

Late complications of electrotherapy — a clinical analysis of indications for transvenous removal of endocardial leads: a single centre experience

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Abstract

Background: Despite advances in electrotherapy, late complications constitute an increasing clinical and therapeutic problem. Transvenous lead extraction (TLE) is becoming a safe and effective approach to the treatment of such complications.

Aim: To assess indications for TLE and to evaluate safety and efficacy of TLE procedures.

Methods: A retrospective clinical analysis of 100 patients with complications of electrotherapy admitted to a tertiary care centre in 2008–2011.

Results: In 2008–2011, the number of electrotherapy complications increased markedly. The most frequent reason for TLE was lead dysfunction (62% of patients, including 31% with an implanted cardioverter-defibrillator [ICD] and 31% with a pacemaker [PM]). The most common type of lead dysfunction was conductor damage (38% of patients, including 23% with ICD, 15% with PM), followed by late myocardial perforation (14% of patients, including 7% with ICD, 7% with PM), abnormal course of the lead (7% of patients, including 1% with ICD, 6% with PM), and lead insulation failure (3% of patients). Other reasons for TLE were infectious complications (24% of patients, including 15% with PM pocket infection), venous insufficiency (17% of patients, including 10% in whom an indwelling lead was a direct obstacle to switching the pacing mode), and the need to switch the pacing mode (4% of patients). Procedural efficacy was 96% (lead fragments were left in place in 4% of patients). No significant clinical complications were observed in any of the patients in the periprocedural period.

Conclusions: Clinical manifestations of electrotherapy complications in the study group varied and included a relatively small number of infectious complications (24%) and a relatively large number of late myocardial perforations (14%). Efficacy and safety of the procedures were very high.

Key words: electrotherapy complications, transvenous leads extraction

Kardiol Pol 2013; 71, 4: 366–372

INTRODUCTION

In the recent years, we have observed an increase in the number of complications related to implanted electrotherapy devices. This is related to a growing number of implantations of increasingly sophisticated devices, not only due to conduction disturbances but also for the treatment of malignant ventricular arrhythmia and advanced heart failure. At the same time, prolongation of patient survival has resulted in an increased rate of repeated procedures, with a secondary

increase in the risk of infections and clinically evident lead dysfunction [1–3]. The presence of foreign bodies in the cardiovascular system is associated with adverse effects resulting from local irritation of vascular walls or cardiac valves. At an increasing rate, we observe such complications as occlusion of large veins and tricuspid valve dysfunction [4–11]. In addition, complications often beget other complications, as exemplified by the development of pulmonary embolism or infective endocarditis as a result of dislodgement of an indwell-

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Received: 26.06.2012 Accepted: 07.11.2012

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Table 1. Complication rates in relation to the number of pacemakers (PM), implantable cardioverter-defibrillators (ICD) and cardiac resynchronisation therapy (CRT) devices implanted in 2008–2011

Year	No. of PM/ICD/CRT implanted annually in the cardiology unit under investigation	No. of patients hospitalised in the same period due to complications of electrotherapy	Complication rate in relation to the number of device implantations (%)	No. of removed leads
2008	781	13	1.7%	21
2009	955	18	1.9%	32
2010	987	23	2.3%	37
2011	1078	46	4.3%	75
Overall	3801	100	Mean 2.6%	165

ing lead or fractured proximal lead ending to an adjacent cardiac chamber or large vessel. Some late complications of electrotherapy result from physical wear and tear of lead sheaths, which is another major factor in the development of thrombi and vegetations [12–14]. Obviously, no long-term randomised multicentre studies evaluating treatment of such complications are available, and due to this lack of solid evidence many recommendations are expert opinions based on personal experience and non-randomised studies, allowing for some flexibility regarding the choice of therapeutic options [15]. For these reasons, it is important to share experiences related to the investigation of electrotherapy complications and indications for transvenous lead extraction (TLE).

