

Research Article

# Defibrillation of Atrial Fibrillation is not Associated with Increased Risk of Ventricular Fibrillation – The VCD-Trial (Clinical Trial of Electrical Therapy for Atrial Fibrillation using R-wave Guided Cardioversion Versus Defibrillation)

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## Abstract

**Background:** Because of a possible risk of induction of Ventricular Fibrillation (VF) by defibrillation of atrial fibrillation (AF) postulated by LOWN and coworkers, synchronized cardioversion is used worldwide. This prospective, randomized study assessed the efficacy and safety between R-wave controlled cardioversion and defibrillation of AF at 2 study centers in Cologne, Germany.

**Hypothesis:** Defibrillation is not significantly different from cardioversion primarily in the occurrence of VF or sustained Ventricular Tachycardia (VT) and secondarily in restoring sinus rhythm, inducing non-sustained VT, asystole, or bradycardia.

**Methods:** 146 patients at an outpatient practice and 122 at the university hospital were randomized to cardioversion ( $n = 140$ ) or defibrillation ( $n = 124$ ).

**Results:** Cardioversion was successful in 92.1% of cases and defibrillation in 87.1%. The difference in efficacy was not statistically significant. In  $n = 1$  patients receiving defibrillation, VF occurred after the first shock (200J) and immediate defibrillation (200J) restored sinus rhythm. In the  $n = 1$  case, asystole occurred during cardioversion which terminated spontaneously. In  $n = 1$  patients cardioverted and  $n = 2$  who were defibrillated, sinus bradycardia occurred requiring Atropine in two cases. There were no thromboembolic events within 10 days.  $N = 9$  patients reverted to AF within two hours. No patients died.

**Conclusion:** Electrical conversion of AF can be performed with similar results and low risk with both R-wave-triggered cardioversion and defibrillation. In particular, defibrillation with higher energies ( $> 100J$ ) can be performed as effectively and safely without a statistically significant increased risk of VF or VT. There was no difference in efficacy and risk between electrotherapy performed in the outpatient and inpatient settings.

## Introduction

Atrial fibrillation is the most common sustained cardiac arrhythmia and is associated with an increased risk of thromboembolism, especially in the presence of specific risk factors. Therapy involves either restoration of sinus rhythm (“rhythm control”) or effective blood thinning and heart rate control (“rate control”) [1]. Which of the two therapeutic

strategies should be preferred remains the subject of ongoing controversy [1,2].

Atrial fibrillation can be converted to sinus rhythm with antiarrhythmic drugs or electroshock [2]. Since the initial description in 1962 by LOWN [3], electrical cardioversion has been performed as an R-wave-triggered delivery of a current pulse and thus differs from defibrillation, which



delivers a current shock without such synchronization. The considerations of R-wave triggered cardioversion were based on animal studies by KING [4], who identified the T-wave in the surface ECG as a vulnerable phase for the induction of ventricular fibrillation. In their animal experimental studies, LOWN and coworkers observed the occurrence of ventricular fibrillation in 1.6% of dogs when non-synchronized shocks (defibrillation) were applied, and in 35% when targeted delivery was between the T-wave and the QRS complex [3]. However, detailed data on the intensity of the applied pulses are lacking. This is relevant insofar as 1. The induction of more ventricular tachyarrhythmias depends on the shock intensity according to recent findings (see below) and 2. In several smaller, non-randomized studies in humans, cardioversion with non-synchronized shocks did not induce ventricular arrhythmias [5-7]. Nevertheless, R-wave-controlled cardioversion is almost exclusively used worldwide for electrotherapy of atrial fibrillation. Controlled trials have not been performed to date.

With the proliferation of implantable Automatic Cardiac Defibrillators (AICDs), sophisticated knowledge of cardiac or conduction system behavior has been acquired through applied electrotherapy. In systematic studies to determine the vulnerability of the heart, it was recognized that there is a limit of shock intensities (ULV=upper limit of vulnerability) above which a current shock cannot induce ventricular fibrillation even in the vulnerable phase of the T-wave [8]. This means that only low shock intensities, but not high ones, are potentially arrhythmogenic. This upper limit is a maximum of 10 joules for internal biphasic shock application [8]. Data on ULV during external defibrillation are not available. With the currently applied shock strengths of at least 100 joules with biphasic or 200 joules with monophasic pulses in the context of external electrotherapy, the risk of inducing ventricular tachycardia or ventricular fibrillation appears to be low, especially since these shock strengths are also used to terminate precisely these cardiac arrhythmias.

