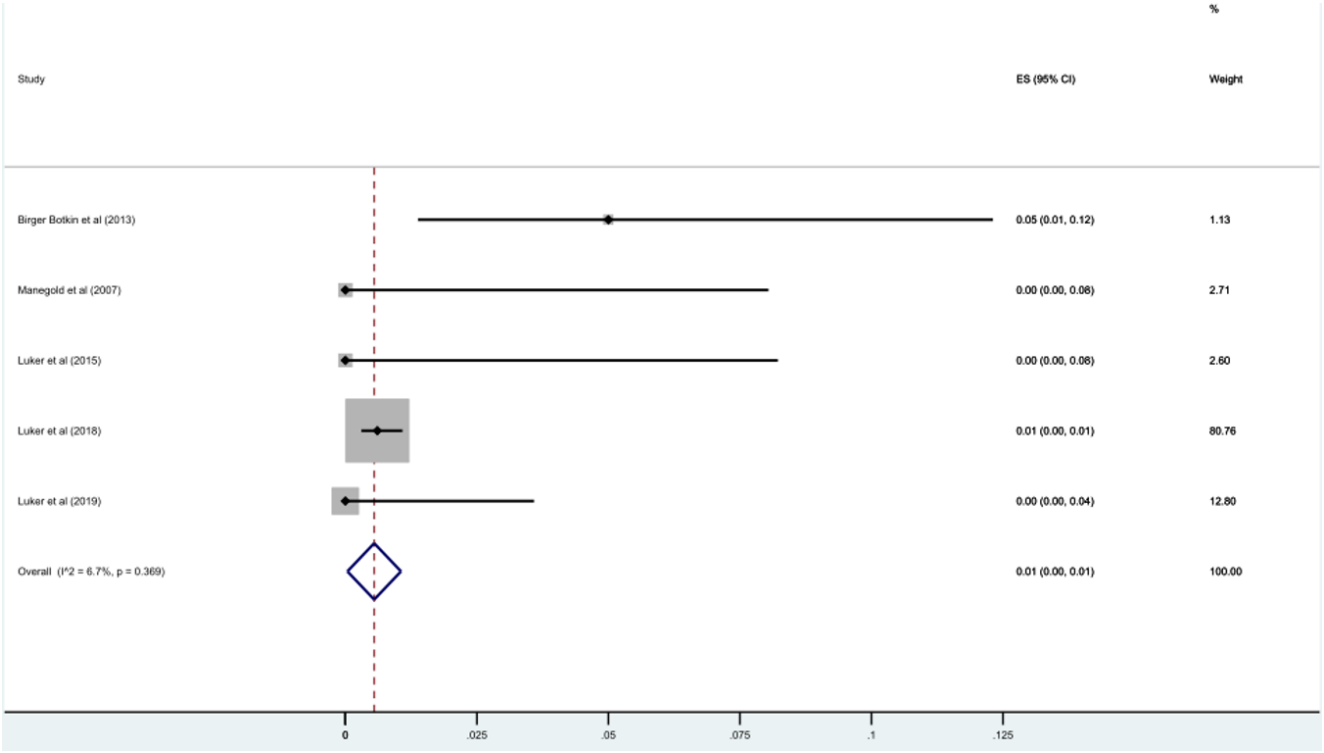


Figure 3: Meta-analysis of the proportion of patients with no clinically relevant modification parameters in the selected studies.

