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Ocena możliwości stosowania podskórnego kardiowertera-defibrylatora u pacjentów wymagających stałej stymulacji serca

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Rozprawę dedykuję moim Rodzicom.

Spis treści

1. Wprowadzenie

Rozprawa doktorska pt. „Ocena możliwości stosowania podskórnego kardiowertera-defibrylatora u pacjentów wymagających stałej stymulacji serca” powstała w oparciu o monotematyczny cykl trzech artykułów opublikowanych w polskich czasopismach naukowych, indeksowanych w bazie PubMed.

1.1. Wykaz publikacji stanowiących rozprawę doktorską:

Tytuł publikacji, autorzy, tytuł czasopisma	Punkty MEiN	Impact Factor
Subcutaneous implantable cardioverter-defibrillators for the prevention of sudden cardiac death: five-year single-center experience. Maciej Kempa, Szymon Budrejko, Agnieszka Zienciuk-Krajka, Ludmiła Daniłowicz-Szymanowicz, Tomasz Królak, **Barbara Opielowska- Nowak**, Joanna Kwiatkowska, Grzegorz Raczak. Kardiol Pol. 2020 May 25;78(5):447-450. doi: 10.33963/KP.15235.	100	3,108
Eligibility of patients with temporarily paced rhythm for a subcutaneous implantable cardioverter-defibrillator **Barbara Opielowska-Nowak**, Maciej Kempa, Szymon Budrejko, Grzegorz Sławiński, Grzegorz Raczak Kardiol Pol 2022;80(12):1231-1237. doi: 10.33963/KP.a 2022.0205.	100	3,710
A survey study of the use of a subcutaneous implantable cardioverter-defibrillator in various clinical scenarios by expert electrophysiologists in Poland. Maciej Kempa, **Barbara Opielowska-Nowak**, Szymon Budrejko, Grzegorz Raczak.	100	3,487

Cardiol J. 2022 Aug 17. doi: 10.5603/CJ.a2022.0073. Online ahead of print. PMID: 35975797		
Podsumowanie punktów	300	10,305

1.2. Wykaz publikacji, które nie zostały włączone do rozprawy doktorskiej:

Tytuł publikacji, autorzy, tytuł czasopisma	Punkty MEiN	Impact Factor
Advantages, limitations and new perspectives on the implantation of subcutaneous cardioverter-defibrillator. **Barbara Opielowska-Nowak**, Grzegorz Raczak, Martyna Badyoczek European Journal of Translational Clinical Medicine.2022;5(2):53-56 DOI:10.31373/ejtcm/156835	40	
100 km run does not induce persistent predominance of sympathetic activity during 24-hour recovery in amateur male athlets. Ludmiła Daniłowicz-Szymanowicz, Małgorata Szwoch, Wojciech Ratkowski, Piotr Gutknecht, Paweł Zagożdżon, **Barbara Opielowska-Nowak**, Zbigniew Jastrzebski, Grzegorz Raczak Hellenic Journal of Cardiology 2015 May-June,56(3):271-2. PMID: 26021254.	40	5,795
Dwukomorowa stymulacja resynchronizująca: analiza czynników wpływających na pozytywną odpowiedź na leczenie w świetle wytycznych ESC/PTK z 2013 roku. **Barbara Opielowska-Nowak**, Ewa Lewicka, Alicja Dąbrowska-Kugacka Folia Cardiologica 2015;10(3):165-171.		

Streszczenie zjazdowe:

Opielowska-Nowak B, Budrejko S, Sławiński G, Raczak G, Kempa M. Zastosowanie podskórnego kardiowertera-defibrylatora u pacjentów wymagających stałej stymulacji serca - czy to bezpieczne? In POLSTIM 2022: XXXIII Konferencja Sekcji Rytmu Serca Polskiego Towarzystwa Kardiologicznego, Katowice, 19-21 maja 2022 r: program. 2022. p. 34–35.

2. Alfabetyczny wykaz używanych skrótów:

ATP - *antytachycardia pacing*/ stymulacja antyarytmiczna

CIEDs - *cardiac implantable electronic devices*/ wszczepialne urządzenia do elektoterapii serca

CRT - *cardiac resynchronization therapy*/ terapia resynchronizująca

EKG - elektrokardiogram

ESC - *European Society of Cardiology* / Europejskie Towarzystwo Kardiologiczne

FDA - *Food and Drug Administration* / Agencji Żywności i Leków

IAS - *inappropriate shocks* / nieadekwatne interwencje wysokoenergetyczne

ICD - *implantable cardioverter-defibrillator* / wszczepialny kardiowerter-defibrylator

SCD - *sudden cardiac death* / nagły zgon sercowy

S-ICD - *subcutaneous cardioverter - defibrillator* / podskórny kardiowerter-defibrylator

T-ICD- *transvenous cardioverter-defibrillator*/ przezżylny kardiowerter defibrylator

3. Wstęp

Nagły zgon sercowy (Sudden Cardiac Death - SCD) w przebiegu arytmii komorowych stanowi 20% pośród wszystkich przyczyn zgonów w populacji krajów zachodnich. [1] Pod koniec pierwszej dekady XXI wieku wśród urządzeń zapobiegających SCD znalazł zastosowanie podskórny kardiowerter - defibrylator (subcoutaneous cardioverter-defibrillator - S-ICD) jako alternatywa dla przezżylnych układów defibrylujących (transvenous cardioverter-defibrillator – T-ICD). W 2012r. urządzenie uzyskało akceptację amerykańskiej Agencji Żywności i Leków (Food and Drug Administration – FDA). [2] Pierwsze implantacje podskórnego kardiowertera defibrylatora w Polsce miały miejsce w 2014 r. w Szpitalu im. Sterlinga w Łodzi oraz w Klinice Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego. [3]

Po raz pierwszy oficjalne zalecenia dotyczące implantacji S-ICD zostały opublikowane w wytycznych Europejskiego Towarzystwa Kardiologicznego (European Society of Cardiology – ESC) w 2014r. [4] Dopuszczono w nich wszczepianie urządzenia u pacjentów z kardiomiopatią przerostową, którzy kwalifikują się do implantacji kardiowertera-defibrylatora a jednocześnie nie posiadają wskazań do stałej stymulacji (klasa wskazań IIb). W 2015 r. implantacja S-ICD zyskała rangę zaleceń w klasie IIa jako alternatywa dla implantacji T-ICD u wszystkich pacjentów mających wskazania, którzy nie wymagają stałej stymulacji, w tym również stymulacji resynchronizującej (cardiac resynchronization therapy – CRT) ani terapii antytachyarytmicznej (antytachycardia pacing - ATP) [5] Wskazania te utrzymano na tym samym poziomie w wytycznych ESC z bieżącego roku. [6] Brak konieczności implantacji elektrody przezżylnej jest optymalną opcją dla pacjentów z utrudnionym dostępem naczyniowym, zwłaszcza u chorych z anomaliami naczyniowymi, z zakrzepicą żylną, z powikłaniami po elektroterapii w wywiadzie (przebyty zabieg usunięcia elektrod, uszkodzenia elektrod) lub obarczonych wysokim ryzykiem odelektrodowego zapalenia wsierdzia (pacjenci przewlekle dializowani lub poddani terapii immunosupresyjnej). Dla takiej grupy chorych według amerykańskich wytycznych z 2017r. S-ICD pozostaje w I klasie zaleceń. [7] S-ICD również dedykowany jest młodym pacjentom z wrodzonymi wadami serca, zagrożonymi nagłym zgonem sercowym w przebiegu komorowych zaburzeń rytmu. W tej grupie pacjentów ze względu na spodziewany długi czas życia istnieje wysokie ryzyko uszkodzenia elektrod układu przezżylnego lub odelektrodowych infekcji

wewnątrzsercowych (klasa wskazań IIb). [5]

Współczesny S-ICD waży 130g i ma 60 cm3 objętości. Elektroda defibrylująca składa się z dwóch pierścieni sterujących, pomiędzy którymi umieszczony jest pierścień defibrylujący o długości 8 cm. Zabieg wszczepienia przeprowadza się w warunkach sali operacyjnej najczęściej w znieczuleniu ogólnym. Obecnie procedurę wykonuje się zwykle metodą 2 cięć. Pierwsze cięcie w linii pachowej przedniej w 5-6 przestrzeni międzyżebrowej po stronie lewej. Pod mięśniem najszerszym grzbietu wytwarzana jest następnie loża dla defibrylatora, w której umieszcza się urządzenie. W następnym etapie elektrodę defibrylującą tunelizuje się podskórnie od loży defibrylatora w kierunku wyrostka mieczykowatego i tu mocuje szwem - drugie cięcie. Część dystalną elektrody układa się podskórnie wzdłuż lewej krawędzi mostka. Aktualnie nie wykonuje się rutynowo trzeciego cięcia w okolicy wcięcia mostka. W trakcie zabiegu praktycznie nie wykorzystuje się aparatury rentgenowskiej. Zastosowanie znajduje tylko krótkotrwała fluoroskopia podczas wstępnego ustalenia położenia elektrody, korpusu urządzenia i lokalizacji punktów anatomicznych do wykonania prawidłowych nacięć. Po implantacji, w przypadku braku przeciwwskazań, wykonuje się test defibrylacji pojedynczym impulsem wysokoenergetycznym o energii 65J. W razie nieskuteczności defibrylacji automatycznie następuje powtórne wyładowanie wysokoenergetyczne impulsem o wyższej energii - 80J. Nieprawidłowa lokalizacja elektrody i korpusu urządzenia w stosunku do serca oraz zbyt wysoki opór defibrylacji należą do najczęstszych przyczyn nieskutecznej terapii. Wiąże się to często ze zbyt płytką lokalizacją układu S-ICD względem powierzchni skóry, gdyż tkanka tłuszczowa znajdująca się wtedy pod elektrodą i korpusem urządzenia znacznie zwiększa opór defibrylacji [8,9].

Rozpoznanie arytmii przez urządzenie odbywa się za pomocą analizy zapisu potencjałów elektrycznych z powierzchni klatki piersiowej z wykorzystaniem jednego z trzech wektorów: pierwszy (primary) - pomiędzy dolnym pierścieniem na elektrodzie a korpusem urządzenia, drugi (secondary) - pomiędzy górnym pierścieniem a urządzeniem, trzeci (alternate) - pomiędzy pierścieniami na elektrodzie bez udziału korpusu urządzenia. Warunkiem prawidłowego działania urządzenia jest odpowiednia jakość uzyskanych sygnałów elektrycznych serca. W tym celu w ramach kwalifikacji do implantacji S-ICD należy wykonać tzw. screening, aby potwierdzić prawidłowe rozpoznawanie arytmii w przyszłości. Wykonuje się go za pomocą programatora producenta systemu. Badanie

polega na rejestracji i analizie zapisu EKG z powierzchni klatki piersiowej z odprowadzeń analogicznych do przyszłego umiejscowienia elektrody i korpusu defibrylatora. Przynajmniej jedno z trzech analizowanych odprowadzeń powinno zostać zaakceptowane do późniejszego zastosowania w implantowanym S-ICD, zaprogramowane bowiem urządzenie nie ma możliwości automatycznej zmiany wybranego odprowadzenia. W trakcie screeningu do podstawowych parametrów podlegających analizie należą: woltaż, morfologia oraz wzajemny stosunek załamków R i T. Po implantacji w przypadku rozpoznania arytmii komorowej urządzenie dostarcza wyładowanie wysokoenergetyczne o energii 80J. Podczas pojedynczego epizodu arytmii istnieje możliwość dostarczenia maksymalnie 5 wyładowań [10].

