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Application of the Bispectral Index (BIS) During Deep Sedation for Patients with ICD Testing

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1. Introduction

Epidemiological studies indicate that in Europe, sudden cardiac death (SCD) is the cause of from 20 to 159 deaths per 100 thousand inhabitants / year. In the United States, therefore, die each year from 300 to 400 thousand people. Unfortunately, as shown by the results of clinical trials, the use of antiarrhythmic drugs doesn't protect the majority of patients before the onset of malignant ventricular arrhythmias which are the main cause of SCD.
Other methods of treatment aimed at eliminating the causes of arrhythmia, such as antiarrhythmic cardiosurgery or transvenous ablation of arrhythmias can be effectively used only in a narrow group of patients.
Thus, the treatment of choice in treating people at risk of SCD became the implantation of cardioverter-defibrillator (ICD). The creator of the idea of this method of treatment was Mieczyslaw (Michel) Mirowski (1924-1990). In the sixties of the last century, he started work on the design of devices capable of cardiac rhythm track, and in case of serious ventricular arrhythmias automatically restore sinus rhythm.
The first implantation of automatic defibrillators (without cardioversion) occurred in the Johns Hopkins Hospital in Baltimore in 1980.
Evaluation of the effectiveness of the ICD in SCD preventing has been the subject of many studies. Based on the results, the indications for ICD implantation can be divided into secondary prevention, for patients after cardiac arrest with ventricular fibrillation (VF) or a previous episode settled ventricular tachycardia (VT) and the primary prevention, including patients without malignant arrhythmias.
Immediately after ICD implantation, and after 3-7 days you need to confirm the correct positioning of defibrillation electrodes. This allows you to confirm the correct location and accuracy of programming. While the study conducted a few days after ICD implantation should confirm the effectiveness of the algorithm of therapy chosen by the proper detection of induced control ventricular fibrillation. There are two methods to identify and then a safety margin between defibrillation pulse energy of the programmed and actual energy

required to terminate VF. These are: a test to verify the effectiveness of defibrillation and defibrillation threshold measurement.

Verification test is relatively simple and involves initiation of ventricular fibrillation (with special functions ICD) and the interruption of the arrhythmia using a defibrillation pulse of a certain energy. This energy has to be correspondingly smaller (usually about half) than the maximum available under the ICD model so as to provide sufficient (double) safety margin taking into account possible fluctuations in defibrillation threshold in the future. After a successful test, defibrillation energy in the ICD is programmed at the highest available value.

Defibrillation threshold (DFT) is the lowest energy allows to interrupt of VF. Measurement of DFT requires several times causing arrhythmia, and then interrupting by the pulse of different energy power. The usual method of DFT testing is protocol of gradually reduced defibrillation energy. The test is typically commenced from the defibrillation pulse energy of 15-20 J. After each successful defibrillation is performed the next, using a pulse of energy usually lower about 10-20%. In this way, determines the highest energy, with which the successive VF is not interrupted. Another way of determining the DFT is to use the protocol with gradually increases defibrillation energy. In this case, the testing deffibrillation pulse has the energy gradually increased (10-20%), ranging from 5-8 J until the determination of the lowest value allowing interrupt VF.

The most commonly used algorithms of VF induction are the two:

1. High-speed "burst-type" stimulation - depending on the model of ICD, shock for ventricular pacing pulse energy of several volts and frequencies of 30-50 Hz for a few to tens seconds (Fig. 1)
2. "Shock on T" method - triggering the ICD pulse of energy from 0.5 J to a few J at the top of the T wave (Fig. 2)