The study aimed to investigate the equivalence (non-inferiority) of non-synchronized defibrillation and R-wave-guided cardioversion in the treatment of atrial fibrillation. While the effectiveness of both methods is theoretically identical at the same shock intensity and should be around 80%, the comparison focuses on the potential acute side effects of the applied electrotherapies.

Parts of this study were conducted for a doctoral thesis at the University of Cologne, which is bibliographically deposited there.

## Methods

### Study design

The term VCD-trial stands for Vorhofflimmern-Cardioversion-Defibrillation-trial, Vorhofflimmern being the German term for atrial fibrillation.

This interventional study was an open comparison between the two methods of electrotherapy for atrial fibrillation – cardioversion versus defibrillation (bicenter, prospective, randomized, single-blinded, parallel groups).

To investigate the equivalence of R-wave guided cardioversion and defibrillation for electrical therapy of AF, patients with atrial fibrillation at the outpatient practice of Franzen Institute and the Clinic III for Internal Medicine of the University of Cologne were randomized to one of the two methods using sealed envelopes. When the respective envelope was opened, the doctor delivering the electric shock was unblinded. The calculation of the number of participants was  $n = 300$  patients. A male-to-female ratio of 2:1 was used.

The study had been approved by the Ethical Commission North Rhine/Germany on 4<sup>th</sup> March 2008. The study entry was in 2008 and was terminated in 2015. The study is listed in the German Clinical Trial Register (DRKS00003691). All patients' informed consent for participating in the study and publication were obtained.

### Pre-treatment examination and procedure

All study patients were preceded by a detailed medical history and a general examination. This included blood pressure and pulse measurement, auscultation of the heart and lungs, a 12-lead-electrocardiogram (ECG), and comprehensive blood testing including the determination of thyroid function values.

All patients were treated with anticoagulant medications for 3-4 weeks in the therapeutic range [9,10]. If electrotherapy took place in the context of emergency treatment such that adequate anticoagulation could no longer be achieved, transesophageal echocardiography was performed to exclude cardiac thrombi.

Electrodes were placed on the chest in an anterior and posterior position [11], and after sufficient analgesia [12], delivery of 1 - 3 electric shocks for both, cardioversion and defibrillation, occurred until sinus rhythm was achieved. The shock intensity ranged from 100 to a maximum of 360 joules in a biphasic mode.

The success of each treatment was defined as the achievement of sinus rhythm with 1- 3 attempts and 100 - 360 joules of biphasic shock. In the case of ventricular fibrillation, immediate defibrillation with 360 joules was performed.

After a monitoring period of 2 hours, an ECG and the final interview were performed before the patient was discharged from the practice under escort. In the clinic, the majority of patients were monitored as inpatients.

Early recurrence was defined as recurrence of AF within the first 2 hours. Late recurrence was defined as a recurrence of AF in the first 6 months after treatment.

If a patient presented again due to recurrence, no new randomization was performed, but the opposite method of electrical rhythm restoration was used.

### Follow-Up

To verify the existence of sinus rhythm and to document the success of the methods, all patients were asked to present to their continuing physician (general practitioner or cardiologist) the following day and to attend two follow-up appointments after 3 and 6 months with a 12-lead-ECG. Anticoagulation should be maintained for at least 3 months - 4 months after cardioversion. Patients were contacted by telephone up to 5 times during this period. If this contact remained unsuccessful, the necessary information was requested from the co-treating general practitioner or cardiologist.

