

Supplementary material

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To grade or not to grade the application of safety requirements for transvenous lead extraction -experience with 2216 procedures

Methods

Unexpected procedure difficulty so-called “technical problems” during TLE - situations which increased procedure complexity but not being complications. They were: break of extracted lead, loss of broken lead fragment – when main part of the lead was dilated and removed but remained free both endings, movable lead fragment which flowed usually into pulmonary vascular bed, block in lead venous entry / subclavian region block in lead venous entry preventing entry into the subclavian vein with a polypropylene catheter, Byrd dilator collapse / fracture, two leads strong scar connection, necessity to utilise other approach than lead venous entry and dislodgement of functional lead

Table 4- additional comment

The main aim of the study was to demonstrate the imperfections of the security grading system and the advantage of performing all TLE under optimal security conditions. As the study was not randomized but is the result of a retrospective analysis - the selection of patients was however random (time interval) and it would be ideal to show that the groups do not differ in risk factors for MC and procedure difficulty. For estimating the risk of MC, we have two calculators (SAFeTY TLE and

EROS scale) and 3 scales for TLE difficulty forecasting based on number of leads, implant duration, presence of ICD lead, passive lead or system infection: MB score, LED score and Mazzone score. Using all of the pointers can reveal group differences that could impact the TLE outcomes.

Table S1- comment

The main criteria for the eligibility for TLE in the cardiac surgery department were: implant duration >12 years, young age at first implantation, female gender, multiple leads, old abandoned leads and passive lead models. Those with implant duration <12 years, older age at first implantation, male gender, having less than 3 leads, and with recent lead models underwent TLE in EP-LAB. The grading of safety requirements was applied in most patients. However, there were situations, when another urgent cardiac surgery had to be performed in the operating theatre. On those occasions TLE was done in EP-LAB in 25 (4.85%) patients with lead implant duration ≥ 12 years and in 51 (9.90%) patients with leads ≥ 10 years old.

The median of implant duration of the extracted lead per group was significantly longer in patients operated on in the cardiac surgery theatre (13.25 years) than in those operated on in EP-LAB (5.08 years). The importance of factors other than implant duration confirms the true risk of major complications estimated using the SAFETY – TLE score calculator: 1.78% in patients operated on in the cardiac surgery department and 0.48% in those operated on in EP-LAB as well as values of EROS score (2.00 vs 1.00). The differences in the values of procedure difficulty indicators (MB score, LED index) based on the analysis of only system-dependent factors were significant, which in total indicates that in patients operated in the cardiac surgery room more difficult and complex procedures and at a higher risk of MC could be expected. As a result of graded approach, TLE procedures were significantly more complex in patients operated on in the cardiac surgery theatre than in EP-LAB which translated into higher rates of major complications (5.29% vs 1.36%) and need for urgent cardiac intervention (2.86% vs 0.78%). There were two procedure-related deaths in EP-LAB but no deaths among those operated on in the cardiac surgery theatre

Table S1

The exact analysis of patients from graded safety precautions era. The comparison of two subgroups of patients in which TLE was performed in EP-LAB (regime as in group3) and in operating theatre (circumstances partially the same as in group 1)

The comparison of graded safety precautions subgroups	Graded safety precautions era. TLE in EP-LAB, without c-surgeon and g. anaesthesia (as in model 3)		Graded safety precautions era. TLE in cardiac surgery operating room. General anaesthesia. Cardiac surgeon in place, available immediately		Statistic
Predominant theoretical criterions of patient's selection	Implant duration <10 years (intentionally), older age during first system implantation, male gender, less than 3 leads, and recent lead models		Implant duration > 12 years (intentionally), younger age during first system implantation, female gender, numerous leads, abandoned lead		A vs B
Organisational safety level	Very low Group A		High Group B		
Number of patients	515		175		
Patient's age during TLE [years] mean (SD)	67.30	12.59	63.27	16.27	<0.001
Patient's age during first system implantation [years] mean (SD)	61.62	13.29	48.91	17.95	<0.001
Sex (% of female patients)	212	41.17%	83	47.43%	0.17
EF average [%] mean (SD)	47.24	14.89	53.30	13.51	<0.001
Carlson's index [points] median (Q1 - Q3)	4.00	(2.00-6.00)	3.00	(1.00-5.00)	<0.001
System and history of pacing (n, %)					
Presence of abandoned lead before TLE (n, %)	32	6.21%	33	18.86%	<0.001
Number of leads in the heart before TLE before TLE mean (SD)	1.91	0.66	2.05	0.85	0.03
Oldest lead body dwelling time [years] median, (Q1 - Q3)	5.08	(3.17-7.33)	(13.25)	11.10-17.22	<0.001
Patients with oldest one lead 12 years and more (n, %)	25	4.85%	116	66.29%	<0.001
Patients with oldest one lead 10 years and more (n, %)	51	9.90%	126	72.00%	<0.001
Average extracted lead age in the group [years] median, (Q1 - Q3)	4.91	(2.92-7.08)	12.85	(9.76-16.03)	<0.001
Cumulative dwell time of extracted lead [years] median, (Q1 - Q3)	6.67	(3.83-10.83)	22.68	(16.23-31.70)	<0.001
SAFeTY – TLE calculator of risk of MC TLE - number of points median (Q1 - Q3)	4.10	(1.36-5.46)	8.82	(5.47-12.48)	<0.001
SAFeTY – TLE calculator of risk of MC TLE - in percentages median (Q1 - Q3)	0.48	(0.23-0.71)	1.78	(0.71-4.78)	<0.001
EROS score [risk of MC] median (Q1 - Q3)	1.00	(1.00-2.00)	2.00	(1.00-3.00)	<0.001
3 EROS score [risk of MC] (n, %)	8	1.55%	85	48.57%	<0.001
MB score number of points [need for advanced tools] median (Q1 - Q3)	2.00	(1.00-3.00)	4.00	(3.00-4.00)	<0.001

