

# German Pacemaker Register

## Report 2002

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## SUMMARY

### **Data base**

The 2002 report of the German Pacemaker Register is the first which has an entirely electronic data base. All data was submitted electronically as a part of the data sets for quality assurance of pacemaker implantations (module 09/1 of the German Quality Assurance Program), pulse generator replacements (module 09/2 of the German Quality Assurance Program) and pacemaker reoperations (module 09/3 of the German Quality Assurance Program). Data analysis was performed by the Expert Group on Cardiac Pacing of the German National Institute for Quality Assurance, BQS gGmbH, Duesseldorf, in 2002.

### **Number of reports**

The quality assurance program is aimed at collecting data from all pacemaker operations performed in German hospitals. In 2002, a total of 36.812 data sets from 632 hospitals which fulfilled the predefined criteria for plausibility and completeness were received. In detail, data sets of 28.763 first implants, 6.553 pulse generator exchange operations, and 1.496 reoperations were submitted, representing approximately 2/3 of all pacemaker operations in 2002. The result could be considered as disappointing, because of the lacking data of roughly 1/3 of pacemaker operations. However, for a project within its first year after introduction of an entirely new procedure, new data sets, new software, new ways of data submission, etc., we consider this result encouraging.

### **Age and sex distribution**

48,4% of the patients were female with a mean age of 76,9 years, while male patients had a mean age of 73 years.

### **Symptoms prior to implantation**

Syncope (22,6%) and dizzy spells (29,2%) were the most common symptoms. Since more than 1 symptom could be reported, the relative incidence of symptoms in % does not completely mirror the clinical practice.

### **ECG indication for pacing**

Sick sinus syndrome made up 39% of all indications, AV block was the indication in 33%, and atrial fibrillation/flutter+bradycardia in 19% of the patients. Further analysis revealed a mean adherence to existing national guidelines of > 95%

### **Mode of pacing**

Pacing devices with atrial contribution (AAI, DDD, VDD), were implanted in roughly 62% of all first implants. An AAI-system was chosen in 1.0%, a DDD-system in 55,8%, and a single-lead VDD-device in 3.6%,

The use of ventricular pacing varied from less than 30% to more than 70% in the different centers, and adherence to the national guidelines varied between 46% and 96%.

In patients with AV block II & III, DDD-pacing was used in 73% and VDD-pacing in about 9% of the patients.

Among patients with sick sinus syndrome, those with a binodal disease (i.e. SSS + AV block) received a DDD system in > 80%, those with a sinus node disease in 76% and those with a bradycardia/tachycardia syndrome in 48%. AAI-mode was less commonly used as compared to the Scandinavian and baltic states.

In patients with atrial flutter/fibrillation and bradycardia, VVI-pacing was used in more than 95%.

Obviously, there is still a substantial variability in selecting a pacing mode among the institutions. This implies that there is still no general agreement about the pacing mode to be used. It is, however, somewhat surprising that roughly one third of all hospitals (33,5%) still use VVI-mode in more than 50%. Maybe, the results of some of the more recent randomized, controlled trials, such as CTOPP, MOST or UK-PACE, were misunderstood as a plea for VVI-pacing.

#### **Lead mixture.**

As already observed in previous years, the usage of bipolar leads once again increased both in the atrium and in the ventricle reaching 97% in the atrium and 62% in the ventricle. This may be due to the more general perception, that currently available bipolar leads will turn out to be more reliable than those used a decade ago. Hopefully, this hypothesis will come true.

#### **Operative data.**

They are available for the first time in Germany. The results show that the surgical technique is - to a certain degree - standardized: The right pectoral side is the preferred location of PM-implantation and cephalic vein cut down is used in a surprisingly high percentage (50%). The unexpected high number of operations performed under general anesthesia (6%) requires further analysis. Possibly, the corresponding item is not defined well enough resulting in an inappropriate understanding of what is asked. In addition, the substantial inter-hospital variability observed for all results concerning the operative procedure (e.g. OP-time, fluoroscopy-time, intraoperative measurements) reflects that a standardized technique does not necessarily lead to standardized results.

#### **Perioperative complications.**

6,3% of the patients experienced at least 1 complication during their mean hospital stay of 7,1 days. Lead dislodgements (2,1%), pocket hematoma (1,4%) and pneumothorax (0,8%) were the most common complications.

An unexpected result was the number of patients who died following implantation of a pacemaker (n=318=1,1%). However, only 25 cases (0,09%) were reported to have been associated with the underlying rhythm disorder or the operation. Nevertheless, this result certainly calls for a more detailed analysis which is currently underway.

**Generator replacements.**

Normal battery depletion was the usual indication for pulse generator replacement in roughly 96% of all cases. Premature battery depletion made up less than 4% of the indications. The mean generator life time of  $8,5 \pm 4,1$  years can be considered a satisfactory result. Single chamber generators had a longer life-time than dual chamber generators, a result which requires further analysis.

**Reoperations.**

They were performed predominantly in patients who had been operated before at the same hospital (73%). Lead related problems were the most common indication for reoperation followed by problems with the pulse generator or the pocket. Lead complications were usually treated by implantation of a new or an additional lead (> 70%) and the problematic lead was usually left in place (50%).

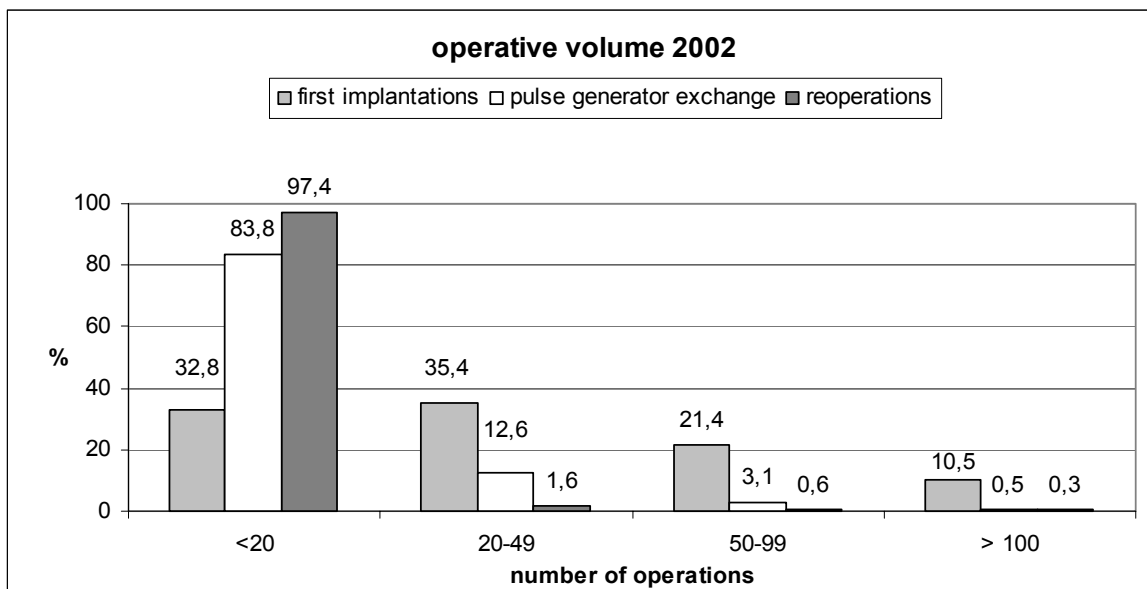
1. Data Base 2002

1.1. Overview

	first implantations	pulse generator exchange	reoperations
number of institutions	622	549	313
number of operations	28.763	6.553	1.496
mean per institution	46,2	11,9	4,8
SD	50,8	16,0	9,2
median	30	7	2
minimum	1	1	1
maximum	517	148	119

1.2. Distribution of pacemaker operations 2002

number of operations	first implantations		pulse generator exchange		reoperations	
	n	%	n	%	n	%
n <20	204	32,8	460	83,8	305	97,4
n = 20-49	220	35,4	69	12,6	5	1,6
n = 50-99	133	21,4	17	3,1	2	0,6
n ≥ 100	65	10,5	3	0,5	1	0,3
<b>total</b>	<b>622</b>	<b>100</b>	<b>549</b>	<b>100</b>	<b>313</b>	<b>100</b>



\* Explanation: for instance, 32,8% of the hospitals had < 20 first implantations, 83,8% less than 20 pulse generator exchanges, and 97,4% of the hospitals had < 20 reoperations