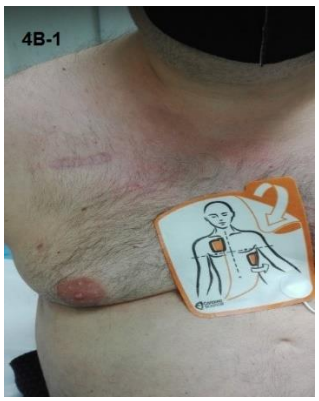
Statistical analysis

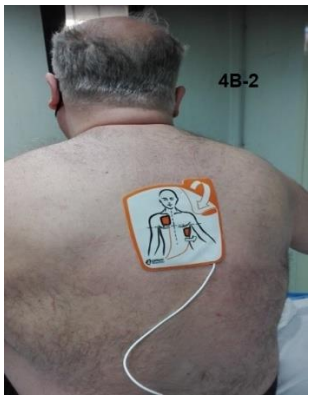
Continuous variables, complications and no clinically relevant modification parameters, were expressed as mean ± standard deviation and categorical data as percentages. Two meta-analyses were performed to assess the proportion of patients whith complications and the proportion of patients with no clinicallly relevant parameter modifications, respectively. The user-written Stata metaprop_one package was used to pool proportions and to present weighted sub-group and overall estimates with inverse variance weights. For this purpose, the random-effects model was applied, and the result displayed as forest plot. Study specific 95% confidence intervals (CI) were calculated using the Clopper-Pearson exact method. Between study heterogeneity was evaluated with Cochran's Q and I square statistics. Statistical analysis was performed using the Stata software 16.0 (StataCorp 4905 Lakeway Drive College Station, Texas 77845 USA).

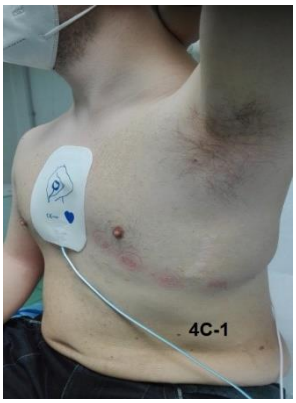
Results

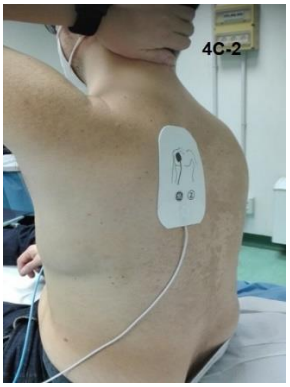
After excluding 100 articles for not meeting inclusion/exclusion criteria, 10 articles remained to be assessed for eligibility. Following assessment of the full-text articles, 5 were excluded for reasons such as: rates of CIED complications were given. This left us with 4 prospective studies and 1 survey to be included in the analysis [11-15] **(Table 1)**. The final population for the meta-analysis included 2077 patients. Years of enrolment for the studies ranged from 2000 to 2021. The first monophasic escalating shock energy was from 200 J vs bifasic shock escalating from 100 J. The antero-posterior orientation was 91%. The bifasic shock was preferrend in 69.6% of patients. In the 2077 patients included in the meta-analysis, only 15 complications occurred i.e., 4 transient loss of pacing capture, 9 elevations pacing threschold, 2 exit blocks. The number of no clinically relevant modification parameters was 49 all pacing impedence and ventricular sensing reduction. The meta-analyses showed a weighted random pooled effect size of 0.55% (95

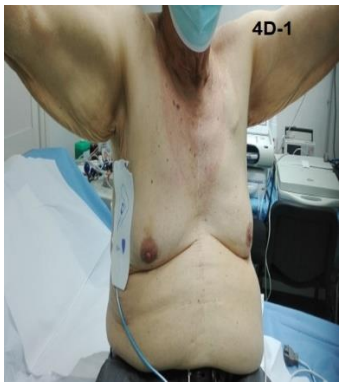
% CI 0.04% − 1.06 %) for complications **(Figure 2),** and of 22.4% (95% CI 2.03% – 42.7%) for no clinically relevant modification parameters **(Figure 3).**











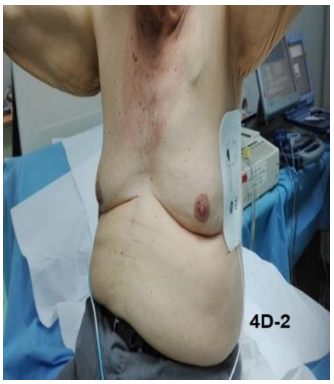


Figure 4A: Correct paddles position in a right pocket subclavian PM (anterior-lateral) with distance >8 cm; **Figure 4B1,4B2:** Correct paddles position in a left pocket subclavian ICD (anterior-posterior); **Figure 4C1,4C2**: Correct paddles position in a left subaxillary pocket S-ICD (anterior-posterior); **Figure 4D1,4D2:** Correct paddles position in a subclavian pocket PM lateral (biaxillary) position