METHODS

We performed a retrospective analysis of clinical data of 100 patients with implanted electrotherapy devices (pacemakers [PM], implanted cardioverter-defibrillators [ICD], and cardiac resynchronisation therapy [CRT] devices) who were referred from a single cardiology unit to a tertiary care centre for TLE in 2008–2011. The present analysis included all patients referred during this period for TLE due to late complications related to an implanted electrotherapy device (PM/ICD/CRT). We evaluated clinical indications for and safety and efficacy of TLE procedures in these patients.

RESULTS

The number of PM/ICD/CRT implantations in the above mentioned cardiology unit increased steadily in 2008–2011, along with growing complexity of the implanted devices. At the same time, we saw a growing number of patients hospitalised due to complications of electrotherapy who were referred to a tertiary care centre for TLE (Table 1).

In the study period, the annual number of new PM/ICD/CRT implantations in the cardiology unit ranged from nearly 800 to 1100, and the proportion of patients referred for TLE increased from 1.7% to 4.3%, averaging 2.6% per year. These figures are in agreement with predictions of the European Heart Rhythm Association that estimated this rate at 1.5–6.0% [16]. Obviously, the growing number

Table 2. Clinical characteristics of the study group

Number of patients (n):	100
Women	33
Men	67
Patient age (years; mean \pm SD)	65.3 \pm 12.9
Women	67.8 \pm 14.0
Men	64.1 \pm 12.2
Removed leads (n):	
Overall	134
Atrial	44
Ventricular:	90
Right ventricular leads	50
Left ventricular leads	3
Defibrillation leads	37
Age of the removed leads (months, mean \pm SD):	
Overall	64.5 \pm 63.3
Atrial	80.1 \pm 70.6
Ventricular	56.9 \pm 58.4
Complexity of the implanted electrotherapy device (%):	
Single lead	42
Double lead	55
Triple lead	3

of implantations of more sophisticated electrotherapy devices and an increasing awareness of potential adverse consequences of dwelling non-functioning leads resulted in a larger proportion of patients referred for procedures involving the need for TLE.

The study group included 100 patients. The total number of removed leads was 134, including only 5 unipolar leads (3.7%). Overall, 102 passive fixation leads (76.1%) and 32 active fixation leads (23.9%) were removed. The mean age of the removed atrial leads in the study group was 80.1 (range: 1–301) months, and the mean age of the removed ventricular leads was 56.9 (range: 1–304) months. Fifty-eight per cent of complications for which TLE was indicated occurred in patients with 2- or 3-lead systems (Table 2).

Various interventions (including PM replacement, lead repositioning, pacing mode switch, and device pocket exploration) were previously undertaken in 76% of patients referred for TLE.

The most common indication for TLE was lead dysfunction (62% of the study population, including defibrillation lead damage in 31% of patients), followed by infectious complications (in 24% of patients). More rarely, TLE was indicated due to venous obstruction that precluded switching of the pacing mode (10% of patients), or the need to remove redundant leads before switching of the pacing mode (4% of patients) (Fig. 1).

Detailed analysis of causes of lead dysfunction revealed that the most common problem was metal conductor damage (38% of cases) leading to failure to capture, failure to sense, and also inadequate discharges of defibrillation leads.

Less common causes of lead malfunction included late perforations (14% of cases) and abnormal course of the lead resulting from its dislodgement to an adjacent cardiac chamber or large vessel (7% of cases). Late perforations were so called dry perforations, without significant pericardial effusion,