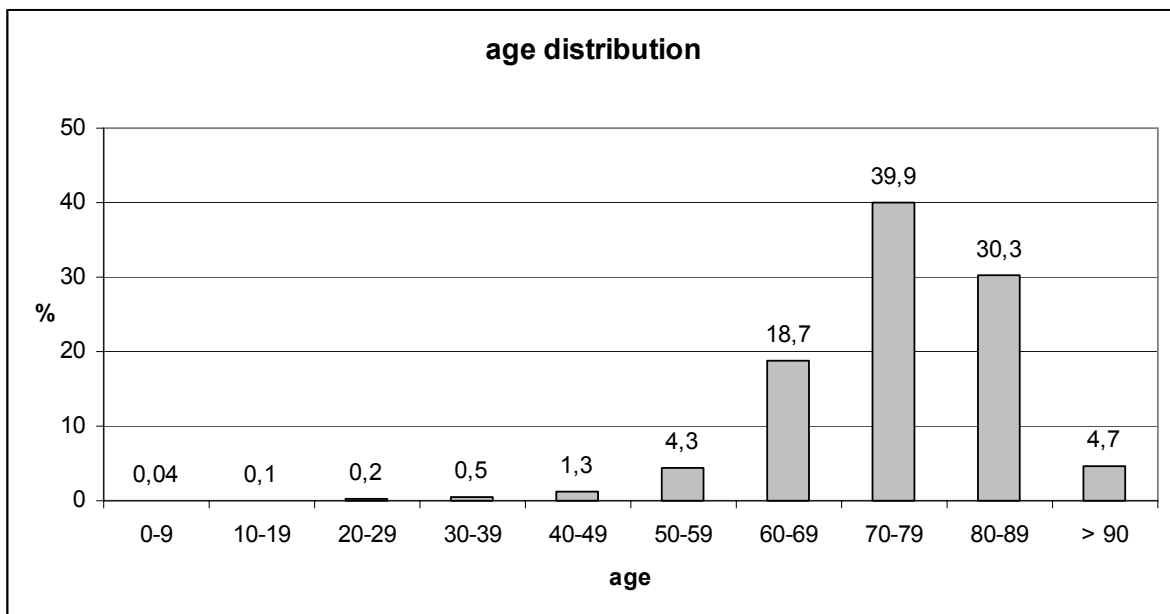
## 2. FIRST IMPLANTATIONS

### 2.1. Demographic Data

	<b>first implantation</b>
<b>women</b>	48,4%
<b>men</b>	51,6%
<b>mean age (years)</b>	
women	76,9
men	73,0
<b>PM-dependent*</b>	26,8%
<b>LOS in hospital (days)</b>	7,1

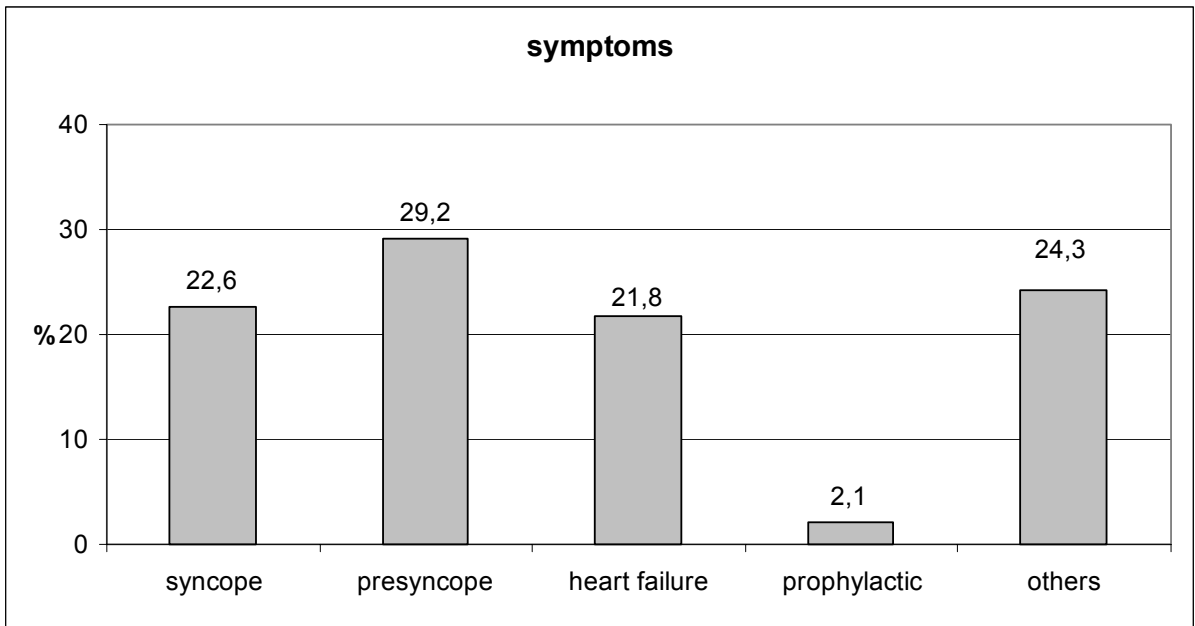
\* PM dependent was defined as an intrinsic rhythm < 40/min

#### 2.1.1. Age distribution





2.2. Symptoms

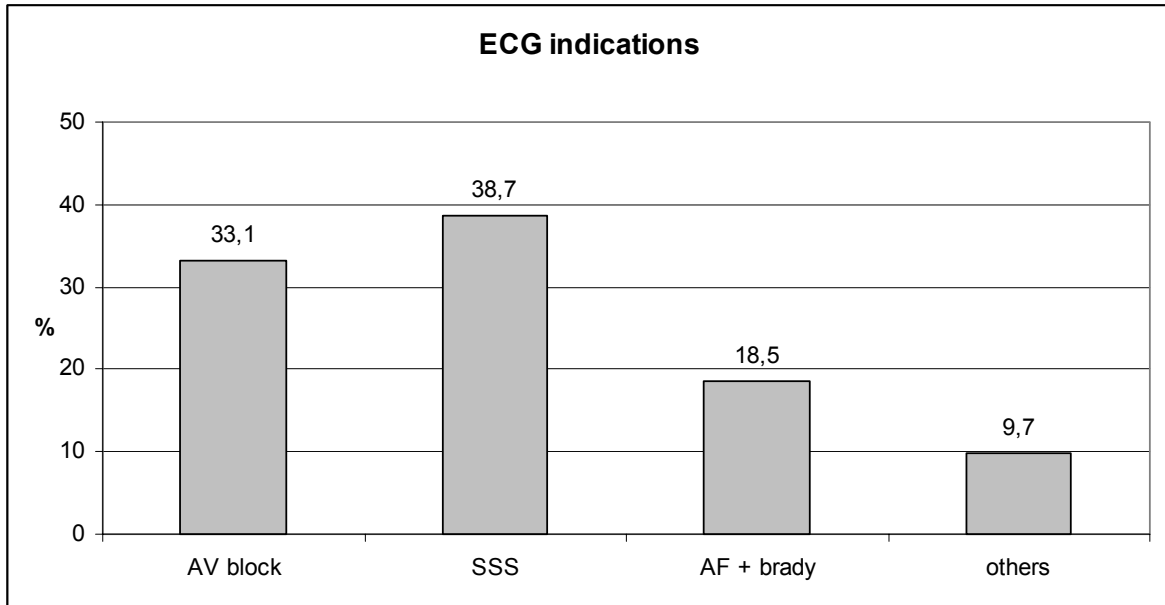


<b>symptoms*</b>	<b>2002</b>
<b>syncope</b>	11.651
<b>presyncope</b>	15.086
<b>heart failure</b>	11.270
<b>prophylactic</b>	1.098
<b>others</b>	12.544
<b>total</b>	<b>51.649</b>

\* more than 1 symptom could be reported

## 2.3. ECG-Indications

### 2.3.1. Overview



SSS = Sick sinus syndrome, AF = atrial flutter/fibrillation, brady = bradycardia

### 2.3.2. Details

ECG-indications	n	%
rhythm uncoded	178	0,62
AV-block I	165	0,57
AV-block II,1	500	1,74
AV-block II,2	2.796	9,72
AV-block III	6.219	21,62
BBB	335	1,16
SSS	6.894	23,97
BTS	4.243	14,75
AF + brady	5.309	18,46
CSS	657	2,28
VVS	73	0,25
SSS + AV block	628	2,18
others	766	2,66
<b>total</b>	<b>28.763</b>	<b>100</b>

BBB = bundle branch block, SSS = Sick sinus syndrome, BTS = Bradycardia/tachycardia-syndrome, AF = atrial flutter/fibrillation, brady = bradycardia, CSS = carotid sinus syndrome, VVS = vaso-vagal syndrome

**2.3.3. ECG indications: adherence to existing national guidelines**

ECG-indications	
adherence to guidelines	%
SSS	95,5
BTS	93,4
AV-block II & III	97,7
AF + brady	97,1
others	84,1
mean	96,3

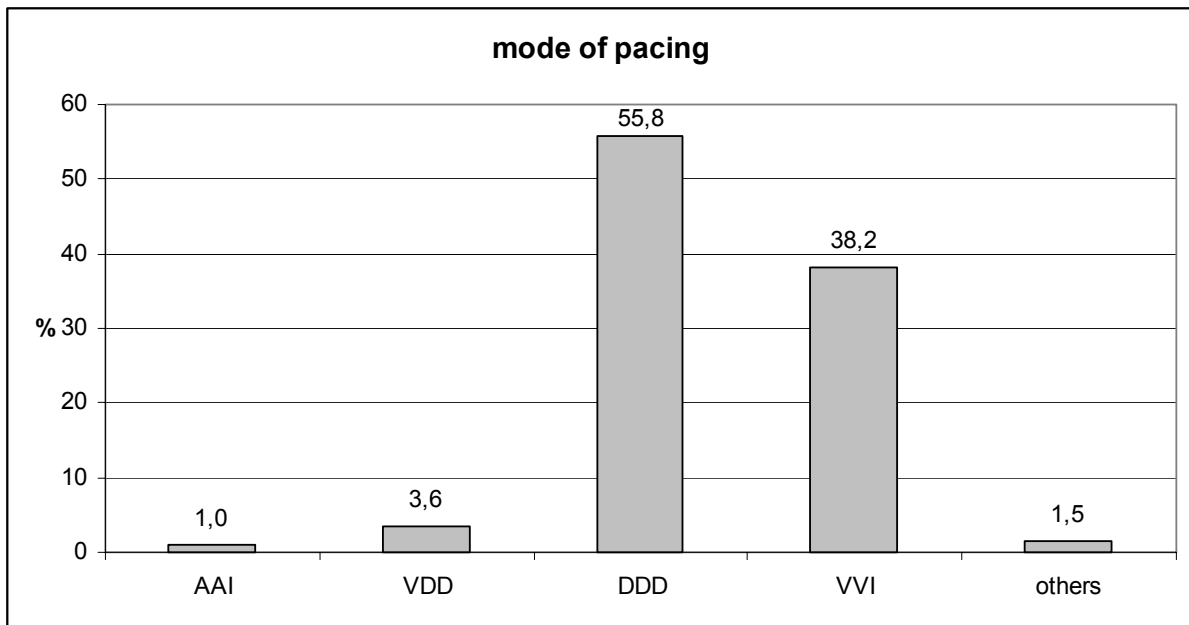
SSS = Sick sinus syndrome, BTS = Bradycardia/tachycardia-syndrome, AF = atrial flutter/fibrillation, brady = bradycardia, others = AV block I, bundle branch block, carotid sinus syndrome, vaso-vagal syndrome, SSS + AV block (binodal disease)

