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Influence of electrical stimulation therapy on permanent pacemaker function

Florian Egger · Christian Hofer · Fabian P. Hammerle · Stefan Löfler · Michael Nürnberg · Lukas Fiedler · Ruxandra Kriz · Helmut Kern · Kurt Huber

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Summary
Background Electrical stimulation therapy (EST) and transcutaneous electrical neuromuscular stimulation (TENS), a modality of EST, have become widely applied, accepted and effective methods for the treatment of musculoskeletal and other pain conditions. According to the rising number of permanent pacemaker (PM) wearers the number of potential candidates for EST with concomitant device implantation is growing. Contradictory recommendations exist regarding the application of EST or TENS on PM wearers.
Aim The study was carried out to evaluate the impact of EST on PM function.
Methods A full size model mimicking the electrical characteristics of the human body was used to evaluate the application of EST on permanent PM devices. Various configurations with respect to energy modality, position of the stimulation electrodes and PM device models were evaluated. Intracardiac PM electrogram tracings (iEGM) were analyzed for the interference of EST with PM function.
Results Unilateral EST application did not cause interference with PM function in any of the configurations (0%; $n=700$). On the contrary, bilateral stimulation (350 configurations in total) caused either ventricular inhibition or switch to V00 back-up pacing due to electrical interference in 165 cases (47.1%) depending on the applied stimulation parameters.
Conclusion The use of EST potentially interferes with PM therapy, especially if the electrodes are positioned bilaterally; however, unilateral EST application appeared to be safe in all tested configurations.

Keywords Transcutaneous electrical neuromuscular stimulation · Device interaction · Chronic pain · Ex-vivo · Full-size model

Abbreviations

EST	Electrical stimulation therapy
ICD	Implantable cardioverter defibrillator
iEGM	Intracardiac pacemaker electrogram tracing
PM	Pacemaker
TENS	Transcutaneous electrical nerve stimulation

Introduction

In physical medicine and rehabilitation transcutaneous electrical nerve stimulation (TENS) and other forms of electric stimulation therapy (EST) are commonly used treatment modalities for various pain conditions [1, 2]. Along with the increasing prevalence of permanent pacemaker (PM) treatment, the number of potential candidates for EST with concomitant device implantation is constantly growing [3]. There exist several case reports and small clinical trials that reported a significant risk for interference between

Florian Egger and Christian Hofer contributed equally to the manuscript.

F. Egger, MD (✉) · F. P. Hammerle · M. Nürnberg, MD · R. Kriz, MD · K. Huber, MD, FESC, FACC, FAHA
3rd Medical Department with Cardiology, Chest Pain Unit and Intensive Care Medicine, Wilhelminenspital, Montleartstraße 37, 1160 Vienna, Austria
dr_egger@icloud.com

C. Hofer, PhD · S. Löfler · H. Kern, MD, PhD
Ludwig Boltzmann Institute of Electrical Stimulation and Physical Rehabilitation, Wilhelminenspital, Montleartstraße 37, 1160 Vienna, Austria

L. Fiedler, MD
2nd Department of Internal Medicine, Hospital Wiener Neustadt, Corvinusring 3–5, 2700 Wiener Neustadt, Austria

K. Huber, MD, FESC, FACC, FAHA
Medical Faculty, Sigmund-Freud University, Freudplatz 3, 1020 Vienna, Austria

EST and cardiac device therapy, such as permenent PM or implantable cardioverter defibrillator (ICD) [4–13]. Regarding the antibradycardic PM function of these devices, inadvertent ventricular oversensing of EST signals has been shown to induce ventricular inhibition and thereby result in bradyarrhythmia or even asystole in PM-dependent patients [10]. Moreover, the theoretical risk of EST-induced ventricular arrhythmia in cases of a switch to V00 safety back-up pacing might further contribute to the restrictive use of this effective treatment modality in patients with ICD. Importantly, TENS and other modalities of EST are commonly applied in an outpatient setting, usually without the supervision of specialized cardiologists or even physicians at all.