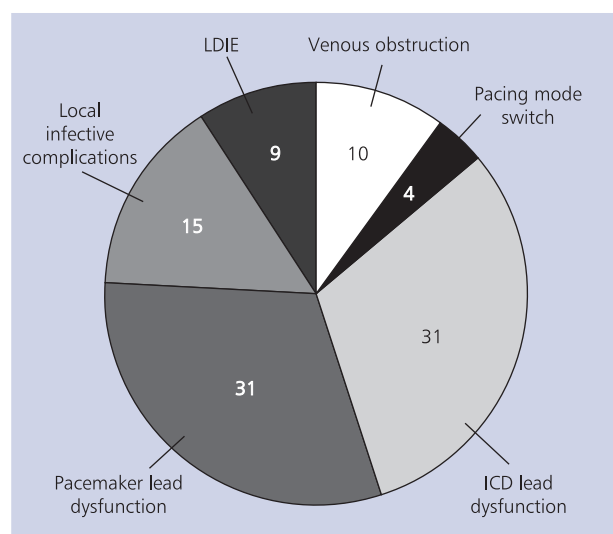


Figure 1. Indications for transvenous lead extraction in the study population; ICD — implantable cardioverter-defibrillator; LDIE — lead-dependent infective endocarditis

and manifested by gradually increasing exit/entry block and impedance changes, and only detailed echocardiographic examination was able to visualise the tip of the lead within the pericardial space. Consequences and symptoms of lead dislodgement varied depending on the lead location, and clinical manifestations included tricuspid valve dysfunction, ventricular arrhythmia, and venous thrombosis and pulmonary embolism.

Lead insulation failure due to physical wear and tear of lead sheath was rarely diagnosed preoperatively (3% of cases) and led to sensing failure (Table 3).

In addition to the most common mechanical complication of lead conductor damage, we found a relatively large rate of late cardiac perforations (14% of cases). In our study population, this complication occurred in 10 men and 4 women (14.9% vs. 12.1%, $p = 0.68$). In all these patients, perforation was caused by a ventricular lead located in the apex.

Another important cause of pacing device malfunction in the study group was dislodgement of an excessively long lead loop within the cardiovascular system, i.e. into an adjacent cardiac chamber or large vessel. This sort of complication was detected in 7 patients, including 5 patients with dislodgement of an atrial lead loop to the right ventricle, and 2 patients with dislodgement of a ventricular lead loop to the pulmonary artery.

Venous obstruction related to the presence of a permanent pacing system was a complication observed in 17 patients in the study group. Reasons for referral of patients with venous obstruction for TLE are shown in Table 4.

Physical wear and tear of lead sheath leading to lead insulation failure was found in 17% of patients, and in 3% of patients this was considered the major cause of lead dysfunction.

Evaluation of the efficacy of TLE procedures showed the radiological success rate of 96% (lead fragments were left in place in 4% of patients), and the clinical success rate was 100%.

DISCUSSION

Indications for intracardiac lead removal may be broadly categorised into infectious and non-infectious [16, 17]. The rate of infectious complications is 1–7%, with an upward trend seen in the recent years [1, 2, 18]. In most centres in Poland, infectious complications comprise 46–49% of all in-

Table 3. Causes of pacemaker and defibrillation lead dysfunction

Mechanism of the complication	Main symptoms	Patients (%)
Lead coil damage	Failure to capture, malsensing, inappropriate discharge	38%
Late cardiac wall perforation	Exit/entry block, varying impedance	14%
Abnormal course/dislodgement of the lead	Tricuspid valve dysfunction, ventricular arrhythmia, venous thrombosis	7%
Lead insulation failure	Malsensing	3%
Overall		62%

Table 4. Indications for lead removal in 17 patients with venous occlusion

Indication	No. of patients
Removal of a functioning lead to regain venous access and implant a new lead	4
Removal of a non-functioning lead to regain venous access and implant a new lead	6
Venous occlusion as an additional complication: device removal due to infection	7

dications for lead removal [19]. Infection of the pacing system is undoubtedly a serious complication, often diagnosed with a large delay due to atypical clinical picture. Lead-dependent infective endocarditis (LDIE) is in fact a chronic sepsis characterised by long-lasting and/or recurrent fever, nocturnal sweating, general malaise, recurrent symptoms of a respiratory infection, development of lung abscesses and right-sided heart failure, but the hallmark of the disease is the appearance of abnormal masses called vegetations that develop within the right heart and are usually anatomically related to the device leads. The most important diagnostic tool in the investigation of LDIE is echocardiography, in particular transoesophageal echocardiography, which often has to be repeated due to the possibility of occasional migration of vegetation to lungs [20, 21]. Of note, our analysis showed an uncommon pattern of complication types, with the lowest proportion of lead-dependent infections (24%) reported in Poland. In addition, local device pocket infection was present in 15 patients, contributing to a relatively rapid decision to remove the implanted device. In other European countries, the proportion of infective indications for lead removal is even higher, up to 70% [22]. The reason for this relatively low proportion of infective complications has likely been an early cooperation with an experienced tertiary care centre which contributed to physician education and more frequent referral of patients with non-infective complications for TLE, thus perhaps even preventing the development of LDIE.