**2.4. Mode of pacing**

**2.4.1. Overview**

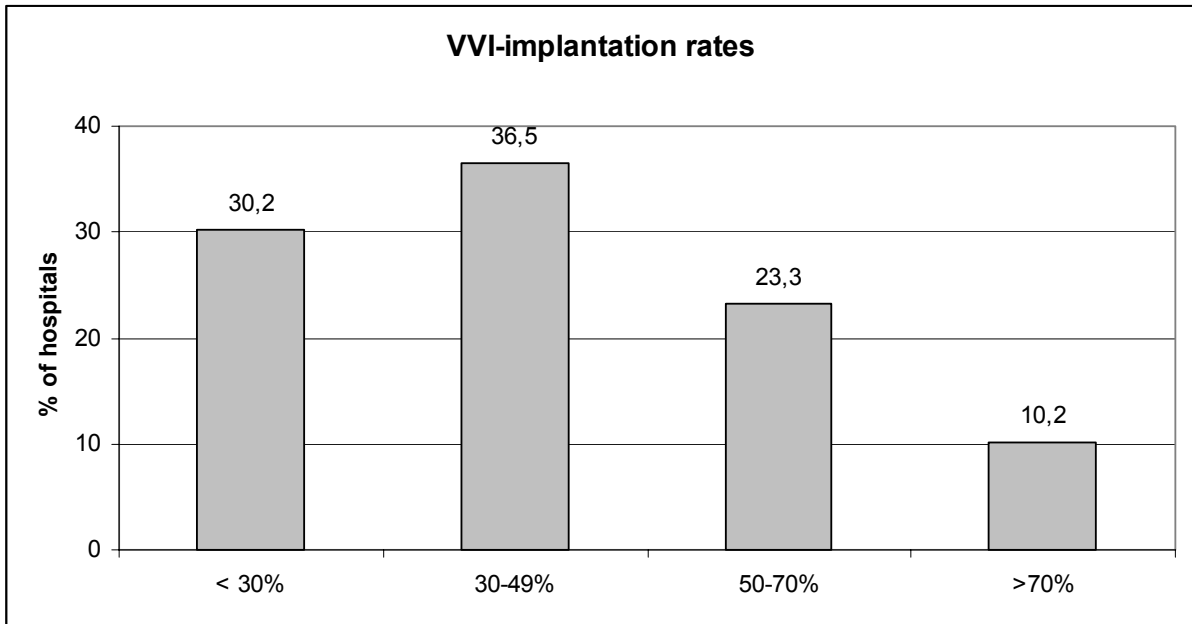
	AAI	VVI	VDD	DDD	CRT	others	total
<b>number of first implantations</b>	302	10.980	1.034	16.039	246	162	28.763

CRT = cardiac resynchronization system



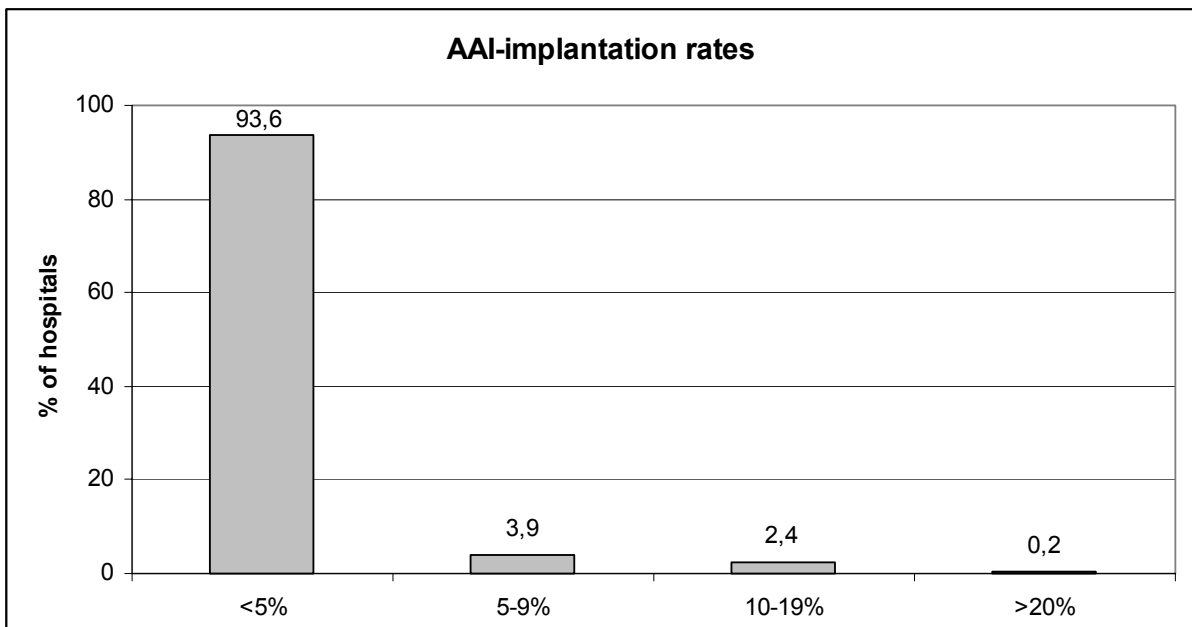
## 2.4.2. Differences in selection of pacing modes

### 2.4.2.1. VVI-mode



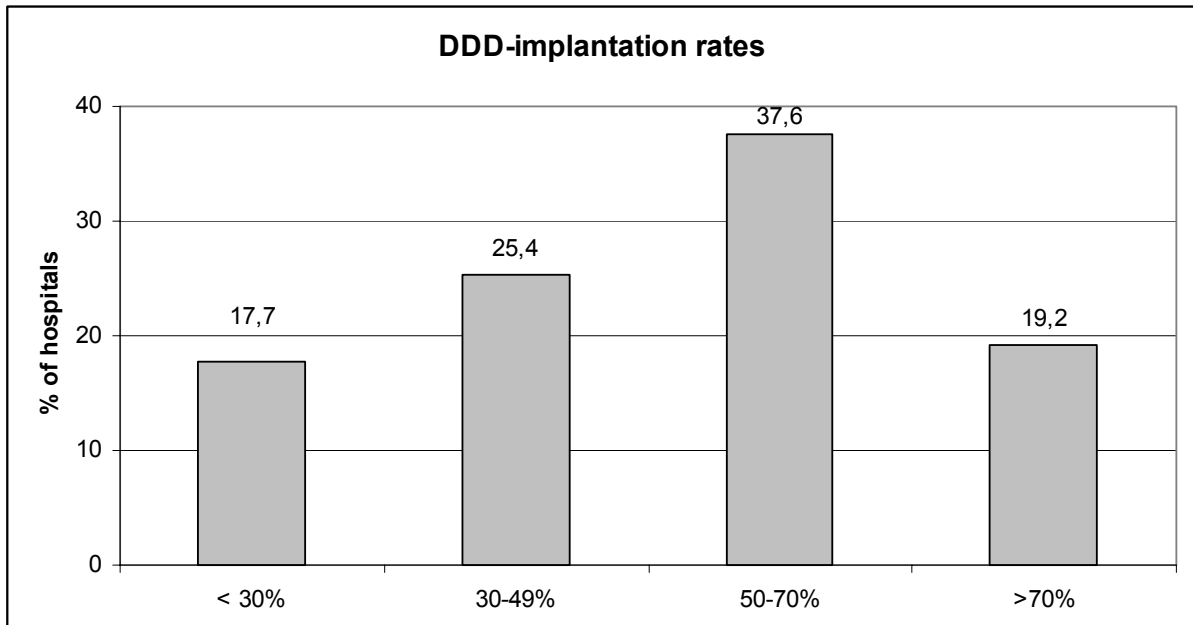
\* Explanation: for instance, 30,2% of the hospitals implanted in less than 30% of the patients VVI systems, or 10,2% implanted in more than 70% VVI-systems