### Inclusion and exclusion criteria

All patients of both sexes aged 18 years and older who were undergoing treatment for atrial fibrillation at the cardiological outpatient practice Franzen Institute or at the University Hospital of Cologne were eligible to participate in the study (Figure 1). Patients with all three types of atrial fibrillation were eligible (paroxysmal, persistent, long-standing). A Transthoracic Echocardiography study (TTE) before electrotherapy was not a prerequisite. The exclusion criteria were:

- Pregnancy
- Serum potassium < 4.0 mmol/l.
- Evidence of a left atrial thrombus
- Latent or manifest thyroid dysfunction
- Non-therapeutic anticoagulation for pre-fibrillation lasting longer than 48 hours or LAA-thrombus by transesophageal echocardiography
- Lack of legal capacity

### Statistics

Statistical analysis was performed with SPSS Statistics version 23 (IBM Corp., Armonk, NY, USA) and was done

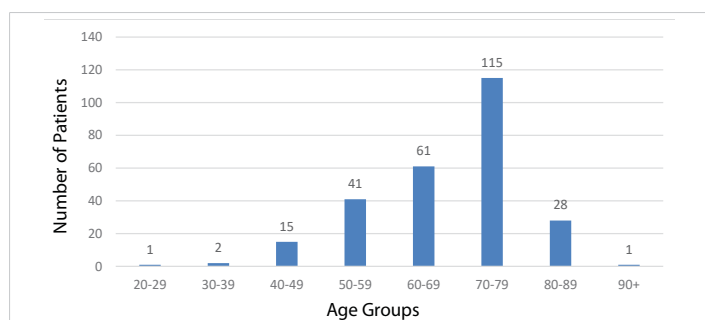


Figure 1: Age distribution.

in collaboration with the Institute of Medical Statistics, Informatics, and Epidemiology at the University of Cologne.

The null hypothesis H0 and the alternative H1 were tested.

The null hypothesis H0 was assumed to be true if defibrillation was worse than cardioversion by greater than or equal to 5%. If it was less than 5%, we assumed the alternative hypothesis H1.

For the evaluation of the long-term stability of sinus rhythm, a loss to follow-up of 10% was assumed.

From the collected data, cross-tabulations were obtained, and their correlations were tested for significance using the chi-square test. Prerequisites for reliable values in the chi-square test were cross-tabulations with more than 2x2 fields, large data sets, and expected frequencies greater than 5. Since these criteria were not or only partially fulfilled, the Fisher's Exact Test was also applied. This provided reliable results even in cases of smaller samples and with a small number of observations.

### Results

The originally planned number of study participants was  $n = 300$  patients. After analysis of the data obtained up to that point, the study was terminated prematurely due to a lack of differences, with a patient number of  $n = 265$ .

Of the  $n = 265$  randomized patients, treatment occurred in  $n = 264$ . In one male patient randomized to the defibrillation group, electrotherapy could not be performed because of thrombi detected by Transesophageal Echocardiography (TEE). Therefore, all further calculations and results refer to a sample number of  $n = 264$  patients. The early termination of the study explains the different number of cardioversions ( $n = 140$ ) and defibrillations ( $n = 124$ ).

As expected, the study participants included more men than women, with a ratio of 3:1.

The number of cardioversions and defibrillations performed were distributed approximately equally between the two sexes. 51.6% of the men were cardioverted, 48.4% defibrillated. Among female participants, 56.8% were cardioverted, 43.2% defibrillated (Table 2).

**Table 1:** Pre-existing conditions – baseline characteristics.

	Frequency (n)	Percentage (%)
Ischemic heart disease	110	41,7
Dilatative Cardiomyopathy	56	21,2
Hypertonia	180	68,2
Cor pulmonale	18	6,8
Diabetes mellitus	53	20,1
Stroke	17	6,4
Emboli	18	6,8
Valvular heart disease	53	20,1

**Table 2:** Number of patients by gender and treatment type.

	Males (n) / (%)		Females (n) / (%)		Total (n) / (%)	
Cardioversion	98	51,6	42	56,8	140	53
Defibrillation	92	48,4	32	43,2	124	47
Total	190	100	74	100	264	100

### Occurrence of ventricular fibrillation and sustained ventricular tachycardia

In  $n = 124$  cases of defibrillation, ventricular fibrillation occurred in  $n = 1$  case (0,81%), namely to a 65-year-old male patient who was admitted to the emergency department of the university hospital with Atrial Flutter, dyspnea NYHA II and thoracic pressure. The patient was included even though he did not fulfill the inclusion criterion. The pre-existing medical conditions were as follows: hypertensive heart disease with diastolic dysfunction. Systolic LV function was regionally abnormal with a global ejection fraction of 58%. The patient received rivaroxaban for anticoagulation in addition to bisoprolol and ramipril. After initial defibrillation after which he developed ventricular fibrillation, he needed two shocks with 200 Joules each to restore sinus rhythm (Figures 2-4) which persisted at the time of discharge, on the following day and after 6 months. No further complications occurred in the course.

