

Možnosti prevencie infekcií asociovaných s CIED.



Národný ústav srdcových a
cievnych chorôb, a.s.



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**XVI. České a Slovenské Sympóziium o Arytmiách a
Kardiostimulácii**

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Úvod

- Celosvetovo i na Slovensku sa počty implantácií CIED zvyšujú
- Veľká rôznorodosť CIED (KS, ICD, CRT, CCM implantabilné monitory, S-ICD, leadless stimul.)
- Infekcie stúpajú viac, akoby sme očakávali
- Máme priestor na zlepšenie???

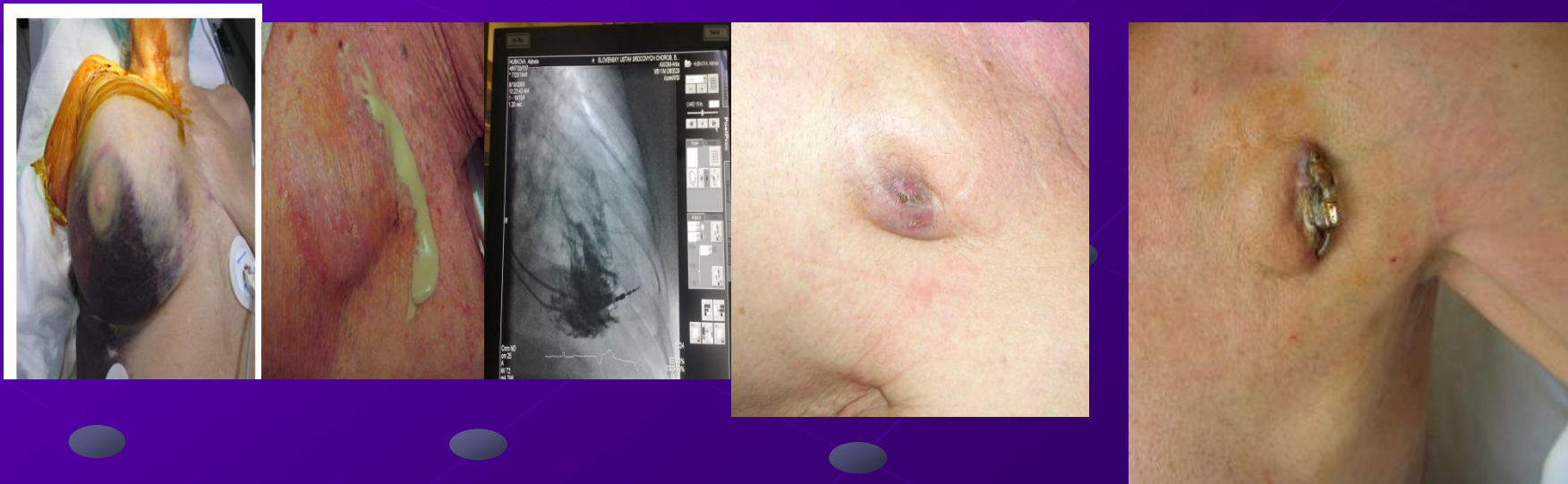
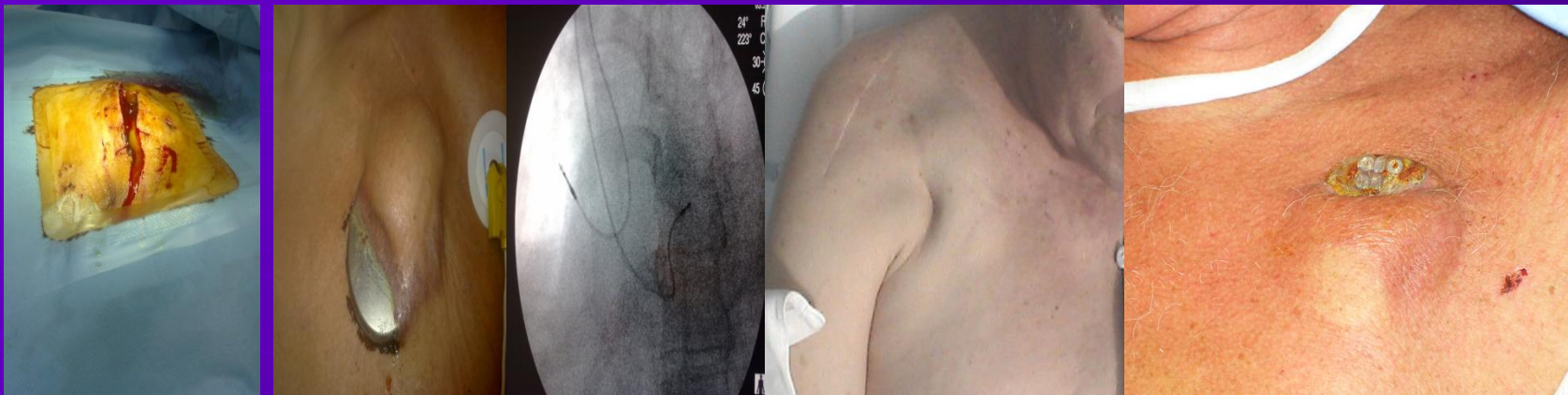
Radostné stránky implantológie



