

Risk of skin erosion and local pocket infections in population of patients with cardiac implantable electronic devices undergoing transvenous lead extraction

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Abstract

The thinning of the skin over the pocket is an occasional phenomenon in patients with cardiac implantable electronic devices (CIEDs) most often associated with the technique of implantation of the device. It is likely that the thinning of the skin over the generator is a risk factor for the development of infectious complications in patients with CIED. Analysis of large database of 3706 patients undergoing transvenous lead extraction (TLE) showed higher number of points of PADIT score and more often previous pocket plastic surgery in patients with too shallow pocket. Most likely, diagnosing only a too shallow CIED pocket is often an early symptom of infection.

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Abstract

The thinning of the skin over the pocket is an occasional phenomenon in patients with cardiac implantable electronic devices (CIEDs) most often associated with the technique of implantation of the device. It is likely that the thinning of the skin over the generator is a risk factor for the development of infectious complications in patients with CIED. Analysis of large database of 3706 patients undergoing transvenous lead extraction (TLE) showed higher number of points of PADIT score and more often previous pocket plastic surgery in patients with too shallow pocket. Most likely, diagnosing only a too shallow CIED pocket is often an early symptom of infection.

Editorial

The thinning of the skin and subcutaneous tissue above the pocket of cardiac implantable electronic devices (CIED) is an occasional phenomenon, which may have many reasons. The most frequently considered are: improper CIED implantation or re-implantation with too shallow design of the pocket, progressive weight loss (cachexia), but it can also be the temporary first visible stage or even first symptom of CIED pocket infection. In the observation of Yatomi et al. risk factors for skin thinning over the generator were: low BMI, low haemoglobin level, heart failure, malignancy and renal dysfunction. In this study, a retrospective analysis of clinical data from a group of 101 patients with an average lead dwell time of 95 months revealed no cases of pocket infections in patients with thinning of the skin over the generator. Authors recognised thinning of the skin in 17 patients (about 17%) which indicates, that the phenomenon is not so rare. According to our observations, too tight skin over a too tight and shallow pocket loses its elasticity and becomes less and less mobile, and after some time, progressive necrotic processes lead to a lack of protection against the penetration of bacteria. Patients with a shallow CIED pocket should be monitored by an electrocardiologist controlling the device (and performing follow-up). Changes in the colour of the skin towards blue or reddening, the appearance of pain or local warming, or the loss of skin sliding over the bed, means the probable beginning of infection, which is an indication for transvenous lead extraction (TLE). In patients with a very superficial generator site, without signs of infection, the possibility of deepening the pocket (so called surgical "plastic of the CIED pocket") is sometimes considered. Theoretically, this type of procedure is possible, but the extremely shallow location of the unit is accompanied by the loop of the lead growing into the skin and the preparation of such leads is often associated with risk of their accidental damage as well as an increased risk of developing infectious complications. It should be emphasized that an excessively shallow pocket is not an indication for transvenous lead extraction. Its consequence in the form of bedsores (limited skin necrosis) or the next stage - purulent fistula over the pocket or loop of the lead - as an infectious complication - is already an indication for TLE (Figure 1, Figure 2).

Figure 1 Four examples of too shallow CIED pockets. A. Visible growth of the lead loops into the skin. B one-way pressure of the pacemaker housing against the wall of the pocket. C Onset of redness, indicating that an infection may start. D. Possibly improperly performed unit replacement; the tension of a too small pocket pushes the pacemaker upwards.

Figure 2 Four examples of infections of too shallow CIED pockets. The lead loop (A) or the edge of the unit (B, C, D) causes progressive skin necrosis and secondary classic infection. Examples of situations where it is much too late for surgical "plastic pocket surgery" and the only solution is to remove the infected system completely.

In our large database of 3706 patients who underwent TLE in the years 2006-until now, 60 patients with too shallow pocket were identified. In 60% of patients in this group, the main indication for TLE was CED-related infection (in 30% local, pocket infection). Among the non-infectious indications, the dominant ones were: lead dysfunctions caused by their mechanical damage and other causes (20% in total). Consistent with guidelines for indications for transvenous lead extraction, a too shallow pocket is not the primary cause of TLE (Table 1).

Table 1 Indications for TLE in 60 patients with thinning of the skin and subcutaneous tissue above the poc

Table 1 Indications for TLE in 60 patients with thinning of the skin and subcutaneous tissue above the poc

Predominant indication for lead extraction - infective

Lead related infective endocarditis certain
 Lead related infective endocarditis probable
 Local (pocket) infection
 All

Predominant indication for lead extraction - non-infective

Mechanical lead damage (electric failure)
 Lead dysfunction (exit/entry block, dislodgement, extracardiac pacing, perforation)
 Abandoned Lead / prevention of abandonment (AF, overmuch of leads)
 Threatener / potentially threatener lead (loops, free ending, left heart, LDTVD)
 Other (MRI indication, cancer, pain of pocket, loss of indication for pacing / ICD)
 Recapture venous access (sympt. occlusion, SVC syndr., lead replacement / upgrading)
 All

A comparative analysis of clinical factors characterizing patients with pocket thinning and patients with non-infectious indications for TLE showed more frequent occurrence of a shallow pocket in elderly male patients, with higher number of HAS-bleed score,. Patients with a confirmed CIED-related infection more often had diabetes, higher Charlson's co-morbidity index, higher inflammatory parameters and lower hemoglobin levels (Table2).