Since there exist contradictory recommendations regarding the use of this treatment modality in permanent PM wearers, this study assessed the impact of EST on PM function, when applied to different stimulation sites and various PM devices in a full size model of the human body.

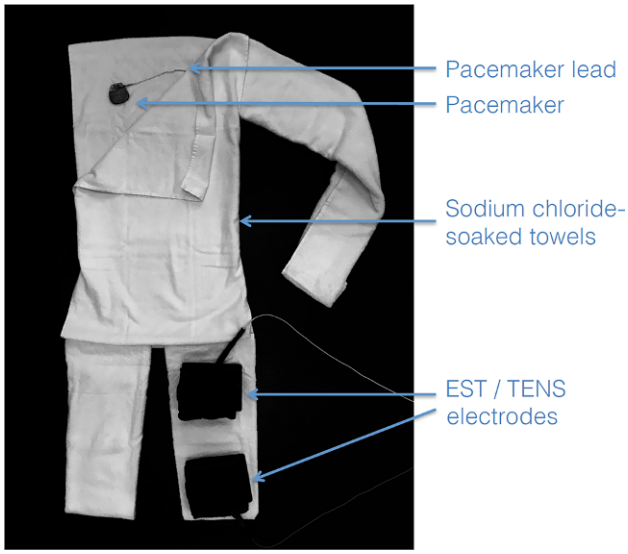

Fig. 1 Towels soaked in sodium chloride solution representing thorax, one arm, abdomen and two legs. One of the towels representing the thorax is partially turned over to show the PM and the connected lead in position. Two electrodes were placed on the left thigh for EST/TENS stimulation. *PM* pacemaker, *EST* electrical stimulation therapy, *TENS* transcutaneous electrical nerve stimulation

Methods

Experimental set-up

Towels soaked with sodium chloride solution were used to create a full size model of the human body as depicted in Fig. 1. The model consisted of a thorax, an abdomen, two thighs and one arm. The concentration of the sodium chloride was titrated based on the model's electrical impedance. Similar values to human body regarding the measured impedance of the PM electrode and the electrodes applied for EST/TENS were targeted and could be achieved as depicted in Table 1.

PM devices

Tests were performed using currently available and routinely implanted PM devices from five different manufacturers programmed to the VVI mode. The different manufacturers where chosen to account for differences in the sensing and pacing algorithms of the respective devices. Furthermore, standard PM leads were used to connect the devices to the tissue. Table 1 shows the list of devices under investigation and their active sensing modes while performing electrical stimulation. The indicated sensing thresholds correspond to the standard settings for the atrial (0.5–1.0 mV) and the ventricular leads (2.0 mV), respectively. All PM were configured to use bipolar vectors for sensing. Both the PM and the connected leads were placed between the sodium chloride-soaked towels according to the position in vivo (Fig. 1).

Table 1 Impedance values of PM device/electrodes and EST device/electrodes as well as PM settings for the experiments

Manufacturer	Model	Ventricular lead impedance (Ω)	Stimulation Electrode Impedance (Ω)	Ventricular Sensing Modes
Biotronik	Epyra 8 SR-T	487	1100	Bipolar 0.5 mV
				Bipolar 2.0 mV
BostonScientific	Vitalio MRI J275	370	270	Bipolar 0.5 mV
				Bipolar 2.0 mV
Sorin	Reply DR W1.55	890	570	Bipolar 1.0 mV
				Bipolar 2.0 mV
Medtronic	Adapta ADSR01	408	308	Bipolar 1.0 mV
				Bipolar 2.0 mV
St. Jude Medical	Accent MRI PM2224	410	1100	Bipolar 0.5 mV
				Bipolar 2.0 mV