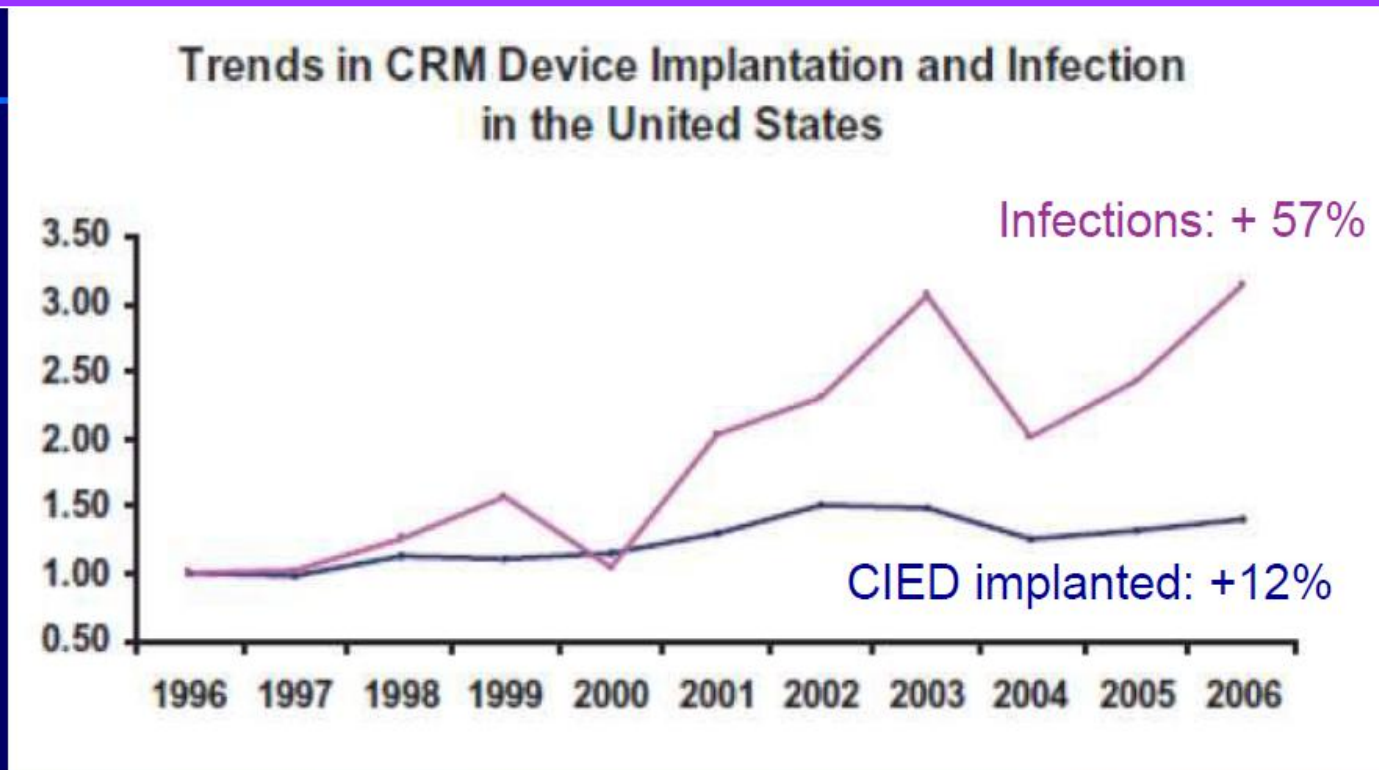
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Tienisté stránky implantológie



Vzostup infekcií CRDM v USA za 10 rokov/ 1996-2006



Infekcie stúpajú rýchlejšie ako počty implantácií

... možné vysvetlenie tejto epidémie- implantujú sa starší, polymorbídni pacienti, viac komplexných procedúr, revízií, upgradeov, rezistencia mikroorg

A Voigt et al, PACE 2010; 33:414-419

Rizikové faktory asociované s infekciou CIED

<u>Patient-Related Factors</u>	<u>Procedure-Related Factors</u>	<u>Device-Related Factors</u>
Age >60 y	Lack of antibiotic prophylaxis	Defibrillator (vs pacemaker)
Male sex	Device replacement/revision	Dual chamber (vs single chamber)
Chronic obstructive pulmonary disease	Early reintervention	Biventricular device
Congestive heart failure	Procedure duration	Abdominal pocket
Diabetes	Operator experience	Epicardial leads
Renal disease (dialysis)	Postimplant hematoma	
Steroid use		
Prior infection		
Presence of a central venous catheter		
Anticoagulant use		
Preoperative fever		

Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis

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Table 1 Characteristics of the included studies (prospective studies)

Study ID	Totals (n)	Male (%)	Age (yrs) ^a	Follow-up (mo) ^b	Infection rate (%) ^c	Identified risk factors ^d
Muers 1981 ³⁴	431	NR	70	22.8 (9–40)	2.1	Lack of antibiotic prophylaxis
Ramsdale 1984 ³⁵	500	50	72	3–12	4.2 (0.6)	–
Bluhm 1984 ²⁸	100	51	73	1–43	8	Lack of antibiotic prophylaxis
Bluhm 1986 ²⁹	106	54	75	14 (7–35)	0	–
Glieda 1987 ³¹	200	66	66	NR	6	Lack of antibiotic prophylaxis
Mueller 1990 ¹⁶	333	57	73	16	0.9	–
Bru 1991 ³⁸	209	53	70	(1–36)	1.4	–
Lüninghake 1993 ³²	302	NR	NR	(12–48)	5	–
Mounsey 1994 ³³	656	55	74	19 (9–26)	2	Lack of antibiotic prophylaxis; reintervention; procedure duration; inexperienced operator
Chauhan 1994 ³⁹	2019	56	NR	1.5	0.8	Temporary pacing
Aggarwal 1995 ³⁶	1059	51	75	2	1.8 (0.9)	Temporary pacing wire
Kron 2003 ⁴²	539	79	65	27	2.6 (2)	Lack of antibiotic prophylaxis; abdominal pocket
Bertaglia 2006 ³⁷	852	56	77	25.6	1.8 (0.7)	Generator replacement; male sex; shorter procedure duration
Klug 2007 ^{6,40}	6134	60	73	12	0.7	Lack of antibiotic prophylaxis*; temporary pacing*; re-intervention*; fever within 24 h before implantation*; device replacement*
Oliveira 2009 ³⁰	649	47	64	6	2 (1.4)	Lack of antibiotic prophylaxis*; procedure duration; haematoma*; generator replacement
Romeyer-Bouchard 2010 ⁴⁷	303	81.5	70	31	4.3	Reintervention*; procedure duration*; haemodialysis*; haematoma; ICD device type*; lead dislodgement
Krahn 2011 ⁴¹	1081	82	66	1.5	2.6 (1.7)	Haematoma
Metais 2011 ⁴⁵	304	69	70	12	2.3	Reintervention; anticoagulant/antiplatelet drug use; history of contralateral implant
Landolina 2011 ⁴³	3253	80	67	Median: 18	1/100 pt-yrs	Generator replacement*; COPD*
MacFadden 2012 ⁴⁴	5213	79	65	12	1.9 (1)	–
Uslan 2012 ⁴⁸	1744	68	70	6	1.3 (0.8)	Abdominal pocket; haematoma