Głównym ograniczeniem S-ICD pozostaje brak możliwości prowadzenia przez urządzenie stałej stymulacji serca, zarówno w przypadku bradykardii jak i stymulacji typu ATP. Potrzeba takiej stymulacji stanowi wręcz przeciwwskazanie do implantacji. Istnieją jednak sytuacje kliniczne, kiedy podczas początkowej kwalifikacji do wszczepienia podskórnego defibrylatora u danego pacjenta nie występowała konieczność stałej stymulacji, co zdecydowało o zastosowaniu urządzenia, a wskazania do jej rozpoczęcia pojawiły się w okresie późniejszym, już po implantacji układu. Podobnie może zaistnieć sytuacja, kiedy to chory z implantowanym pierwotnie stymulatorem serca nabywa wskazań do wszczepienia ICD. W obu przypadkach zastosować można jednocześnie S-ICD i stymulator. Pozostaje to rozwiązaniem alternatywnym dla usunięcia wcześniej implantowanego elektronicznego urządzenia (cardiac implantable electronic device - CIED) i wszczepienia przezżylnego kardiowertera-defibrylatora mającego standardowo opcję stałej stymulacji. Jednak zabieg usuwania wcześniej wszczepionych CIED jest obarczony ryzykiem istotnych powikłań i z tego powodu opcja doszczepienia drugiego urządzenia wydaje się być korzystna. Zachodzi jednak wątpliwość czy zmiana morfologii zespołów QRS podczas stałej stymulacji nie spowoduje zaburzeń sterowania S-ICD.

Dane z piśmiennictwa na temat jednoczesnego stosowania układów stymulujących i S-ICD są ograniczone, choć nie wykluczają takiego postępowania [11,12,13]. Brak jest także zaleceń wskazujących czy korzystniej jest, w razie potrzeby, doszczepić drugie urządzenie danemu choremu czy usunąć dotychczasowe i implantować przezżylny defibrylator z opcją potrzebnej stymulacji. Brak danych uzasadnia prowadzenie badań, a uzyskane wyniki mogą ułatwić podejmowanie decyzji terapeutycznych w przedstawionej sytuacji klinicznej.

Jako że w populacji pacjentów leczonych za pomocą S-ICD w Klinice Kardiologii

i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego także wystąpiła sytuacja konieczności prowadzenia jednoczesnej stałej stymulacji serca, postanowiłam przeanalizować częstość występowania takiej potrzeby oraz efekty jednoczesnego stosowania S-ICD i stymulatora serca. Ponadto postanowiłam zbadać możliwości bezpiecznego stosowania S-ICD u pacjentów uprzednio poddanych implantacji stymulatora serca a także przeanalizować jak potencjalna konieczność stosowania obu urządzeń jest rozwiązywana we wiodących ośrodkach elektroterapii w Polsce.

4. Cele pracy

1. Ocena wyników stosowania S-ICD w jednoośrodkowej obserwacji z uwzględnieniem rezultatów jednoczesnego stosowania systemu S-ICD i stymulatora serca.

2. Ocena możliwości zastosowania S-ICD u pacjentów wymagających stałej stymulacji komorowej.

3. Uzyskanie opinii i poznanie preferencji dotyczących możliwości implantacji S-ICD u pacjentów wymagających stałej stymulacji komorowej wśród polskich ekspertów elektroterapii z ośrodków referencyjnych.

5. Metodyka

5.1. Populacja badana

W **pierwszej pracy oryginalnej** przeanalizowano dane wszystkich pacjentów hospitalizowanych w Klinice Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego w latach 2014-2019 poddanych implantacji S-ICD.

Dokonano analizy populacji pod względem wieku, płci, wskazań do implantacji, etiologii schorzenia podstawowego oraz powikłań w okresie 5 lat obserwacji. Analizowano rodzaj powikłań okołooperacyjnych oraz ilość adekwatnych i nieadekwatnych interwencji S-ICD. Szczegółowo przeanalizowano przypadki pacjentów leczonych jednocześnie za pomocą S-ICD oraz stymulatora serca. Oceniono zaburzenia sterowania wynikające ze współistnienia dwóch urządzeń wszczepialnych. Analizowane zdarzenia zostały szczegółowo scharakteryzowane.

W **drugiej pracy oryginalnej** badaną populacją była grupa 100 pacjentów hospitalizowanych w Klinice Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego z implantowanymi urządzeniami umożliwiającymi stymulację komorową. W grupie badanej wykonywano screening S-ICD podczas rytmu własnego i w trakcie stymulacji komorowej. Na tej podstawie oceniono możliwość jednoczesnego zastosowania defibrylatora podskórnego i stymulatora serca. Analizowane parametry zostały szczegółowo scharakteryzowane. Protokół badań został zatwierdzony przez Niezależną Komisję Bioetyczną do Spraw Badań Naukowych przy Gdańskim Uniwersytecie Medycznym (NKBBN//44/2018).

W **trzeciej pracy oryginalnej** do badania włączono grupę 30 polskich ekspertów w dziedzinie elektroterapii z doświadczeniem w implantacji S-ICD. Została ona powołana z osób biorących aktywny udział w tworzeniu rejestru implantacji S-ICD prowadzonego przez Sekcję Rytmu Serca Polskiego Towarzystwa Kardiologicznego. Eksperci zostali zaproszeni do wzięcia udziału w anonimowej ankiecie prowadzonej elektronicznie. Pytania w ankiecie dotyczyły ewentualnego postępowania w różnych sytuacjach klinicznych z uwzględnieniem konieczności jednoczesnego stosowania S-ICD i stymulatora serca. Kompletna lista pytań i odpowiedzi została zawarta w załączniku do publikacji.

5.2. Analizy statystyczne

Praca oryginalna nr 1 - Do analizy danych zastosowano opisowe metody statystyczne.

Praca oryginalna nr 2 - Zmienne ciągłe przedstawiono jako średnią i odchylenie standardowe lub medianę i rozstęp międzykwartylowy w przypadku rozkładu innego niż normalny. Zmienne jakościowe przedstawiono w postaci liczbowej i procentowej. W celu sprawdzenia normalności rozkładu zmiennych wykorzystano test W Shapiro-Wilka. Do porównania grup zastosowano odpowiednio dla danej zmiennej test $\chi 2$, test t-Studenta lub test U Manna-Whitneya (w zależności od analizy rozkładu i wariancji). Wartość p poniżej 0,05 uznano za istotną statystycznie. Analizy statystyczne zostały przeprowadzone z użyciem oprogramowania Microsoft Excel i Statistica 13.1 (TIBCO Software, Palo Alto, CA, US).

Praca oryginalna nr 3 - Analizy statystyczne zostały przeprowadzone z użyciem oprogramowania Microsoft Excel i opisane za pomocą procentów i wskaźników.

6.Wyniki i omówienie poszczególnych prac dysertacji.

6.1. Omówienie pracy oryginalnej nr 1

Maciej Kempa, Szymon Budrejko, Agnieszka Zienciuk-Krajka, Ludmiła Daniłowicz-Szymanowicz, Tomasz Królak, **Barbara Opielowska- Nowak**, Joanna Kwiatkowska, Grzegorz Raczak. *"Subcutaneous implantable cardioverter-defibrillators for the prevention of sudden cardiac death: five-year single-center experience".* Kardiol. Pol. 2020 May 25;78(5):447-450. doi: 10.33963/KP.15235. (punkty: Impact Factor -3,108; MEiN - 100)

W pracy przedstawiono 5 letnie doświadczenie związane z implantacją S-ICD w Klinice Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego. Poddano ocenie grupę wszystkich 25 pacjentów w tym 13 kobiet i 12 mężczyzn. Analizowano: dane demograficzne, kliniczne wskazania do implantacji, etiologię schorzenia, stopień upośledzenia funkcji skurczowej lewej komory serca, sposób wytworzenia loży dla generatora impulsów, występowanie powikłań chirurgicznych, wyniki przeprowadzonych testów defibrylacji, występowanie adekwatnych i nieadekwatnych interwencji wysokoenergetycznych (inappropriate shocks - IAS). Szczegółowo przedstawiono przypadki 2 pacjentów, którzy poza S-ICD implantowane mieli stymulatory serca. U tych właśnie chorych za wystąpienie IAS były odpowiedzialne zaburzenia sterowania S-ICD spowodowane stałą stymulacją. U pierwszego pacjenta z implantowanym stymulatorem serca za możliwą przyczynę IAS przyjęto zmienną morfologię załamka R podczas stymulacji komorowej. Zmiana ustawień stymulatora, a także próby zmiany parametrów detekcji S-ICD nie pozwoliły na rozwiązanie problemu. Ostatecznie z powodu poprawy funkcji skurczowej lewej komory i braku dalszych wskazań w prewencji pierwotnej SCD pacjentowi wyłączono S-ICD. W drugim przypadku obserwowano wystąpienie IAS u pacjenta ze stymulatorem DDD w trakcie stymulacji przedsionkowej. Wynikało to z nakładania się wystymulowanego załamka P na załamek T w przebiegu bloku przedsionkowo-komorowego I st. i jego nieprawidłowej detekcji przez S-ICD. W tym przypadku po przeprogramowaniu parametrów stymulacji i sterowania nie obserwowano więcej nieadekwatnych interwencji wysokoenergetycznych.

W podsumowaniu pracy oryginalnej podkreślić należy, że:

- Aktualne zalecenia wskazują, że konieczność stałej stymulacji serca stanowi przeciwwskazanie do implantacji S-ICD. Prawdopodobne jednak jest, że część pacjentów rozwinie wskazania do stymulacji już po implantacji podskórnego kardiowertera - defibrytora.

- W grupie badanych implantacja S-ICD w 2 przypadkach dotyczyła pacjentów z wcześniej implantowanymi układami stymulującymi. Była to jedyna możliwa terapia wobec istniejących przeciwwskazań do implantacji wewnątrzjamowej elektrody defibrylującej.

- Żaden z pozostałych pacjentów po implantacji S-ICD nie nabył w trakcie obserwacji wskazań do stymulacji serca.

Zaburzenia sterowania S-ICD i wynikające z tego nieadekwatne interwencje wysokoenergetyczne, związane ze współistnieniem defibrylatora i stymulatora serca stały się przyczyną dalszych badań nad możliwością jednoczesnego stosowania obu urządzeń u tego samego pacjenta.

6.2. Omówienie pracy oryginalnej nr 2

Barbara Opielowska-Nowak, Maciej Kempa, Szymon Budrejko, Grzegorz Sławińsk, Grzegorz Raczak "*Eligibility of patients with temporarily paced rhythm for a subcutaneous implantable cardioverter-defibrillator"* Kardiol Pol 2022;80(12):1231-1237. doi: 10.33963/KP.a 2022.0205.
(punkty: Impact Factor - 3,710; MEiN - 100)

W pracy oceniano wpływ stałej stymulacji komorowej na morfologię zespołu QRS i wynikające z tego zmiany wyniku screeningu wskazującego na możliwość zastosowania S-ICD jednocześnie ze stymulatorem serca.

W grupie kolejnych 100 pacjentów, poddanych implantacji CIEDs w Klinice Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego, wykonano screening S-ICD podczas zapisu rytmu własnego oraz w trakcie stymulacji komorowej. Pozytywny wynik screeningu podczas zapisu rytmu własnego w zakresie przynajmniej jednego analizowanego wektora (tego samego w pozycji leżącej i stojącej) uzyskano u 80% pacjentów a w przypadku dwóch wektorów - u 59% pacjentów. Przeprowadzenie natomiast badania podczas stymulacji komorowej dało zaskakujące rezultaty. Pozytywny bowiem wynik screeningu podczas rytmu stymulowanego przynajmniej w zakresie jednego wektora uzyskano zaledwie u 36% pacjentów a w przypadku dwóch wektorów tylko u 15% pacjentów. W kolejnym etapie oceniono w jakiej grupie pacjentów zarejestrowano co najmniej jeden akceptowalny i ten sam wektor podczas analizy rytmu własnego i stymulowanego. Okazało się, że wynik taki uzyskano u 23 % pacjentów. Co najmniej 2 te same akceptowalne wektory rejestrowano już tylko u 8% pacjentów. A zatem grupa chorych, u których możliwe byłoby zastosowanie S-ICD jednocześnie ze stymulatorem serca okazała się bardzo mała i liczyła 23 osoby ze 100 pierwotnie badanych.