Discussion

Procedural advisories for ECV or ED in patients with CIED have been developed by professional societies: The American Heart Association (AHA), the American Society of Anesthesiologists (ASA), the Heart Rhythm Society (HRS), the German Cardiac Society [30-34]. The recommendations of these Society was heterogeneous and differ in regards to ECV or ED use in CIED patients. Paddle placement on the chest wall has two conventional positions: antero-lateral and antero-posterior (**Figure 4A, 4B1, 4B2)**. In the antero-lateral position, a single paddle is placed on the left fourth or fifth intercostal space on the midaxillary line. The second paddle is placed jiust to the right of the sternal edge on the second or third intercostal space. In the antero-posterior position, a single paddle is placed to the right of the sternum and the other paddle is placed between the tip of the left scapula and the spine. Most consultants, ASA members, and HRS members agree that positioning the ECV adesive pads as far as possible from the CIED should be done and agree that the anterior-posterior position should be used and that a clinically appropriate energy output should be used regardless of the type of the CIED and,in particular, the ASA recommends to avoid placing a pad directly over the device, if at all possible [32,33]. When a device is located in an area where a pad would normally be placed, the AHA recommends positioning the ECV pads in the antero-apex position at least 2.5 cm away from the device [31]. In contrast, the consultants and ASA members agree with the recommendation that if ECV or ED is required, attempt to keep the CIED at least 10 cm away and out of the shock wave [34]. Our meta-analysis of literature [11-15], suggest that the general precautions for ECV and ED in patients with CIED attempt to minimize the current delivered to the CIED system by using the minimal effective energy setting and placing the defibrillator paddles at least 10 cm away from the

CIED, ensuring that the paddles are placed perpendicular to the dipole of the pacing system. When placing the adhesive pads on the patients chest, the goal is to “sandwich” the heart (**Figure 4B1,4B2**) [34]. No specific recommendation is present for patients with a CIED in suxifoideal abdominal pocket and epicardial electrodes. In such cases, we suggest to apply the patches in posterior-apical position with a distance from the device of at least 10 cm. (**Figure 4C1,4C2**) or lateral (biaxillary) position (**Figure 4D1,4D2**). Unlike AF, the feasibility of ED with an anterior-posterior paddle position for ventricular fibrillation/ventricular tachycardia remains unknown. The AHA guidelines [30,31] for cardio-pulmonary resuscitation do not mention the anterior-posterior paddle position but recommend lateral (biaxillary) position and posterior-apical position in addition to conventional anterior-lateral position. Although the lateral (biaxillary) position and the posterior-apical position seem to be somewhat safer for the CIED than the anterior-lateral position, these positions have not been widely applied, and the posterior-apical position is apparently not practical without the use of an adhesive pad, since interruptions in chest compressions should be minimized [35-39]. However, do not withhold therapy for fear of damaging the CIED. Case reports suggest that optimal positioning of the ECV pads or paddles may be an important factor in the prevention of adverse CIED-related outcomes [40]. The study of Manegold et al [12] suggests that ECV in patients with dual-chamber PM is safe and that biphasic schock and antero-posterior electrode placement is preferable. Previous case reports on standard PM revealed that ECV may temporarily or permanently alter device parameters [9] or cause battery discharge [10]. Recent case reports [41-43] showed cases of defibrillation threshold testing and defibrillation of ventricular tachycardia in combinations of a Transcatheter Pacing System leadless (TPS) MICRA VR (Medtronic) and a subcutaneous internal cardioverter-defibrillator (S-ICD) EMBLEM (Boston) without observed adverse events. Moreover, in the case report of Filipovic et al [44] ECV in patient with a preexisting TPS no complications and no significant changes in device parameters in comparison to the preacquired values were observed. In the survey of Lüker et al. [14], based of German Cardiac Society guidelines [34], the reported incidence of shock associated complications during ECV was only 0.6%, despite the fact that 38% of centers perform ECV with an antero-lateral shock orientation and 28% of centers chose a first shock energy of 200 J. If the implanted PM delivers a synchronized low-energy shock in the attempt to use an ECV, it will simply be necessary to wait for 30 to 60 seconds for the PM to complete the shock. For the patient with an ICD or CRT-D and antiarrhythmic therapies that have been disabled by programming, consider reenabling therapies through programming. If the above activities fail to restore ICD function, proceed with emergency ED. After any episode of ECV, proper function of the CIED should be verified [45]. For ICD or CRT-D interrogate the device, perform a manual capacitor reformation, verify battery status, shock counters and pacing, and ensure that the programmable parameters did not change. If ECV is applied, a warning message may be displayed upon interrogation. On the contrary, for PM the ECV could cause a temporary battery voltage reduction, which would cause the device to enter a reset condition. Should this occur, the programmer would display a warning message upon interrogation. Infact, myocardial stimulation threshold is markedly increased during ECV or ED therapy and even though most sensing and pacing problems are transient, a thorough evaluation of the pacing system, including interrogation and programming functions, should be made after the resuscitation procedure [45]. The ICD can cause capacitive coupling with the endocardial lead, causing direct discharge at the electrode-endocardium interface, thus leading to transient/permanent failure to sense and capture even in the absence of apparent damage to the pulse generator itself. Damaged circuitry, changes in programmed mode of function, complete PM failure and microdislodgement of the lead can also occur [31]. Modern CIED are equipped with