Table 2 Characteristics of the included studies (retrospective studies)

Study ID	Totals (n)	Male (%)	Age (yrs) ^a	Follow-up (mo) ^b	Infection rate (%) ^c	Identified risk factors ^d
Case-control studies						
Bloom 2006 ¹¹	4856	77	67	NR	1.6	Generator replacement*; diabetes mellitus; renal insufficiency*; oral anticoagulants*; CHF*; male sex*; age
Sohail 2007 ¹⁶	12 799	76	63	39	0.23	Lack of antibiotic prophylaxis*; device replacement/upgrade; CVC; malignancy; corticosteroids*; history of device infection; number of device-related procedures (> 2); number of leads (> 2)*
Marschall 2007 ⁵²	116	63	62	NR	16.4	Device replacement/revision; abdominal pocket
Lekkerkerker 2008 ⁵¹	3410	73	60.5	NR	2.2	Device replacement/revision*; diabetes mellitus; renal insufficiency*; elevated serum Cr; oral anticoagulants*
Gould 2008 ⁴⁹	451	72	67	12	4 (2.2)	Consultant operator
Nery 2010 ⁵³	2417	67	68.5	NR	1 (0.9)	Generator replacement*; lead dislodgement; dual/triple-chamber device*
Sohail 2011 ¹⁵	204	81	Median: 65.5	44.4	NA	Temporary pacing; haematoma; haemodialysis; COPD*; history of device infection; chronic skin disorders; number of device-related procedures (≥ 3); duration of hospital-stay (≥ 2 d)*; Charlson index (≥ 4); epicardial lead*; any post-operative complication*
Raad 2012 ⁵⁴	72	72	70	NR	NA	Generator/lead replacement; haematoma; dual-chamber device; history of device infection; post-procedural trauma
Herce 2013 ⁵⁰	2868	60	73	NR	1.2	Reintervention; diabetes mellitus*; dual-chamber device*; heart disease*; simultaneous invasive procedure
Retrospective cohorts						
Rao 1974 ⁷²	401	55.4	NR	NR	0.75	–
Mugica 1977 ⁷⁰	2016	NR	NR	NR	2	Lack of antibiotic prophylaxis
Hartstein 1978 ⁶⁵	298	59.8	72	NR	3	Use of drains
Wunderly 1990 ⁷⁷	263	NR	NR	19	3	–
Trappe 1995 ⁷⁶	335	91	56	22	3.9	Epicardial lead placement
Spinler 1998 ¹²	171	80	61	(15.6–102)	4.5	Diabetes mellitus*
Smith 1998 ⁷⁴	1831	78	63	NR	1.2	Presence of subcutaneous defibrillation patch*
Harcombe 1998 ⁶⁴	2621	59	74	NR	0.7	Device replacement
Kiviniemi 1999 ⁶⁸	446	41	72	27 (0–72)	1.8	–
Higgins 2000 ⁶⁶	174	84.5	69	NR	1.7	Device upgrade to dual chamber
Mela 2001 ⁶⁹	1406	NR	NR	35	1.2	Abdominal pocket
Wiegand 2004 ¹³	3164	58	72	3	0.3	ICD device type
Al-Khatib 2005 ⁵⁵	9854	78	> 65	3	1.1	Operator experience*
Gil 2006 ⁶³	423	86	60	NR	2.4	Abdominal pocket; two-stage surgery; subcostal approach of lead placement; trauma at pocket; decubitus ulcer
Catanchin 2007 ⁵⁹	1481	56	Median: 75	Median: 29.3	1.6	Male sex; number of prior procedures (> 1)
Dasgupta 2007 ⁶²	164	71	65	NR	3 (1.8)	–
Ito 2009 ⁷⁸	71	80	58	37.6	1.4	–
Pakarinen 2010 ⁷¹	567	51	72	3	1.9 (1.2)	Reintervention; temporary pacing
Cengiz 2010 ⁶⁰	890	57	Range: 18–104	34.8	2.5	Lack of antibiotic prophylaxis*; generator replacement*; haematoma; anticoagulants; corticosteroids; CVC*; age*
Borleffs 2010 ⁵⁸	3161	80	62	38	1.2/100 ICD-yrs	Device (generator/lead) replacement
Margey 2010 ^{e-14}	3105	69	Median: 69	NR	1.3	CRT device*; number of leads (> 2); screening time