W podsumowaniu pracy oryginalnej należy podkreślić, że:

- Zastosowanie podskórnego kardiowertera-defibrylatora u pacjentów ze stymulacją komorową związane jest z wysokim ryzykiem wstąpienia zaburzeń sterowania S-ICD. Dotyczy to głównie pacjentów, u których występuje naprzemiennie rytm własny i stymulacja komorowa.
- W przypadku, gdy pierwszym urządzeniem implantowanym jest stymulator, ocena ryzyka zaburzeń sterowania przed planowanym zastosowaniem S-ICD jest możliwa. Wymaga to wykonania screeningu zarówno podczas rytmu własnego jak i podczas stymulacji komorowej.
- W sytuacji, gdy pierwszym implantowanym urządzeniem jest S-ICD, bardzo trudno przewidzieć ryzyko wystąpienia zburzeń sterowania, ponieważ praktycznie nie jest możliwe wykonanie screeningu podczas stymulacji komorowej przed implantacją stymulatora.
- Ryzyko przedstawionego zjawiska powinno być brane pod uwagę przy kwalifikacji pacjentów do jednoczesnego stosowania S-ICD i stymulatora serca.

Uzyskane wyniki wskazujące na istotny problem jakim jest stosowanie stałej stymulacji serca u osób zabezpieczonych S-ICD skłoniły mnie do próby oceny jak w przypadku takiej potrzeby postępują polscy eksperci w dziedzinie elektroterapii w innych ośrodkach referencyjnych.

6.3 Omówienie pracy oryginalnej nr 3

Maciej Kempa, **Barbara Opielowska-Nowak**, Szymon Budrejko, Grzegorz Raczak. *"A survey study of the use of a subcutaneous implantable cardioverter-defibrillator in various clinical scenarios by expert electrophysiologists in Poland"*. Cardiol J. 2022 Aug 17. doi: 10.5603/CJ.a2022.0073. Online ahead of print. PMID: 35975797
(punkty: Impact Factor -3,487; MEiN - 100)

Artykuł prezentuje zebrane, anonimowe opinie polskich ekspertów w dziedzinie elektroterapii, doświadczonych w implantacji zarówno T-ICD jak i S-ICD dotyczące postępowania medycznego w hipotetycznych sytuacjach klinicznych. Do ankietowanych przesłano fikcyjne scenariusze kliniczne związane z potencjalnym wszczepieniem S-ICD. Głównym przedmiotem zainteresowania były opinie ekspertów dotyczące implantacji S-ICD chorym z układem stymulującym bądź doszczepienia rozrusznika do implantowanego wcześniej S-ICD. Pytania w anonimowej ankiecie dotyczyły również proponowanej terapii w innych sytuacjach klinicznych uwzględniając takie zagadnienia jak: pierwotną vs wtórną prewencję SCD, decyzje w zależności od wieku i wagi ciała pacjentów, a także podłoża zaburzeń rytmu i historii prowadzonego wcześniej leczenia a także przebytych powikłań elektroterapii.

Wśród 30 zaproszonych ekspertów reprezentujących 18 ośrodków klinicznych, 25 ostatecznie wypełniło ankietę. Wyniki wskazują, że w przypadku nabycia wskazań do stałej stymulacji przez pacjentów z uprzednio implantowanym S-ICD, respondenci podejmowali decyzję łączenia obu urządzeń wszczepialnych w zależności od wymaganego rodzaju stymulatora. I tak 56% ekspertów skłaniało się bardziej do doszczepienia stymulatora jednojamowego do działającego S-ICD niż do usunięcia S-ICD i zastąpienia go układem przezżylnym z opcją stymulacji. Odsetek ankietowanych preferujących współistnienie dwóch urządzeń malał wraz ze zwiększeniem stopnia skomplikowania koniecznego układu stymulującego i tym samym ilości implantowanych elektrod. Tylko 44% z nich opowiedziało się za doszczepieniem stymulatora dwujamowego a 32% za implantacją CRT do działającego już S-ICD. W sytuacji odwrotnej, kiedy wskazania do wszczepienia defibrylatora pojawiają się u pacjentów po implantacji stymulatora, większość badanych skłaniała się do usunięcia dotychczasowego stymulatora i zastąpienia go T-ICD zamiast do doszczepienia S-ICD

do istniejącego układu stymulującego. Takie rozwiązanie zaproponowało 68% badanych w przypadku stymulującego układu jednojamowego i 72% w sytuacji istnienia układów wieloelektrodowych. Z uwagi na potencjalne ryzyko związane z przezżylnym usuwaniem elektrod, powyższe opinie ekspertów są pewnym zaskoczeniem. W przypadku planowania doszczepienia S-ICD do istniejącego stymulatora, możliwe jest wykonanie screeningu podczas rytmu stymulowanego. Pozytywny screening umożliwia doszczepienie S-ICD z dużą szansą prawidłowego sterowania podczas stymulacji komorowej. W sytuacji odwrotnej, gdy planowana jest implantacja stymulatora choremu z S-ICD, istnieje wysokie ryzyko wystąpienia zaburzeń sterowania i nieadekwatnych interwencji związanych ze zmianami morfologii zespołu QRS podczas rytmu własnego i stymulowanego. Podobne przypadki były już opisywane. [14] Uzyskane opinie polskich ekspertów zestawiono z dostępnymi w piśmiennictwie danymi z ośrodków europejskich. Zaobserwowano istotne różnice. Eksperci z Francji preferują usunięcie S-ICD i zastąpienie go T-ICD w przypadku konieczności stałej stymulacji komorowej. Natomiast u pacjentów posiadających stymulator, większość ankietowanych przychylała się do doszczepienia S-ICD w przypadku konieczności, aniżeli do usuwania układu stymulującego i zastępowania go T-ICD [15].

Podsumowując wyniki przedstawionej pracy oryginalnej, należy podkreślić, że:

- Wyniki przeprowadzonej ankiety wykazują istotne różnice pomiędzy opiniami polskich ekspertów dotyczącymi implantacji podskórnego kardiowertera - defibrylatora w tych samych sytuacjach klinicznych.

- Przy nabyciu wskazań do prewencji SCD u pacjentów z wcześniej implantowanym stymulatorem, większość badanych skłaniała się do usunięcia stymulatora i zastąpienia go T-ICD zamiast do doszczepienia S-ICD do istniejącego układu stymulującego.

- W przypadku nabycia wskazań do stałej stymulacji wśród pacjentów z S-ICD, respondenci podejmowali decyzję łączenia urządzeń wszczepialnych w zależności od wymaganego rodzaju stymulatora. Odsetek osób preferujących współistnienie dwóch urządzeń malał wraz ze zwiększeniem ilości koniecznych elektrod implantowanych stymulatorów.

- Wykazano istnienie różnic pomiędzy opiniami polskich ekspertów w porównaniu z ekspertami europejskimi dotyczącymi łączenia terapii za pomocą S-ICD i stymulatora serca u tego samego chorego.

7.Wnioski

Wyniki przeprowadzonych i opublikowanych badań pozwalają na wyciągnięcie następujących wniosków:

1. Wyniki jednoośrodkowej obserwacji potwierdzają, że S-ICD jest skutecznym i bezpiecznym sposobem zapobiegania nagłym zgonom sercowym, jednak jego stosowanie u osób wymagających jednocześnie stałej stymulacji wiąże się z ryzykiem nieadekwatnych interwencji wysokoenergetycznych.

2. Ryzyko wystąpienia takich interwencji można znacznie zredukować przeprowadzając specjalistyczną analizę EKG (tak zwany screening) podczas rytmu spontanicznego i w czasie stymulacji komorowej.

3. Istnieją wyraźne różnice pomiędzy opiniami polskich ekspertów dotyczącymi możliwości łączenia terapii za pomocą S-ICD i stymulatora serca u tego samego chorego.

8. Streszczenie w języku polskim

Implantacja podskórnego kardiowertera-defibrylatora jest uznaną metodą zapobiegania nagłym zgonom sercowym w mechanizmie komorowych zaburzeń rytmu. Głównym ograniczeniem urządzenia pozostaje jednak brak możliwości prowadzenia stałej stymulacji serca. W określonych sytuacjach klinicznych może zatem zaistnieć konieczność jednoczesnego stosowania S-ICD i stymulatora serca u tego samego chorego. Rodzi to ryzyko wystąpienia zaburzeń sterowania defibrylatora z powodu zmian morfologii załamka R elektrokardiogramu wywołanych stymulacją komorową. W trzech opublikowanych pracach oryginalnych wchodzących w skład rozprawy doktorskiej przeanalizowano możliwości i wyniki jednoczesnego stosowania S-ICD i stymulatora serca oraz wyniki wieloośrodkowej ankiety przedstawiającej stanowisko polskich ekspertów elektroterapii dotyczące łączenia obu metod terapii u tego samego chorego.

W pierwszej pracy oryginalnej przeanalizowano wyniki pięcioletniej obserwacji pacjentów Kliniki Kardiologii i Elektroterapii Serca Gdańskiego Uniwersytetu Medycznego poddanych implantacji S-ICD. Szczególnie skupiono się na przypadkach chorych, którym poza S-ICD implantowano stymulator serca. Przeanalizowano mechanizm zarejestrowanych nieadekwatnych interwencji defibrylatora spowodowanych stałą stymulacją. Zaobserwowanie zaburzeń działania S-ICD spowodowanych współistnieniem obu urządzeń u jednego chorego było przyczyną kontynuacji badań nad możliwością implantacji S-ICD u pacjentów wymagających stałej stymulacji komorowej.

Celem drugiej pracy oryginalnej było dokładne określenie wpływu stałej stymulacji komorowej na morfologię zespołu QRS i wynikające z tego zmiany wyniku screeningu wskazującego na możliwość zastosowania S-ICD jednocześnie ze stymulatorem serca. Do badania włączono 100 pacjentów poddanych implantacji CIEDs, u których wykonano screening S-ICD podczas zapisu rytmu własnego oraz w trakcie stymulacji komorowej. Wykazano, że zaledwie u 23% pacjentów zarejestrowano co najmniej jeden akceptowalny wektor sensingu podczas analizy rytmu własnego i stymulowanego. Co najmniej 2 akceptowalne wektory rejestrowano już tylko u 8% pacjentów. Na podstawie uzyskanych wyników wykazano, że zastosowanie podskórnego kardiowertera-defibrylatora u pacjentów ze stymulacją komorową związane jest z wysokim ryzykiem wstąpienia zaburzeń sterowania S-ICD. Dotyczy to głównie pacjentów, u których występuje naprzemiennie rytm własny i stymulacja komorowa.

W celu poznania polskich doświadczeń i opinii dotyczących potencjalnego łączenia dwóch urządzeń wszczepialnych: S-ICD i układu stymulującego, przeprowadzono ankietę wśród polskich ekspertów w dziedzinie elektroterapii. Wyniki zostały szczegółowo przedstawione w trzeciej pracy oryginalnej. Wykazano istotne różnice w opiniach respondentów. Przy nabyciu wskazań do implantacji defibrylatora przez pacjentów z wcześniej wszczepionym stymulatorem, większość badanych skłaniała się do usunięcia układu stymulującego i zastąpienia go T-ICD zamiast do doszczepienia S-ICD do istniejącego układu stymulującego. W przypadku nabycia wskazań do stymulacji u pacjentów z S-ICD, respondenci podejmowali w większości decyzję łączenia obu urządzeń w zależności od proponowanego rodzaju stymulatora. Odsetek preferujących współistnienie dwóch urządzeń malał wraz ze zwiększeniem ilości elektrod, które należało implantować. Wykazano także odmienności proponowanych rozwiązań z decyzjami podejmowanymi przez ekspertów w innych krajach.

Przedstawione analizy miały pewne ograniczenia. Należy zaznaczyć, że w pierwszej pracy przeprowadzono analizę retrospektywną na stosunkowo nielicznej grupie pacjentów pochodzących z jednego ośrodka. W drugiej pracy wyniki uzyskano w oparciu o badanie chorych z implantowanym stymulatorem serca, pośród których tylko nielicznym wszczepiono układ resynchronizujący, co ograniczało możliwość przeprowadzenia pewnych analiz. W tej grupie nie badano także związku pomiędzy lokalizacją elektrody lewokomorowej a wynikami screeningu. W trzeciej pracy przeprowadzono ankietę wśród ograniczonej do 30 liczby ekspertów mających doświadczenie w implantacji S-ICD. Wynikało to ze stosunkowo rzadkiego stosowania S-ICD w Polsce i małej liczby ośrodków stosujących ten rodzaj leczenia.

