IMPACT OF SUBPECTORAL IMPLANTATION OF THE IMPLANTABLE CARDIOVERTER DEFIBRILLATORS ON DEFIBRILLATION THRESHOLD

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ABSTRACT

Aims: the aim of this study is to find out the effect of subpectoral implantation of unipolar active case Implantable Cardioverter Defibrillators (ICD), on defibrillation threshold (DFT), compared to the conventional subcutaneous approach.

Methods: unipolar, active case ICDs were implanted subcutaneously in 7 patients (group I), and subpectoraly in another 7 patients (group II); all patients were diagnosed with ischemic cardiomyopathy. DFT, shock lead impedance, R wave amplitude, slew rate, pacing lead threshold and pacing lead impedance were compared between the two groups.

Results: DFT was significantly lower in group II, 14.8±5.5 vs 7.29±5.1 J (P=0. 017) in groups I and II respectively. Other parameters were comparable in the two groups. One patient with high DFT on subcutaneous ICD implantation showed an acceptable reduction of DFT when the device was implanted subpectoraly.

Conclusion: reduction in DFT with subpectoral implantation of ICDs is among the benefits of this approach, which is an easy and workable approach to high DFT patients.

Keywords: Implantable Cardioverter Defibrillator, Subpectoral Pocket, Defibrillation Threshold, Shock Lead Impedance.

INTRODUCTION

Over the past decade, Implantable Cardioverter Defibrillators (ICD) have become the standard of care for patients at risk for sudden cardiac death [1, 2]. ICD implantation has been shown to reduce absolute mortality by 8% in primary prevention recipients [3]In the same time there was a reduction of 7% in secondary prevention recipients [4]. Defibrillation Threshold (DFT) testing has traditionally been part of ICD implantation [5]. DFT is the minimum amount of energy required to reliably defibrillate the heart and represents one of the points of a patient's probability-of-success curve. It is determined by inducing ventricular arrhythmias often under deep sedation and allowing the ICD to detect and deliver therapy to terminate the arrhythmia. Although there have been reports suggesting that DFT testing does not predict survival or improve clinical outcomes in ICD recipients, there is no clear consensus about steering away from this convention [6, 7]. High DFT is defined as an absolute value of shock energy >25Joules (J) or a safety margin of <10J below the maximum output of the device. This is assessed by two successful shocks of same strength [8] and the reported incidence of high DFT is from 2 to 24%. Russo et al reported a 6.2% prevalence of high DFT (n=1139) [9] which was replicated in a separate study by Osswald and colleagues in a larger population (n= 2803) [10]. A high-implant DFT predicts an adverse prognosis, even when an adequate ICD safety margin is present [11]. During implantation of an ICD in a thin patient, for whom a subpectoral pocked was prepared, we noticed that the DFT was lower than usual. This observation was emphasized by a case report published recently [12]. The aim of this study is to prove that subpectoral implantation of the ICD generator can reduce the DFT, which help to extend the battery life and to deliver fewer shocks to the patient.

PATIENTS AND METHODS

The study population consists of 14 patients undergoing ICD implantation for standard clinical indications [13]. Written Informed consent was obtained from each patient. Each subject had a single coil defibrillation lead and an active left pectoral pulse generator according to our unit protocol [14]. Subcutaneous pre-pectoral pocket was used to implant the ICD in 7 patients, and subpectoral pocket was used in the remaining 7 patients.

Subpectoral Pocket preparation: a skin incision was made extending infromedial from the coracoid process of the scapula, and extended for 5 cm orthogonal to the deltopectoral groove. The subcutaneous tissue was dissected to the pectorals major muscle. A dissection plan was identified - between the clavicular and the sternal heads of the pectoralis major muscle- by a pad of fat (figure1). A medially directed blunt dissection was used to separate the two heads, avoiding the neuro-vascular bundle running on the lateral edge of the pectoralis minor muscle, the pocket was cleaned and hemostasis was performed. After implantation of the ICD generator the two heads of the pectoralis major were approximated by two non-absorbable sutures.