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Table 2 Continued

Study ID	Totals (n)	Male (%)	Age (yrs) ^a	Follow-up (mo) ^b	Infection rate (%) ^c	Identified risk factors ^d
Bloom 2011 ⁵⁷	624	68	70	1.9	0.5	–
Johansen 2011 ^{1,67}	56 657	54	Median: 76	NR	7.14/1000 PPM-yrs	Lack of antibiotic prophylaxis*; device replacement; dual-chamber device; male sex*; younger age (20–49 yrs)*; implantation during the early yrs of study*; procedure complexity; number of prior procedures*; indication (AV block)
Charytan 2011 ⁶¹	9528	70	64.5	16.8	4.2/100 pt-yrs	COPD; age; black race (vs. caucasian); dialysis modality (vs. haemodialysis)*; recent infection*; cerebrovascular accident/TIA*; GI bleeding
Tompkins 2011 ⁷⁵	1440	65	65	2	0.5	Renal insufficiency; end-stage renal disease
Lyman 2011 ⁸¹	38 992	77	66	3	1.2	–
Armaganijan 2012 ⁵⁶	4814	57	76	61.2	NR	–
Schuchert 2013 ⁷³	402	79	68	12	1.2	–
Peterson 2013 ⁸⁰	32 034	74	74	3	0.7	–
Palmisano 2013 ⁷⁹	2671	57	74	Median: 27	1.1	Generator replacement/system upgrade*; CRT device*

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Table 3 Variables identified as significant risk factors for CIED infection in at least two studies^a

	Prospective studies (n)		Case-control studies (n)		Retrospective cohorts (n)	
	Univariate	Multivariate	Univariate	Multivariate	Univariate	Multivariate
Host-related factors						
Age			1 ¹¹		3 ^{60,61,67}	3 ^{14,60,67}
Male sex	1 ³⁷		1 ¹¹	1 ¹¹	2 ^{59,67}	1 ⁶⁷
Diabetes mellitus			3 ^{11,50,51}	1 ⁵⁰	1 ¹²	1 ¹²
Renal insufficiency			2 ^{11,51}	2 ^{11,51}	1 ⁷⁵	
ESRD/dialysis	1 ⁴⁷	1 ⁴⁷	1 ¹⁵		1 ⁷⁵	
COPD	1 ⁴³	1 ⁴³	1 ¹⁵	1 ¹⁵	1 ⁶¹	
Anticoagulants	1 ⁴⁵		2 ^{11,51}	2 ^{11,51}	1 ⁶⁰	
Corticosteroids			1 ¹⁶	1 ¹⁶	1 ⁶⁰	
CVC			1 ¹⁶		1 ⁶⁰	1 ⁶⁰
History of device infection			3 ^{15,16,54}			
Implant site trauma			1 ⁵⁴		1 ⁶³	
Procedure-related factors						
Lack of antibiotic prophylaxis	7 ^{28,30,31,33,34,40,42}	2 ^{30,40}	1 ¹⁶	1 ¹⁶	3 ^{60,67,70}	2 ^{60,67}
Device replacement/revision	3 ^{30,37,43}	2 ^{40,43}	6 ^{11,16,51–54}	3 ^{11,51,53}	6 ^{58,60,64,66,67,79}	2 ^{60,79}
Reintervention	5 ^{31,33,40,45,47}	2 ^{40,47}	1 ⁵⁰		1 ⁷¹	
No. of prior device-related procedures			2 ^{15,16}		2 ^{59,67}	1 ⁶⁷
Temporary pacing	3 ^{36,39,40}	1 ⁴⁰	1 ¹⁵		1 ⁷¹	
Procedure duration	4 ^{30,33,37,47}	1 ⁴⁷				
Operator experience	1 ³³		1 ⁴⁹		1 ⁵⁵	1 ⁵⁵
Lead dislodgement	1 ⁴⁷		1 ⁵³			
Post-op haematoma	5 ^{30,31,41,47,48}	1 ³⁰	2 ^{15,54}		1 ⁶⁰	
Device-related factors						
ICD device	1 ⁴⁷	1 ⁴⁷			1 ¹³	
CRT					2 ^{14,79}	2 ^{14,79}
Dual-chamber system			2 ^{50,54}	1 ⁵⁰	1 ⁶⁷	
No. of leads			1 ¹⁶	1 ¹⁶	1 ¹⁴	
Abdominal pocket	2 ^{42,48}		1 ⁵²		2 ^{63,69}	
Epicardial leads			1 ¹⁵	1 ¹⁵	1 ⁷⁶	

Faktoři:
Modifikovatelné
Nemodifikovatelné

Modifikovatelné a nemodifikovatelné rizikové faktory

Modifiable risk factors

- (1) Colonization with *S. aureus*
- (2) Optimization of comorbid conditions such as DM, CHF, CKD
- (3) Chronic steroid therapy
- (4) Skin antiseptics prior to procedure
- (5) Preoperative antibiotic prophylaxis
- (6) Antibiotic impregnated envelope
- (7) Peri-procedure anticoagulation
- (8) Central venous catheter as potential source of bacteremia
- (9) Experience level of device implanter
- (10) Presence of abandoned leads

Non-modifiable risk factors

- (1) Age
- (2) Comorbid conditions (DM, CHF, CKD, Malignancy)
- (3) Temporary pacing lead before permanent device implantation
- (4) History of multiple device-related procedures
- (5) History of CIED infection
- (6) Presence of >2 electrode leads
- (7) Recent device manipulation
- (8) Presence of epicardial leads
- (9) Chronic skin conditions (psoriasis, dermatitis)
- (10) Autoimmune diseases requiring immunosuppressive therapy

CHF: congestive heart failure; CIED: cardiac implantable electronic device; CKD: chronic kidney disease; DM: diabetes mellitus.