### 2.4.2.2. AAI-mode



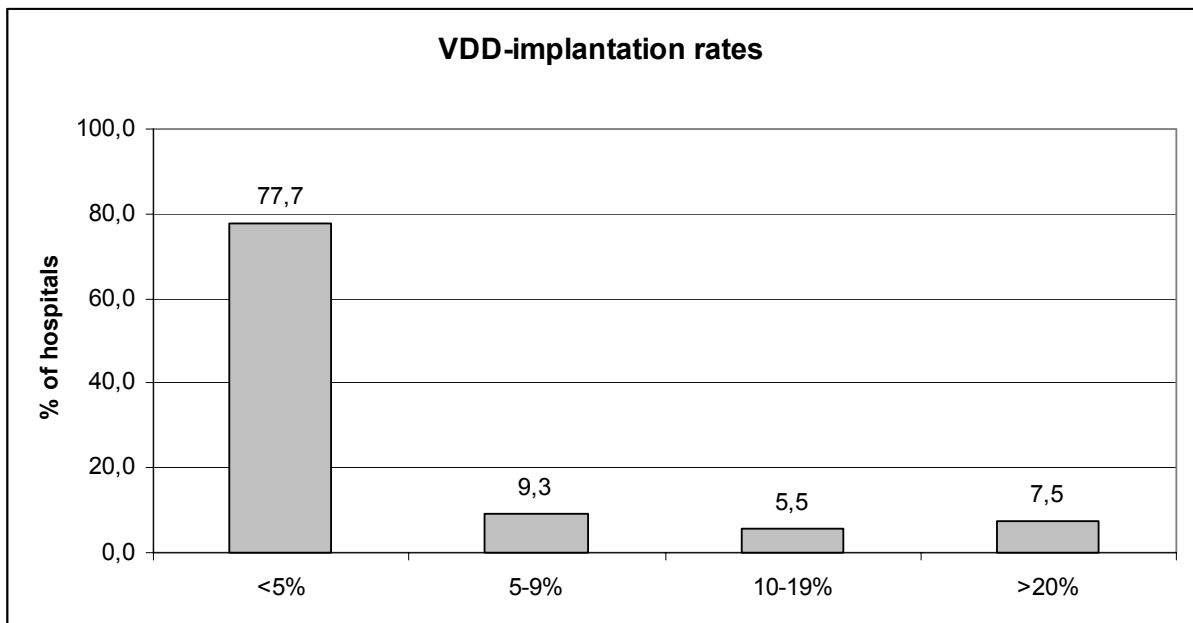
\* Explanation: for instance, 93,6% of the hospitals implanted in less than 5% AAI systems

**2.4.2.3. DDD-mode**



\* Explanation: for instance, 17,7% of the hospitals implanted in less than 30% DDD systems

**2.4.2.4. VDD-mode**



\* Explanation: for instance, 77,7% of the hospitals implanted in less than 5% VDD systems

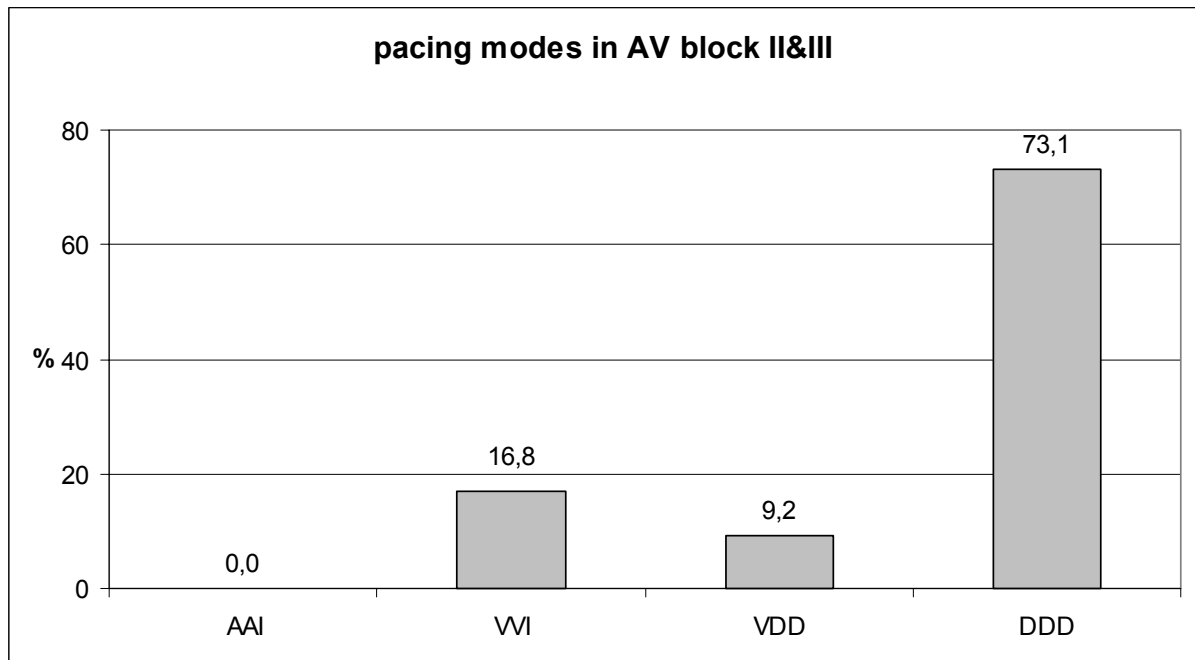
**2.4.3. Mode of pacing according to ECG indications**

**2.4.3.1. Overview**

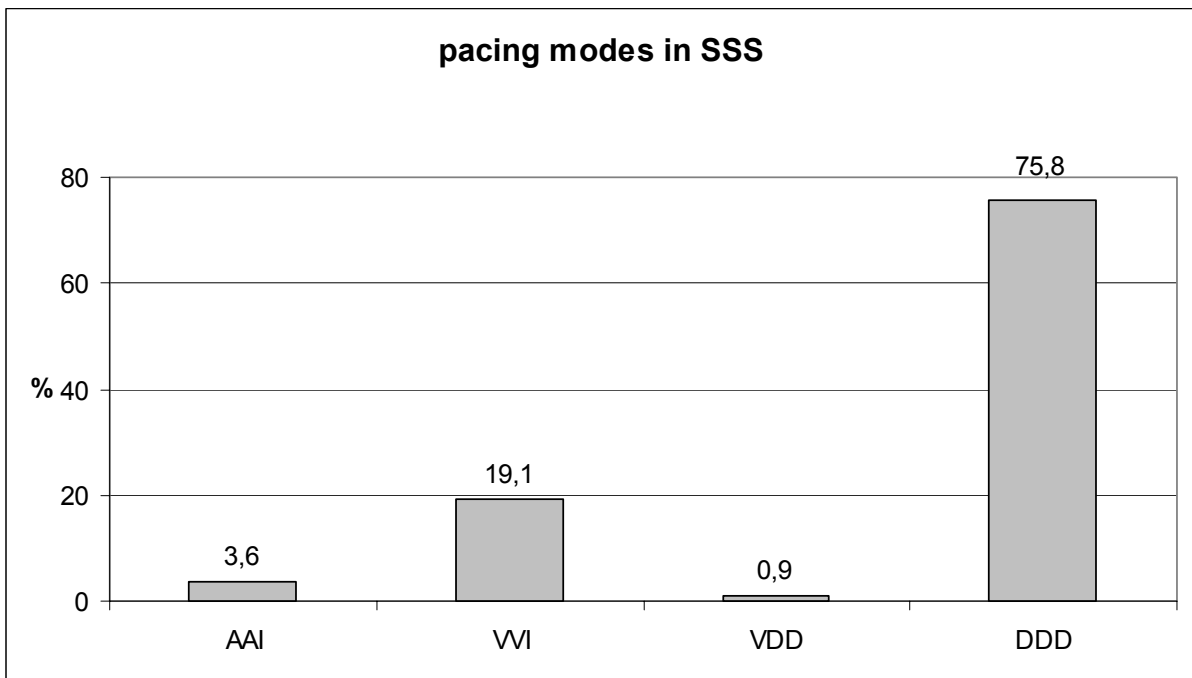
number	AAI	VVI	VDD	DDD	CRT	others	total
AV-block II&III	1	1.603	877	6.955	25	54	9.515
SSS	247	1.320	62	5.229	14	22	6.894
BTS	32	2.119	34	2.014	15	29	4.243
SSS + AV-Block	1	96	6	506	11	8	628
AF + brady	5	5.056	8	212	14	14	5.309
others	16	786	47	1.123	167	35	2.174
<b>total</b>	<b>302</b>	<b>10.980</b>	<b>1.034</b>	<b>16.039</b>	<b>246</b>	<b>162</b>	<b>28.763</b>

number	AV-Block II&III	SSS	BTS	SSS + AV-Block	AF + brady	others	total
AAI	1	247	32	1	5	16	302
VVI	1.603	1.320	2.119	96	5.056	786	10.980
VDD	877	62	34	6	8	47	1.034
DDD	6.955	5.229	2.014	506	212	1.123	16.039
CRT	25	14	15	11	14	167	246
others	54	22	29	8	14	35	162
<b>total</b>	<b>9.515</b>	<b>6.894</b>	<b>4.243</b>	<b>628</b>	<b>5.309</b>	<b>2.174</b>	<b>28.763</b>