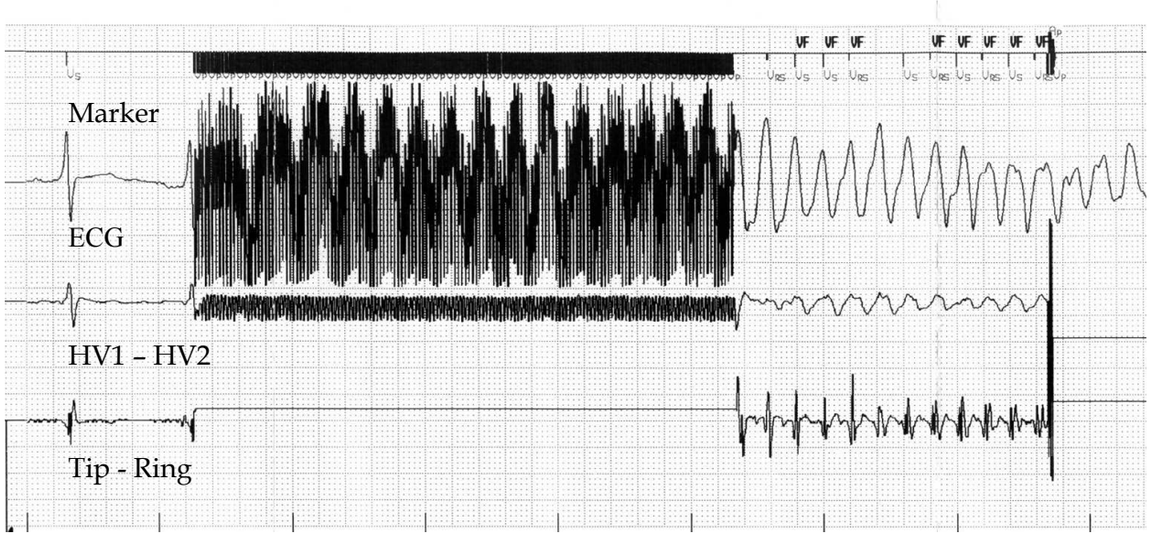


Fig. 1. An example of initiation of ventricular fibrillation by "burst-type" stimulation. Record of the Biotronik 1000 TMS programmer. Implantable cardioverter-defibrillator Belos VR - Biotronik. Paper travel 25 mm / sec.

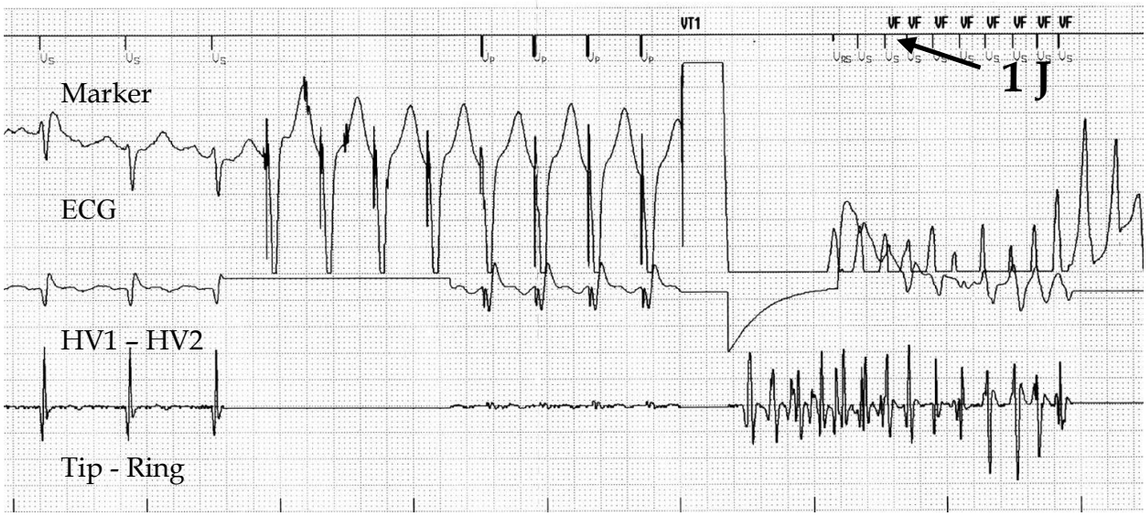


Fig. 2. An example of initiation of ventricular fibrillation by "shock on T " method. Record of the Biotronik 1000 TMS programmer. Implantable cardioverter-defibrillator Belos VR - Biotronik. Paper travel 25 mm / sec.

In some patients, repeated attempts to induce VF using both methods didn't cause arrhythmia.[1] Then you need to induction of VF by stimulation of burst-type beam pulses from the ICD connected with simultaneous induction of unsynchronised impulse from an external defibrillator.[2,3] This method is sometimes called as a "shock,on burst".[4]

1.1 Indications for ICD implantation

The subject of many randomized controlled trials was to establish a factor to identify patients at risk of SCD. Because coronary artery disease is the basis of ventricular arrhythmias in 80% of cases and cardiomiopathies (especially dilated cardiomiopathy) in 15%, that is why these diseases were a major subject of study in clinical trials of primary prevention.

Although coronary heart disease and dilated cardiomyopathy are the most common cause of ventricular arrhythmias, European Society of Cardiology guidelines allow implantation of the ICD in primary prevention in patients with less recognizable diseases. An example is hypertrophic cardiomyopathy (HCM) with the associated additional risk factors such as syncope, family history, left ventricular wall thickness of over 30 mm, abnormal pressure response during exercise and paroxysmal ventricular tachycardia (Indications class IIa /C). Patients with HCM and episodes of ventricular fibrillation or ventricular tachycardia should undergo ICD implantation in secondary prevention.

In the course of arrhythmogenic right ventricular cardiomyopathy, ICD in primary prevention can be used in patients with syncope of unknown etiology or in the case of family history, and when the disease process coverage also includes the left ventricle (Indications class IIa/C)

Also, a genetic disease such as long QT syndrome (LQTS), a polymorphic ventricular tachycardia-dependent catecholamine or Brugada syndrome may be the indication for prophylactic ICD implantation. In the case of LQTS, ICD can be implanted for primary prevention in patients with recurrent syncope despite beta-blocker therapy (Indications class IIa /B) or those without syncope but with known types of LQT2 and LQT3 treated as being particularly strongly associated with risk of SCD (Indications class IIb/B). Patients with Brugada syndrome with characteristic changes in the resting ECG, recurrent syncope, as well as those with polymorphic ventricular tachycardia dependent on catecholamines and syncope, may also be secured in the ICD in primary prevention (Indications class IIa /C).