Table 2 Clinical characteristics of compared groups

Patient-related risk factors of infection and additional clinical information	CIED pocket thinning (mixed sub-group with co-existing an-other indication for TLE)	CIED pocket thinning (mixed sub-group with co-existing an-other indication for TLE)	Noninfectious TLE indications		Pocket infection with or without LRIE		Isolated LRIE (without pocket infection)		P 1 vs 2	P 1 vs 3	P 1 vs 4
			Noninfectious TLE indications	Noninfectious TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)			
Number of patients / group number	60	1	2511	2	789	3	349	4			

Patient-related risk factors of infection and additional clinical information		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Noninfective TLE indications	Noninfective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
		Count / average	%/Sd	Count / average	%/Sd	Count / average	%/Sd	Count / average	%/Sd			
Form of results presentation (count/average; Sd/%)												
Patient's age during TLE	Aver±Sd	68,95	12,56	64,77	16,38	69,51	13,23	66,38	14,27	0,05	0,45	0,00
Patient's age during first system implantation	Aver±Sd	62,00	13,10	55,93	17,98	61,87	14,14	68,61	15,65	0,01	0,94	<0,01
Sex of male patients (%)	n (%)	33	55,00%	1452	57,83%	564	71,48%	243	69,63%	0,64	<0,01	0,00

Patient-related risk factors of infection and additional clinical information	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Noninfective TLE indications	Noninfective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Underlying heart disease: IHD, MI, NYHA III & IV Congestive heart failure (symptomatic presently)	35	58,33%	1410	56,15%	442	56,02%	177	50,72%	0,71	0,70	<0,05
LVEF average (%)	49,73	14,13%	49,99	15,46%	48,520	14,64%	47,37	15,45%	0,90	0,54	0,001
LVEF significantly limited / decreased / reduced (<30%)	7	11,67%	304	12,1%	104	13,18%	55	15,76%	0,90	0,71	0,001

Patient-related risk factors of infection and additional clinical information		CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	Noninfect TLE indications	Noninfect TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Renal failure (any)	n (%)	12	20,00%	465	18,52%	181	22,94%	133	38,11%	0,76	0,60	0,40
Diabetes (any)	n (%)	7	11,67%	452	18,00%	179	22,69%	101	28,94%	0,21	0,05	0,05
Malignancy in history	n (%)	4	6,67%	160	6,37%	48	6,08%	26	7,45%	0,91	0,84	0,84
Treatment with steroids in history	n (%)	0	0,00%	29	1,15%	18	2,28%	15	4,30%	0,40	0,23	0,23
Permanent AF presence	n (%)	12	20,00%	536	21,35%	206	26,11%	89	25,50%	0,80	0,27	0,27
Mechanical valve presence	n (%)	1	1,67%	132	5,26%	35	4,44%	15	4,30%	0,21	0,28	0,28
Long-term anticoagulation was necessary	n (%)	26	43,33%	982	39,11%	290	36,76%	146	41,83%	0,49	0,29	0,29

Patient-related risk factors of infection and additional clinical information		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Noninfective TLE indications	Noninfective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Long-term antiplatelet therapy in recent history	n (%)	29	48,33%	1055	42,02%	342	43,35%	150	42,98%	0,31	0,46	<0,01
CHA2DS2-VASc scale - number of points	Aver±Sd	3,20	0,01	2,90	1,73	3,19	1,67	3,17	1,75	0,18	0,96	0,00
HAS-BLED scale - number of points	Aver±Sd	1,73	0,01	1,34	1,03	1,62	1,02	1,64	1,16	<0,01	<0,01	<0,01

Patient-related risk factors of infection and additional clinical information		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Noninfective TLE indications	Noninfective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Charlson's co-morbidity index - number of points	Aver±Sd	4,28	3,05	4,48	3,62	5,13	3,63	5,56	4,02	0,67	0,08	0,00
BMI	Aver±Sd	27,65	4,66	27,95	5,74	27,72	3,87	27,65	4,48	0,69	0,08	1,00
CRP level	Aver±Sd	15,56	34,90	10,67	24,65	29,09	43,45	75,40	77,84	0,13	0,02	<0,001
WBC (thousands)	Aver±Sd	8,22	2,82	7,73	3,41	8,37	3,33	11,08	6,25	0,27	0,73	<0,001
Haemoglobin	Aver±Sd	13,03	1,79	13,28	1,76	12,68	1,88	11,26	2,14	0,28	0,16	<0,001

Abbreviations: CIED- cardiac implantable electronic device, CRP- C-reactive protein, LRIE- lead related infective endocarditis, LVEF- left ventricular ejection fraction, TLE- transvenous lead extraction, WBC- white blood count

Thinning of the pocket was more often observed in patients with higher number of leads and higher number of CIED-related procedures before TLE especially surgical plastic surgery. This group of patients was also characterized by shorter lead dwell time, shorter time since last CIED-related procedure and higher score on the PADIT scale (Table 3).