Riziko infekcie u pacientov s CIED

- Pacemaker 1% after 1 year
- ICD 1.7% after 6 months
- CRT 9.5% after 2 yrs



- 2-4 fold risk after device replacement or upgrades

- Mortality lead extraction: 0.3-0.8%

- Delayed device removal 3-fold increase in 1 year mortality

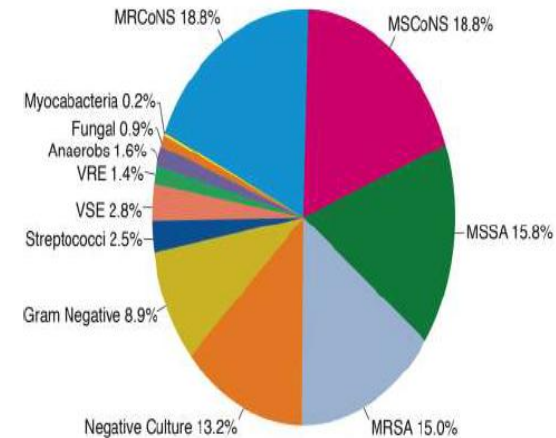
- Conservative therapy 7-fold increase in 30-day mortality



Microbiology in 816 patients who underwent CIED extraction for infection at Cleveland Clinic between 2000-2011

MRSA = methicillin-resistant Staphylococcus aureus; MSSA = methicillin-sensitive Staphylococcus aureus; MRCoNS = methicillin-resistant coagulase-negative staphylococcus; MSCoNS = methicillin-sensitive coagulase-negative Staphylococcus; VRE = vancomycin-resistant Enterococcus species; VSE = vancomycin-sensitive Enterococcus species.

Poznaj svojho nepriateľa



Nielsen JC et al. Eur Heart J 2015;36:2484
 Sekiguchi Y. J Arrhythm 2016;32:293
 Margery R et al. Europace 2010; 12:64-70

Princípy prevencie infekcií

6 článkov v reťazci
prenosu infekcie



4 oblasti záujmu

Hygiena rúk



Chirurgické nástroje



Antiseptická
Príprava kože

Enviromentálny
manažment

Prevenca komplikácií CIED

CAVE

Výber optimálneho kandidáta na implantáciu
- Odporúčania na implantácie KS, ICD a
CRT 2013,2015,2016

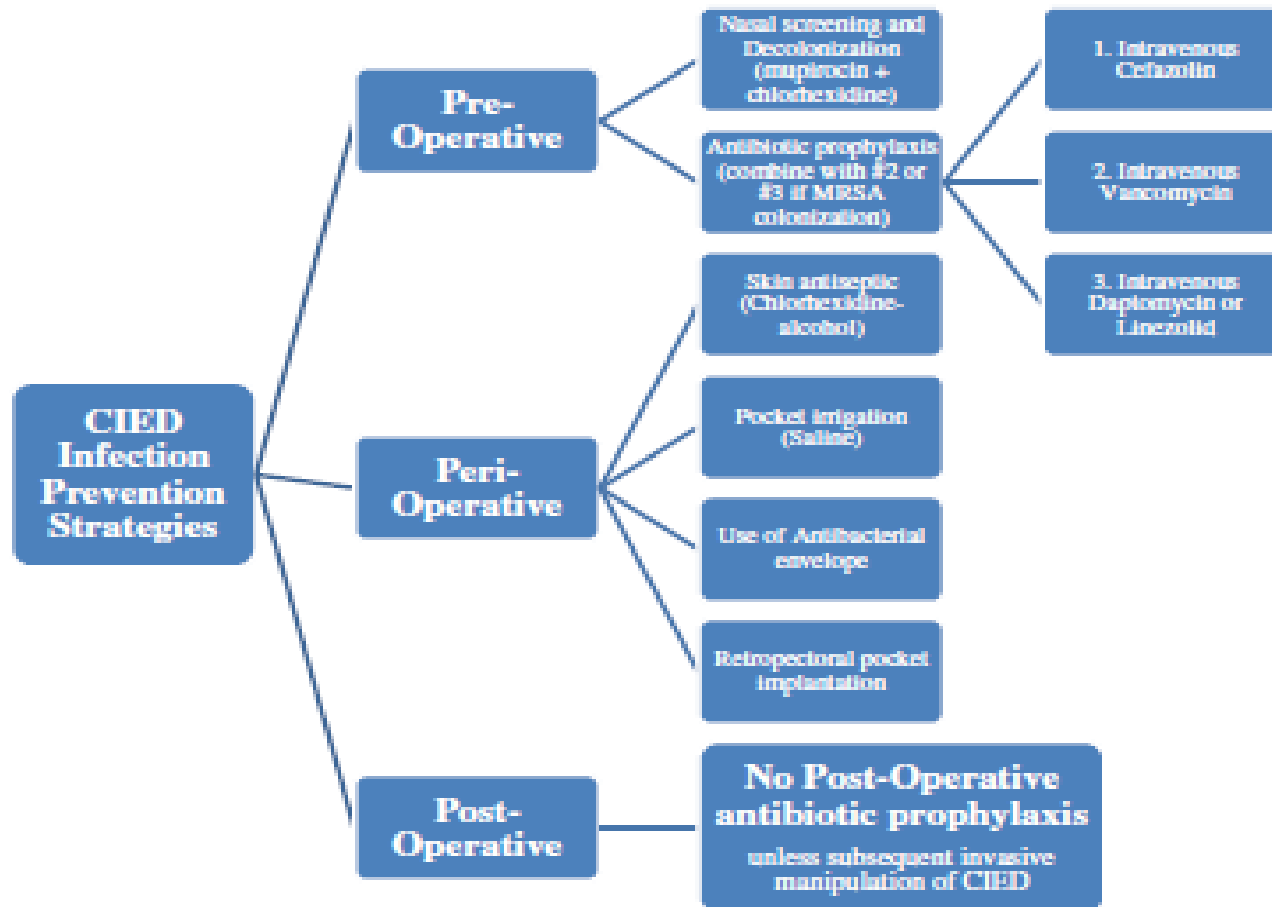
Memento

Je implantácia vôbec potrebná?