protection mechanisms against damage from shock, most common of which is the Zener diode, which directs a surge in current toward the electrode, protecting the CIED circuitry but delivering this energy to the endocardium. Regarding energy requirements for termination of atrial fibrillation (AF), the German protocol [34] suggest lower energy levels (100 J biphasic, 150 J monophasic) together with a sufficient distance to the implanted device (>8 cm) may further protect CIED. The AHA issued in 2010 the guidelines for initial energy requirement for monophasic and biphasic waveforms: AF energy requirements are 200 J for monophasic and 120-200 J for biphasic devices, atrial flutter energy requirements are: 100 J for monophasic and 50-100 J for biphasic devices [36]. For ECV resistant cases, two simultaneous shocks have also been used off-label. In the experience of Alaeddini et al [46] under anesthesia, QRS synchronous shocks were delivered across antero-posterior electrodes in the following sequence: a single 360 J shock; another single 360 J shock within 2 minutes; 30 minutes of rest, reinduction of anesthesia and delivery of two simultaneous monophasic 360 J shocks. The recommendations also apply to emergency situations in hospital settings, of ventricular tachyarrhythmia in patients with implanted CIED. Thus, it is important to convey the information to the medical staff in emergency facilities that ECV is safe in patients with devices if the precautions outlined above are considered. Recent literature [47,48] proposes the double sequential external defibrillation and vector change defibrillation as viable options for patients in refractory VF. However, the evidence supporting the use of novel defibrillation strategies is inconclusive. Effects of this new method on CIED have not been yet investigated. Finally, no widely accepted guidelines by international medical societies for a ECV or ED protocol of CIED patients exist, therefore we suggest the advisory recommendations in emergency ECV or ED for PM or CRT-P (**Figure 5)** and ICD and CRT-D patients **(Figure 6).**