Table 3. System- related and history of pacing- related risk factors of CIED complications in compared groups

System-related risk factors of CIED-related complications		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Non-infective TLE indications	Non-infective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
		Number of patients / group number	Units	Count / average	%/Sd	Count / average	%/Sd	Count / average	%/Sd	Count / average	%/Sd	
Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system	Kind of CIED system
Pacemaker	(%)	42	70,00%	1796	71,53%	559	70,85%	235	67,34%	0,79	0,87	0
ICD	(%)	12	20,00%	573	22,82%	151	19,14%	80	22,92%	0,61	0,86	0
CRT-D	(%)	6	10,00%	142	5,66%	79	10,01%	34	9,74%	0,15	0,99	0
History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing	History of pacing

System-related risk factors of CIED-related complications		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Non-infective TLE indications	Non-infective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Number of leads in the heart before TLE before TLE 4 and > 4 in the heart before TLE	Aver±Sd	2,08	0,74	1,89	0,71	2,06	0,75	2,13	0,87	0,04	0,84	0
	n (%)	4	6,67%	52	2,07%	39	4,94%	22	6,30%	0,02	0,54	0
Number of CIED-related procedures before lead extraction	Aver±Sd	1,98	0,93	1,72	0,96	2,24	1,25	1,93	1,25	<0,01	0,11	0

System-related risk factors of CIED-related complications		CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	Non-infective TLE indications	Non-infective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Presencen of abandoned lead before TLE n (%)	8	13,33%	221	8,80%	132	16,73%	52	14,90%	0,21	0,49	0	0
Time since last CIED-related procedure (any) n (%)	Aver±Sd 28,53	31,75	51,42	37,06	31,27	29,43	44,54	36,15	<0,01	0,49	<	<
Surgical plastic of unit pocket in history n (%)	2	3,33%	13	0,52%	202	25,60%	16	4,58%	<0,01	<0,01	0	0

System-related risk factors of CIED-related complications		CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing another indication for TLE)	Non-infective TLE indications	Non-infective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Dwell time of old-est one lead in the patient [months]	Aver±Sd	84,12	65,59	106,6	78,58	92,57	69,81	93,94	72,06	0,03	0,36	0
Mean lead dwell time before TLE mean [months]	Aver±Sd	77,22	59,51	99,55	69,79	82,26	60,04	85,34	61,29	0,01	0,53	0
Cumulative dwell time of ex-tracted lead (in years) in the patient	Aver±Sd	12,86	9,8	15,77	13,14	14,04	11,51	15,94	14,79	0,09	0,44	0

System-related risk factors of CIED-related complications		CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	CIED pocket thinning (mixed subgroup with co-existing an-other indication for TLE)	Non-infective TLE indications	Non-infective TLE indications	Pocket infection with or without LRIE	Pocket infection with or without LRIE	Isolated LRIE (without pocket infection)	Isolated LRIE (without pocket infection)	P 1 vs 2	P 1 vs 3	P 1 vs 4
Risk of infection – PADIT calculation – number of points	Aver±Sd	4,13	3,21	3,37	2,82	4,16	3,04	4,01	2,93	0,04	0,094	0

Abbreviations: CIED- cardiac implantable electronic device, CRT- cardiac resynchronization therapy, ICD- implantable cardioverter defibrillator, LRIE- lead related infective endocarditis, TLE- transvenous lead extraction, WBC- white blood count

Current analysis of a very large database of patients undergoing TLE confirmed the clinical importance of thinning of the CIED pocket in the development of infectious complications.

Patients with pocket infections (with or without lead-related endocarditis) were more often undergoing surgical plastic surgery before TLE (27%). This clearly indicates that previously recognized only too shallow CIED pockets were already an early symptom of an infection which, despite the deepening of the pocket, developed into a full-blown infection after some time. Despite the fact that in the group of patients with a shallow pocket of the CIED, only 60% of patients had an infection, the highest values of the PADIT score were recorded in this group of patients. These observations suggest the possibility of an earlier development of microorganisms in a too shallow pockets. Previous studies based on small populations confirm the presence of early contamination of the pocket with a tendency to subsequent colonization and development of full-blown infection. It seems that in patients with a shallow pocket, the infectious process may begin early after implantation and proceed covertly, therefore, presented by Yatomi et al. the concept of measuring skin thinning over the generator can be a form of detailed control of patients particularly at risk of developing

infectious complications..

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