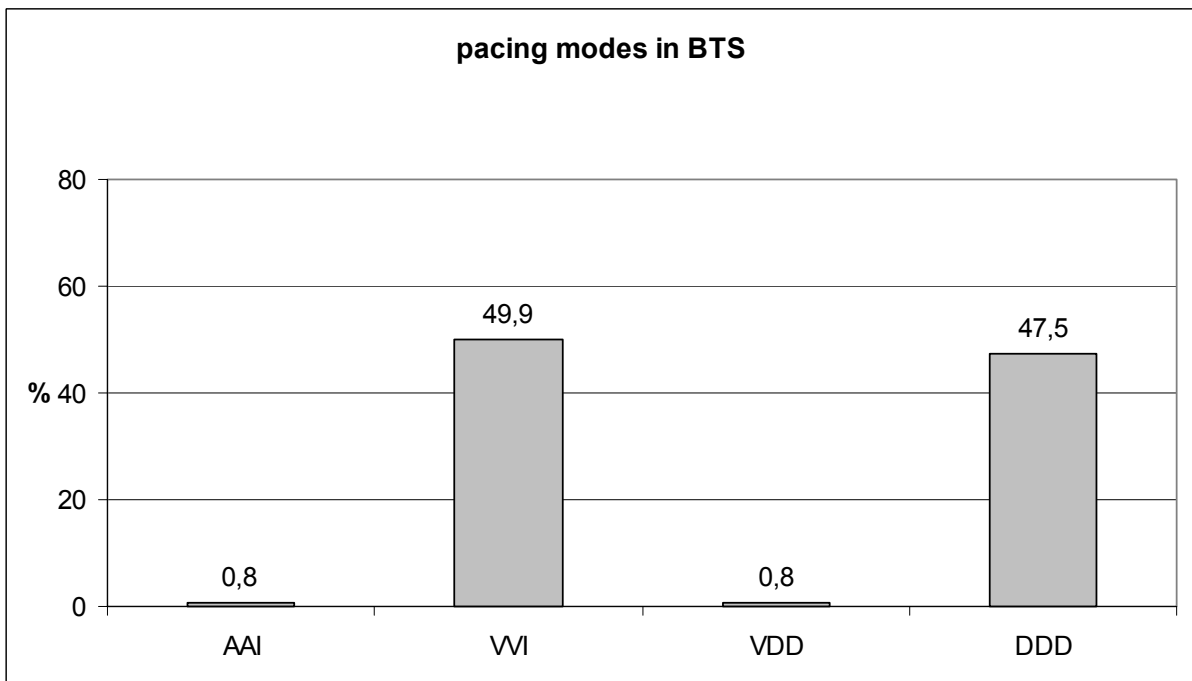
**2.4.3.2. AV block II & III**



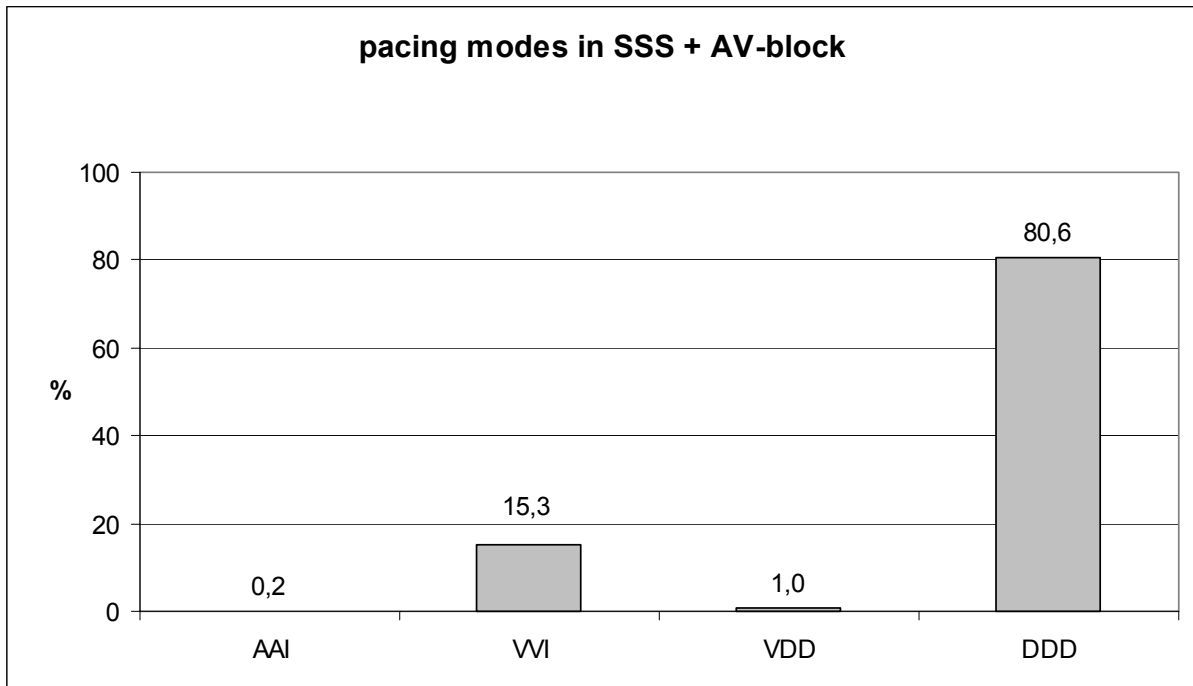
**2.4.3.3. Sick sinus syndrome**



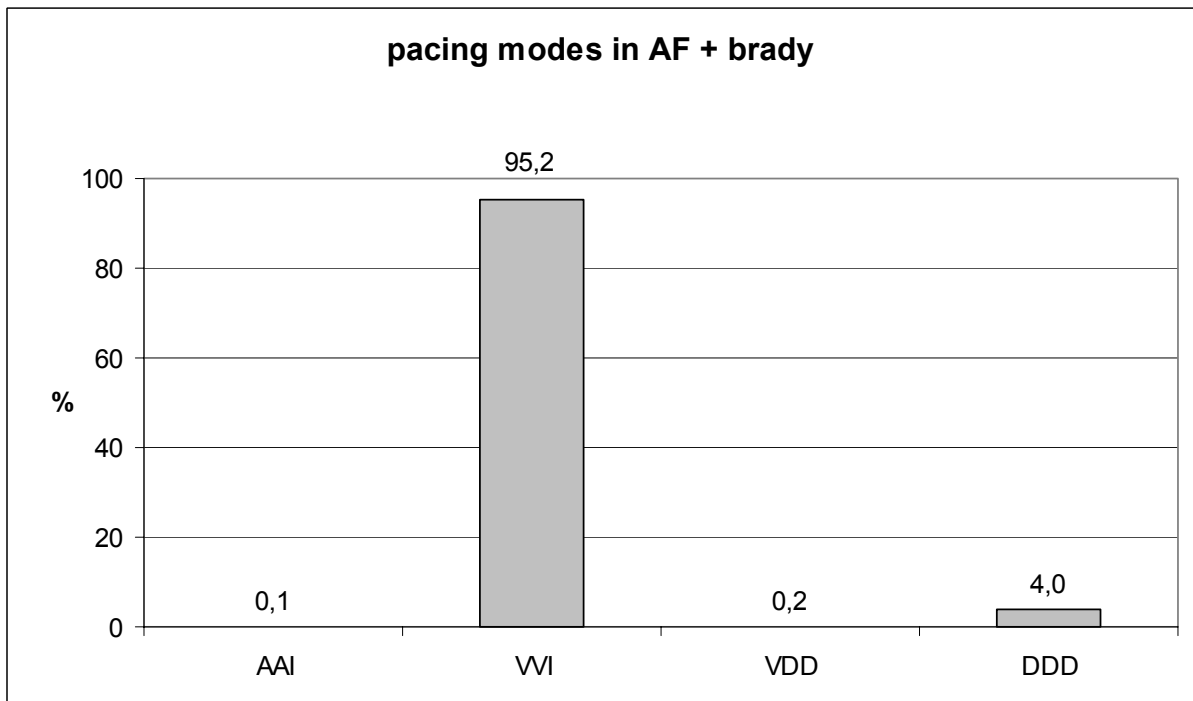
**2.4.3.4. Bradycardia/tachycardia syndrome (BTS)**



**2.4.3.5. Sick sinus syndrome + AV-block (binodal disease)**



**2.4.3.6. Atrial flutter/fibrillation + bradycardia**





**2.4.4. Mode of pacing: adherence to existing national guidelines**

<b>adherence to guidelines</b>	<b>%</b>
SSS	82,3
BTS, frequent episodes	45,6
SSS/BTS, few episodes	99,4
AV-block	89,8
AF + brady	95,7
others	77,9

SSS = Sick sinus syndrome, BTS = Bradycardia/tachycardia-syndrome, AF = atrial flutter/fibrillation, brady = bradycardia, others = AV block I, bundle branch block, carotid sinus syndrome, vaso-vagal syndrome, SSS + AV block (binodal disease)

## 2.5. Lead characteristics

	atrium		ventricle	
<b>electrode configuration</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
unipolar	492	2,98	10.524	37,19
bipolar	15.965	96,56	17.496	61,83
multipolar	76	0,46	279	0,99
<b>fixation mechanism</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
active	13.093	79,19	3.220	11,38
passive	3.207	19,40	24.052	84,99
none	233	1,41	1.027	3,63
<b>insulation material</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
polyurethane	3.486	21,09	5.884	20,79
silicone rubber	11.195	67,71	19.050	67,32
both	1.852	11,20	3.365	11,89
<b>drug elution</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
steroid	11.745	71,04	16.984	60,02
non-steroid	205	1,24	354	1,25
none	4.583	27,72	10.961	38,73