Thus, in  $n = 124$  cases of defibrillation, ventricular fibrillation occurred in  $n = 1$  case. This results in a rate of 0.81%.

Among  $n = 140$  patients who underwent R-wave synchronized cardioversion, no ventricular fibrillation occurred.

No patient of any treatment group suffered from sustained ventricular tachycardia.

The  $p$ -value is 0,470 for both the Qi-square and the Fisher's Exact Test. Thus, the  $H_0$  hypothesis and the assumption that defibrillation is statistically significantly worse than cardioversion about the probability of triggering ventricular fibrillation is rejected.

### Primary success in restoring sinus rhythm

In 89.8% of cases ( $n = 237$ ), sinus rhythm could be achieved primarily. In 10.2% ( $n = 27$ ) electrical treatments were unsuccessful and atrial fibrillation persisted.

R-wave guided cardioversion was used to treat  $n = 140$  participants, defibrillation in  $n = 124$ . The imbalance between the two methods was explained by the premature end of the study. Of  $n = 124$  defibrillations performed,  $n = 108$  proceeded successfully, that is, sinus rhythm was achieved. This results in a defibrillation success rate of 87.1%. Of  $n = 140$  cardioversions,  $n = 129$ , and thus 92.1% were successful.

Of the  $n = 27$  unsuccessful treatments,  $n = 16$  were defibrillations and  $n = 11$  were cardioversions.

$N = 113$  treatments at the university hospital and  $n = 124$  at the outpatient practice were successful.

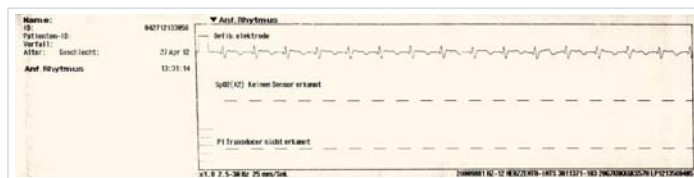


Figure 2: Initial ECG before treatment (Atrial Flutter, uncommon type).

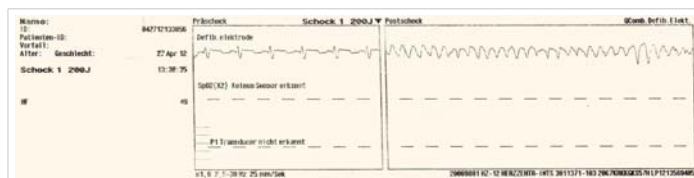


Figure 3: ECG of first shock delivery (Atrial Flutter – Shock – Ventricular Fibrillation [Vfib]).

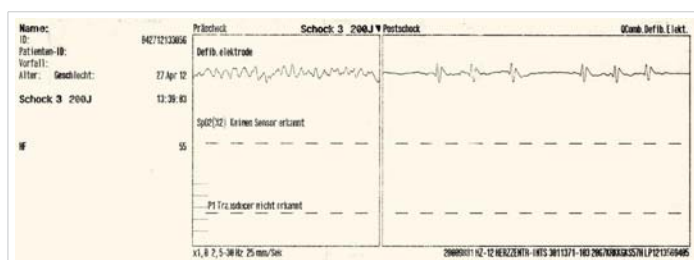


Figure 4: ECG of second shock delivery (Vfib – Shock – Sinus Rhythm with SVES).

### Relapses

After 48 hours, sinus rhythm still persisted in  $n = 207$  patients out of  $n = 237$  primary successful treatments. This decreased the primary success rate from 89.8% to 74.8% in the first two days after treatment. Among the  $n = 30$  cases of recurrence,  $n = 9$  were early recurrences in the first 2 hours after treatment, including  $n = 3$  with cardioversion and  $n = 6$  with defibrillation.