2. Indications for ICD implantation in primary prevention (Chart 1)

Definitely relate to more potential patients than secondary prevention (Existing guidelines of the European Society of Cardiology)

a. Prior myocardial infarction (after more than 40 days after MI)
    1. NYHA II or III, EF ≤ 35%, the expected survival time exceeds one year. (Indication class I/A)
    2. NYHA I, EF ≤ 30-35%, the expected survival time exceeds one year. (Indications Class IIa /B)
b. Dilated cardiomyopathy noncoronarogenes
    1. NYHA II or III, EF ≤ 35% of the expected survival time exceeds one year. (Indication class I/B)
    2. NYHA I, EF ≤ 30-35%, the expected survival time exceeds one year. (Indications class IIb /C)
c. Cardiomyopathy, whatever the reasons (coronary and noncoronary)

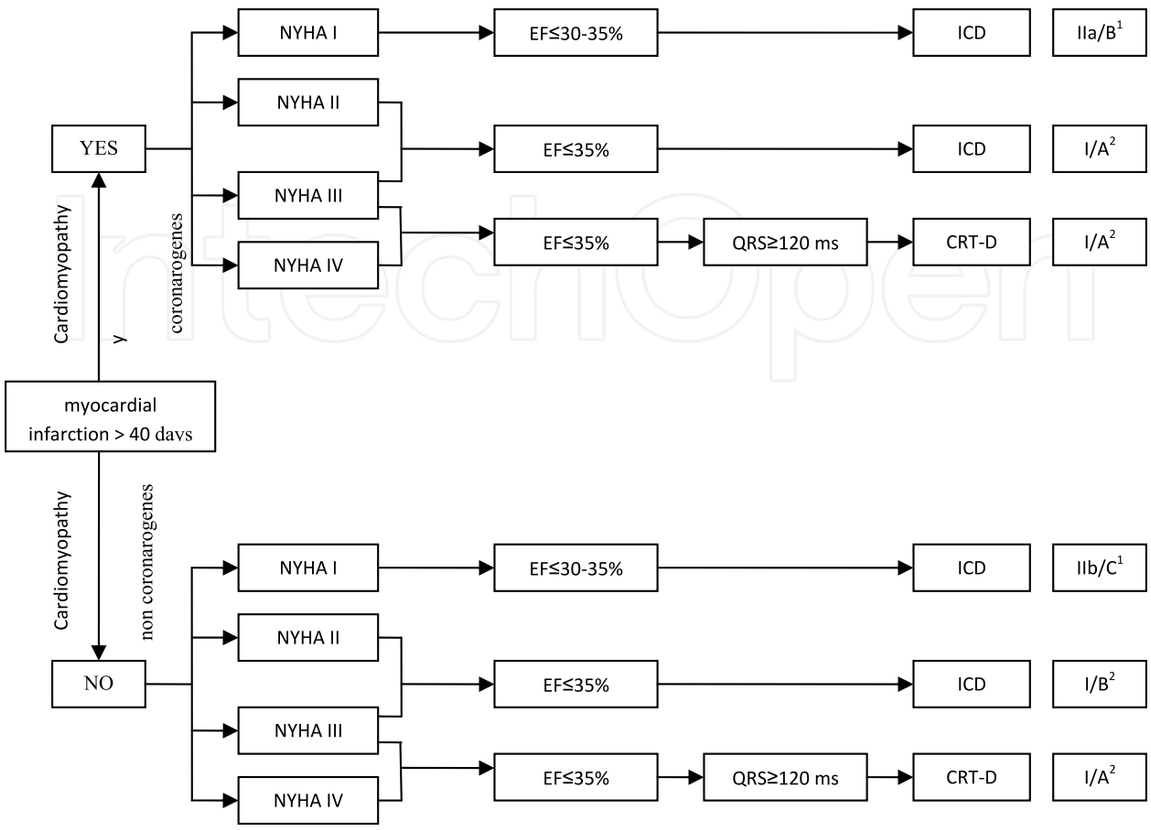
NYHA III and IV, EF ≤ 35%, the duration of the QRS complex > 120 msec is recommended ICD implantation with the function resynchronisation stimulation (Indications Class I/A).

3. Indications for ICD implantation in secondary prevention

1. Past cardiac arrest caused by ventricular tachyarrhythmias in the mechanism irreversible or unknown.
2. Ventricular tachycardia leading to unconsciousness.
3. Syncope of unknown etiology, in patients in whom in electrophysiological examination there was haemodynamically not tolerated VT or VF.