In our study group, the most commonly encountered indication for TLE was lead dysfunction. Analysis of the mechanisms of lead dysfunction revealed that the most prevalent problem was metal conductor damage (38% of cases). In defibrillation leads (23% of cases), it manifested primarily with malsensing leading to inappropriate ICD discharges, and in case of pacing lead dysfunction (11% of cases) it resulted in failure to sense and/or failure to capture manifesting by temporary interruption of pacing.

The rate of lead dysfunction, particularly of defibrillation leads, has recently increased and this problem is not confined to the Sprint Fidelis family of defibrillation leads. Many leads are still damaged by a too tight ligature that has been put to fix the lead, or due to crush syndrome, and the likely cause of dysfunction may be determined only after the lead has been removed [23].

Detailed investigations in patients with lead dysfunction and decreased intracardiac potentials, increasing pacing

threshold or fluctuating impedance found during interrogation of the pacing device confirmed that a common cause of dysfunction in these patients is late dry cardiac perforation (14% of cases, including 7% of ICD leads and 7% of PM leads). Late perforations have been only rarely reported as a complication of electrotherapy. Late perforation is defined as a perforation occurring at least 1 month after device implantation, and the reported rates are about 0.1–0.8% of all complications following PM implantation and 0.6–5.2% of all complications following ICD implantation [23, 24]. Our 14% rate of late perforations in the present study is thus surprising but in previous studies it was likely underestimated due to a relatively mild clinical course and diagnostic problems. A mild course of such perforations is related to a tendency for self-sealing of the cardiac wall by fibrosis and contraction of adjacent myocardial fibres [24] and, as we believe, due to “sealing” properties of the pericardial fat tissue. An increased risk of intrapericardial penetration has been attributed to particular lead types (Riata, St. Jude Medical) but this has not been clearly documented [25]. Another possible factor contributing to the occurrence of late perforation is the location of the lead tip in the right ventricular apex, as with this lead location, the rate of late perforation was found to be higher compared to the location at the septum or within the right ventricular outflow tract [26]. We also confirmed this in our study population. Clinical risk factors for late perforation include older age, female gender, and low body mass index ($< 20 \text{ kg/m}^2$) [13–15]. In our study, the mean age of patients with late perforation was about 5 years higher than the mean age in the overall study population, and the number of perforations in women and men was comparable. Clinical presentation of a late intrapericardial penetration is nonspecific and may vary, as was also confirmed in our study. Perforation is usually associated with an increase in pacing threshold and a decrease in intracardiac potential. In our study population, such constellation of findings was noted in 6 patients (43% of perforations) but this complication is not necessarily accompanied by “electrical”: abnormalities, as normal pacing parameters were often found in patients with a clear echocardiographic diagnosis of perforation [24]. Similarly, varying clinical manifestations that include chest pain, dyspnoea, syncope associated with pacing failure, abdominal pain, pacing of the diaphragm, and inappropriate ICD discharges do not allow unequivocal confirmation of this diagnosis [10]. For these reasons, the diagnosis of a late perforation is difficult, and routine investigations include chest

X-ray which may show the lead tip location outside the cardiac silhouette, echocardiography which is often fraught with much difficulties when attempting to visualise the lead tip, and chest computed tomography which is a diagnostic gold standard, particularly in difficult cases. Clearly, echocardiography plays a major role in the diagnosis of late perforation, as transthoracic echocardiography may visualise lead penetration to pericardial fat, often with a small amount of fluid around the lead tip. In our patients, perforation was confirmed and documented by an experienced echocardiographer in the tertiary care centre before lead removal.