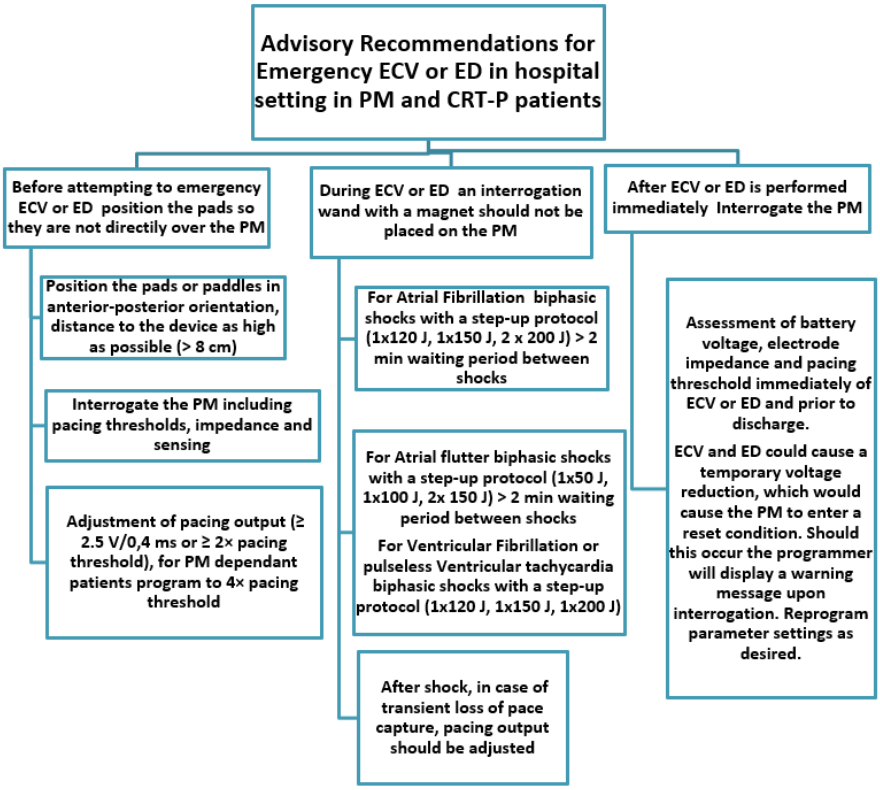


Figure 5: Advisory Recommendations for Emergency electrical cardioversion or electrical defibrillation in hospital setting in pacemaker and cardiac resinchronization therapy-pacemaker patients