4. Cause of reversible and irreversible of cardiac arrest

The cause is reversible, such as ventricular fibrillation, which occurred in the course of acute ischemia, myocardial infarction or acute phase of myocarditis is not an indication for ICD implantation, but the underlying disease requires treatment of any subsequent verification of indications.



(1) According to ACC / AHA / ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death[5].

(2) According to ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008[6].

Chart 1. Indications for ICD implantation for primary prevention of SCD.

The cause is irreversible, eg electrolyte abnormalities associated with cardiac arrest or an adverse impact pharmacotherapy consisting of induction of arrhythmias. Irreversibility in these situations is the result of inability to confirm that any of these factors have been isolated and not accompanied to any other cause leading to arrhythmia. Furthermore, it's no possible to prevent with 100% certainty a recurrence of the situation. Thus, experts agree that in their current situation to propose ICD implantation for patient.

5. Anesthesia for ICD patients

ICD implantation is used in heavily loaded cases (see - the indications for implantation). Their ejection fraction (EF) is often reduced to 10-15%. Therefore, the anesthetic drugs used and their dosage must be carefully chosen. At the same time dose must be sufficient to run the entire test of the defibrillator. Can not be allowed to shallow sedation or anesthesia.
In the Medical University of Gdansk, ICD is implanted since 1995. Initially, the ICD was implanted under general anesthesia. Prolonged surgery and prolonged anesthesia deteriorating general condition of patients. Since 1999, the ICD is implanted under local

anesthesia and deep sedation is performed to verify the proper functioning of the ICD and to determine the defibrillation threshold.

6. Preparing the patient for deep sedation

Patients presenting to the ICD implantation are being prepared for surgery by cardiologists. After determining cardiac indications, patients are evaluated in the ASA & NYHA scales. Due to the burden that is the heart muscle disease and often accompanies circulation failure, patients should be anesthetized by an experienced anesthesiologist. Before the procedure, EF is evaluated in ECHO-cardiography. In the operating room is used hemodynamic monitoring and oxygen therapy. It is advisable to monitor the depth of anesthesia because the ICD test is performed 2 - 4 times to set the parameters of defibrillation and monitoring its effectiveness. The interval between the performance of subsequent tests claims of at least 2 - 3 minutes. You can't afford to have shallowing of anesthesia. Anesthesia or deep sedation to the ICD test have to be short. Initiation of ventricular fibrillation isn't a painful process. Therefore, in this type of anesthesia isn't used painkillers.

7. Hypnotics used to the ICD test

1. Etomidate (marketed as Amidate by *Labeler*)- carboxyl derivative of imidazole. Its anesthetic effect is a consequence of the depressant effects on the brain stem reticular creation, through stimulation of GABA. After etomidate injection some patients may appear myoclonus and dyskinesia. Etomidate causes luxury perfusion the heart muscle. Oxygen consumption by the myocardium under the influence of etomidate doesn't change, while the coronary circulation increases by 20%. This action is preferable to a thiopental actions on the myocardium, which also increases coronary blood flow but may also increase oxygen consumption by the myocardium. Etomidate doesn't affect heart rate, slightly decreases peripheral resistance, which increases cardiac output. Onset of action after 15 - 45 sec. Duration of action 3 - 12 min.
2. Sodium thiopental - (marketed as thiopental by Biochemie) - thiobarbiturate soluble in lipids. Its anesthetic effect is inhibiting formations in the brain stem reticular. The drug rapidly decreases blood pressure but slow injection causes compensatory mechanisms, and this decline is poorly defined. This drug has a beneficial effect on peripheral vascular resistance, because it increases slightly due to a compensatory increase in sympathetic activity. Heart rate after administration of thiopental is usually increased. . Thiopental exerts a direct negative inotropic effect on the myocardium. Reduces stroke volume. Onset of action after 20 sec. Duration of action 5 - 10 min.
3. Propofol (marketed as Diprivan by Astra Zeneca) is a derivative of phenol. Changes in heart rate are less pronounced than after thiopental. Often, however, patients taking beta - blockers are observed bradycardia. Propofol causes hypotension, which is causing a negative inotropic effect and a decrease in peripheral resistance. Onset of action after 15 - 45 sec. Duration of action 5 - 10 min.
4. Midazolam (marketed as Dormicum by Roche) - a water-soluble derivative of benzodiazepine. The action arises upon binding the drug to benzodiazepine receptors which enhance the inhibitory effect of GABA on the transfer of stimulus. The action of midazolam on the cardiovascular system is poorly expressed. Heart rate does not change or slightly increases. Myocardial contractility decreases slightly. Oxygen

consumption by heart muscle and blood flow don't change. Onset of action after 30 - 60 sec. Duration of action 15 - 30 min.