PM pacemaker, *EST* electrical stimulation therapy

Table 2 Characteristics of the applied EST currents

Current type	Single pulse parameters		Single pulse frequency (Hz)	Envelope parameters		Envelope frequency (Hz)
	Duration (ms)	Pause (ms)		Duration (ms)	Pause (ms)	
aS	0.4	15	65	3600	4500	0.12
aS	0.8	15	63.3	3600	4500	0.12
EXPO100	130	1500	0.6	NA	NA	NA
EXPO100	260	1500	0.57	NA	NA	NA
EXPO200	270	2000	0.44	NA	NA	NA
EXPO200	540	2000	0.4	NA	NA	NA
EXPO300	370	2450	0.35	NA	NA	NA
EXPO300	740	2450	0.31	NA	NA	NA
EXPO500	570	3000	0.28	NA	NA	NA
EXPO500	1140	3000	0.24	NA	NA	NA
FM	0.4	30–300	3.3–32.9	2200	3000 modulation	0.2
FM	0.8	30–300	3.3–32.5	2200	3000 modulation	0.2
GALV[a]	NA	NA	no	NA	NA	NA
HV100	0.05	10	99.5	NA	NA	NA
HV100	0.1	10	99	NA	NA	NA
HV250	0.05	4.2	235.3	NA	NA	NA
HV250	0.1	4.2	232.6	NA	NA	NA
IG100	0.4	5	185.2	100	150	4
IG100	0.8	5	172.4	100	150	4
IG150	0.4	5	185.2	150	200	2.9
IG150	0.8	5	172.4	150	200	2.9
IG30	40	80	8.3	NA	NA	NA
IG30	80	80	6.3	NA	NA	NA
IG50	0.4	5	185.2	50	100	6.7
IG50	0.8	5	172.4	50	100	6.7
MF10	0.22	NA	4500	100	NA	10
MF10	0.44	NA	2300	100	NA	10
MF100	0.22	NA	4500	10	NA	100
MF100	0.44	NA	2300	10	NA	100
TENS BuT	0.2	9.8	100	60	450	2
TENS BuT	0.4	9.8	98	60	450	2
TENS HFT	0.2	9.8	100	NA	NA	NA
TENS HFT	0.4	9.8	98	NA	NA	NA
TENS LFT	0.2	500	2	NA	NA	NA
TENS LFT	0.4	500	2	NA	NA	NA

aS surge current, *EST* electrical stimulation therapy, *EXPO* exponential current, *FM* frequency modulated current, *GALV* galvanic current, *HV* high voltage current, *IG* impulse galvanization, *MF* medium frequency current, *TENS* transcutaneous electrical nerve stimulation, *BuT* burst TENS (transcutaneous electrical nerve stimulation), *HFT* high frequency TENS (transcutaneous electrical nerve stimulation), *LFT* low frequency TENS (transcutaneous electrical nerve stimulation)
[a] parameters not applicable for GALV

EST devices

For electrical stimulation two devices were used: one commonly used for TENS therapy (N604 TENS Everyway Medical, New Taipei City, Taiwan), the other device (Stimulette R2x, Schuhfried GmbH, Vienna, Austria) capable of applying various modalities typically used in EST. Currents of type aS; EXPO (100, 200, 300, 500); FM; GALV; HV (100, 250); IG (30, 50, 100, 150); MV (10, 100); TENS (BuT, HFT, LFT) were applied as described in Table 2. Each of these modalities was tested in different configurations with the stimulation devices set to the maximum allowed stimulation intensity.

The positions of the stimulation electrodes that were tested are shown in Fig. 2. Each set-up was evaluated with the current activated for 10 s, whereas measurements were repeated with different adjustments according to polarity and PM sensitivity. During the application of current the device was connected to the programmer and intracardiac pacemaker electrogram tracings (iEGMs) were continuously analyzed for the