9. Streszczenie w języku angielskim.

Implantation of a subcutaneous cardioverter-defibrillator is a recognized method of preventing sudden cardiac death due to ventricular arrhythmias. The inability to perform permanent cardiac pacing is the main limitation of the device. Therefore, in certain clinical situations, it may be necessary to use an S-ICD and a pacemaker in the same patient. It creates the risk of sensing disturbances due to changes in the morphology of the R wave of the electrocardiogram caused by ventricular pacing. In three published original papers included in the doctoral dissertation, the possibilities and results of the simultaneous use of an S-ICD and a pacemaker, and the results of a multi-center survey presenting the opinion of Polish electrotherapy experts on combining both methods of therapy in the same patient were analyzed.

The first original paper contained the results of a five-year observation of patients treated at the Department of Cardiology and Electrotherapy of the Heart of the Medical University of Gdańsk who underwent S-ICD implantation. Particular attention was paid to patients who had a pacemaker implanted in addition to an S-ICD. The mechanism of recorded inappropriate shocks caused by permanent pacing was analyzed. The observation of S-ICD malfunctions caused by the coexistence of both devices in one patient was the reason for continuing the research on the possibility of S-ICD implantation in patients requiring permanent ventricular pacing.

The aim of the second original paper was to precisely determine the effect of permanent ventricular pacing on the morphology of the QRS complex, and the resulting changes in screening, indicating the possibility of using an S-ICD simultaneously with a pacemaker. The study included 100 patients with CIEDs, who underwent S-ICD screening during intrinsic rhythm and ventricular pacing. It was shown that only 23% of patients had at least one acceptable sensing vector during the analysis of intrinsic and paced rhythm. At least 2 acceptable vectors were registered in only 8% of patients. Based on the obtained results, it was shown that the use of a subcutaneous cardioverter-defibrillator in patients with ventricular pacing is associated with a high risk of S-ICD sensing disorders. This mainly affected patients who alternate between intrinsic rhythm and ventricular pacing.

Next, a survey was conducted among Polish experts in electrotherapy to investigate their experience and opinion regarding the potential combination of two implantable devices: S-ICD and a pacemaker. The results are presented in detail in the

third original paper. Significant differences in the opinions of responders were shown. When patients with previously implanted pacemakers developed indications for a defibrillator implantation, most of the responders were inclined to remove the pacing system and replace it with a T-ICD instead of adding an S-ICD to the existing pacing system. In the case of acquiring indications for pacing in patients with S-ICD, the majority of responders decided to combine both devices depending on the proposed type of pacemaker. The percentage of experts who preferred the coexistence of two devices decreased as the number of electrodes that had to be implanted increased. Differences between the proposed solutions and decisions made by experts in other countries were also demonstrated.

The presented analyzes had some limitations. It should be noted that in the first study, a retrospective analysis was carried out on a relatively small group of patients from one center. In the second study, the results were obtained based on the study of patients with an implanted pacemaker, among whom only a few were implanted with a resynchronization system, which limited the possibility of performing certain analyses. The relationship between the location of the left ventricular lead and the results of screening was not studied in this group. In the third paper, a survey was conducted among a limited number (30) of experts experienced in S-ICD implantation. This was due to the relatively rare use of S-ICD in Poland and the small number of centers using this type of treatment.

10. Piśmiennictwo

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11. Opublikowane artykuły wchodzące w skład rozprawy doktorskiej

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2. Barbara Opielowska-Nowak, Maciej Kempa, Szymon Budrejko, Grzegorz Sławiński, Grzegorz Raczak "*Eligibility of patients with temporarily paced rhythm for a subcutaneous implantable cardioverter-defibrillator"* Kardiol Pol 2022;80(12):1231-1237. doi: 10.33963/KP.a 2022.0205.
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3. Maciej Kempa, Barbara Opielowska-Nowak, Szymon Budrejko, Grzegorz Raczak. *"A survey study of the use of a subcutaneous implantable cardioverter-defibrillator in various clinical scenarios by expert electrophysiologists in Poland"*. Cardiol J. 2022 Aug 17. doi: 10.5603/CJ.a2022.0073. Online ahead of print. PMID: 35975797
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Subcutaneous implantable cardioverter--defibrillators for the prevention of sudden cardiac death: five-year single-center experience

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Introduction A totally subcutaneous implantable cardioverter-defibrillator (S-ICD) is an established method of treatment in patients at risk for sudden cardiac death (SCD). Both the American and European guidelines recommend its application as a class IIa recommendation, in case of indications for implantable cardioverter--defibrillator in patients who do not require permanent cardiac pacing or antitachycardia pacing.[1] The high cost of the device and limited reimbursement result in a relatively small number of patients treated with S-ICD and centers using that method in Poland. In this study we present the 5-year single-center experience with the use of S-ICD.

Methods The study group included 25 patients (13 women and 12 men) at the mean (SD) age of 49 (17) years (range, 13–70 years). One patient (number 1) had his device implanted abroad, and he underwent a pocket repair procedure in our center. The S-ICD was implanted for secondary prevention of SCD in 18 patients. The decision to choose S-ICD was based on additional clinical factors, and in many cases multiple factors were present (obstructed vascular access in 9 patients, high risk for infective complications in 6, young age in 8, and a history of failures of transvenous leads in 7; 1 indication in 9 patients [36%], 2 in 10 patients [40%], 3 in 4 patients [16%], 4 in 1 patient [4%], and 5 in 1 patient [4%]). Left ventricular ejection fraction was 15% to 66% (mean [SD], 48% [15%]). Detailed data are presented in TABLE 1.

The S-ICD implantation procedure was performed under general anesthesia. In the first 3 cases, the S-ICD pocket was subcutaneous, an in the remaining cases, intermuscular. In 21 patients, the defibrillation test was performed, and in 4 patients, it was abandoned due to contraindications (see Supplementary material, *Table S1*).

Only descriptive statistical methods were used.

Due to observational nature of the study, no additional patient consent was required.

Results and discussion No perioperative complications were observed.

Out of 21 patients in whom the defibrillation test was performed, in 20 cases, the first 65-J shock was effective. In one patient, the shock polarity inversion was required to achieve termination of ventricular fibrillation.

No late surgical complications were observed during the follow-up.

Subcutaneous implantable cardioverter-defibrillator interventions An adequate antiarrhythmic intervention of S-ICD was observed in one patient (4%, patient number 9). Ventricular arrhythmias occurred 5 times and they were terminated by the first 80-J shock. The patient died 9 months following the implantation due to progressive heart failure and pneumonia.

Inadequate interventions were observed in 5 patients (20%). In 2 cases (8%), they were related to atrial fibrillation (AF), in 1 case (4%) to an interaction between S-ICD and pacemaker, and in the remaining 2 cases (8%), the exact

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TABLE 1 Clinical and demographic data of the study group

Patient no.	Sex	Age, y	NYHA class	LVEF, %	Cardiac rhythm	Indication for S-ICD	SCD prevention	Prior CIED	Prior extraction of CIED	CIED present at S-ICD implantation	Indication for pacing	Indication for S-ICD[a]	Follow-up, mo
1	M	40	I	65	SR	IVF	Secondary	No	No	No	No	3	68
2	F	57	I	60	SR	IVF	Secondary	No	No	No	No	1, 2	61
3	F	62	I	30	SR	ICM	Primary	No	No	No	No	1, 2	56
4	F	34	I	50	SR	ARVC	Primary	ICD VR	Yes	No	No	1, 2, 3, 4, 5	48
5	M	70	II	40	SR	ICM	Secondary	Epicardial VVI	No	Epicardial VVI	Paroxysmal AVB III	2	41
6	M	39	I	60	SR	HCM	Primary	DDD	No	DDD (both leads inactive)	No	1, 3	38
7	F	60	I	55	SR	IVF	Secondary	ICD VR	Yes (only device can)	No (only abandoned lead)	No	1	36
8	M	60	I	35	AF	NICM	Secondary	ICD VR	Yes	ICD VR	No	1, 6	35
9	F	63	II	25	AF	LVNC	Secondary	ICD VR	Yes	No	No	2, 4, 5	9
10	F	68	I	30	SR	ICM	Primary	ICD VR	Yes	ICD-VR	No	1, 6	32
11	M	65	II	35	SR	ICM	Secondary	ICD VR	Yes	ICD-VR	No	1, 6	30
12	F	69	I	50	SR	IVF	Secondary	No	No	No	No	2	29
13	M	16	III	15	SR	NICM	Primary	DDD	No	DDD	LBBB, AVB I/II/III	1, 3	2 (followed by heart transplant)
14	F	59	I	35	SR	ICM	Secondary	ICD VR	Yes	ICD VR	No	1, 6	23
15	F	48	I	60	SR	LQTS	Secondary	ICD DR	Yes	ICD DR	No	1, 6	19
16	F	16	I	66	SR	LQTS	Secondary	No	No	No	No	3	18
17	M	45	II	43	SR	DCM	Primary	ICD VR	Yes	No	No	2, 3, 4, 5	18
18	F	38	I	50	SR	IVF	Secondary	ICD VR	Yes	ICD VR	No	1, 3, 6	18
19	F	48	I	62	SR	IVF	Secondary	No	No	No	No	3	15
20	M	13	I	60	SR	LQTS	Secondary	No	No	No	No	3	9
21	F	31	I	60	SR	IVF	Secondary	No	No	No	No	3	7
22	M	51	I	60	SR	IVF	Secondary	ICD VR	Yes	No	No	2, 4, 5	2
23	M	66	II	35	AF	ICM	Primary	No	No	No	No	1, 2	1
24	M	44	III	60	SR	ARVC	Secondary	ICD VR	Yes	No	No	2, 4, 5	1
25	M	58	I	60	SR	IVF	Secondary	No	No	No	No	2	0

a 1 – problematic vascular access; 2 – high risk of infection; 3 – young age; 4 – history of cardiac implantable electronic device infection; 5 – history of infective endocarditis; 6 – prior lead failure and transvenous lead extraction

Abbreviations: AF, atrial fibrillation; ARVC, arrhythmogenic right ventricular cardiomyopathy; AVB, atrioventricular block; CIED, cardiac implantable electronic device; F, female; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; IVF, idiopathic ventricular fibrillation; LBBB, left bundle branch block; LQTS, long QT syndrome; LVEF, left ventricular ejection fraction; LVNC, left ventricular noncompaction; M, male; NICM, nonischemic cardiomyopathy; NYHA, New York Heart Association; SCD, sudden cardiac death; S-ICD, subcutaneous implantable cardioverter-defibrillator; SR, sinus rhythm; TLE, transvenous lead extraction

nature of interventions could not be determined. Patient 5 experienced inadequate interventions twice. The first one occurred during the early postoperative period. The analysis of recordings from the device memory (in cooperation with the manufacturer) did not result in any conclusive explanation of the nature of noise registered by the device.[2] The second inadequate intervention occurred in month 36 of the follow-up. It was due to inappropriate detection, most certainly resulting from the R-wave morphology change during permanent cardiac pacing delivered by a DDD pacemaker with epicardial leads. Repeated automated screening for S-ICD failed to confirm any possibility of appropriate sensing in that patient. As no ventricular arrhythmia was recorded during the follow-up period and the patient presented substantial improvement in left ventricular ejection fraction, a decision was made to switch the S-ICD device off.

Patient 6 experienced inadequate interventions 3 times while staying abroad. Due to the fact that no explanation for the noise that caused those interventions could be found by consulting electrophysiologists or manufacturer's representatives, the whole S-ICD system was replaced with a new one (new S-ICD) in a local hospital.

Patient 8 experienced inadequate interventions due to a sudden 2-fold increase of the ventricular rate of permanent AF. As a solution, the device settings were modified and rate-lowering treatment intensified.