8. Monitoring depth of sedation

1. EEG (Narcotrend) - this device is an attempt to automatic analysis of EEG. Induction of anesthesia is characterized by a decrease of frequency and amplitude of EEG waves. With deepening anesthesia theta waves appear. Delta waves are characteristic of deep anesthesia. The next stage is the occurrence of burst supression until the abolition of the electrical activity of the brain characterized by the occurrence of isoelectric line.
2. BIS - bispectral index - includes data of bispectral and conventional EEG analysis. Unites the different EEG parameters into a whole by presenting the average value of diversified parameters of bioelectrical activity of the brain. BIS is an absolute number from 0 to 100, where 100 represents the state of vigilance, and 0 is an electric silence (tab.1). With values of BIS from 83 to 89 amnesia occurs, and with values from 64 to 72 - loss of consciousness.

BIS 100	the standby, preserved the memory
BIS 65- 80	sedation
BIS 40 – 65	moderate to profound loss of consciousness with amnesia recommended for general anesthesia
BIS < 40	coma

Table 1. The interpretation of the BIS value.

3. AEP - auditory evoked potentials - assess the electrical activity of the brain caused by an acoustic stimulus. The severity of the waves depends on the state of consciousness. The smallest is asleep. The patient before anesthesia is placed in the ear headphones, which emit a loud signal. The patient's skin as opposed to the measure by BIS should be prepared. Abrasive tape rubs calluses, as to produce a skin reaction in the form of browning.
4. Entropy of EEG - (Datex Ohmeda Entropy). Evaluation of depth of anesthesia consists of an analysis of two parameters: ST-state entropy - the value characteristic for the brain's electrical activity - EEG and RE - response entropy - includes EEG and electromyography of facial muscles. During deep anesthesia, these values didn't differ. Unexpected increase in RE in relation to the SE may be a sign of inadequate anesthesia.

Among these depth of sedation monitoring techniques, least time-consuming and the simplest for interpretation is the BIS. Enhanced monitoring of patients for testing the ICD provides a good opportunity to assess the quality of anesthesia, while you carefully assess the condition of patients wake up after surgery. This monitoring is particularly important in patients at increased risk of general anesthesia.

9. A study comparing etomidate, sodium thiopental and propofol[7]

From the data presented in the literature shows that thiopental and propofol should be used in people with heart disease with caution. On the other hand, studies conducted in patients treated with electrotherapy because of arrhythmia, demonstrated safety of these

anesthetics[8,9,10].We resigned from the use of etomidate because of the substantial degree of severe myoclonus which persisted even after waking patients, which is observed by Pacifico et al[11].Before our study thiopental and propofol was used in smaller doses (3 mg / kg and 1 mg / kg). Such proceedings require additional doses of medication between validation tests of the defibrillator-cardioverter. Determination of the dose of sodium thiopental 5 mg / kg and propofol 1.5 mg / kg allowed testing the ICD after a single dose in most patients. This has created a comfortable environment for staff and patients. Increasing the dose of drugs wasn't accompanied by an increased incidence of side effects such as apnea or prolonged time to recovery of full consciousness.

The study group comprised 50 patients in whom anesthesia was performed using propofol (27 patients) or thiopental (23 patients). Ejection Fraction (EF) was assessed before the treatment by echocardiography. Patients weren't premedication. Monitoring of the patient in the operating room included ECG, blood pressure by the indirect method, pulse oximetry and bispectral index (BIS). In the operating room was used passive oxygen therapy by mask with oxygen flow 6 l / min. Anesthesia for this procedure was intravenous anesthesia without intubation. For anesthesia was administered a single dose of propofol (1.5 mg/kg) or sodium thiopental (5 mg/kg) during 30 sec. Evaluation of the parameters was started after the administration of hypnotics.Statistical analysis was performed using Statistica 7.1 PL (StatSoft, Tulsa, USA).The results, depending on the nature of their distribution, verified by test W (Shapiro and Wilk) , presented as arithmetic mean (standard deviation) or median (range). To compare the data with normal distribution and comparable variances (Levene's test verification) was used T-test for independent variables, in the absence of homogeneity of variance was used T-test with separate variance estimation (Welch test). In cases of non-normality of variables, the comparison test was used Mann-Whitney test. Relationships between variables were tested using the R-Spearman's test of rank correlation. Adopted for significant p-value $p<0.05$.

10. Results

The results are shown in Table 2.

Parameter	Thiopental		Propofol		p
	Median	Range	Median	Range	
EF (%)	30	15–75	40	15–70	0,55
Loss of ciliary reflex (sec)	51	27-83	55	20-240	0,45
Ciliary reflex recovery time (sec)	315	123–776	440	214-660	0,0099
BIS output	98	94-99	98	89 –98	0,47
BIS minimum	38	23–76	42	32 –82	0,05
BIS minimum - time after the administration of medicines	93	50-312	140	54-570	0,04
BIS after waking	75	59-84	72	59-89	0,74
SpO_2 output	98	96–100	98	95-100	0,17
final SpO_2	98	97-100	98	95-100	0,9
Time from wake up to return to baseline BIS (sec)	397	181-841	253	122–549	0,0004
Final BIS	98	94–99	98	89-98	0,47

Table 2. Results of the variables studied.