## 2.6. Operative data

## 2.6.1. Overview

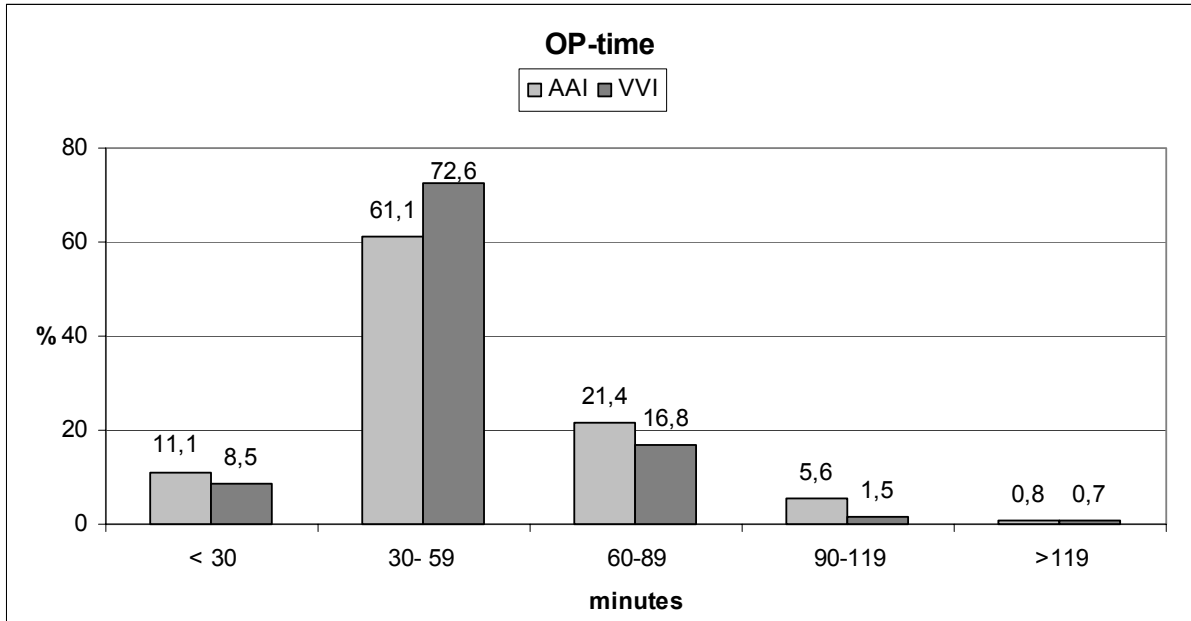
<b>anesthesia</b>	<b>n</b>	<b>%</b>
local	27.015	93,92
general	1.748	6,08
<b>venous approach</b>	<b>n</b>	<b>%</b>
cephalic vein cut down	15.410	49,89
subclavian vein puncture	15.074	48,81
others	401	1,30
<b>implantation</b>	<b>n</b>	<b>%</b>
left sided	7.054	24,46
right sided	21.784	75,54

## 2.6.2. Operation time

<b>OP-time (min)</b>	<b>n</b>	<b>mean</b>	<b>SD</b>	<b>median</b>
AAI	302	47,8	22,2	45,0
VVI	10.977	44,5	24,0	40,0
VDD	1.032	52,0	28,3	45,0
DDD	16.034	64,3	31,9	60
CRT	246	158,7	108,3	126
others	162	59,7	38	50
<b>total</b>	<b>28.753</b>	<b>56,8</b>	<b>33,3</b>	<b>50</b>

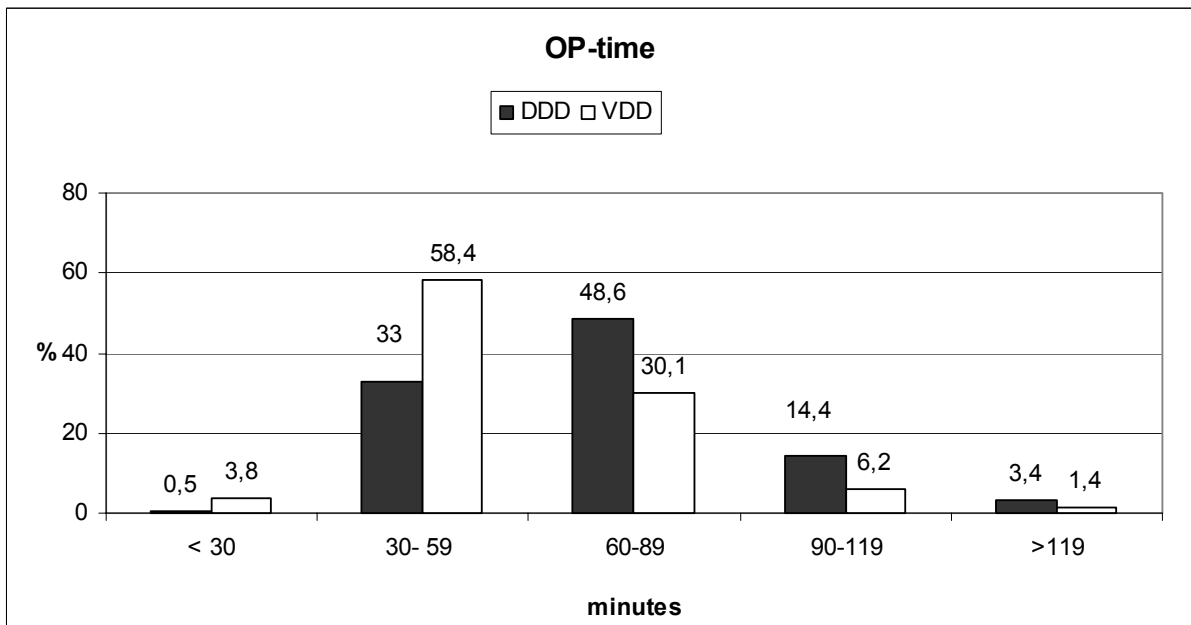
**2.6.3. Distribution of average OP-times according to pacing mode\***

**2.6.3.1. Single-chamber (AAI, VVI)**



\* Explanation: for instance, 11,1% of the hospitals had a mean operation time of < 30 minutes for AAI systems, and 8,5% of the hospitals had a mean operation time of less than 30 minutes for VVI-systems

**2.6.3.2. Dual chamber (DDD, VDD)\***



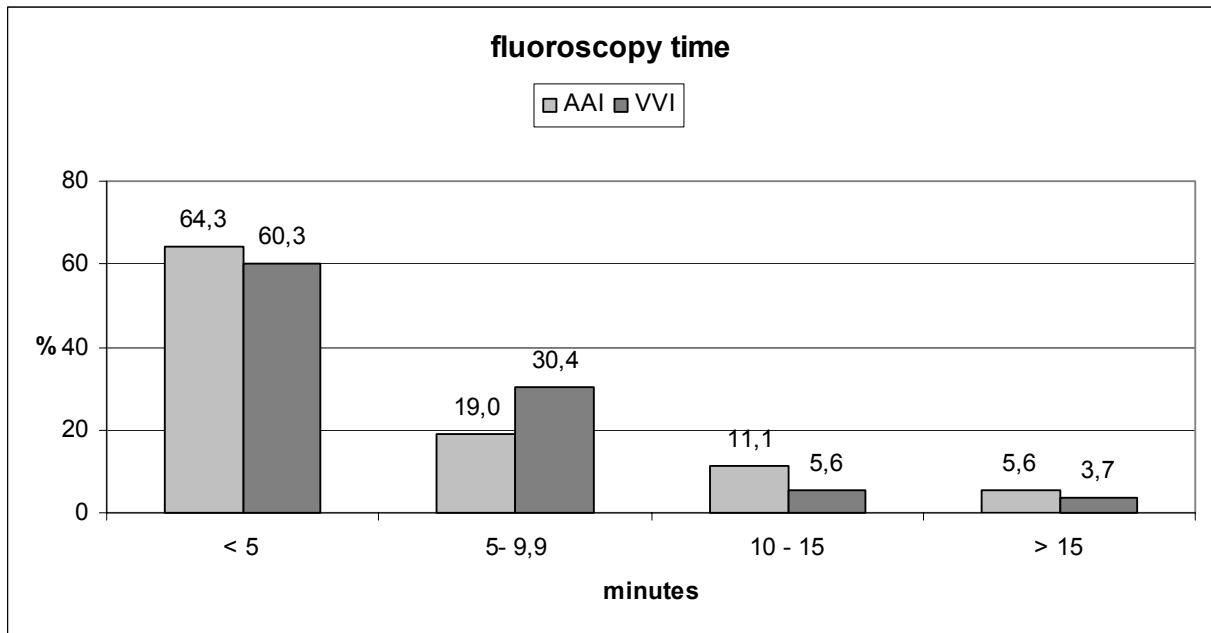
\* Explanation: for instance, 0,5% of the hospitals had a mean operation time of < 30 minutes for DDD systems, and 3,8% of the hospitals had a mean operation time of less than 30 minutes for VDD-systems

**2.6.4. Fluoroscopy time**

fluoroscopy time (min)	n	mean	SD	median
AAI	291	4,4	4,8	3
VVI	10.753	5,2	18,8	3
VDD	1020	5,2	6,2	3
DDD	15.874	7,9	18,4	5
CRT	223	29,3	21,5	22
others	141	9,6	8	4
<b>total</b>	<b>28.302</b>	<b>6,9</b>	<b>18,4</b>	<b>4</b>