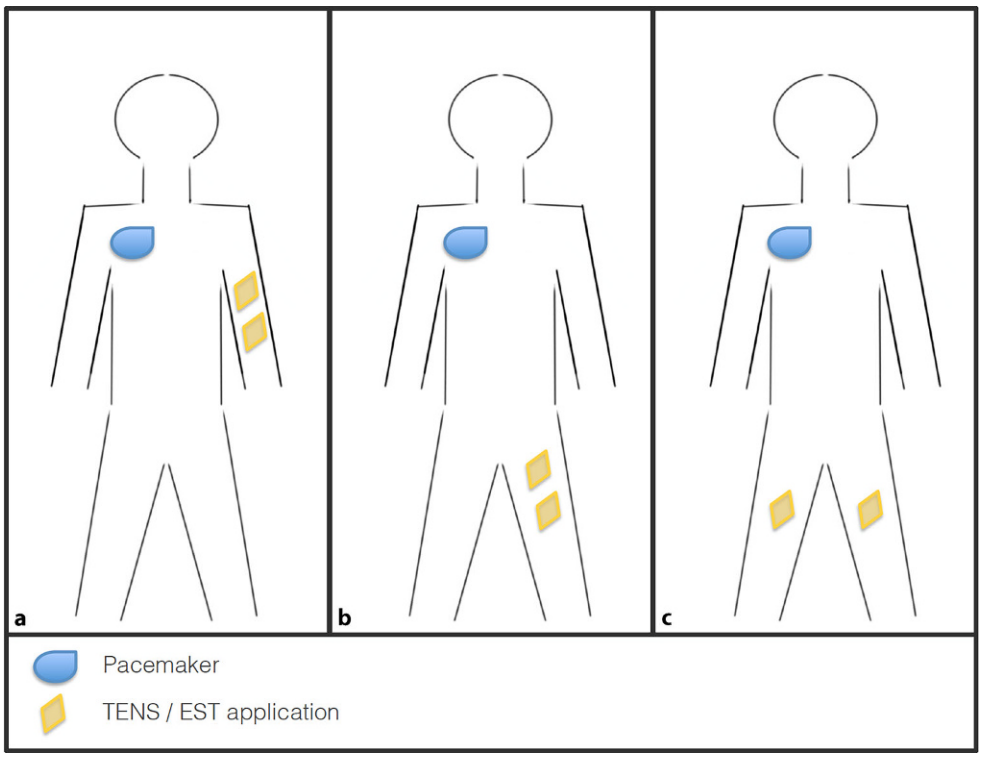

Fig. 2 Localization of PM device and EST application. **a** unilateral upper arm, **b** unilateral thigh, **c** bilateral both thighs. *PM* pacemaker, *EST* electrical stimulation therapy, *TENS* transcutaneous electrical nerve stimulation

effect of EST on PM function. The iEGMs represent ECG tracings that are recorded from the endocardium by the PM leads of the respective device. Different effects on PM function were encountered during the application of various currents:

1. If the applied current did not interfere with the PM sensing function, VVI stimulation was not affected.
2. If the selected current was classified as "noise" by the PM device, switch to a V00 safety back-up pacing mode was observed.
3. In cases of "oversensing" (PM device algorithm interprets EST current as intrinsic cardiac activity), inhibition of VVI stimulation occurred.

Statistics

Categorical variables were reported as frequency counts and percentages. Differences between groups were investigated using Pearson's χ^2-test with Yates' continuity correction. Significance was assumed in case of 2-sided p-values <0.01. Statistical analysis was conducted using R version 3.2.3 (A Language and Environment for Statistical Computing; R Foundation for Statistical Computing, Lucent Technologies Network Systems GmbH, Murray Hill, NJ, USA, www.r-project.org).

Results

With this full size model, the effect of 18 different current strengths commonly used in EST was evaluated using 5 PM devices programmed to VVI mode. The experimental set-up was tested with different settings regarding the location and polarity of stimulation as well as the sensitivity of the PM sensing function cumulating to a total of 1050 single measurements.