Patient 17 had 5 episodes of AF with fast ventricular rate leading to inadequate interventions, and therefore pulmonary vein isolation was performed with good outcome.

Patient 13 experienced single inadequate shock in the postoperative period. The intervention was due to AAI pacing from the previously implanted permanent dual-chamber pacemaker with a first degree atrioventricular conduction block, which resulted in the overlay of paced P and T waves, and oversensing of that modified T-wave by the S-ICD. The settings for pacing of the pacemaker and detection of the S-ICD were reprogrammed. The problem was never observed again.

No other inadequate interventions were observed. Data concerning coexisting devices may be found in Supplementary material (*Table S2*).

The efficacy of S-ICD in defibrillation testing in clinical studies is estimated at over 90%,[3] and a need for surgical repositioning can occur in 5% of cases. In our population with 21 defibrillation tests performed, there was a need for shock polarity reversal only in 1 case (4.7%). In all the remaining cases, an impulse of 65 J proved effective. The device can was placed dorsally in relation to the midaxillary line, and such a location may promote lowering of the defibrillation threshold.[4] Our results seem to confirm that hypothesis (100% efficacy of the 65-J impulse).

Surgical complications of S-ICD implantation were reported to affect between 10% and 20% patients in the early years of the method. With increasing experience, the percentage of complications decreased to 3% in the first postoperative month.[5] In our cohort, we did not observe surgical complications in any of the de-novo implantations during the whole follow-up.

Inadequate interventions of S-ICD during the follow-up were observed in 5 patients (20%). In early-stage publications, the annual rate of inadequate interventions was between 7% and 13%, and has then been reduced to several percent due to improved detection and programming of 2 detection zones.[6] In our cohort, the inadequate intervention was caused by AF only in 2 cases. In the next 2 cases, inadequate therapies were due to interaction of a S-ICD with a coexisting pacemaker. In the last case, the cause of inadequate interventions could not be determined. In that patient, the whole system was replaced. In conclusion, inadequate interventions related to supraventricular arrhythmias were observed in 2 patients (8%), which is in line with the rates observed in other studies.

In our cohort, we observed 2 patients with a coexisting S-ICD and pacemaker. In both cases, inadequate interventions of S-ICD occurred due to the possible interaction between the devices. In patient 5, the possible cause of intervention was the decreased voltage of R-wave with concurrent myopotentials associated with physical activity. Permanent cardiac pacing from the DDD pacemaker as the reason for R-wave morphology change could neither be confirmed nor excluded. On repeated screening, none of the 3 electrocardiography vectors registered during pacing were appropriate for the use of S-ICD. The producer's representative suggested S-ICD system replacement, but with no guarantee that it would solve the problem. The decision was made to discontinue the S-ICD use, and the device was switched off.

The second patient requiring permanent cardiac pacing (patient 13) also experienced inadequate intervention, despite prior positive screening for S-ICD. It was caused by T-wave oversensing of the T wave changed in morphology due to overlay of P and T waves in the course of first-degree atrioventricular block. The problem was solved with pacemaker reprogramming.

As the S-ICD system cannot provide permanent cardiac pacing, the issue of possible interactions between a pacemaker and S-ICD is of paramount importance. Current guidelines state that S-ICD implantation is contraindicated in case of bradycardia requiring cardiac pacing.[1] Nonetheless, it may be expected that indications for permanent cardiac pacing may develop in some patients after the implantation of S-ICD. In populations of patients with S-ICD,

the absolute indication for pacemaker occurred in 2 patients out of 882 during 2 years (0.2%). In our cohort, both patients had the pacemaker implanted prior to S-ICD qualification, and the S-ICD system was implanted nonetheless, because no other therapeutic option was available in those patients. In no other case did we observe an indication for pacemaker develop after S-ICD implantation.

Summary The authors acknowledge that a small study group is the main limitation of the above analysis. Nonetheless, the aim of our report was to present our single-center results and troubleshoot specific real-life problems. A small number of patients with S-ICDs in our cohort is mainly caused by limited reimbursement of the system by the National Healthcare Fund in Poland. Our results confirm the efficacy of the treatment option and low risk of surgical complications, which suports its further more widespread application in Poland.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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Eligibility of patients with temporary paced rhythm for a subcutaneous implantable cardioverter-defibrillator

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ABSTRACT

Background: A concomitant use of a pacemaker and a subcutaneous implantable cardioverter-defibrillator (S-ICD) may be required in some patients.

Aims: Our study aimed to evaluate the influence of permanent cardiac pacing on the morphology of the QRS complex in the context of S-ICD screening.

Methods: One hundred patients with cardiac electronic implantable devices (CIEDs) were included in whom S-ICD screening could be performed both during intrinsic and paced rhythm.

Results: The positive result of screening during spontaneous rhythm for at least one vector (in both supine and standing positions) was obtained in 80% and for 2 vectors in 59% of patients. Positive screening during paced rhythm for at least one vector was recorded in 36% of patients (78% right ventricular and 22% biventricular pacing) and for 2 vectors in 15% of patients (93% right ventricular and 7% biventricular pacing). At least one vector acceptable during both types of rhythm and in both positions was recorded in 23% of patients and at least 2 vectors in 8% of patients.

Conclusions: The use of S-ICD in patients with paced ventricular rhythm is associated with a serious risk of inappropriate sensing due to different QRS morphology during intrinsic and paced rhythm, and it is particularly high in patients in whom periods of spontaneous rhythm interchange with periods of ventricular pacing. That risk has been hardly acknowledged in available reports, but according to our data, it is significant, and therefore it should be considered during S-ICD screening.

Key words: cardiac pacing, implantable cardioverter-defibrillator, subcutaneous implantable cardioverter-defibrillator, sudden cardiac arrest, sudden cardiac death

INTRODUCTION

A subcutaneous implantable cardioverter-defibrillator (S-ICD) has recently become a recognized method of treatment used for prevention of sudden cardiac death [1]. The S-ICD system detects ventricular arrhythmias based on the analysis of one of three available electrocardiogram (ECG) vectors. Those vectors are recorded between either the upper or lower sensing ring on the lead located along the left margin of the sternum and the device can or between those two rings without involvement of the device can. Sensing signals of appropriate quality are required for accurate operation of the system. Therefore, a patient qualified for implantation has to undergo a dedicated ECG test (the so-called ECG screening) that is intended to ensure the correct detection of the cardiac rhythm by the device. Screening is performed with the use of specialized software provided by the manufacturer. It relies on the automated analysis of the ECG signal recorded from the surface of the patient's chest, using vectors similar to the predicted location of the lead and can of the S-ICD system. At least one of the three available vectors should be acceptable to allow for implantation of S-ICD, but some authors require at least two acceptable vectors to consider screening positive.

The S-ICD system has become widely used in current clinical practice although its use is still limited by the inability to perform permanent cardiac pacing and cardiac resynchronization therapy. As a consequence, the need for permanent cardiac pacing is one of

WHAT'S NEW?

In patients with paced ventricular rhythm the risk of inappropriate sensing by a coexisting subcutaneous implantable cardioverter--defibrillator is high, especially if periods of spontaneous rhythm and ventricular pacing interchange constantly. Following the results of our study we postulate that the issue is significant, it has been underestimated in the available reports, and it definitely should be considered during subcutaneous implantable cardioverter-defibrillator screening.

contraindications for S-ICD therapy [1]. But the indication for pacing may develop later even if it was not present at the time of S-ICD implantation. In such a situation, the change of QRS morphology during paced rhythm may potentially lead to inappropriate sensing of cardiac activity by the S-ICD system. A similar problem occurs in a patient with an implanted pacemaker who develops indications for an implantable cardioverter-defibrillator (ICD). If the patient does not give their consent to implantation of a transvenous ICD or there is no possibility to perform such a procedure (that requires transvenous extraction of the existing right ventricular pacing lead with all its risks), S-ICD implantation may become one of the options. But then, again, the transient changes of the QRS morphology during spontaneous and paced rhythm may lead to inappropriate sensing and inadequate interventions. And last but not least, infective complications may require extraction of the transvenous ICD system and implantation of an epicardial pacemaker in pacing-dependent patients, which ceases protection against ventricular arrhythmias. The S-ICD system implanted in addition to the epicardial pacemaker might be a solution in such a complex case. At least one sensing vector acceptable both during intrinsic and paced rhythm should be confirmed before the decision is made to use S-ICD together with a pacemaker. Notably, it has to be the same vector for both types of rhythm as the S-ICD system cannot adjust the sensing vector automatically to the changing rhythm and QRS morphology when the intrinsic and paced rhythm are constantly interchanging. The sensing vector can be altered only by a physician during the follow-up procedure. Our study aimed to evaluate the influence of permanent cardiac pacing on the morphology of the QRS complex in the context of S-ICD screening and on the possibility of concomitant use of S-ICD and a permanent pacemaker.

METHODS

The study was designed to include 100 consecutive patients hospitalized in the Department of Cardiology and Electrotherapy of the Medical University of Gdańsk, Poland who had just undergone implantation of cardiac electronic implantable devices (CIEDs) due to sick sinus syndrome, atrial fibrillation with bradycardia, or heart failure. We collected data regarding demographical parameters, rates of concomitant diseases, left ventricular ejection fraction (based on echocardiography), cardiac rhythm and pacing mode of the implanted device, and registered standard ECG for assessment of cardiac rhythm and measurement of standard electrocardiographic parameters. Data collection was performed between July and December 2021. We included patients in whom it was possible to record both spontaneous rhythm with intrinsic conduction to the ventricles and paced ventricular rhythm forced by the implanted device in any mode of ventricular pacing (DDD, VVI, or biventricular). Patients with an advanced atrioventricular block and ventricular escape rhythm (or no escape rhythm at all) were not qualified for the study. The eligibility screening for S-ICD was performed with the Boston Scientific programmer and EMBLEM™ automated screening tool software within 5 days from implantation of CIED. The ECG signal was recorded for 3 vectors: primary (the proximal pole on the lead [on the left margin of the xiphoid process] to the device can [in the position of ECG lead V6]), secondary (the distal pole on the lead [14 cm above the proximal pole, on the left margin of the sternomanubrium junction] to the device can), and alternate (the distal pole to the proximal pole on the lead). Only the standard set of vectors and typical positioning were performed in our study. Body surface ECG was recorded for those 3 vectors in supine and standing positions both during intrinsic rhythm and ventricular pacing. To record the intrinsic rhythm, the implanted device was set to VVI mode with a basic rate of 30 bpm. To force ventricular pacing, the device was set to DDD or VVI mode with a basic rate of 10 bpm more than the intrinsic rhythm, and in the case of DDD or cardiac resynchronization therapy (CRT) devices — with the atrioventricular delay time short enough to force ventricular pacing (interventricular delay was set to 0 ms in all CRT devices). Since experts hold different views on the definition of positive screening (one or two passing vectors), both those situations were analyzed, as is stated and underlined in this article at every occurrence of that issue. We analyzed the percentages of positive screening during intrinsic and paced rhythm and then by groups divided according to the mode of pacing (right ventricular pacing in comparison with biventricular pacing). And finally, we planned a comparison of patients with positive screening during spontaneous rhythm (at least 2 vectors acceptable, both supine and standing positions) divided into subgroups with either negative or positive results of screening during paced rhythm. That analysis was intended to include demographical variables (age, sex) and clinical variables (heart rate, electrocardiographic parameters, left ventricular ejection fraction, mode of pacing, and rates of

Table 1. Clinical data of patients in the study group

Total number, n (%)	100 (100)
Male, n (%)	65 (65)
Age, mean (SD), range, years	73 (12), 28–94
Coronary artery disease, n (%)	42 (42)
Non-ischemic cardiomyopathy, n (%)	19 (19)
Heart failure, n (%)	62 (62)
LVEF, median (IQR), %	40 (27–55)
Sinus rhythm, n (%)	69 (69)
Atrial fibrillation, n (%)	31 (31)
Type of the implanted device, n (%)	
VVI pacemaker	8 (8)
DDD pacemaker	43 (43)
ICD single-chamber	14 (14)
ICD dual-chamber	6 (6)
CRT pacemaker	5 (5)
CRT defibrillator	24 (24)

Abbreviations: CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction; SD, standard deviation

concomitant diseases). The study design was approved by the Ethical Board at the Medical University of Gdańsk, Poland.