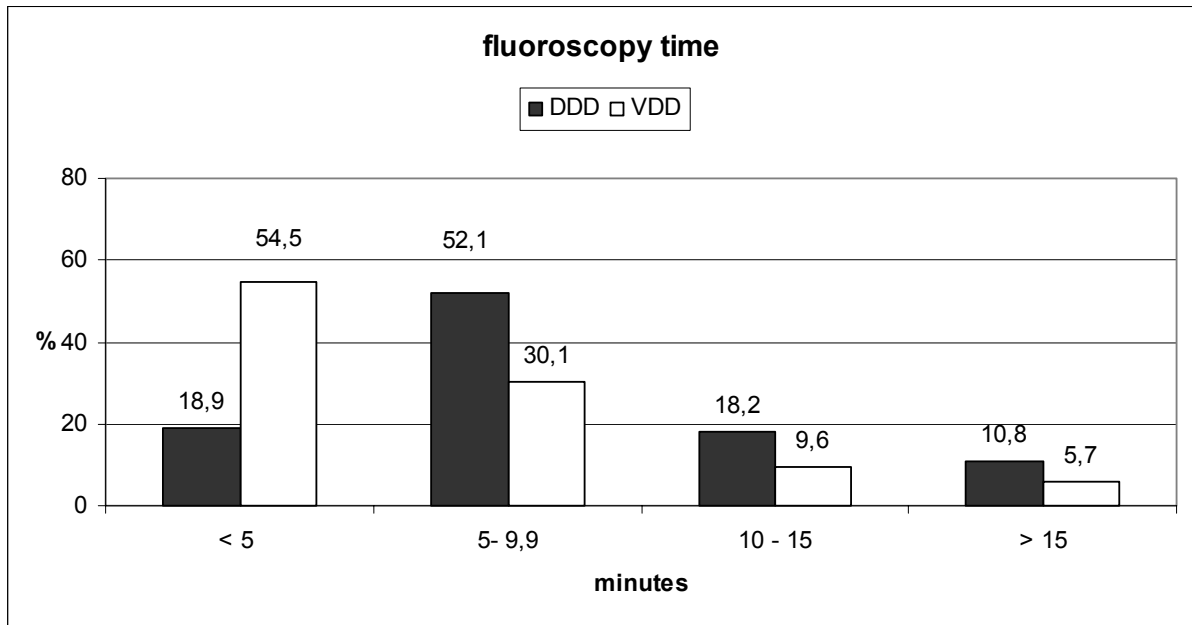
**2.6.5. Distribution of average fluoroscopy times according to pacing mode \***

**2.6.5.1. Single-chamber (AAI, VVI)\***



\* Explanation: for instance, 64,3% of the hospitals had a mean fluoroscopy time of < 5 minutes for AAI systems, and 60,3% of the hospitals had a mean fluoroscopy time of less than 5 minutes for VVI-systems

**2.6.5.2. Dual chamber (DDD, VDD)\***



\* Explanation: for instance, 18,9% of the hospitals had a mean fluoroscopy time of < 5 minutes for DDD systems, and 54,5% of the hospitals had a mean fluoroscopy time of less than 5 minutes for VDD-systems

**2.6.6. Intraoperative measurements**

<b>stimulation thresholds (V)</b>	<b>n</b>	<b>mean</b>	<b>SD</b>	<b>median</b>
right atrium	16.836	0,7	0,7	0,7
right ventricle	28.427	0,5	0,5	0,4
left ventricle	258	1	0,9	0,9
<b>intracardiac signals (mV)</b>	<b>n</b>	<b>mean</b>	<b>SD</b>	<b>median</b>
right atrium	17.019	3,3	3,6	2,8
right ventricle	28.415	12,6	8,1	12
left ventricle	257	11,5	7,9	11

**2.6.7. Manufacturer**

Manufacturer	n	%
Biotronik	8.626	30,0
Cook	12	0,0
CPI/Guidant	2.111	7,3
ELA/Medical	876	3,0
Intermedics	32	0,1
Implantronik	3	0,0
Medtronic	8.978	31,2
Osypka	14	0,0
Pacesetter	3.685	12,8
Siemens	88	0,3
Sorin Biomedica	776	2,7
Stöckert	29	0,1
Telectronics	2	0,0
Vitatron	2.813	9,8
other	718	2,5
<b>total</b>	<b>28.763</b>	<b>100</b>

**2.7. Perioperative complications**

**2.7.1. Overview**

	n	% *
<b>Patients with at least 1 complication</b>	1.817	6,3

**2.7.2. Detail**

type of complication	n	% *	% of all complications (n = 1.991)
asystole	102	0,4	5,1
ventricular fibrillation	55	0,2	2,8
atrial flutter/fibrillation	212	0,7	10,6
pneumothorax	228	0,8	11,5
- requiring chest tube insertion	74	0,3	3,7
tamponade	31	0,1	1,6
pocket hematoma	403	1,4	20,2
hemothorax	27	0,1	1,4
lead dislodgement	614	2,1	30,8
- atrium	278	1,0	14,0
- ventricle	312	1,1	15,7
- both	24	0,1	1,2
Infection	61	0,2	3,1
- requiring reoperation	39	0,1	2,0
others	258	0,9	13,0
cardio-pulmonary resuscitation necessary	46	0,2	2,3

\* related to all first implantations

## GERMAN PACEMAKER REGISTER – REPORT 2002

	<b>n</b>	<b>% *</b>
<b>death</b>	318	1,11
- related to rhythm disorder	25	0,09
- pacemaker/lead malfunction	6	0,02

\* related to all first implantations

### 3. PULSE GENERATOR REPLACEMENTS/EXPLANTATIONS

#### 3.1. Demographic Data

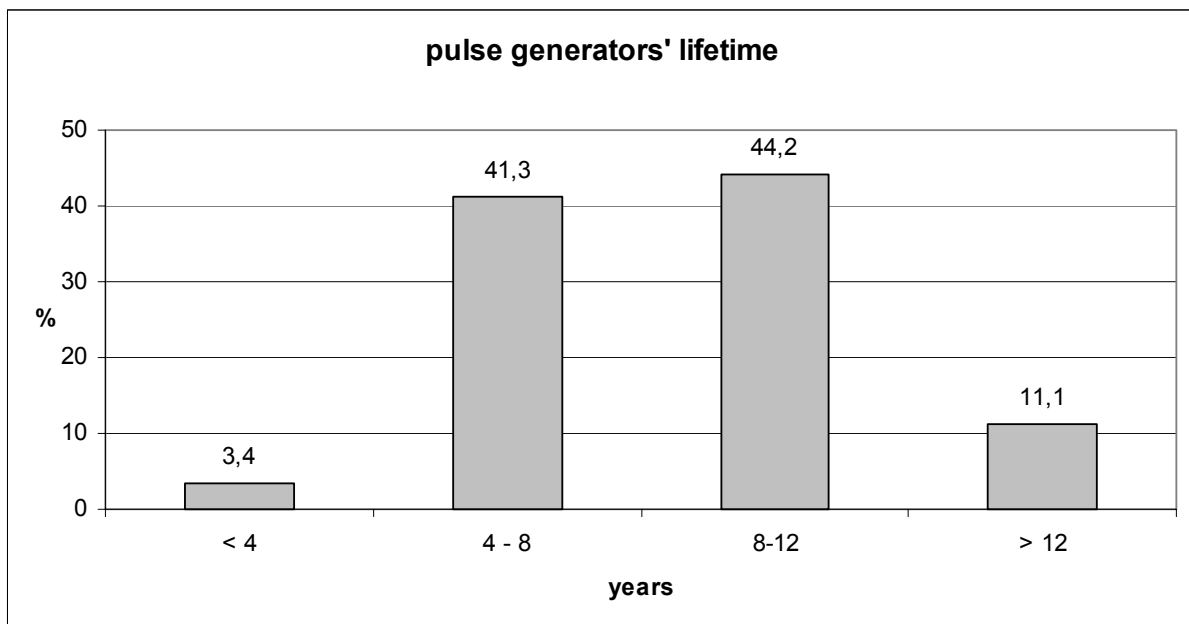
	<b>pulse generator exchange</b>
<b>women</b>	51,8%
<b>men</b>	48,2%
<b>mean age (years)</b>	
women	77,7
men	75,3
<b>PM-dependent*</b>	40,5%
<b>LOS in hospital (days)</b>	4,5

\* PM dependent was defined as an intrinsic rhythm < 40/min

#### 3.2. Indications for replacement/explantation

<b>indication for replacement/explantation</b>	<b>n</b>	<b>%</b>
<b>battery depletion</b>	6.299	96,1
<b>premature battery depletion</b>	254	3,9
<b>total</b>	<b>6.553</b>	<b>100</b>
<b>life time until EOL (years)</b>	<b>mean + SD</b>	<b>median</b>
	8,5 + 4,1	8

#### 3.3. Distribution of pulse generators' lifetime



\* Explanation: for instance, 3,4% of the pulse generators had a lifetime < 4 years