Location of EST application

Unilateral application (both electrodes placed on one thigh or both electrodes placed on one arm; $n=700$) did not cause interference with PM function in any of the tested configurations. Only the use of bilateral EST (one electrode placed on each thigh; $n=350$) was capable of inducing changes in the default PM mode. Altogether, 47.1% ($n=165$) of bilateral configurations caused interference with PM function. In 78.8% ($n=130$) of these cases an inhibition of VVI pacing was observed, whereas in 21.2% ($n=35$) a switch to V00 safety back-up pacing occurred during EST application. The effects on PM function are described in Fig. 3.

Mode of stimulation

For every location of EST application each current was evaluated in 20 different configurations regarding polarity, the tested PM device and the chosen sensitivity (10 monophasic and 10 biphasic configurations, 5 different devices and sensitivity either set to 0.5/1.0 mV simulating an atrial lead set-up or 2.0 mV simulation a ventricular lead set-up). Unilateral stimulation ($n=700$) did not show any effect on PM function in any of the tested configurations. During bilateral

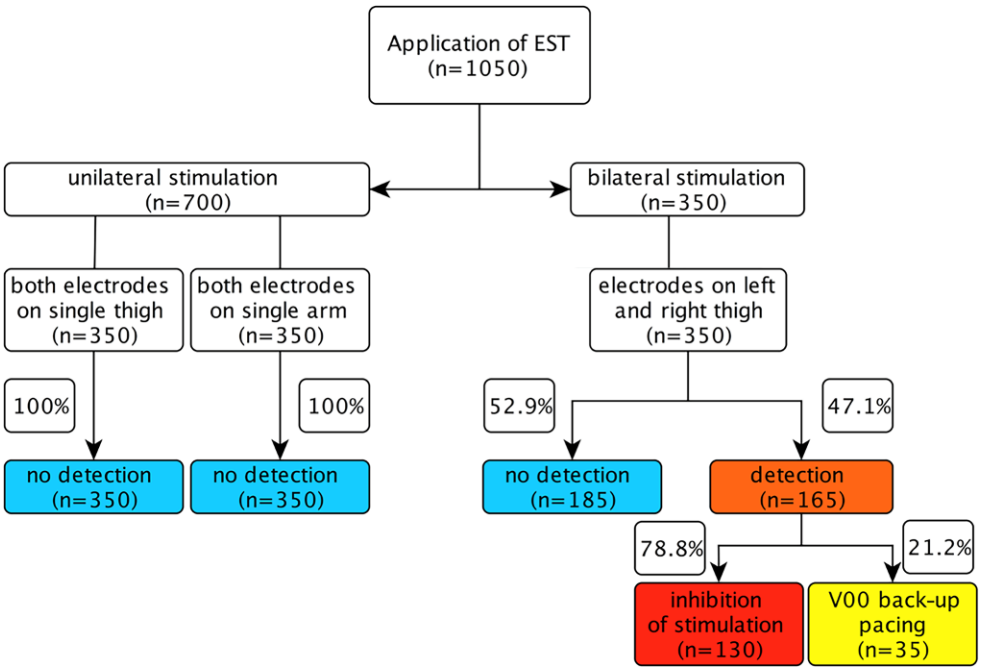

Fig. 3 Flowchart of the changes in PM device mode due to EST application. *PM* pacemaker, *EST* electrical stimulation therapy

stimulation in monophasic mode ($n=180$) 16 out of 18 tested currents interfered with PM function with rates between 10% and 100% depending on the selected sensitivity and the PM device. During bilateral stimulation in biphasic mode ($n=170$) 14 out of 17 tested currents (biphasic stimulation with GALV technically not possible) interfered with PM function with rates between 20% and 90% as described in Fig. 4. Both oversensing with inhibition of stimulation as well as switch to V00 safety back-up pacing could be observed with higher rates of PM disturbance when monophasic current was applied. If no electrical interferences were sensed by the PM device during monophasic stimulation with a specific current, there was largely also no sensing during EST application with the same current in the biphasic mode (no interference in monophasic mode but sensing in biphasic mode occurred only in 1 case or 1.6% of configurations with interference in biphasic mode).