Indikácia, selekcia pacienta, optimálne
načasovanie...

12-55% pacientov po extrakciách nebolo
reimplantovaných!!!

Preventívne stratégie na minimalizáciu infekcií



Prevenencia komplikácií CIED

Čo urobiť preimplantačne?

- Optimálny výber pacienta, posúdenie individuálnej miery rizika a benefitu
- Indikácia ? Optimalizácia typu CIED (veľkosť, tvar, komplexnosť...)
- CAVE: dočasná KS (minimalizácia trvania, špička ad K+C)
- CAVE: zápalový sy, febrility, subfebrility (odložiť výkon!!!)
- Preliečenie kožných afekcií a ulcerácií (dostať všetko pod kontrolu)
- Konštitúcia, BMI, žilová kresba, známky SZ, CVK, ochlpenie v mieste op.
- Predchádzajúce jazvy v mieste op., tumor,hygiena pac.!!! +oholenie op.poľa
- Kontrola medikácie- osobitne antitrombotiká a antikoagulanciá

Prevenencia komplikácií CIED

Čo urobiť perimplantačne?

- „režim operačky“ na implantačnej sále (minimalizácia osôb a pohybu na op)
- ATB profylaxia
- Správna technika rúškovania pacienta, inštitucionálny protokol!
(chlorhexidín versus povidon-iodine)
- trvanie výkonu (implantačný čas čo najkratší)
- hemostáza
- správna chir. technika (irigácia kapsy-ATB/antiseptiká/FR-bez dôkazov)
(kapsulektomia nie!!!)
- Používanie zdvojenia rukavíc (funguje na redukciu infekcií)
- Redukcia „hardware“

Aké antiseptikum?

ORIGINAL ARTICLE

Chlorhexidine–Alcohol versus Povidone–Iodine for Surgical-Site Antisepsis

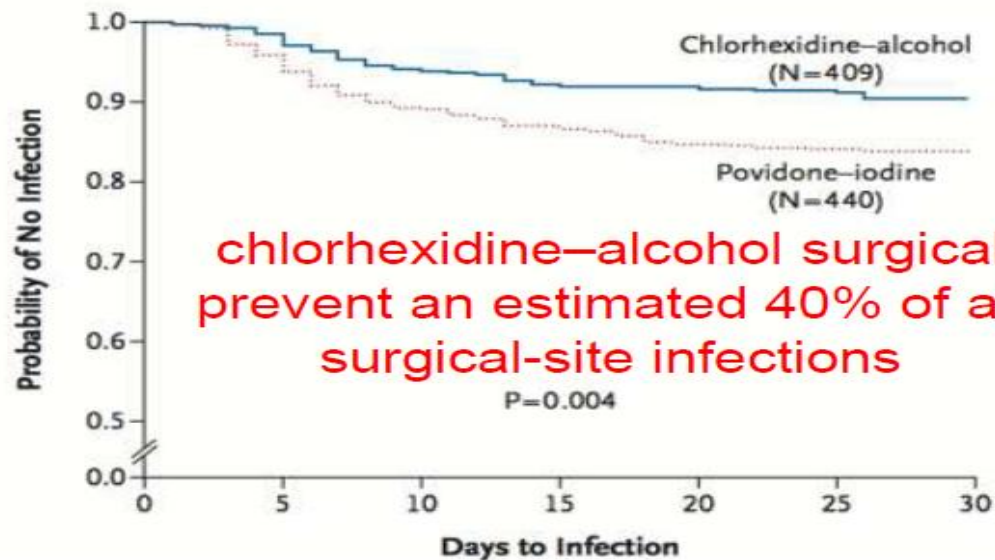


Figure 2. Kaplan–Meier Curves for Freedom from Surgical-Site Infection (Intention-to-Treat Population).

Patients who received chlorhexidine–alcohol were significantly more likely to remain free from surgical-site infection than were those who received povidone–iodine ($P=0.004$ by the log-rank test). In the chlorhexidine–alcohol group, 39 patients had events (9.5%) and data from 370 patients (90.5%) were censored; in the povidone–iodine group, 71 patients had events (16.1%) and data from 369 patients (83.9%) were censored.



Príprava kože: Chlorhexidín vs povidone iodine

- On 4/30/2010 The use of Chlorhexidine in the EP lab was discontinued and we started using Betadine

- Did that affect our CIED infection rate?

Reviewed all device procedures 1 year before and 1 year after 4/30/2010

• Conclusion

In one large cohort of patients undergoing CIED procedures, the antiseptic agent used for skin preparation (chlorhexidine-alcohol vs povidone-iodine) was not associated with increased risk of developing CIED infection.

The Impact of Changing Antiseptic Skin Preparation Agent used for Cardiac Implantable Electronic Device (CIED) Procedures on the Risk of Infection

MOHAMMED QINTAR, M.D.,* CMEED ZARDKOCHI, M.D.,†
MUHAMMAD HAMMADAH, M.D.,* AMY HSU, M.S.,‡ OUSSAMA WAZNI, M.D.,‡
BRUCE L. WILKOFF, M.D.,‡ and KHALDOUN G. TARAKJI, M.D., M.P.H.‡

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Qintar, Wazni, Wilkoff, Tarakji. *PACE*. 2015;38:240

Skin preparation: Chlorhexidine-Alcohol vs Povidone-Iodine

- 1,326 consecutive patients undergoing CIED
 - 2010: 648 povidone-iodine
 - 2011: 678 alcoholic povidone iodine
- Follow up 26 months
- 32 CIED infection (2.4%)
- No significant difference between 2 agents



Správna chirurgická technika

Guideline for Prevention of Surgical Site Infection, 1999

Alicia J. Mangram, MD; Teresa C. Horan, MPH, CIC; Michele L. Pearson, MD; Leah Christine Silver, BS; William R. Jarvis, MD; The Hospital Infection Control Practices Advisory Committee

- Gentle traction
- Effective hemostasis
- Removal of devitalized tissues
- Obliteration of dead space
- Irrigation of tissues with saline to avoid excessive drying
- Use of fine, non-absorbed monofilament suture material
- Judicious use of closed suction drains
- Wound closure without tension

From Altemeier, et al. 1984.⁵⁴

SSIs = surgical site infections.