### 3.4. Pulse generators' lifetime according to the mode of pacing

lifetime (years)	n	mean	SD	median
AAI	169	8,9	3	8
VVI	2.069	9,7	4,9	9
DDD	1.845	7,3	2,6	7
VDD	144	6,4	1,7	6
<b>total</b>	<b>4.296</b>	<b>8,5</b>	<b>4,1</b>	<b>8</b>

### 3.5. Perioperative complications

#### 3.5.1. Overview

	n	% *
<b>Patients with at least 1 complication</b>	161	2,5

#### 3.5.2. Detail

type of complication	n	% *	% of all complications (n = 175)
asystole	28	0,4	16,0
ventricular fibrillation	1	0,0	0,6
atrial flutter/fibrillation	19	0,3	10,9
pocket hematoma	72	1,1	41,1
Infection	13	0,2	7,4
- requiring reoperation	3	0,0	1,7
others	42	0,6	24,0

\* related to all generator replacements

	n	% *
<b>death</b>	19	0,3
- related to rhythm disorder	3	0,05
- pacemaker/lead malfunction	0	0,00

\* related to all generator replacements

## 4. REOPERATIONS

### 4.1. Demographic Data

	reoperation
women	48,4%
men	51,6%
<b>mean age (years)</b>	
women	75,1
men	72,4
<b>PM-dependent*</b>	35,5%
<b>LOS in hospital (days)</b>	7,4

\* PM dependent was defined as an intrinsic rhythm < 40/min

### 4.2. Overview

Reoperations	n	%
reports	1.496	
generator or pocket problem	787	40,7
lead problem	969	50,1
others	178	9,2
<b>total *</b>	<b>1.934</b>	

\* more than 1 problem could be reported

### 4.3. Detail

#### 4.3.1. Generator or pocket problems

generator or pocket problem	n	% of all problems (n = 1.934)	% of all generator or pocket problems (n = 1.080)
battery depletion			
- premature	46	2,4	4,3
- regular	456	23,6	42,2
PM malfunction	55	2,8	5,1
PM recall	2	0,1	0,2
system change			
- between PM-systems	260	13,4	24,1
- from PM to ICD	2	0,1	0,2
pectoral muscle twitching	17	0,9	1,6
pocket hematoma	21	1,1	1,9
infection	69	3,6	6,4
other pocket problem	34	1,8	3,1
perforation	39	2,0	3,6
others	79	4,1	7,3
<b>total *</b>	<b>787</b>	<b>40,7</b>	<b>100</b>

\* more than 1 problem could be reported

#### 4.3.2. Lead problems

lead problem	n	%
location reported	856	
atrium	241	28,2
ventricle	495	57,8
both	120	14,0

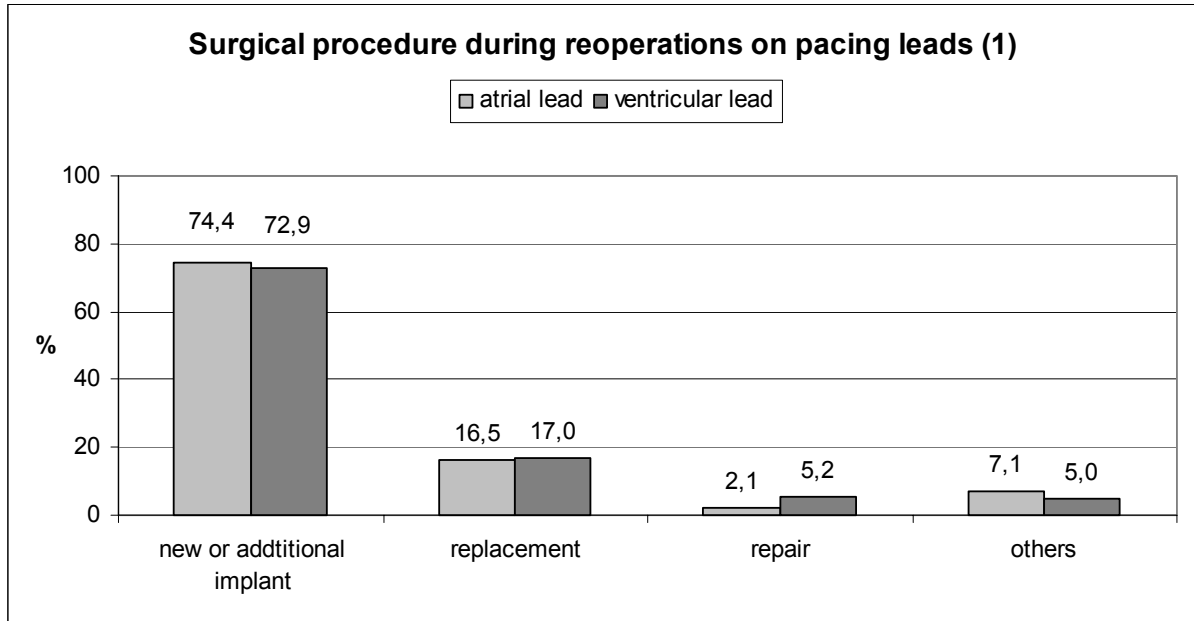
lead problem	n	% of all reoperations (n = 1.934)	% of all lead problems (n = 1.208)
dislodgement	284	14,7	23,5
fracture	79	4,1	6,5
insulation failure	92	4,8	7,6
connector failure	20	1,0	1,7
diaphragmatic stimulation	21	1,1	1,7
oversensing	27	1,4	2,2
undersensing	143	7,4	11,8
loss of pacing	377	19,5	31,2
infection	52	2,7	4,3
perforation	21	1,1	1,7
others	92	4,8	7,6
<b>total *</b>	<b>969</b>	<b>50,1</b>	<b>100</b>

\* more than 1 problem could be reported

#### 4.3.3. Surgical procedure

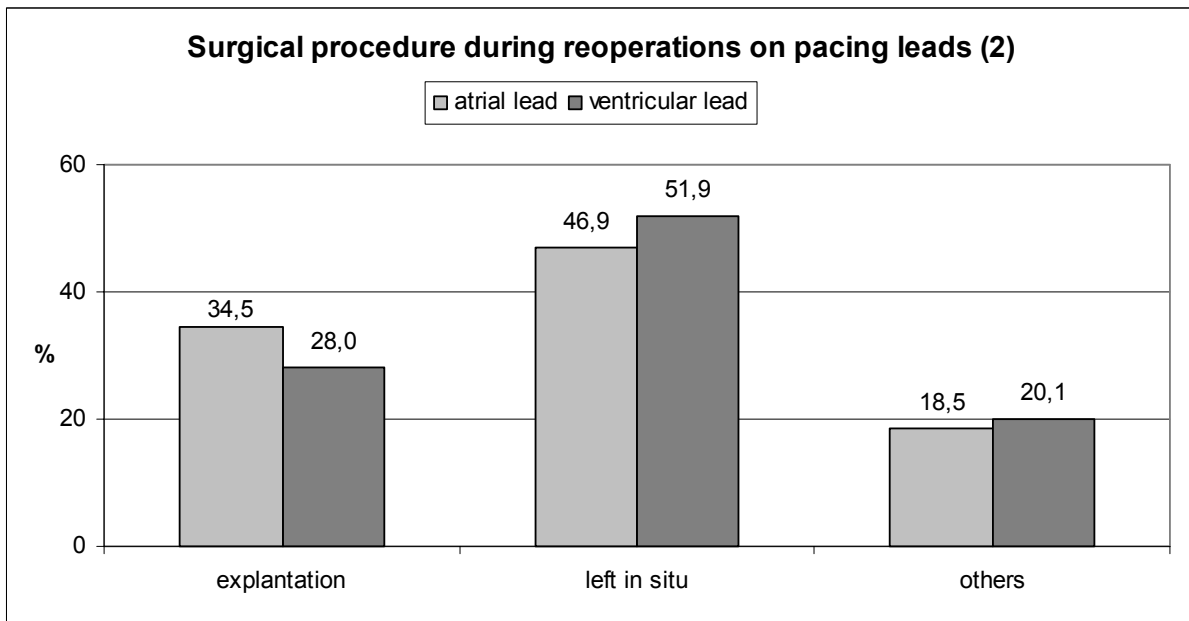
##### 4.3.3.1. New hardware

new hardware	atrial lead	ventricular lead	generator
new or additional implant	432	631	818
replacement	96	147	70
repair	12	45	
others	41	43	69



**4.3.3.2. Old hardware**

old hardware	atrial lead	ventricular lead	generator
explantation	164	194	800
left in situ	223	360	
others	88	139	71



4.4. Perioperative complications

4.4.1. Overview

	n	% *
<b>Patients with at least 1 complication</b>	88	5,9

4.4.2. Detail

type of complication	n	% *	% of all complications (n = 96)
asystole	4	0,3	4,2
ventricular fibrillation	3	0,2	3,1
atrial flutter/fibrillation	4	0,3	4,2
pneumothorax	15	1,0	15,6
- requiring chest tube insertion	12	0,8	12,5
tamponade		0,0	0,0
pocket hematoma	21	1,4	21,9
hemothorax	3	0,2	3,1
lead dislodgement	29	1,9	30,2
- atrium	16	1,1	16,7
- ventricle	13	0,9	13,5
Infection	5	0,3	5,2
- requiring reoperation	5	0,3	5,2
others	12	0,8	12,5
cardio-pulmonary resuscitation necessary	3	0,2	3,1

	n	%
<b>death</b>	8	0,1
- related to rhythm disorder	1	0,02
- pacemaker/lead malfunction	0	0,00