PM devices

In this experimental set-up five different PM devices programmed to the VVI mode were tested. Inadvertent inhibition of pacing due to oversensing during bilateral EST application occurred in all tested PM models; however, with a wide range depending on the respective device (20–50% of tested configurations). Furthermore, noise detection and switch to V00 back-up pacing was observed in all but one PM devices tested with rates ranging between 2.9% and 25.7%. Generally, interference with regular VVI stimulation was observed more frequently if the devices were programmed at a higher sensing sensitivity (0.5/1.0 mV depending on the technical thresholds of the device standard setting for atrial lead) corresponding to 101 cases (57.7% of bilateral configurations). In contrast, a setting with a lower sensing sensitivity level (2.0 mV standard setting for ventricular lead) interference occurred only in 64 cases (36.6% of bilateral configurations); however, in 4 cases without any device interferences in the more sensitive mode (0.5/1 mV), switching the device to a less sensitive setting (2.0 mV) caused interference with the PM function.

Discussion

This experimental set-up confirmed the potential risk of electrical interference between EST and cardiac device therapy. The location of EST application appears to be a crucial parameter, since interference with PM device therapy was observed only during bilateral stimulation protocols.

Concomitant use of EST and PM

The prevalence of permanent PM therapy in people aged 75 years and above ranges around 3% in the western society and values are steadily increasing [14]. Furthermore, epidemiological data show an excessive rate of patients suffering from chronic pain [15, 16]. Accordingly, there exist a considerable number of patients who have undergone permanent PM or ICD implantation and are afterwards confronted with the opportunity to benefit from EST for treatment of the pain condition [17]. In cases of electrical interference between EST and cardiac device therapy different effects on PM function might be observed: If the applied current is classified as “noise” by the PM device due to interference with the sensing function a switch to