DFT testing was performed under conscious sedation with fentanyl and midazolam, before closure of the pocket. During testing, 12 surface electrocardiographic leads and simultaneous intracardiac electrograms were monitored continuously. Ventricular fibrillation was induced by means of a low energy shock delivered during the T wave. The coupling interval and shock strength were altered until ventricular fibrillation was induced. Ventricular fibrillation was defined as a chaotic rhythm on the surface electrocardiographic leads with irregular intracardiac electrograms at a mean cycle length <200 ms. All defibrillation shocks for study purposes were delivered through the ICD using default polarity (right ventricular coil as anode), biphasic waveforms with 50/50% tilts. If the initial defibrillation shock failed, a maximum output shock was delivered through the device, if the second shock failed; an external DC shock was delivered at 200 J biphasic. Sufficient time (>3 minutes) was allowed between trials for full hemodynamic recovery. Binary search algorithm was used for testing DFT [15], (figure2).

We compared patients with subcutaneous pocket (group I), to those with subpectoral pocket (group II) in DFT, shock lead impedance, R wave amplitude, slew rate, pacing lead threshold and pacing lead impedance.

Statistical methods: All data were analyzed using SPSS software statistical package for social science version 16 (SPSS, Inc. Chicago, IL, USA). Results were presented as mean value ± SD for continuous variables and as frequency (%) for categorical variables. Data were tested for normality using Kolmogorov-Smirnov test. Means were compared in independent groups using Student t-test or Mann-Whitney test.

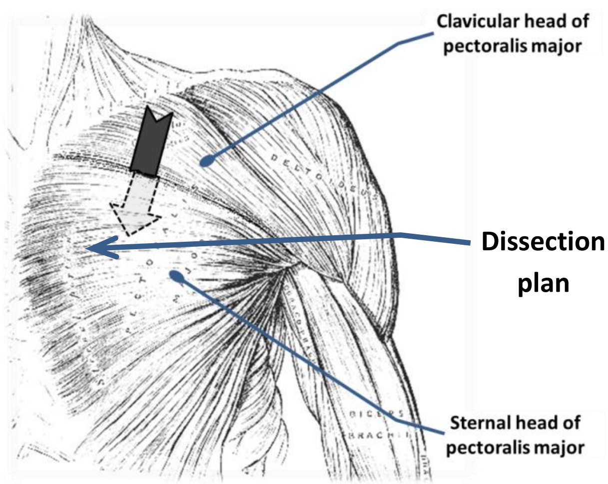


Figure 1: anatomical illustration of the anterior subpectoral approach. Modified by the author [16]

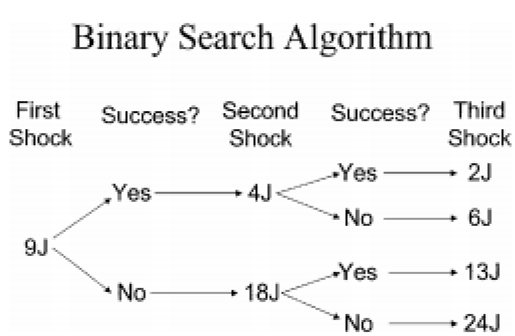


Figure 2: flow chart of the binary search algorithm used in DFT determination

RESULTS

Fourteen patients were included in the study, in the period from January 2012 and September 2013. Mean age in group I and group II were 62±4.3 and 59±4.5 years respectively (p=0.165). All patients were males except one female patient in group II. All patients were diagnosed with ischemic cardiomyopathy, under oral amiodaron and beta blockers treatment. The mean left ventricular ejection fraction (EF) was 0.42±0.06 and 0.39±0.06% in groups I and II respectively (P=0.33).

The two groups showed no significant difference in the test parameters, tables (1 and2) except for DFT which was significantly lower in group II 7.29±5.1 vs 14.8±5.5J in group I P=0.017. Shock lead impedance, R wave amplitude, slew rate, pacing threshold and pacing impedance were comparable in both groups. During the study one patient who was assigned to group I (patient number 12) showed an unacceptably high DFT>24J. When the ICD was implanted in a subpectoral pocket, the DFT threshold reduced to 18J.