ATB a antiseptiká predchádzajú infekciám pri impl. CIED

Metaanalýza 15 štúdií- 3970 pacientov

DAROUICHE, ET AL.

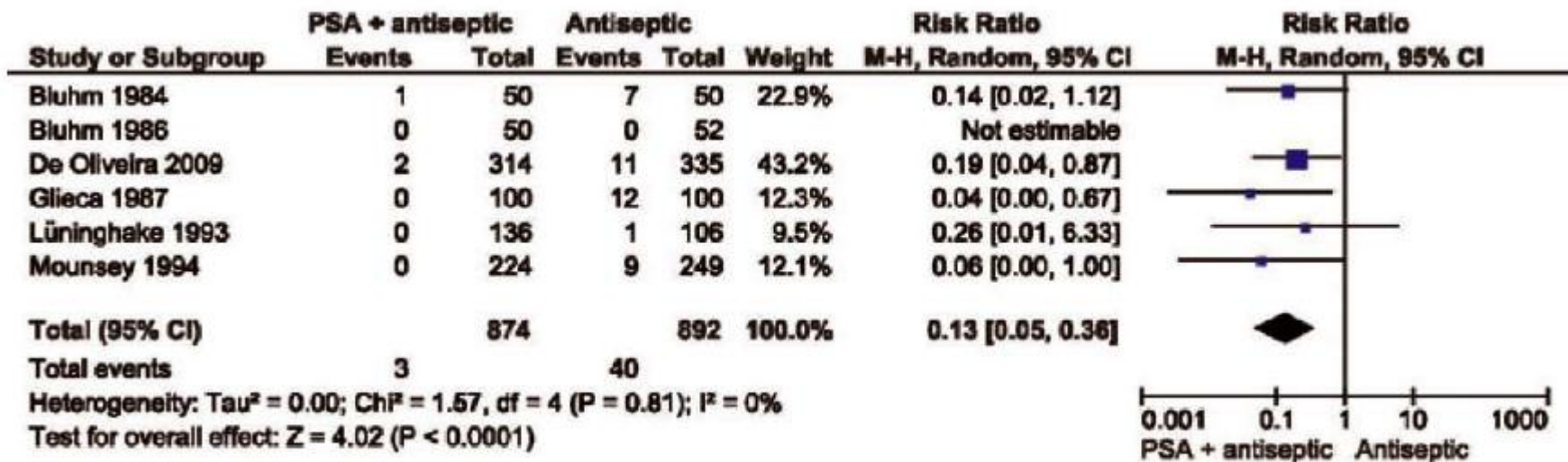


Figure 3. Forest plot of risk ratio for infections: PSA plus antiseptics versus antiseptics.

ATB profylaxia

Pre-operative Antibiotics Prevent Infection

Meta analysis	Antibiotics	Controls
No. of Patients	1011	1012
Infections	5 (0.5%)	37 (3.7%)

p=0.005

Brazil Controlled Trial 2009	Cefazolin 1g	Controls
No. of Patients	314	335
Infected	2 (0.64%)	11 (3.28%)
Superficial	0	4
Pocket	2	7
Systemic	1	4

p=0.016

Infected patients

longer procedures
more pocket haematomas
replacements (10/13)

Prevencia komplikácií CIED

Čo urobiť počas FU

☐ Redukuj počet výmen !!!

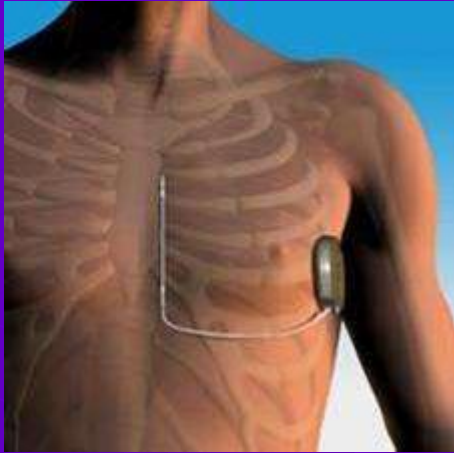
Optimalizácia životnosti

☐ Upgrade len ak je nevyhnutný !!!

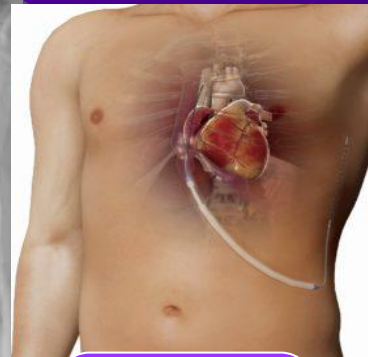
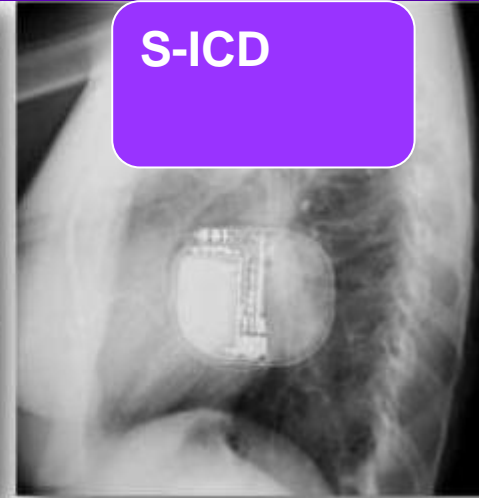
☐ Prevencia neskorých/meta inf.!!!