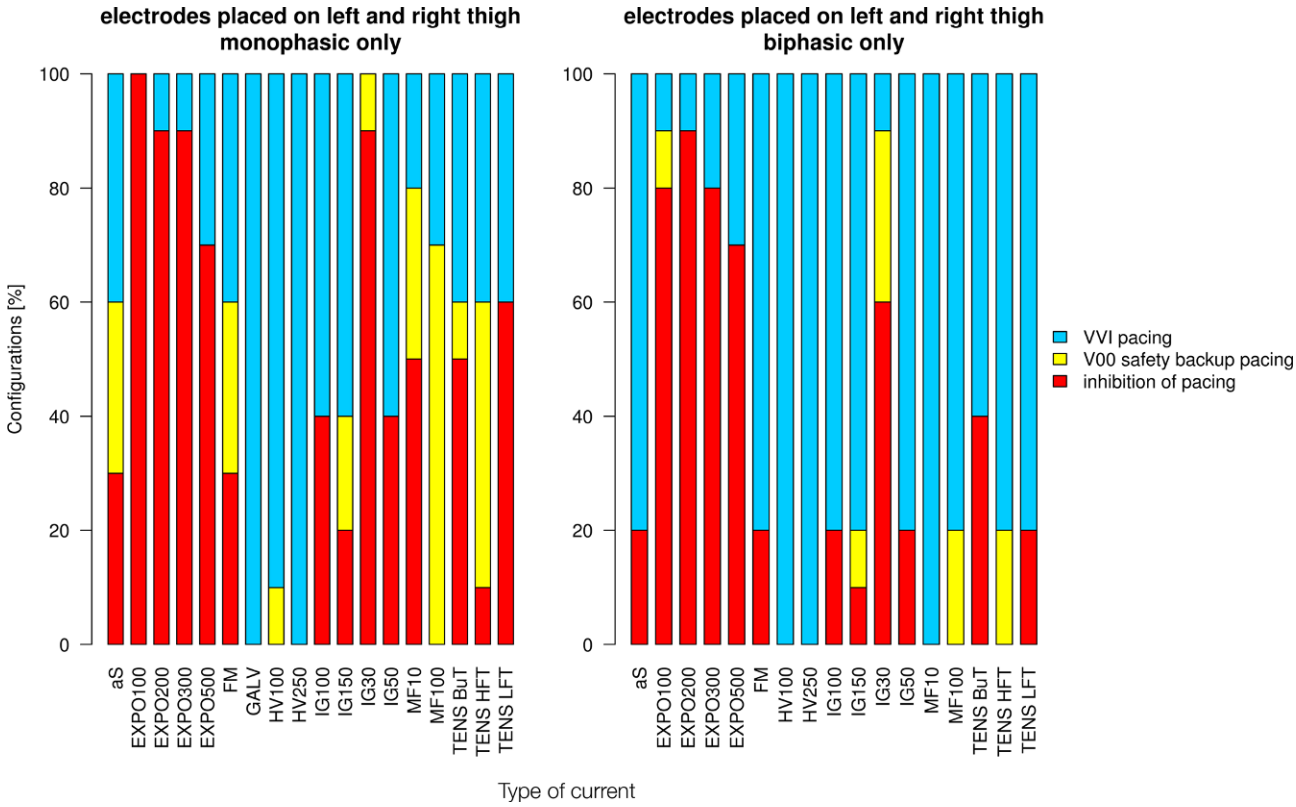

Fig. 4 Frequency and type of interference between EST and PM stratified by polarity and type of current. *PM* pacemaker, *EST* electrical stimulation therapy, *aS* surge current, *EXPO* exponential current, *FM* frequency modulated current, *GALV* galvanic current, *HV* high voltage current, *IG* impulse galvanization, *MF* medium frequency current, *TENS* transcutaneous electrical nerve stimulation, *BuT* burst TENS, *HFT* high frequency TENS, *LFT* low frequency TENS

a V00 safety back-up pacing mode commonly occurs, which is of minor clinical relevance in PM-dependent patients; however, in patients with an intrinsic cardiac activity at higher rates than V00 safety back-up pacing (70–90 bpm for most devices), there is the theoretical risk for the induction of ventricular arrhythmia or even ventricular fibrillation. In case of oversensing (PM device algorithm interprets EST current as intrinsic cardiac activity) the inhibition of VVI stimulation might result in asystole in PM-dependent patients. In patients with D(Dual A+V)D(Dual A+V)D(Dual T+I) PM devices (not evaluated within this study), atrial oversensing during EST might trigger ventricular pacing at high rates; however, this situation is not likely to cause serious harm since these patients would be protected by the upper rate limit setting.

Interference between EST and cardiac device therapy has been a well-known problem for many years. Back in 1988 Rasmussen et al. studied the effects of TENS, a specific modality of EST, in 51 patients with 20 different PM models. With a mean stimulation frequency of 24.7 Hz no episodes of interference, inhibition or reprogramming of the respective devices could be detected. Neither the position of the electrodes nor the proximity of the pulse generator to the stimulation site showed any significant effect on the outcome [9]; however, Carlson et al. could show that TENS potentially induces ventricular oversensing and inhibition in patients with permanent PM therapy in up to 81% when the electrodes were placed above the mammilla [10]. Consequently, device manufacturers have published recommendations regarding EST in patients after permanent PM implantation, such as the deactivation of specific PM settings or the use of continuous heart rate monitoring; however, these recommendations differ between the manufacturers and there is a lack of precise instructions on how to perform EST in these patients. Furthermore, changes of the PM settings before each application appear to be impractical for routine clinical use. Finally, most of these recommendations refer to the treating physician as the person responsible in cases of complications, which is a major limitation in the absence of specific guidelines for this setting. With respect to the data from this study the use of EST such as TENS seems to be safe provided that unilateral placement of the stimulation electrodes (both electrodes placed on the same limb) is used. Tests with bilateral placement of the stimulation electrodes showed greater variability regarding the interference with PM function. Consequently, their use in patients with permanent PMs cannot be encouraged at the moment.