Statistical analysis

Continuous variables were presented as mean and standard deviation or median and interquartile range in case of non-normal distribution. Categorical parameters were presented as numbers and percentages. The normality of distribution was tested with the Shapiro-Wilk test. The $\chi 2$ test and Student's t-test or the Mann-Whitney U test (depending on the analysis of distribution and variance) were used to compare the groups, as appropriate for a given variable. A *P* value below 0.05 was considered statistically significant. Data management and statistical analysis were performed with Microsoft Excel and Statistica 13.1 software (TIBCO Software, Palo Alto, CA, US).

RESULTS

One hundred consecutive patients with a pacemaker or ICD were included in the study group. Clinical data of the patients are summarized in Table 1. All the right ventricular leads were in the apical position.

Screening during spontaneous rhythm (implanted device inactive)

Data regarding the number of vectors acceptable for S-ICD implantation are presented in Figures 1 and 2. The positive result of screening, if at least one acceptable vector was required (both in supine and standing positions), was eventually obtained in 80 patients (80%) and if two positive vectors were required — in 59 patients (59%).

Screening during paced ventricular rhythm forced by the implanted device

Data on the number of vectors acceptable for S-ICD implantation are presented in Figures 1 and 2. The positive

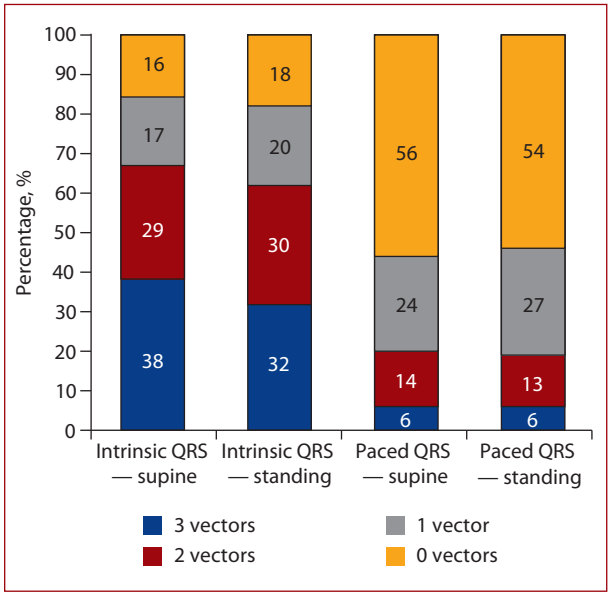

Figure 1. Percentages of patients with different numbers of vectors acceptable in S-ICD screening during spontaneous and paced rhythm

Abbreviation: S-ICD, subcutaneous implantable cardioverter-defibrillator

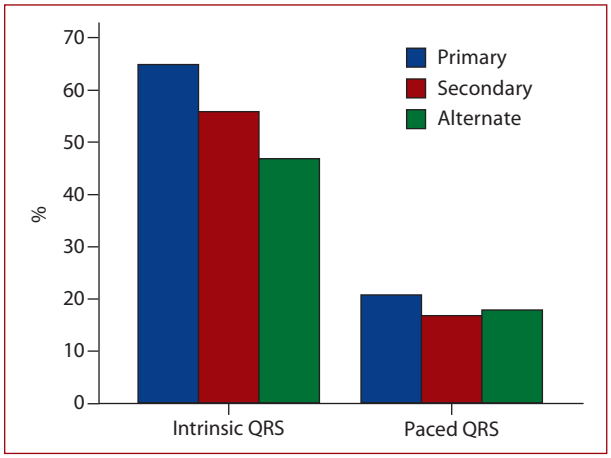

Figure 2. Percentages of vectors acceptable in S-ICD screening during spontaneous and paced rhythm

Abbreviation: see Figure 1

result of screening if at least one acceptable vector was required (both in supine and standing positions) was eventually obtained in 36 patients (36%). In that subgroup, 28 patients (78%) had right ventricular (RV) pacing and 8 (22%) — biventricular (BiV) pacing. But 8 of those 36 patients (22%) had none of the vectors acceptable during spontaneous rhythm. If two positive vectors were required, the positive result of screening was achieved in 15 patients (15%). In that subgroup, RV pacing was present in 14 cases (93%) and BiV pacing in one case (7%).

In the group of 100 patients, we obtained at least one acceptable sensing vector during both spontaneous and paced rhythm only in 28 cases (28%). Furthermore, in 5 patients, it was not the same vector for those two types of

Table 2. Comparison of patients with positive screening results during spontaneous rhythm (at least 2 vectors acceptable, both supine and standing positions) divided into subgroups with either the negative (group 1) or positive (group 2) results of screening during paced rhythm

Variable	Group 1 (n = 51)	Group 2 (n = 8)	*P*-value
Age, median (IQR), years	73 (68–82)	74.5 (71.5–80)	0.89
Male sex, n (%)	30 (58.82)	5 (62.5)	0.84
Heart rate, median (IQR), bpm	70 (61–82)	62 (52–70.5)	0.08
Intrinsic QRS, median (IQR), ms	109 (90–160)	128.5 (100–150)	0.63
Paced QRS, median (IQR), ms	160 (150–170)	175 (150.5–189.5)	0.13
Difference between paced and intrinsic QRS width, median (IQR), ms	54 (0–72)	48.5 (31.5–63.5)	0.93
QT, mean (SD), ms	424.39 (56.06)	422.75 (46.19)	0.96
QTc, mean (SD), ms	455.86 (48.61)	424.75 (34.59)	0.06
LVEF, median (IQR), %	40 (25–50)	55.5 (50–60)	0.01
CRT, n (%)	20 (39.22)	0 (0)	0.03
AF, n (%)	17 (33.33)	2 (25)	0.64
RBBB, n (%)	4 (7.84)	2 (25)	0.14
LBBB, n (%)	13 (25.49)	0 (0)	0.11
IVCD, n (%)	5 (9.8)	2 (25)	0.28
ICM, n (%)	23 (45.1)	1 (12)	0.08
HA, n (%)	37 (72.55)	6 (75)	0.89
DCM, n (%)	13 (25.49)	0 (0)	0.11
CHF, n (%)	33 (64.71)	3 (37.5)	0.14

Group 1 — positive screening without pacing, negative during pacing; group 2 — positive screening both without pacing and during pacing

Abbreviations: AF, atrial fibrillation; CHF, chronic heart failure; DCM, dilative cardiomyopathy; HA, hypertension; ICM, ischemic cardiomyopathy; IVCD, intraventricular conduction disturbances; LBBB, left bundle branch block; RBBB, right bundle branch block; other — see Table 1

rhythm. Eventually, only in 23 cases of the initial 100 (23%), we managed to find at least one vector acceptable during both types of rhythm (the same vector in both situations) and in both body positions (5 patients with BiV and 18 with RV pacing). If 2 vectors were required for positive screening (the same 2 vectors for both rhythms and both body positions), the final positive results of screening were obtained only in 8 patients (all with RV pacing).

In the context of pacing modality, 29 patients (29%) had BiV pacing, and 71 (71%) — RV pacing. If one acceptable vector was enough, 5 patients of 29 with BiV pacing (17.2%) and 18 of 71 with RV pacing (25.4%) could be considered to have a positive result of screening ($P = 0.38$ for the difference). If two vectors were required, none of the patients with BiV pacing (0%) and 8 with RV pacing (11%) could be considered positive ($P = 0.06$). Therefore, the type of pacing did not influence the chance of having a positive result of screening with either one or two vectors required.

While analyzing which of the vectors were positive during spontaneous and paced rhythm, we found that it was predominantly the primary vector in both situations (65% and 21%, respectively, see Figure 2).

Then we analyzed the variance among patients with positive screening according to the criteria used typically in our department (two passing vectors) during spontaneous rhythm, dividing them into subgroups with the negative (group 1) or positive (group 2) results of screening during paced rhythm. Variables in that analysis included age, sex, left ventricular ejection fraction (LVEF), underlying cardiac disease, history of chronic heart failure, and electrocardiographic measurements (the width of paced QRS complex and intrinsic QRS complex, the increment of QRS width with pacing, the QT interval, and the presence of right or left bundle branch block). Only LVEF was significantly different between those subgroups, and it was 40% (25%–50%) in group 1 and 55.5% (50%–60%) in group 2. The results are presented in Table 2.

DISCUSSION

The inability to provide permanent cardiac pacing is one of the major limitations of the S-ICD system. The predicted rate of the need for pacemaker implantation was found to be between 2% and 6.8% per year of follow-up in numerous studies of patients with transvenous ICDs, and the rate of the need for CRT — between 0.6% and 0.8% per year [2–5], but it should not be directly extrapolated to populations of potential S-ICD recipients. The reported risk of developing indications for permanent cardiac pacing in real-life populations of patients with implanted S-ICD systems is lower. In the analysis of early cumulative results of the EFFORTLESS and IDE studies, the need for permanent cardiac pacing occurred only in 2 of 889 patients during 22 months of follow-up [6]. In another report from Germany, the low risk of such a scenario was confirmed. In 28 patients, no need for pacemaker implantation was reported during follow-up until S-ICD battery depletion [7]. Finally, in recently published results of the prolonged follow-up of the EFFORTLESS study population (median implant duration 5.1 years), the need for conversion from S-ICD to transvenous ICD due to indications for cardiac pacing occurred only in 13 of 984 patients [8].

Therefore, the risk that a patient with pre-existing S-ICD will need a permanent cardiac pacemaker is low, yet not negligible. The opposite scenario seems more probable,

in which a patient with a pre-existing cardiac pacemaker develops heart failure with reduced LVEF and, therefore, an indication for ICD in primary prevention of sudden cardiac death. In a study by Khurshid et al., [9] a decrease in mean LVEF from 62.1% to 36.2% over a mean follow-up period of 3.3 years occurred in 19.5% of the study population.

Two solutions for such a problem are available. One is to upgrade the pacemaker to transvenous ICD or CRT-D, possibly after transvenous extraction of the right ventricular pacing lead. The second solution is to implant an S-ICD system as a companion to the existing pacemaker.

Data on the concomitant use of pacing systems and S-ICDs are limited although such a solution has been successfully used and reported. Reports are available of S-ICD systems co-existing with both transvenous and epicardial pacemakers [10–13]. Moreover, in isolated cases, the S-ICD system was used together with a leadless pacemaker [14–16]. On the other hand, several cases were reported where the implanted pacemaker changed QRS morphology to such an extent that continuation of S-ICD therapy was not possible [17]. Therefore, the concomitant use of pacemakers and S-ICD systems is associated with a significant risk of undesired interactions between those devices. Careful programming may reduce the risk of such interactions. When programming a pacemaker, it is recommended to use low pulse amplitudes with minimal safety margins, as well as to turn off the automatic threshold and automatic switch-of-polarity functions. In DDD and CRT devices, the upper rate limit should be set lower than half of the first therapy zone in S-ICD [18]. But that recommended programming algorithm cannot completely eliminate the problem of unacceptable QRS morphology change due to ventricular pacing, which may preclude appropriate QRS sensing by the S-ICD device.

To evaluate the significance of that phenomenon, we analyzed data acquired from 100 consecutive patients in whom the ventricular rhythm was forced in the form of RV or BiV pacing. In that group, screening in only 36 patients (36%; 28 RV, 8 BiV) was acceptable for at least one vector, and in 15 cases (15%) for at least 2 vectors (14 RV, 1 BiV). The analysis of the results of screening by the mode of pacing showed that in patients with BiV pacing at least one vector was acceptable in 8 of 29 patients (28%) and with RV pacing — in 28 of 71 patients (39%). Those values are significantly lower than the rates reported by Ip et al. [19]. Those authors reported positive screening in 80% of patients with biventricular pacing and 46% of patients with RV pacing. That analysis was performed manually using the Boston Scientific screening templates while in our population, the automated screening was performed.