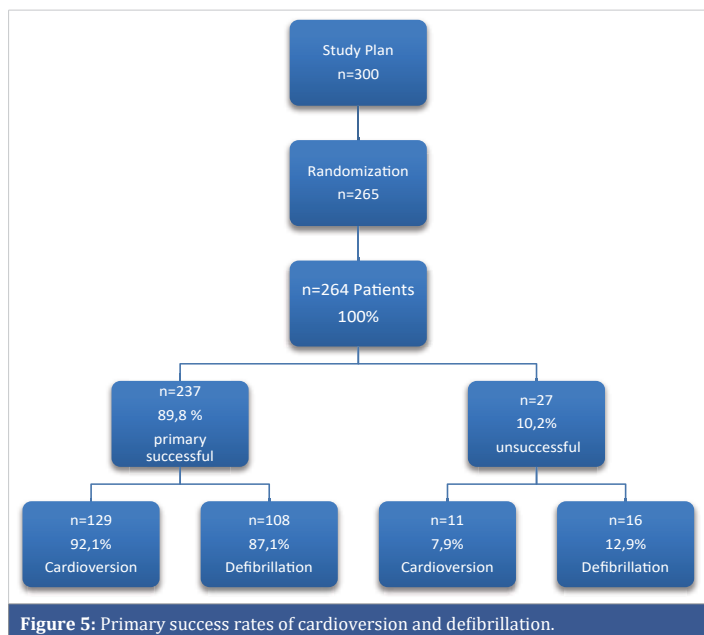
In another  $n = 21$  cases, recurrence occurred within 48h. Of these,  $n = 13$  subjects had undergone cardioversion and  $n = 8$  had undergone defibrillation. Early recurrences and recurrences after 48 hours amounted to  $n = 9$  in the clinic and  $n = 12$  in the practice.

After an observation period of 48 hours, there is statistically no difference between the two methods cardioversion and defibrillation about atrial fibrillation recurrences ( $p = 0,223$ ) (Figure 5).

After an observation period of 6 months, the number of patients with recurrence of atrial fibrillation increased by an additional  $n = 95$  patients. Of these,  $n = 48$  were from the cardioversion group and  $n = 47$  with defibrillation. In the design of this study, a "loss to follow-up" of 10% was anticipated. With  $n = 6$  patients who died,  $n = 4$  patients who refused information, and  $n = 1$  patients who could not be reached, the loss to follow-up rate was 4.2%.

The primary success rate was 89.8%. Due to recurrences of atrial fibrillation, it decreased to 74.8% at 48 hours and





38.3% at 6 months with no statistically significant difference between the two methods ( $p = 0,428$ ).

### Secondary study endpoints

In addition to the primary study points, the occurrence of asystole, non-sustained ventricular tachycardia, and thromboembolism within the first 10 days after electrotherapy were considered. The time window to be observed began with the first applied shock and ended two hours after the completion of electrotherapy.

Asystole occurred in a 71-year-old male patient following cardioversion at the University Hospital.

Apart from anticoagulation using Rivaroxaban the patient had been on Bisoprolol and Enalapril medication to control hypertension.

Potassium and thyroid levels were unremarkable. Asystole occurred after a single biphasic shock application of 100 joules and persisted for five seconds. Sinus rhythm established spontaneously without further action. During the further observation period, recurrence of atrial fibrillation occurred after 3 months.

Non-sustained tachycardia occurred in a 66-year-old male patient in the defibrillation group. He suffered from dilated cardiomyopathy and was treated with a beta blocker, ACE inhibitor, diuretics, and phenprocoumon. Sinus rhythm was achieved after re-defibrillation.

In the collective study, no thromboembolic event occurred within ten days.

Temporary bradycardia occurred in  $n = 3$  subjects after treatment, including  $n = 1$  subject who were cardioverted and  $n = 2$  who were defibrillated.