Experimental set-up

Since interactions between EST and PM devices are potentially harmful for the patients, the present investigation was performed using a full size model of the human body. By testing impedance levels of PM electrodes and the electrodes of the EST devices, electrical conduction properties similar to the human body were targeted (Table 1). Since this experimental set-up did not consider the three-dimensional structure of the human body (trunk), with the heart embedded electrically isolated in the thoracic cavity, the in vivo condition was considered even less likely regarding interference between EST and PM therapy.

Location of EST application and stimulation parameters

The outcomes of this study suggest that electrical interferences with PM stimulation primarily occur during bilateral stimulation with the electrodes placed on different limbs (e. g. left and right thigh). In this configuration, the stimulation current flows from one electrode to the other through the trunk of the human body. Thus, interference with the PM is more likely compared to a unilateral placement of the electrodes (e. g. both electrodes placed on the same limb) that caused no episodes of interference such as inhibition or switch to V00 safety back-up pacing. Furthermore, the application of EST using monophasic currents was more likely to cause interference with PM devices compared to the same set-up using biphasic currents as shown in Fig. 4; however, the underlying causes for this finding could not be determined within this analysis and might be the subject of further investigations. Consequently, recommendations for such a setting would be speculative and cannot be offered at present.

With respect to bilateral stimulation configuration, stimulation parameters with either a low pulse frequency of approximately 2 Hz or a stimulation burst frequency (envelope of the pulses) in the same range are more likely to cause electrical interference such as inadequate sensing of the PM. Apparently, the PM algorithm is not able to differentiate between the distinct EST impulses and heart activity if the frequency is close to the physiological heart rate. These results are in line with data from Carlson et al. who also detected a tendency towards a higher rate of interference with PM function during stimulation with lower stimulation frequencies and burst frequencies [10]. Furthermore, the sensing threshold of the tested PM devices was a relevant parameter in this study, since a higher sensing sensitivity was related to a higher rate of electrical interference with EST. This might also be especially relevant for a set-up evaluating DDD PM devices with different sensitivity settings for the atrial and the ventricular leads.

Strengths and limitations

This study represents a comprehensive assessment on the effect of different EST modalities on PM function. Since data were gathered with an experimental set-up using a model of the human body, the results cannot directly be extrapolated to human beings. Although impedance levels of the stimulation circuit and the electrodes of the PM were similar to the values in vivo, not all electrophysiological properties of the human body, such as capacitive resistance and compartmentation, were reproduced in this model. Nevertheless, the conditions in the tested model were considered to cause even stronger electrical interference with PM function than expected in vivo. Further investigations in-vivo are necessary to confirm these findings.

The currently available PM devices of all manufacturers in Europe were tested. The devices under investigation were programmed to the VVI mode with only one lead either simulating atrial or ventricular settings. In theory, the use of other device models ,such as DDD PMs with different software algorithms could reveal different results. Nevertheless, for the main finding of this study (the possibility to apply unilateral EST without the risk for PM device interference) the location of EST application appears to be more relevant than differences in specific PM software algorithms.

Conclusion

This analysis confirmed the potential risk of electrical interference between EST and cardiac device therapy; however, the location of EST application appears to be a crucial parameter. Interference with PM devices therapy was observed only during bilateral stimulation protocols. Consequently, this treatment modality can be safely used when considering certain limitations, such as unilateral application only.

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Conflict of interest F. Egger reports personal fees from Medtronic outside the submitted work. M. Nürnberg reports personal fees from Medtronic, Biotronik, Boston Scientific, St. Jude Medical/Abbott and Sorin outside the submitted work. L. Fiedler reports personal fees from Boston Scientific and St. Jude Medical/Abbott outside the submitted

work. C. Hofer, F.P. Hammerle, S. Löfler, R. Kriz, H. Kern and K. Huber have no conflicts of interest with respect to this publication.

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