EF ranged from 15 to 75% in both groups. The average age in both groups did not differ significantly. There was no difference in the disappearance of ciliary reflex in both groups (fig. 3), but its disappearance followed later in patients treated with propofol than in patients treated with thiopental (fig 4).

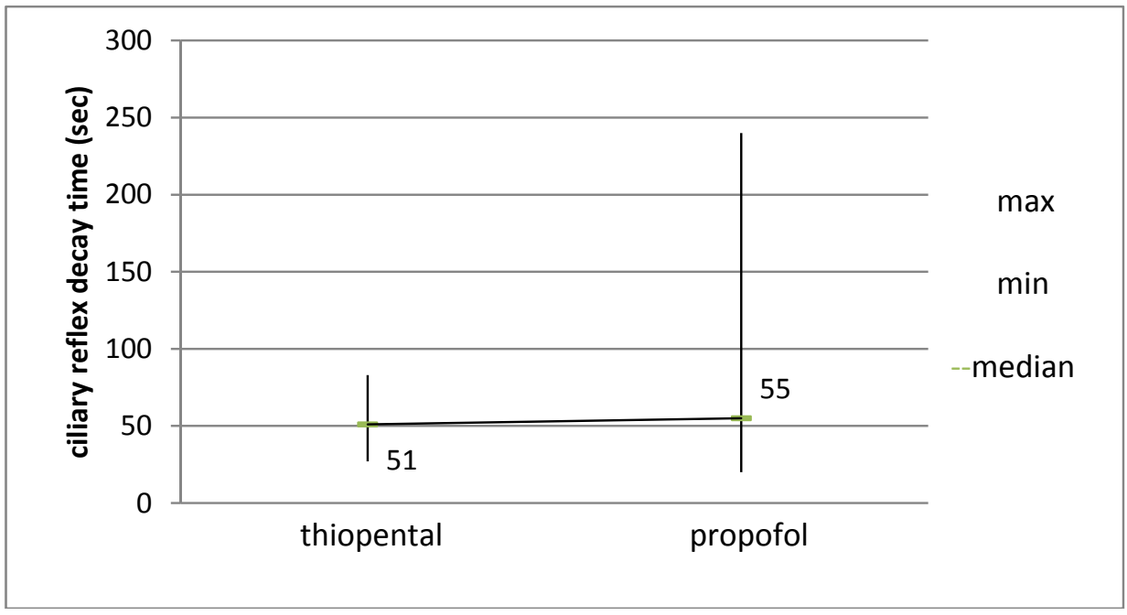


Fig. 3. Ciliary reflex decay time (sec).

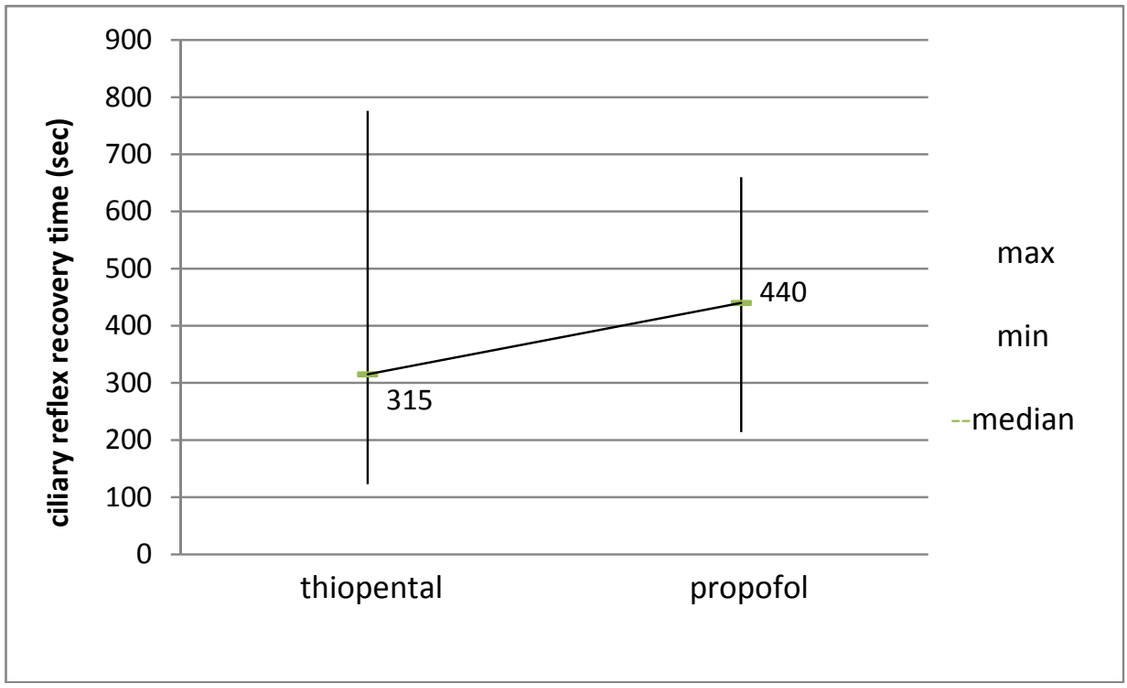


Fig. 4. Ciliary reflex recovery time (sec).