The first case involved an 85-year-old male patient in the cardioversion group. After a single application of 200 joules, sinus rhythm was restored. Postintervention sinus bradycardia occurred with a rate of 27/min. Following intravenous administration of 0.5 mg atropine the heart rate increased.

In a 40-year-old patient, sinus rhythm was achieved directly by defibrillation using 200 joules; sinus bradycardia 30/min was successfully treated with intravenous administration of 0.25 mg atropine.

In the third case, a 46-year-old male patient was successfully defibrillated with 150 joules in the first attempt. He showed sustained sinus bradycardia at 36/min, which was attributed to oral amiodarone premedication.

None of the secondary complications occurred statistically significantly more frequently in either treatment group ( $p = 0,530/0,470/0,602$ ) (Table 3).

### Discussion

The worldwide practice of R-wave triggered cardioverting is based on the pioneering experiments of LOWN and coworkers [3].

They showed that electric shocks to dog hearts delivered during the vulnerable phase of the electrocardiogram (in particular just before and during the T-wave) were associated with a high incidence of ventricular fibrillation (VF) as opposed to shocks outside this phase. Although several other studies challenged these observations [5,6], up-to-date electrical cardioversion was considered an optimal and safe treatment for the electrical restoration of sinus rhythm.

The present study aimed to address the central question of whether electrotherapy of atrial fibrillation by defibrillation causes ventricular fibrillation statistically significantly more often than R-wave triggered cardioversion.

The results of this randomized study in 264 patients showed no significant differences between defibrillation and cardioversion of atrial fibrillation in terms of efficacy and safety. With energy doses >100 Joule, conversion rates do not seem to depend on synchronization with the R-wave. In addition, as shown by Franzen, et al. in 2006 [13], ambulatory and in-hospital procedures were not associated with a different outcome.

The concept of induction of ventricular fibrillation had been

**Table 3: Secondary Complications.**

	Asystole (n)	Non-sustained Vtach (n)	Thrombo-emboli (n)	Brady-cardia (n)
Cardioversion	1	0	0	1
Defibrillation	0	1	0	2
Total	1	1	0	3



evaluated with the emerging role of implantable cardioverter defibrillators. Induction of VF by direct low-dose current to the vulnerable phase of the T-wave was common practice to test the efficacy of the implanted device [14].

It must be postulated that high-energy doses (> 100 joules biphasic) do not trigger VF even if the shock hits the vulnerable phase in the descending part of the T-wave. In this respect, the question must at least be raised as to whether future defibrillators will have to carry an R-wave trigger.

On the other hand, atrial fibrillation being a non-life-threatening condition is usually electively terminated and thus requires a safe and reproducible termination without even the slightest suspicion of a higher risk of ventricular fibrillation.

As in many studies of electrical therapy for atrial fibrillation, a high primary success rate of 89.4% (92.1% for cardioversion and 87.1% for defibrillation) is shown, with a low general risk of complications. However, recurrence of atrial fibrillation after primary successful therapy is frequent. Causes include structural myocardial disease and especially left atrial dilation/remodeling with a high amount of atrio-muscular fibrosis. However, the question of the long-term cumulative high recurrence rate remains in the background as this was not the focus of the study.

## Conclusion

The VCD trial presented here provides a strong signaling effect about the innovative approach to convert atrial fibrillation with defibrillation without a higher incidence of the previously feared ventricular fibrillation. However, further studies with higher participant rates are needed to support the results obtained here and to initiate a paradigm shift. Electrical conversion of atrial fibrillation, both as cardioversion and defibrillation, shows a very high primary success rate. Both methods are equally suitable for electrical conversion to sinus rhythm. Neither method was shown to be superior to the other.

Thus, the far more expensive devices for R-wave delivering shocks are no longer needed.

Among the  $n = 264$  participants, complications occurred in only  $n = 6$  cases. This results in a percentage of 2.3%. In a treatment method with already low complications, larger numbers of participants are useful to be able to make more detailed statements regarding the occurrence of very rare adverse events, such as ventricular fibrillation.

In the observation period up to 6 months, the rate of patients who reverted to atrial fibrillation increased dramatically.

This focuses attention not only on the type of performance as well as the avoidance of recurrences of atrial fibrillation.

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