MB score points 4.5 [need for advanced tools] (n, %)	54	10.49%	92	53.57%	<0.001
LED index - [predicted fluoroscopy time] median (Q1 - Q3)	7.00	(5.00-9.00)	17.00	(10.00-21.00)	<0.001
LED index - values >16 points [predicted fluoroscopy time] (n, %)	9	1.75%	86	49.14%	<0.001
Mazzone scale (1-4) [need for advanced TLE techniques] median (Q1 - Q3)	2.00	(1.00-3.00)	2.00	(2.00-3.00)	0.095
Mazzone scale – 4 points [need for advanced TLE techniques] (n, %)	31	6.02%	7	4.00%	0.41
TLE complexity and outcomes					
Single lead extraction time (global sheath to sheath time / number leads extracted) [minutes] median (Q1 - Q3)	4.00	(4.00-4.00)	6.50	(4.00-11.00)	<0,001
“Technical problem” during TLE (any) (n, %)	63	12.23%	42	24.00%	<0.001
Two or more “technical problems” (n, %)	9	1.75%	9	5.15%	0.03
Utility of additional tools					
Metal sheath (n, %)	24	4.66%	17	9.71%	0.024
Lasso catheter / snare / basket catheter (n, %)	8	1.55%	17	9.71%	<0.001
TLE efficacy and complications					
Major complications (any) (n, %)	7	1.36%	11	5.29%	0.001
Hemopericardium (n, %)	6	1.17%	9	5.14%	0.005
Tricuspid valve damage during TLE (severe) (n, %)	1	0.19%	3	1.71%	0.087
Rescue cardiac surgery (n, %)	4	0.78%	5	2.86%	0.087
Death procedure related (intra-, post-procedural) (n, %)	2	0.39%	0	0.00%	0.991
Partial radiological success (remained tip or < 4 cm lead fragment) (n, %)	17	3.30%	12	6.86%	0.071
Full clinical success (n, %)	505	96.06%	166	94.86%	0.049
Full procedural success (n, %)	496	96.31%	159	90.86%	0.008

EF- ejection fraction, EP-LAB- electrophysiology laboratory, TLE- transvenous lead extraction

Comment to table S2

The multivariate analysis of the impact of the main organizational factors on the occurrence of complications and the effectiveness of TLE did not confirm that the logistics of TLE influenced the occurrence of major complications and thus the effectiveness of the procedure. The link between the presence of a cardiac surgeon as a co-operator should be commented upon. It should be emphasized that this is a retrospective analysis. During the grading of safety measures, we tried to ensure that the cardiac surgeon was present during the procedures considered to be potentially the most dangerous. Probably the age of the removed leads, the younger age of the patient resulted in worse TLE results in these cases. The seemingly worse

results of TLE in cardiac surgery theatre or hybrid room were also caused by the selection of more difficult patients for the most safe organizational conditions. The apparently unfavourable (statistically insignificant) effect of general anaesthesia and blood pressure monitoring should be interpreted similarly. There is a positive (but always significant) trend when procedures have been monitored with TEE.

Table S2

Table S2. Complications and effectiveness - Impact of logistic of TLE.

	Univariable regression		
	OR	95% CI	<i>P</i>
Major complications			
Surgeon as co-operator [yes / no]	1.70	0.85-3.39	0.134
Cardio surgery operating / hybrid room [yes / no]	2.52	1.31-4.85	0.006
Electrophysiology laboratory [yes / no]	0.40	0.21-0.76	0.006
TLE monitored by TEE [yes / no]	0.43	0.10-1.78	0.24
Minor complications			
Surgeon as co-operator [yes / no]	0.57	0.37-0.90	0.02
Cardio surgery operating / hybrid room [yes / no]	0.60	0.38-0.95	0.03
Electrophysiology laboratory [yes / no]	1.66	1.06-2.62	0.03
TLE monitored by TEE [yes / no]	0.38	0.18-0.77	0.008
Full clinical success			
Surgeon as co-operator [yes / no]	0.92	0.50-1.71	0.80
Cardio surgery operating / hybrid room [yes / no]	0.84	0.45-1.45	0.47
Electrophysiology laboratory [yes / no]	1.24	0.69-2.25	0.47
TLE monitored by TEE [yes / no]	2.55	0.79-8.23	0.12
Full procedural success			
Surgeon as co-operator [yes / no]	1.02	0.69-1.53	0.92
Cardio surgery operating / hybrid room [yes / no]	0.87	0.54-1.39	0.56
Electrophysiology laboratory [yes / no]	1.15	0.72-1.84	0.56
TLE monitored by TEE [yes / no]	2.17	0.94-5.01	0.07