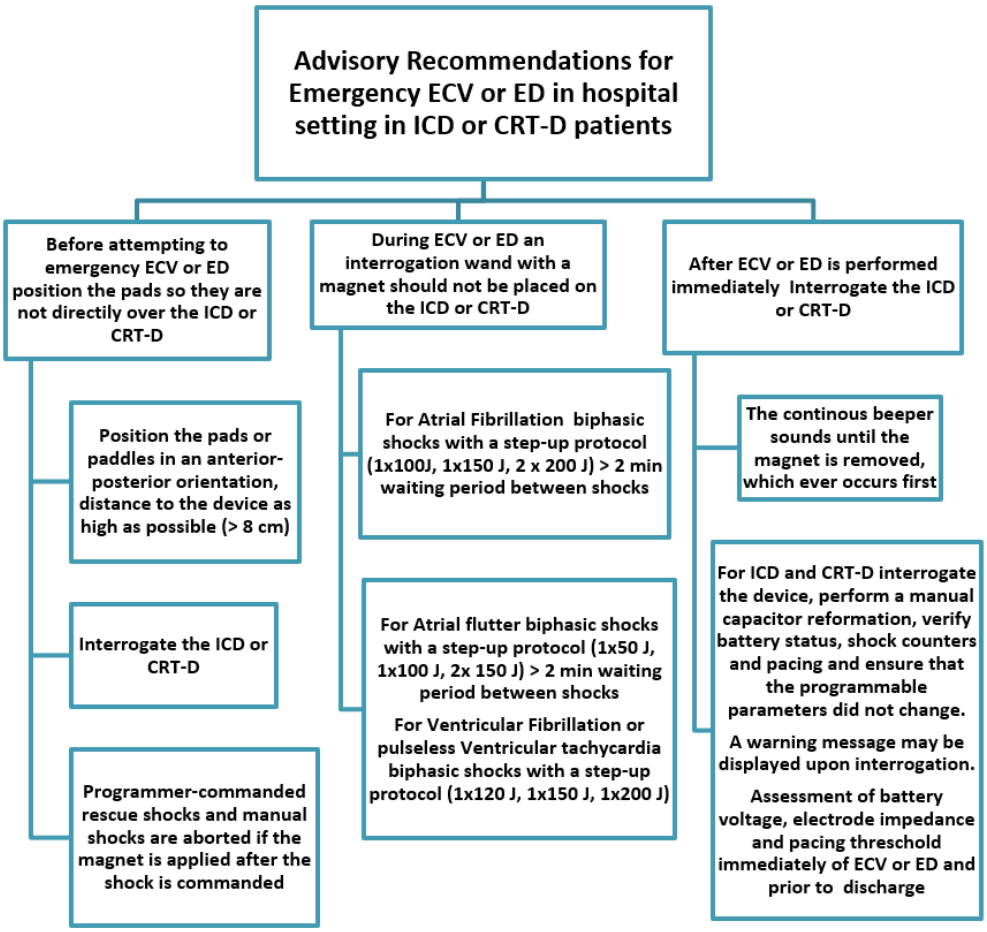


Figure 6: Advisory Recommendations for Emergency electrical cardioversion or electrical defibrillation in hospital setting in implanted cardioverter defibrillator and cardiac resinchronization therapy-defibrillator patients

A thorough evaluation of the pacing system should be performed and if loss of capture occurs, and then immediate reprogramming or temporary pacing should be done with increased PM output. In ICD and CRT-D patients, before attempting emergency ECV or ED the magnet-disabled therapies and the magnet should be removed to re-enable antitachycardia therapies and then consider re-enabling therapies through programming. During the perioperative period, the primary concern is to minimize the current flowing through the PM and lead system. If the patient has a PM implanted, it will be just below the skin, usually in the upper left chest. A PM keeps the heart beating at the proper rate and from beating too slow. It helps control abnormal heart rhythms, and it will only activate if it is needed. If dealing with an ICD it will be a slightly bigger device, but similar to a PM. It sends electrical pulses, or shocks, to the heart when it senses any abnormalities in heartbeat, and helps those who have an irregular heartbeat, or are at risk for sudden cardiac arrest. The biggest difference between an ICD and PM is that an ICD continually monitors heart rhythm and can send low or high-energy electrical pulses to correct an abnormal heart rhythm. ICD will initially send low-energy pulses to restore heart rhythm but switch to high-energy pulses when the low-energy shocks are ineffective. PM, however, only give low-energy electrical pulses to restore regular heartbeat. It is always a possibility for both devices to malfunction and fail to deliver the lifesaving intervention a victim needs. Finally, during the Covid 19 pandemic period the guidelines suggests for emergency electrophysiology procedures should be performed based on risk-benefit analysis [49]. In hospital setting of a ECV or ED, the number of personnel in the room should be minimized and social distancing

should be practiced. Non urgent or non-emergency procedures should be postponed to a later date. Resource conservation including personal protective equipment is of utmost importance. All staff should have on personal protective equipment prior to entering the patient room.

Conclusions

The meta-analysis of literature demonstrates less dysfunction of chest implanted CIED in patients treated with ECV or ED. Procedural advisories have been developed by many professional societies, but the recommendations of these societies differ regarding ED and ECV protocol. While managing such patients for ECV or ED, specific issues related to equipment characteristics and troubleshooting should be a priority for the medical staff. A systematic review of advisory analized the preoperative preparation, the intraoperative and postoperative management of CIED patients and outline that it is imperative to understand the CIED characteristics before attempting ECV or ED procedures. The urgent or emergent electrical procedures should be performed based on risk-benefit analysis. Emergent ED, which may be life-saving, and elective ECV should be used cautiously, with attention to patient selection and proper techniques. Repetitive, futile attemps at ECV should be avoided.

Conflict of interest: There was no financial support from any sponsor.

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