Output BIS values in both groups were identical. There was a significant statistical difference in the minimal BIS value, and the time, in which the minimal BIS was achieved. Minimum BIS values were lower in patients receiving thiopental than in patients receiving propofol (fig 5).

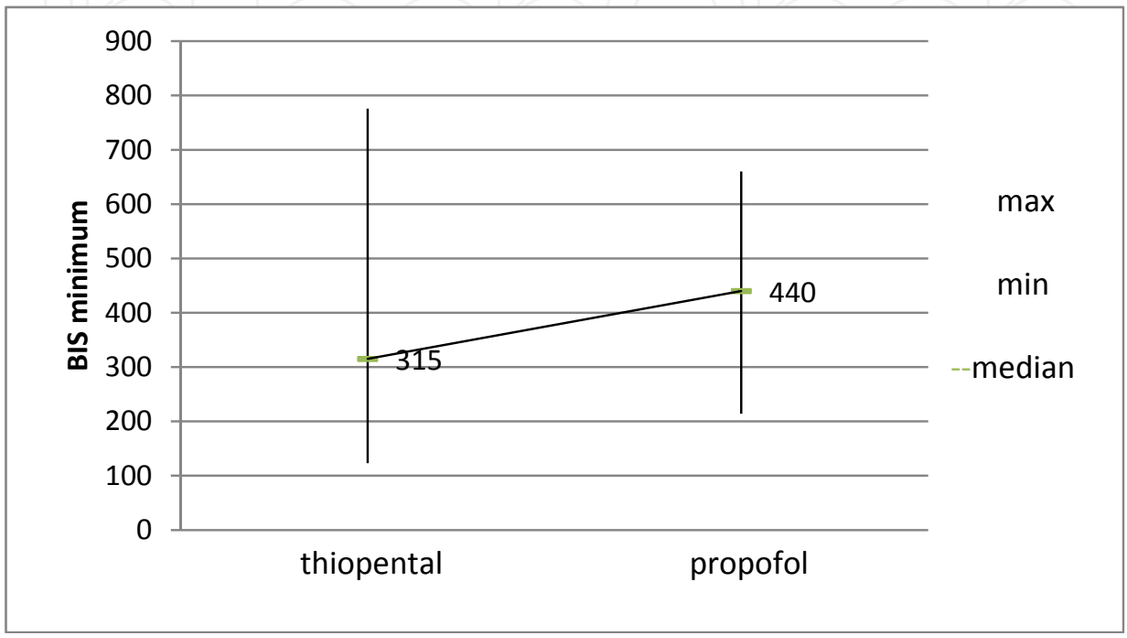


Fig. 5. BIS minimum.

BIS value at which managed to make verbal-logical contact with the patients were comparable in both groups (72 in patients receiving thiopental and 73 in patients receiving propofol). Only the time of return to baseline BIS, was differed in both groups. It was significantly shorter in patients receiving propofol than in patients receiving thiopental (fig. 6).

11. Discussion

Implantable cardioverter defibrillators are implanted under general anesthesia [12,13,14] or under local anesthesia [11,15]. Schematic procedure depends on the experience and standards of conduct [7]. For short-term cardiac procedures are recommended short-acting drugs, without the depressive effects on the cardiovascular system [11-15]. Clinical research comparing effects of etomidate, propofol and sodium thiopental, used for anesthetic during cardiac procedures didn't show any hemodynamic differences in these patients [8,9,10]. Data from the literature shows that sodium thiopental and propofol should be used in people with heart disease with caution. On the other hand, studies in patients treated with electrotherapy because of arrhythmia, demonstrated safety of these anesthetics [8,9,10].