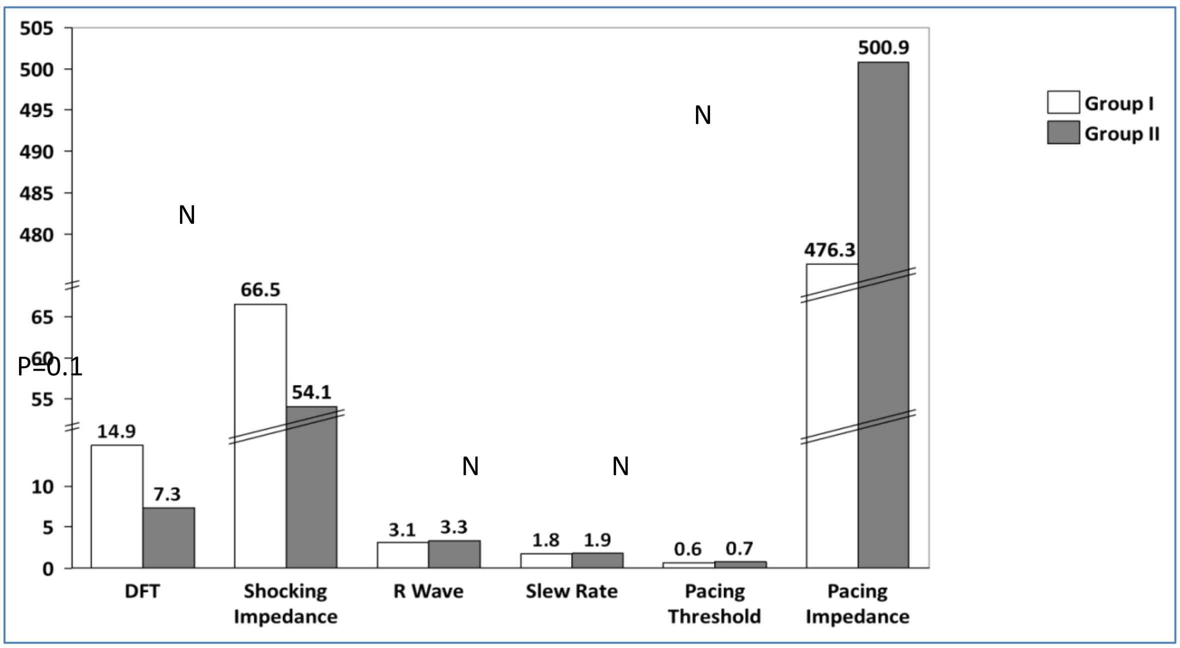
Table 1: demographic, clinical and intraoperative measures of all patients included in the study

number	age	sex	comorbidities	DFT	SL imp	R amp	slew	PL th	PL imp
Group I									
1	61	m	HTN	13	39.0	3.62	2.68	0.43	558
2	65	m	DM, AF	18	83.2	2.45	1.10	0.58	489
3	56	m		9	56.5	3.05	2.54	0.85	453
4	63	m	COPD	13	57.3	2.82	1.43	0.78	429
5	67	m	DM	9	54.3	3.75	1.12	0.56	452
6	68	m	AF	18	84.4	1.99	1.86	0.72	482
7	59	m	HTN, DM	24	90.7	4.11	1.53	0.35	468
mean	62.7			14.8	66.50	3.11	1.75	0.61	476.2
SD±	4.37			5.46	19.45	0.76	0.64	0.18	41.27
Group II									
8	55	m	HTN	6	50.4	2.4	3.4	1.0	436
9	64	m	COPD, AF	9	66.5	4.5	2.3	0.5	614
10	53	m		4	38.8	3.9	1.9	0.8	518
11	61	m	DM	4	45.6	2.6	1.2	0.8	640
12	63	m	COPD,HTN,DM	18	70.0	3.2	1.7	0.8	525
13	55	m		6	57.7	2.9	1.9	0.6	387
14	62	f	DM,AF	4	49.9	3.5	0.8	0.6	383
mean	59			7.29	54.12	3.27	1.86	0.73	500.87
SD±	4.5			5.06	11.26	0.74	0.84	0.19	103.30

SL imp: shock impedance
HTN: hypertension
R amp: R wave amplitude
DM: diabetes mellitus
PL th: pacing threshold
PL imp: pacing impedance

Table 2: Comparison of age and intraoperative measurements, of patients included in the study.