There are other reports on the influence of permanent cardiac pacing on the QRS morphology and the impact of that phenomenon on S-ICD screening. Those reports were based on populations of patients with CRT or His bundle pacing. In those reports, S-ICD screening was acceptable in most patients with cardiac pacing, contrary to our results. The rates of positive screening were 82% to 85% for BiV pacing and 90% for His bundle pacing [20–22]. But the authors of those publications analyzed only the results of screening in paced rhythm and did not include the possible temporary change of rhythm for the intrinsic one. Such an event may occur in a setting of transient atrioventricular conduction disturbances, supraventricular tachycardia, or ineffective ventricular pacing. In our study group, in 36 of 100 patients (36%), we could find at least one acceptable vector during ventricular pacing, but in 8 patients of those 36, none of the vectors was acceptable during intrinsic activation when ventricular pacing was switched off. Therefore, those patients, if equipped with an S-ICD, would be at risk of inappropriate interventions in the case of reoccurrence of the intrinsic rhythm. In the subsequent analysis of the remaining 28 patients, we noticed that in 5 of them the vectors acceptable during spontaneous activation and ventricular pacing were different. The S-ICD system cannot automatically change the sensing vector depending on the type of ventricular activation (spontaneous versus paced). Therefore, those 5 patients would also be at risk of inappropriate interventions. Only 23 patients (23%) could be eventually deemed as having the positive result of screening with minimal requirements, that is at least one vector acceptable both during spontaneous rhythm and ventricular pacing and in both supine and standing positions. Assuming that the reasonable number of acceptable vectors to guarantee long-term safety is 2 (the same vectors in both body positions and both types of cardiac rhythm), the number of patients meeting such restricted criteria was 8 (8%). The phenomenon of the QRS morphology change between spontaneous and paced rhythm and its influence on S-ICD screening, was reported by Giammaria et al. [23]. In the group of 48 patients with biventricular pacing, at least one vector was acceptable in 34 patients (71%). However when pacing was switched off, that number was reduced to 22 (46%) during intrinsic ventricular activation.

Limitations of the study

A limited number of patients included in the study and a relatively low number of CRT recipients (because we included consecutive patients undergoing implantation of CIEDs) resulted in small subgroups, which restricted statistical analysis (especially for comparisons of proportions). We did not analyze the relationship between the position of LV leads and the result of screening, as it would further subdivide those relatively small groups.

CONCLUSIONS

The use of S-ICD is associated with a serious risk of inappropriate sensing in patients with other cardiac implantable electronic devices in whom periods of spontaneous rhythm interchange with periods of ventricular pacing. If a pacemaker is implanted first, analysis of such a risk is possible and requires repeated screening in both paced and intrinsic rhythms. However if the S-ICD system is implanted first, it

is very difficult to predict the possible risk of inappropriate sensing because screening for the paced rhythm cannot be performed before the pacemaker implantation.

Article information

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A survey study of the use of a subcutaneous implantable cardioverter-defibrillator in various clinical scenarios by expert electrophysiologists in Poland

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Abstract

Background: *A subcutaneous implantable cardioverter-defibrillator (S-ICD) has become a recognized alternative to a traditional transvenous implantable cardioverter-defibrillator (T-ICD). Despite the growing evidence of non-inferiority of S-ICD, there are no clear clinical guidelines for selection of either of the two available systems. The aim of the study was to analyze the decisions made in predefined typical clinical scenarios by Polish cardiologists experienced in the use of both S-ICDs and T-ICDs.*

Methods: *A group of 30 experts of cardiac electrotherapy experienced in the use of S-ICDs was recruited and invited to participate in a web-based anonymous survey. The survey questions regarded the proposed therapy in various but typical clinical scenarios.*

Results: *From the invited 30 experts representing 18 clinical centers, 25 completed the survey. 72% of them declared that the number of S-ICDs implanted at their center during the preceding 12 months exceeded 10, and 40% — that it was over 20. Rates of responders preferring S-ICD or T-ICD in various clinical scenarios are reported and discussed in detail.*

Conclusions: *Significant divergence of opinion exists among Polish experts regarding the use of a subcutaneous cardioverter-defibrillator. It is especially pronounced on the issue of the use of the system in middle-age patients, in case of complications of the hitherto ICD therapy, or the need of upgrading the existing cardiac implantable electronic device.* (Cardiol J)

Key words: implantable cardioverter-defibrillator, subcutaneous implantable cardioverter-defibrillator, sudden cardiac death, ventricular fibrillation, ventricular tachycardia

Introduction

A subcutaneous implantable cardioverter-defibrillator (S-ICD) is an efficient tool used to protect patients at risk of malignant ventricular tachyarrhythmias against sudden cardiac death [1]. According to the current guidelines of the European Society of Cardiology, it may be used alternatively to a transvenous cardioverter-defibrillator (T-ICD), unless the patient qualified for the device has indications for permanent cardiac pacing or a history of sustained ventricular tachycardia that can be treated with antiarrhythmic pacing [2]. According to the authors of the guidelines, the level of evidence behind that indication is low (level C). Despite the growing evidence of non-inferiority of S-ICD compared to T-ICD in terms of complication rate and risk of inappropriate interventions, there are no clear clinical guidelines for selection of either of the two available implantable defibrillator systems [3, 4].

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S-ICDs have been implanted in Poland since 2014 [5, 6], but the number of implantations has increased significantly in only just the last 3 years [7]. Despite legal regulations, the decision to choose S-ICD or T-ICD is made by the implanting cardiologist on an individual basis for each patient [8]. That decision is based not only on the personal experience of the physician, but also on other factors, such as the local availability of the method, its cost and the reimbursement regulations set by the National Health Fund. Such a setting may lead to the diversity of clinical decisions made by different clinicians in similar or even identical clinical cases. Therefore, it was decided to undertake an analysis of the accuracy and consistency of clinical decisions made in similar clinical scenarios involving potential implantable cardioverter-defibrillator (ICD) recipients.

The aim of the study was to analyze the decisions made in predefined typical clinical scenarios by cardiologists experienced in the use of both subcutaneous and transvenous ICDs.

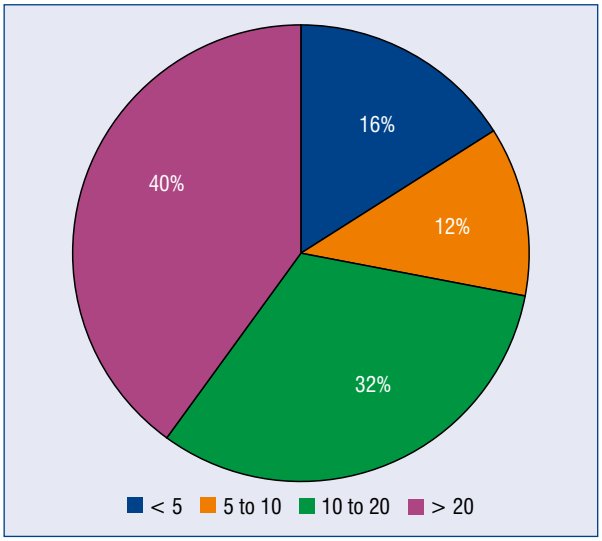

Figure 1. The number of subcutaneous implantable cardioverter-defibrillator devices implanted in centers of responders over the preceeding 12 months.

Methods

For the purpose of the study, a list of 30 Polish experts of cardiac electrotherapy experienced in the use of S-ICDs was established. That group was recruited among clinicians actively reporting data to the registry of S-ICD implantations held by the Heart Rhythm Section of the Polish Cardiac Society, and co-authoring publications based on the data from that registry.

They were invited by e-mail to participate in a web-based survey. The survey was completely anonymous to the extent that even the mere fact of completing the study or not by a given responder was confidential. The survey questions regarded the proposed therapy in various but typical clinical scenarios, as discussed in the following paragraphs (a complete list of questions and possible answers is reported as **Supplementary data**).

Data were collected and analyzed in a Microsoft Excel spreadsheet, and reported as rates and percentages.

Results and discussion

From the 30 experts invited, representing 18 clinical centers, 25 completed the survey. 72% of them declared that the number of S-ICDs implanted at their center during the preceding 12 months exceeded 10, and 40% — that it was over 20 (Fig. 1).

The majority of responders (92%) declared, that the choice of the device is not influenced by the history of sudden cardiac arrest (secondary prevention) as contrary to the primary prevention, unless the patient has a history of ventricular tachycardia potentially eligible for termination with antiarrhythmic pacing. That percentage is significantly higher (almost twice) than the value reported in another similar survey conducted in European countries several years ago [9]. At the same time, that observation confirms a previously recognized increasing tendency of Polish cardiologists to qualify patients for S-ICD devices in primary prevention [7]. Over 65% of S-ICD implantations in Poland are performed for primary prevention, and that data is in conformity with other reports concerning the European population [10]. That notion seems reasonable, as the history of sudden cardiac arrest is not considered to be a decisive factor for the choice of ICD type in the current guidelines. To quantify the potential future risk of the need for permanent cardiac pacing, other factors should be considered, such as the existing atrioventricular or intraventricular conduction disturbances, the stage of heart failure, and a history of prior cardiac surgery, as it was shown in the MADIT II and SCD-HeFT populations and in the study of de Bie et al. [11, 12]. In summary, the risk of conversion from the S-ICD to the T-ICD system due to the need for permanent cardiac pacing is low [13].

If an indication for pacing developed in an S-ICD patient, these responders would weigh their choice in relation to the mode of pacing. In case of

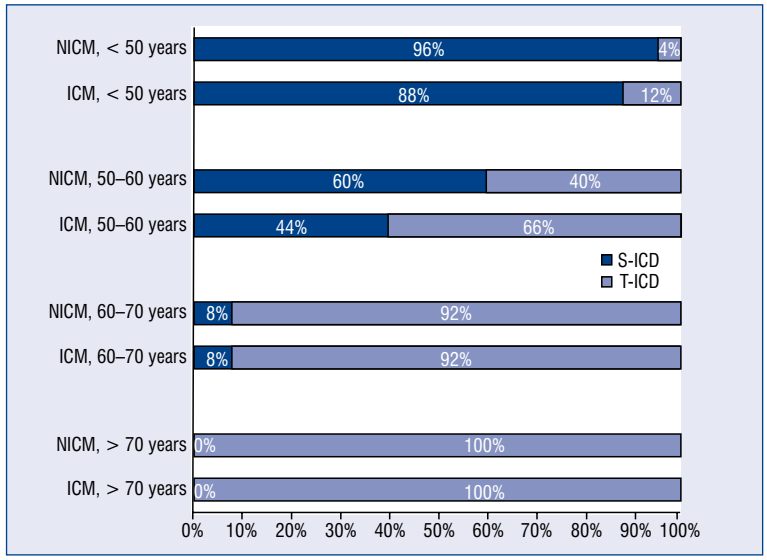

Figure 2. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients with non-ischemic cardiomyopathy (NICM) and ischemic cardiomyopathy (ICM) with no history of arrhythmia and no indications for permanent pacing for different age groups.

VVI pacing, as many as 56% of them would prefer to implant a single chamber ventricular pacemaker as a device concomitant to the S-ICD system rather than to extract the S-ICD and implant a transvenous system instead. The rate of responders preferring two coexisting cardiac implantable electronic devices (CIEDs) decreases with an increasing complexity of the pacing mode, and equals 44% and 32% for dual-chamber pacing and resynchronization therapy, respectively. Interestingly, in the opposite situation, that is if indications for prevention of sudden cardiac death occurred in a patient with a pacemaker already in place, a majority of responders would extract the pacemaker to replace it with a T-ICD system rather than implant an S-ICD in addition to the pacemaker. Such a solution was selected by 68% of responders for a VVI system and 72% for multi-lead pacing systems. Those results are surprising, taking into account the potential risk of transvenous lead extraction. Moreover, if an addition of an S-ICD system to a pre-existing pacemaker was planned, screening during paced rhythm would be possible prior to final decisions, and it might warrant appropriate sensing of the paced rhythm by the S-ICD device. On the other hand, if a pacemaker was added to the pre-existing S-ICD system, there would be a substantial risk of inappropriate sensing and inadequate interventions of the defibrillator due to the change in QRS morphology between paced and intrinsic rhythm. Such problems have been previously reported [14, 15].