*Dôsledné preliečenie všetkých
afekcií a infekcií*

Alternativy CIED



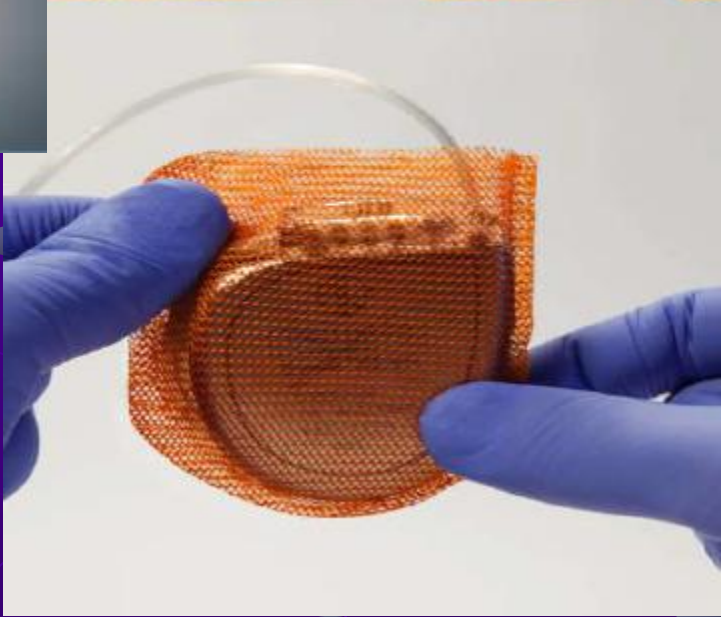
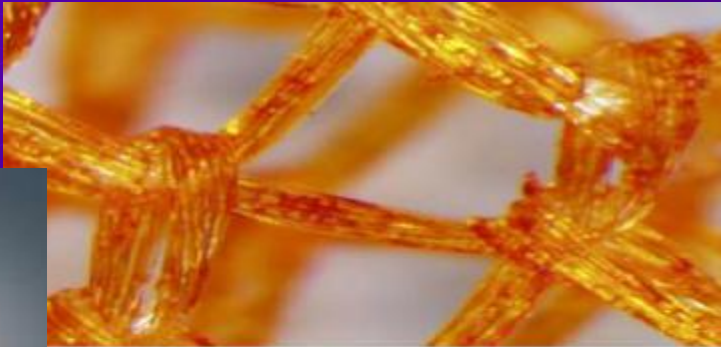
S-ICD



Bezelektrodový-leadless
systém

Strunový
defibrilátor

TYRX™ Antibiotická obálka



Obálka pri implantácii

4 týždne po

9 týždňov po

World-wide Randomized Antibiotic Envelope CIED Infection Prevention Trial (WRAP-IT)

- Randomized, prospective, multi center, international, single blinded post market study
- Target population:
 1. CIED replacement of upgrade (PPM, CRT-P, ICD, CRT-D)
 2. De novo CRT
- About 7,000 patients
- Randomized 1:1 (envelope vs no envelope)

Tarakji KG, Mittal S, Kennergren C, Corey R, Poole J, Stromberg K, Lexcen DR, Wilkoff BL. Worldwide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT). Am Heart J 2016;180:12–21.

Prevention of Arrhythmia Device Infection (PADIT)

- Prospective, randomized, unblinded cluster crossover clinical trial
- 11,000 patients (Secondary procedures)
- Sites (not patients) are randomized into 2 strategies for preoperative antibiotic
 - Conventional: Single preop dose of Cefazolin (or vancomycin for penicillin-allergic patients)
 - Incremental:
 - Single preop dose of Cefazolin **AND** Vancomycin (In patients allergic to Penicillin, vancomycin alone)
 - Intraoperative bacitracin pocket wash
 - 2 Days postop antibiotics (Cefalexin or Cephadroxil (or Clindamycin in penicillin allergic patient)

Závery

- ❑ Infekčné komplikácie CIED nie sú zriedkavé a sú na vzostupe. Prevencia začína pred rozhodnutím implantovať CIED!!!

- ❑ Prevencia je dôležitá a závisí od výberu harvéru, techniky, op.teamu. Treba zodpovedať otázky: -
 - otázka indikácie
 - otázka načasovania
 - otázka pripravenosti pac.
 - zdravá kapsa /chir.technika/
 - ATB profylaxia

- ❑ Pri každej implantácii myslieť na event. budúcu **EXTRAKCIU!!!**

- ❑ Nové postupy / TYRX, PADIT, Leadless KS, S-ICD .../

Aké sú riziká pre vznik infekcie?

PATIENT PROCEDURES	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Early Reintervention*	15.04
CRT-D vs ICD/PM	7.57
>2 Leads in Place	5.41
Device Replacement/Revision**	3.67
Temporary Pacing Wire	2.46

PATIENT MEDICATIONS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Corticosteroid Use***	13.90
Oral Anticoagulant	2.82

PATIENT CHARACTERISTICS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Renal Failure	11.97
Fever <24 hr Prior to Implantation	5.83
Renal Insufficiency	5.46
Congestive Heart Failure	2.57
Male Gender	2.23

Klug D et al. Circulation 2007;116(12):1349-1355. - Lekkerkerker JC et al. Heart 2009;95(9):715-720.
Margey R et al. Europace 2010;12(1):64-70. - Sohail MR et al. Clin Infect Dis. 2007;45(2):166-173.
Bloom H et al. Pacing Clinical Electrophysiology 2006;29(2):142-145.