Another issue is the optimal approach to patients with established lead penetration into the pericardial space. According to the 2009 Heart Rhythm Society (HRS) guidelines, TLE is not recommended in patients with known atypical lead location (a class III recommendation, level of evidence C) [15]. In our patients, however, leads perforating the right ventricular wall were removed with a clinical success rate of 100%, i.e. without any complications. Thus, it seems that currently available TLE techniques allow safe treatment of such cases providing all necessary precautions are made.

Another cause of intracardiac lead dysfunction is lead dislodgement within the cardiovascular system to an adjacent cardiac chamber or large vessel. In our study population, this complication was seen in 7% of patients referred to a tertiary care centre. The main dangers of lead dislodgement are related to the risk of malignant ventricular arrhythmias and severe tricuspid insufficiency, and to venous wall irritation leading to local thrombosis and subsequent pulmonary embolism. These phenomena are induced by a loop or the proximal ending of abnormally located lead [3, 6, 8]. This complication was not referred to in the 2009 HRS guidelines and no guidance regarding optimal management approach was offered in this document [15]. Based on previous experience, it is known that redundant lead loops not only cause a significant tricuspid valve dysfunction but with time they also adhere to the tricuspid valve apparatus, which may result in disruption of chordae tendinae and significant tricuspid valve damage during an attempt to remove the lead. Such a sequence of events was observed in one of our patients. In our study population, the efficacy of TLE procedures in patients with dislodged leads was 100%.

Of note, successful TLE allowed avoiding a cardiac surgical procedure in cases of both late perforations and lead dislodgement, and the decision to choose such treatment approach illustrates how much trust was given to the experience of the tertiary care centre.

Another complication of permanent pacing is venous occlusion related to chronic irritation of the venous wall by a lead present in the vessel lumen, which results in connective tissue growth with fibrosis in the venous system [3–6].

The incidence of venous occlusion in patients with PMs has been estimated at 30–75%, probably with an increasing

trend in the recent years due to introduction of stiffer and thicker bipolar leads and multi-lead systems [6, 26–28]. This complication usually runs a completely asymptomatic course but constitutes a major problem if it becomes necessary to implant additional leads [29]. In our study group, venous occlusion was found in 17% of patients, including 4% who required pacing mode switch with removal of a functioning lead, 6% who required removal of a damaged, non-functioning lead and regaining venous access, and the remaining 7% in whom venous occlusion was identified as an additional complication before TLE performed due to other reasons. In patients referred for TLE, our routine approach was to use venography to image systemic veins returning to the heart on the PM side, and then to remove redundant leads, which allowed implantation of a new pacing system with a 100% success rate. This approach is consistent with the current HRS guidelines (class IIa recommendation, level of evidence C) [15].

Another cause of lead dysfunction, which is currently a subject of detailed investigations, is intracardiac lead insulation failure due to wear and tear of the silicone sheath. The rate of these sheath defects has been estimated at about 25% of patients undergoing lead removal procedures due to various reasons [30]. In our study group, we identified this problem in 17% of patients referred for TLE. It is generally thought that most cases of lead insulation failure are completely asymptomatic until a deep perforation of the lead sheath ensues, resulting in lead dysfunction. In 3 of our patients, a deep perforation of the lead sheath was believed to cause lead dysfunction and was the major reason why the specific patient was referred for TLE. Factors that increase the probability of lead insulation failure due to wear and tear of the lead sheath include age and number of leads, presence of a lead in the coronary sinus, and presence of redundant abnormal lead loops in the right atrium and the right ventricle [13, 14, 30]. Lead insulation failure is now increasingly thought to significantly increase the risk of LDIE, as with perforation of the lead sheath, blood may penetrate to the space surrounding the external coil, and in this location bacteria are well protected from both the body defence mechanisms and antibiotics [13, 14, 30]. In the present study, lead insulation failure was confirmed in 4% of patients with LDIE and this issue warrants further studies.