It is noteworthy that the opinions of Polish experts diverge from the reported attitude of other researchers. French experts tended to choose the opposite options. The majority of them voted for S-ICD removal and replacement with a T-ICD in cases where permanent cardiac pacing was needed. But when a patient was already equipped with a pacemaker, most of them tended to add an S-ICD if needed rather than to extract the pacing system to replace it with a T-ICD [16]. Nonetheless, the use of S-ICD in patients with pacemakers and paced rhythm is possible and has been reported for transvenous, epicardial and leadless pacemakers [17–19].

The age of ICD recipients seems to be as important as the potential need for pacing when choosing between S-ICD and T-ICD. According to the present responders, the age of a patient was more important than the etiology of heart failure when choosing the device for primary prevention. The responses were similar for ischemic cardiomyopathy (ICM) and non-ischemic cardiomyopathy (NICM), detailed percentages are reported in Figure 2. The responders preferred S-ICD only slightly more frequently in case of NICM. Patients in the age range of between 50 and 60 years were most problematic. In that age group the experts were divided almost in half in terms of the choice of the type of ICD. But it is the young age of a patient that is crucial for S-ICD choice from the advent of that treatment method in Poland. It is consistent

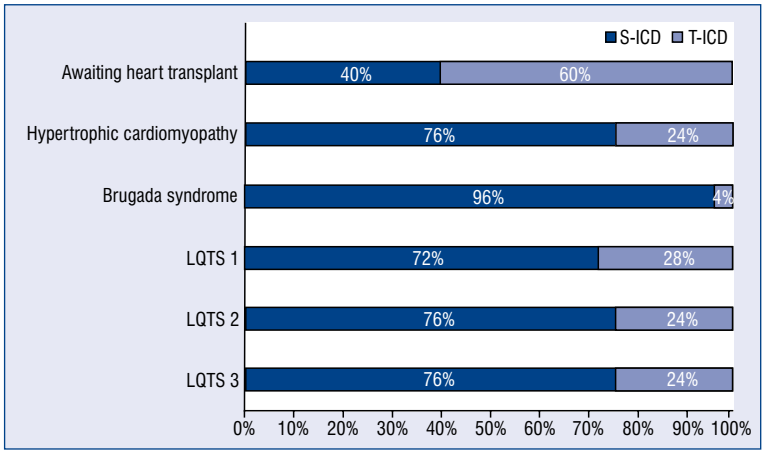

Figure 3. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients with indications for an implantable cardioverter-defibrillator, with no history of arrhythmia and no indications for permanent pacing in various clinical scenarios; LQTS — long-QT syndrome.

with the tendency observed in other European countries [9, 10, 20].

Inherited arrhythmia syndromes and hypertrophic cardiomyopathy are relatively frequent in the young population of potential ICD recipients. If such patients have indications for an ICD, most responders would choose S-ICD. In long QT syndromes (LQTS), depending on the type of LQTS, as many as 72–76% of responders would opt for an S-ICD. That rate reached 96% in case of Brugada syndrome and 76% for hypertrophic cardiomyopathy (Fig. 3). Although the agreement of responders to prefer S-ICD over T-ICD in those clinical entities was high, one should remember that subcutaneous systems have their limitations in those populations. The key issue is the risk of inappropriate sensing and interventions. Therefore, some researchers underline the importance of meticulous preimplant screening, and in some specific situations (for example in Brugada syndrome) — they advise performing an exercise test and pharmacological provocation tests [21, 22]. Careful screening allows avoiding future inappropriate interventions to a reasonable extent, and in the comparative analysis of S-ICDs and T-ICDs in that patient population, the efficacy of S-ICD was comparable to T-ICD with the benefit of a lower risk of lead failure [23]. One should mind though that in some channelopathies (e.g., LQTS 2) associated with bradycardia, the need for pacing may occur, especially in case of therapy with beta-blockers. The use of an S-ICD incapable of permanent cardiac pacing would not be advised in such a clinical setting [16].

A young population of potential ICD recipients has a relatively high representation of patients with congenital heart disease. Vascular anomalies and altered cardiac anatomy speak in favor of S-ICD in those patients. Importantly, the clinical studies underlying Food and Drug Administration approval of the S-ICD system, as well as subsequent updates of the relevant clinical guidelines, did not include patients below 18 years of age. The evidence behind the use of S-ICDs in children remains limited. The main issue associated with S-ICDs in that population is the relatively large volume of the device can, carrying the risk of surgical complications (such as pocket decubitus, but also lead erosion) [24, 25]. Implantation of the system may be limited by the small chest size of a patient, precluding the correct placement of the lead and device. Despite that fact, there are reports of S-ICD implantation in patients at the age of 4 to 5, with non-standard placement of the system components [26, 27]. The relatively fast heart rate in youngsters (both during sinus rhythm and supraventricular tachycardia) may lead to inappropriate interventions [25]. Despite those limitations, the available reports indicate that the rate of all the adverse effects is lower than 15% in the first-year post-implant, and the procedure becomes safer when the body mass index exceeds 20 kg/m^2 [25, 28, 29]. In patients with congenital heart disease and body mass lower than 30 kg only 56% of Polish experts would choose S-ICD. But over 30 kg of body mass the percentage of votes in favor of S-ICD increased to 72%. With the body mass over 40 kg and 50 kg, 84% and 92% respond-

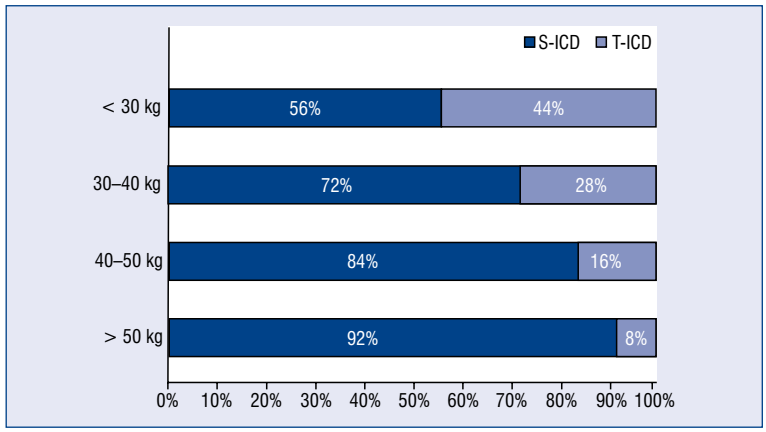

Figure 4. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients wih congenital heart disease (not precluding transvenous implant) qualified for an implantable cardioverter-defibrillator, with no history of arrhythmia and no indications for permanent pacing, for different weight categories.

ers, respectively, would opt for an S-ICD (Fig. 4). The Polish reports published so far confirm the efficacy and safety of such an attitude [14, 30].

Protection against sudden cardiac arrest of patients awaiting heart transplant is a complex issue. On one hand, an S-ICD seems to be an optimal solution due to the low risk of lead-related or systemic infection, it does not involve the vascular system and does not lead to lead-related thrombosis, which may be crucial for a patient's future treatment after heart transplant. On the other hand, if a patient is qualified for an assist device as a bridge to transplant, the S-ICD presence may be troublesome. Patients with assist devices are at risk of inappropriate interventions due to sensing issues, and of painful discharges in case of ventricular arrhythmias, which in the presence of an assist device may be well tolerated and treated with a shock before the loss of consciousness occurs. Despite those drawbacks, 60% of responders voted for S-ICD over T-ICD in the group of patients awaiting heart transplant. That question of the survey did not specify if the patients were already equipped with an assist device or potentially qualified for one.

Extraction of a CIED system is a cornerstone of therapy in many complications of cardiac electrotherapy, both infective and noninfective (e.g., lead damage). In case of high risk of infection, the American guidelines consider the use of S-ICD as class I recommendation, while in the European guidelines such a situation is considered to be a class IIb recommendation [2, 31]. According to the Polish expert consensus from 2018, the high risk of infection is among major indications for preference of S-ICD over T-ICD [32]. In the present survey though, 8% of responders did not consider a history of infective complications as justifying the replacement of the extracted T-ICD with an S-ICD. In case of lead extraction due to its failure, even if there was no need for permanent cardiac pacing or no history of ventricular arrhythmias requiring antiarrhythmic pacing, only 40% of responders would change the T-ICD system for a subcutaneous one. That percentage is relatively low, especially in the light of the opinion of the French experts, who unanimously opted for switching to an S-ICD in case of complications [16]. Similarly, the responders of the European Heart Rhythm Association (EHRA) survey also declared their preference of a subcutaneous system over transvenous one if the history of prior complications of transvenous electrotherapy was reported (80%) or a significant risk of infective complications occurred (63%) [9].

The expected divergence of opinions among Polish experts on the potential use of S-ICD system encouraged us to formulate a survey question regarding the most important reasons for not implanting S-ICD in cases, where it might be indicated. In response to that multiple-choice question the most frequent reason (68%) was the potential risk of the need for conversion from a subcutaneous to a transvenous system if indications develop in the future. But one third of responders also chose the financial reasons: 44% of them responded that they discontinued implanting S-ICDs due to the high cost of the system, and 28% due to the fear that the center will not receive reimbursement of the costs for the procedure (Fig. 5). Similar data was reported

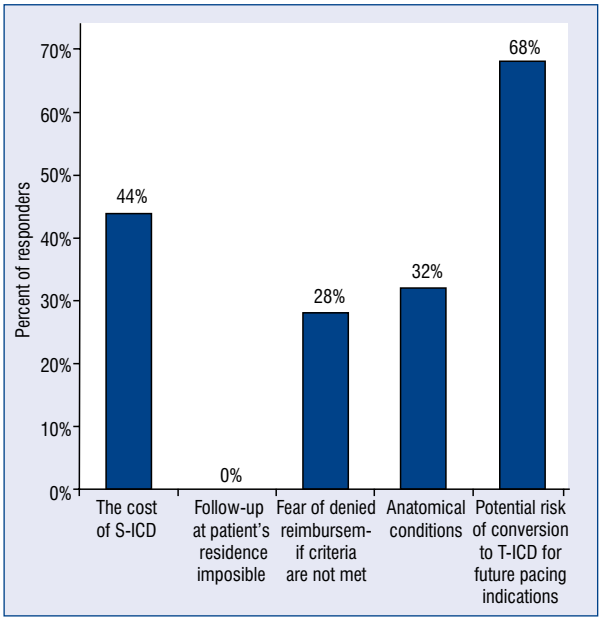

Figure 5. Main factors determining the preference of transvenous implantable cardioverter-defibrillator (T-ICD) over subcutaneous implantable cardioverter-defibrillator (S-ICD) in patients eligible for S-ICD (multiple choice question).

by the authors of the European survey, but in the present analysis those results are surprising, because the current regulations in Poland guarantee the complete reimbursement of S-ICD implantation procedure [8, 9]. Additional indications required to justify the choice of S-ICD and not T-ICD include the high risk of infective complications, the risk of lead failure, the risk of venous occlusion and the predicted long-life expectancy of the patient. Those requirements are consistent with the current guidelines from the scientific societies. The further limitation of S-ICD use in Poland is associated with the requirements for centers in terms of equipment and experience to include that method of treatment into their portfolio. That issue could not have influenced the responses to our survey, as all the participants represented centers meeting the requirements mentioned above and were themselves active implanters of S-ICD systems. Therefore, the financial issues and unjustified fear of lack of reimbursement are limiting the potential utilization of S-ICD in almost 30% of cases.

Conclusions

The results of the survey prove that a significant divergence of opinion exists among Polish experts regarding the use of a subcutaneous cardioverter-defibrillator. It is pronounced especially in the issue of the use of the system in middle-aged patients, in case of complications of the hitherto ICD therapy, or the need of upgrading the existing cardiac implantable electronic device.

Conflict of interest: None declared

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