		Mean ±SD	U	P
age	Group I	62.7±4.3	13	0.165
	Group II	59±4.5		
DFT	Group I	14.8±5.5	6	0.017
	Group II	7.29±5.1		
shock lead impedance	Group I	66.5±19.5	15	0.259
	Group II	54.1±11.3		
R amplitude	Group I	3.11±0.76	22	0.805
	Group II	3.27±0.7		
slew rate	Group I	1.75±0.64	21	0.71
	Group II	1.9±0.8		
pacing threshold	Group I	0.61±0.18	14	0.209
	Group II	0.7±0.2		
pacing impedance	Group I	476.2±41.3	22	0.805
	Group II	500±103.3		



DISCUSSION

The first ICDs were implanted by opening the chest and placing wire mesh patches directly on the heart or pericardium in order to deliver a high energy shock. Epicardial pacing leads were also placed to sense the heart rate. Multiple approaches to placing the leads on the heart were developed. These included median sternotomy, lateral thoracotomy, sub-costal, sub-xyphoid, as well as combinations of these approaches with a transvenous endocardial lead for sensing and pacing the heart. Eventually nonthoracotomy transvenous systems were devised to eliminate the need for opening the chest. These required placing multiple leads in the right ventricle, superior vena cava, subclavian vein, inominate vein, and/or the coronary sinus. In many cases a subcutaneous patch or wire array were needed to provide effective therapy. The most advanced devices now combine the ease of using a single lead. That combines pacing, sensing and one or more high energy coils for shocking the heart. With an “active” or “hot” ICD case that acts as another shocking surface. This advanced hardware in combination with more efficient biphasic shock waveforms has allowed ICD implant to be performed in 30 minutes under local anesthesia [17].The pectoral unipolar ICD implantation is now the most commonly used approach, after extensive evaluation it appears to be the most feasible approach[18]. Subpectoral approach was previously popular, but now reserved for patients at risk of pocket erosion [19, 20], or for cosmetic reasons [21]. In addition to the safety, good cosmetic results and freedom from erosion, this approach was not tested as a solution for high DFT, except in case reports [12], as far as we know this is the first study comparing the DFT in subcutaneous and subpectoral unipolar ICD system implantation. It is expected that implantation of the active generator case subpectoral, will reduce the tissue bulk between the anode and the cathode, reducing the tissue impedance and at the same time reducing the DFT. The reduction in impedance was not demonstrable as the difference did not reach the statistical significance due to small sample size; in this case larger sample size is required to prove this assumption.

STUDY LIMITATIONS

Small sample size was a major limitation for this study. The low incidence of high DFT makes it difficult to study sufficient number of patients after subpectoral implantation. In this study we had one such patient.

CONCLUSION

In addition to many advantages of subpectoral implantation of ICDs, it is considered as an easy and feasible technique to solve the problem of high DFT.

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تاثير زراعة صادمات القلب الداخليه تحت عضلة الصدر علي عتبة ازالة الرجفان البطيني

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الهدف من الدراسة: بحث تاثير زراعة صادمات القلب الداخلية ذات القطب الواحد نشيطة الغلاف تحت عضلة الصدر علي عتبة ازالة الرجفان البطيني بالمقارنة بالمقاربة التقليديه لزراعتها تحت الجلد.
طرق البحث: تمت زراعة 7 صادمات تحت الجلد لعدد من المرضي (المجموعة الاولي) و 7 صادمات اخري تحت العضلة الصدرية لعدد اخر (المجموعة الثانية)، كان جميع المرضي يعانون من اعتلال عضلة القلب الاقفاري. تمت مقارنة كل من : عتبة ازالة الرجفان البطيني و مقاومة القطب الصادم و ارتفاع موجة آر و سرعة ارتفاع موجة آر و عتبة التنظيم و مقاومة القطب المنظم بين المجموعتين.
النتائج: كانت عتبة ازالة الرجفان البطيني اقل بصورة ملحوظة في الصادمات التي زرعت تحت عضلة الصدر 7.29 ±5.1 جول مقارنة بـ 14.8±5.5 جول للصادمات التي زرعت تحت الجلد، في حين كانت كل القياسات الاخري متقاربه، وقد تمكنا في اثناء الدراسة من معالجة مريض كلن يعاني من ارتفاع عتبة ازالة الرجفان وذلك بوضع الصادم الخاص به تحت عضلة الصدر بدلا من مكانه السابق تحت الجلد.
الاستنتاجات: ان تقليل عتبة ازالة الرجفان البطيني هو احد فوائد زرع الصادمات الكهربية الداخلية تحت عضلة الصدر، ويعتبر من المقاربات اليسيره والممكنه لعلاج ارتفاع هذه العتبه.