Evaluation of the efficacy of TLE procedures in the study group showed a radiological success in 96% of patients. In 4% of patients, a lead fragment was left in place, including firmly adhered tips of ventricular leads (6-, 7-, and 8-year-old, respectively) in 3 cases, and a fragment of an 11-year-old atrial lead in 1 patient. Clinical success rate was 100%. Both during TLE procedures and until hospital discharge, no major or minor clinical complications were observed in any of the patients, except for significant worsening of tricuspid regurgitation in 1 patient but without the need for cardiac surgical intervention.

CONCLUSIONS

Our analysis of complications of electrotherapy showed a large variation of clinical symptoms in patients referred for TLE to a tertiary care centre. Investigation of lead dysfunction is thus difficult and requires cooperation between cardiac electrophysiologists and clinicians. Notably, we found a low rate of infective complications and a relatively large proportion of late perforations. In our study, TLE procedures were very effective and safe, also in clinical situations which are not considered in the current guidelines.

Conflict of interest: none declared

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Późne powikłania elektroterapii — analiza kliniczna wskazań do przezżylnego usuwania elektrod wewnątrzsercowych: doświadczenia jednego ośrodka

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Streszczenie

Wstęp: Wraz z rozwojem elektroterapii obserwuje się coraz większą liczbę późnych powikłań stanowiących problem kliniczno-terapeutyczny. Przezżylnie usuwanie elektrod wewnątrzsercowych (TLE) jest coraz częściej stosowanym skutecznym i bezpiecznym sposobem leczenia powikłań.

Cel: Celem pracy była ocena przyczyn kwalifikacji chorych do TLE oraz skuteczności i bezpieczeństwa takich zabiegów.

Metody: Retrospektywną analizą kliniczną objęto populację 100 chorych kierowanych z jednego Centrum Kardiologii do Ośrodka Referencyjnego z powodu powikłań elektroterapii w latach 2008–2011.

Wyniki: W latach 2008–2011 zaobserwowano wzrost liczby powikłań elektroterapii. Najczęstszą przyczyną kwalifikacji do TLR w badanej populacji była dysfunkcja elektrod [62% pacjentów: 31% z kardiowerterami-defibrylatorami (ICD) i 31% z kardiostymulatorami (PM)]. Najczęstszym typem dysfunkcji elektrod było uszkodzenie przewodnika metalowego elektrod (38%, w tym 23% z ICD, 15% z PM), późne perforacje ścian serca (14%, w tym 7% z ICD, 7% z PM), nieprawidłowy przebieg elektrod (7%, w tym 1% ICD i 6% z PM) oraz wewnątrzsercowe przetarcie osłonki elektrody (3%). Kolejne przyczyny obejmowały: powikłania infekcyjne (24% pacjentów, w tym 15% z miejscową infekcją łoży), niedrożność żylną (łącznie stwierdzaną u 17% osób, w tym u 10% stanowiącą bezpośrednią przeszkodę do zmiany trybu stymulacji) oraz konieczność zmiany trybu stymulacji (4% pacjentów). Skuteczność radiologiczna zabiegów wynosiła 96% (u 4 osób pozostawiono fragmenty elektrod). W okresie okołozabiegowym nie zaobserwowano żadnych istotnych powikłań klinicznych.

Wnioski: Obraz kliniczny powikłań elektroterapii w badanej populacji pacjentów charakteryzuje duża różnorodność. Wykazano małą liczbę powikłań infekcyjnych (24%) i dużą liczbę późnych perforacji serca (14%). Udokumentowano również bardzo wysoką skuteczność i bezpieczeństwo wykonywanych zabiegów.

Słowa kluczowe: powikłania elektroterapii, przezżylnie usuwanie elektrod

Kardiologia 2013; 71, 4: 366–372

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Praca wpłynęła: 26.06.2012 r. Zaakceptowana do druku: 07.11.2012 r.