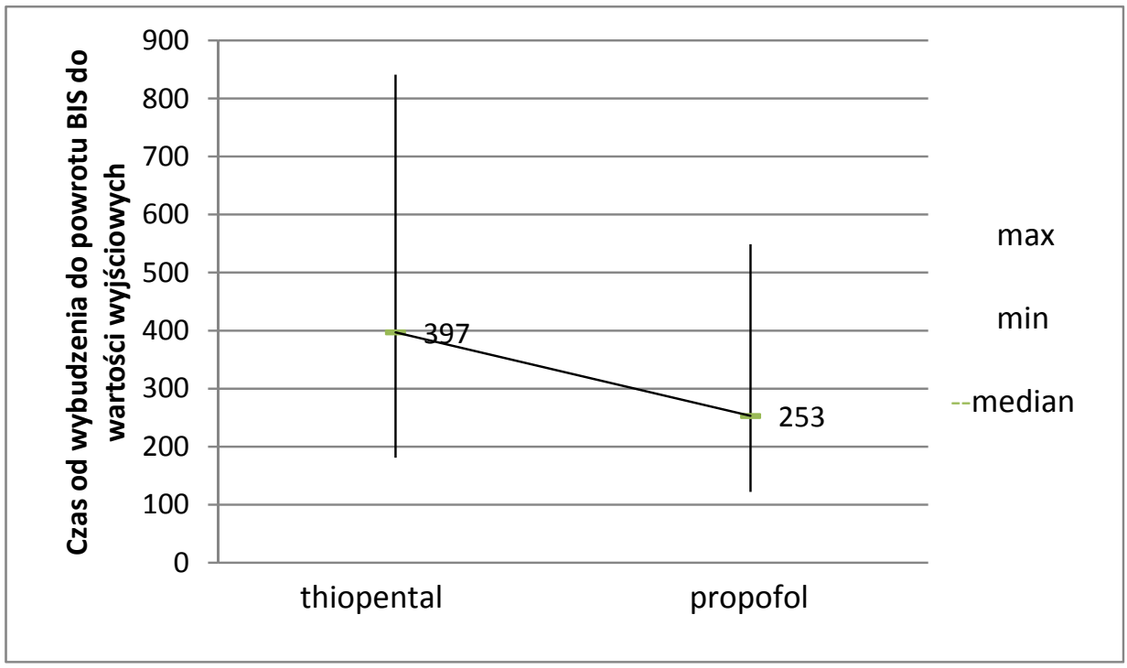


Fig. 6. Time of the return of baseline BIS.

During anesthesia, there was no reduction in oxygen saturation in patients receiving propofol and in patients receiving sodium thiopental. Monitoring depth of anesthesia was performed using the BIS [16]. The study of quality of sedation was made based on its evaluation. [16]. In our study we observed that BIS values before and after anesthesia were almost identical. We noticed a statistically significant difference in the values of the minimum BIS. In patients who received sodium thiopental, this value was lower than the minimum value of BIS in patients who received propofol. Time after which the BIS has reached the minimum value was shorter in patients treated with thiopental (93 s) than in patients who received propofol (140s). The value of the BIS prior to anesthesia (98 v 98) was identical to the value of BIS after anesthesia (98 v 98). Baker et al in their clinical research showed same[17]. Although the BIS value before and after anesthesia were identical, but the BIS value at which managed to make a verbal-logical contact with the sick was lower by 17.6% from baseline (72.4 v 73) in both groups.

Fall asleep time of patients assessed as ciliary reflex decay time didn,t differ significantly in both groups, as well as the time between drug administration and awake. However, BIS recovery time after waking up to pre-sedation value was significantly shorter in patients receiving propofol. This moment was considered the end of the sedation and the patient returned to the clinic of cardiology. Similar acted Baker et al [17]. Time since the recovery of verbal-logical contact with the patient until the return of BIS values to baseline was longer in

patients who received sodium thiopental (385 s) than in patients who received propofol. (253 s). Administration of each drug in a single dose was sufficient to realize the ICD tests. Shorter BIS recovery time shows greater utility of propofol than thiopental for use in the sedation to the ICD tests.

12. Conclusions

1. Propofol at a dose of 1.5 mg / kg and thiopental 5 mg / kg provide sufficiently deep sedation for defibrillator testing - cardioverter.
2. Shorter BIS recovery time in patients receiving propofol demonstrates the increased usefulness of this drug for sedation to the ICD tests.
3. Anesthesia for ICD test using thiopental or propofol is safe for patients with low ejection fraction.
4. During sedation with sodium thiopental and propofol, there was no significant hemodynamic differences in patients undergoing ICD tests.
5. BIS is the easiest ability to assess depth of anesthesia because of the ease of implementation and low invasiveness.

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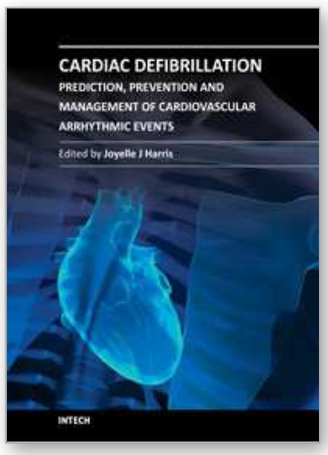

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Millions of people throughout the world currently depend on appropriate, timely shocks from implantable cardioverter defibrillators (ICDs) to avoid sudden death due to cardiovascular malfunctions. Therefore, information regarding the use, applications, and clinical relevance of ICDs is imperative for expanding the body of knowledge used to prevent and manage fatal cardiovascular behavior. As such, the apt and timely research contained in this book will prove both relevant to current ICD usage and valuable in helping advance ICD technology. This book is divided into three comprehensive sections in order to cover several areas of ICD research. The first section introduces defibrillator technology, discusses determinants for successful defibrillation, and explores assessments of patients who receive defibrillation. The next section talks about predicting, preventing, and managing near catastrophic cardiovascular events, and research presented in the final section examine special cases in ICD patients and explore information that can be learned through clinical trial examinations of patients with defibrillators. Each chapter of this book will help answer critical questions about ICDs.

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