German Pacemaker Register

Report 2004

Specialty Group for Cardiac Pacemakers*
and
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(*German National Agency for Performance Measurement in Health Care*)**
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Introduction

Such large a pacemaker (PM) data base as that collected in 2004 (n=86,252) has never been recorded. This is presumably not alone due to a virtual increase in the number of interventions, but also the result of a change in the mode of registration (the so called “QS-Filter” which is a special algorithm to trigger the selection of cases for documentation). In previous years, data were collected according to the reimbursement codes for pacemaker surgery which, however, did not include reoperations without pulse generator exchange. Since 2004, all inpatient cases undergoing operative pacemaker procedures have to be included. Depending on the particular ICPM-code, one of the pacemaker data records, either 09/1 (initial implants), 09/2 (pulse generator replacements) or 09/3 (explantation/revision or a combination of these interventions), is triggered.

With this volume of registered data, the German pacemaker register (1) remains the most expansive pacemaker registry of the world. Only those pacemaker interventions that have been performed on an outpatient basis are not included.

As far as the contents in 2004 are concerned, only minor changes as compared to previous years were observed. So we will limit our comments concerning the figures in the following to consider only those which have demonstrated substantial changes.

Data basis

Data volumes

As seen in **Table 1**, all numbers regarding the volume of interventions have increased in 2004, both the number of hospitals as well as the number of interventions, as compared with the findings from the previous years. The number of hospitals with a high volume of reported operations was seen to increase, while the number of hospitals with fewer interventions per year was seen to be reduced (see **Table 2, Figure 1, Appendix, Table 1**).

Data Base	2002	2003	2004
hospitals reporting			
09/1: initial implants	622	898	985
09/2: replacement operations	549	792	914
09/3: reoperations	313	601	881
total	632	907	989
interventions			
09/1: initial implants	28,763	51,904	62,382
09/2: replacement operations	6,553	12,484	14,622
09/3: reoperations	1,496	4,042	9,248
total	36,812	68,430	86,252

Table 1: Review of the evaluated data which has been reported in comparison with those findings from the previous years

number of pacemaker operations reported	2002	2003	2004
	n	n	n
<20	176	162	143
20-49	209	275	283
50-99	146	255	305
100-199	82	160	194
200-299	13	35	44
≥ 300	5	13	17
Total	**631**	**900**	**986**

Table 2: Volume of surgery (new implantations and replacements) from the reporting hospitals
n = number of hospitals

The number of new implantations actually reported is 62,382, which represents 756 implantations per 1 million inhabitants in Germany, a figure which increased once again. We will discuss this rate in more detail, also in comparison with other international pacemaker registers (see Comment).

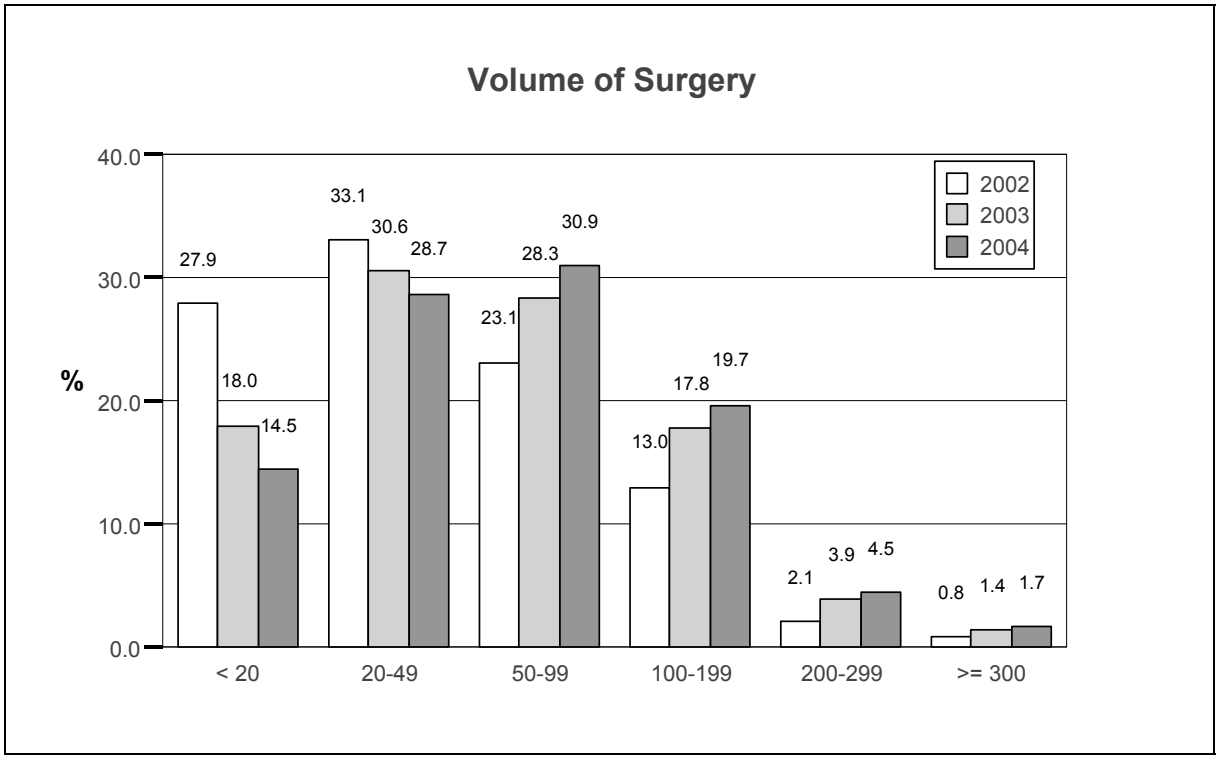

Figure 1: Distribution of the volume of surgery in the individual institutions (Example: In the year 2002, 27.9% of the institutions carried out < 20 PM operations, in 2003 this volume category was reduced to 18.0% and to 14.5% in the year 2004)

The increase in the number of reoperations (see **Table 4**) seems to be surprising: The number of hospitals in which reoperations had been reported increased by a factor of 1.5 in 2004 as compared with 2003, while the number of surgical procedures even increased by a factor of 2.3. Here, the primary cause for the increase in these figures can presumably be related to the new methods of data collection described in the introduction, so that the

reported number of reoperations in the report from the previous year has probably underestimated the true number of reoperations substantially.
The problem here is that the proportion of reoperations from all interventions, which we assumed to be 4.1% (2002) or 5.9% (2003) in the preceding years, respectively, has meanwhile risen to a somewhat disappointing level of 10.7%. As an approximation, one could thereby conclude that more than 10% of the implantations were ultimately seen to result in problems demanding a further surgical procedure. Consequently, one could presume that pacemaker implantations may have a certain potential for optimization.

Due to a new statistical reference parameter which detailed description is beyond the scope of this report, the estimation of the completeness of data sets in 2004 is substantially more accurate than in the past years.
In spite of the greater number of interventions performed in the year 2004, there is a reduction in the completeness of the survey (see **Table 4**) as compared with 2003 (see **Table 3**). In particular, completeness for the explantations/revisions is lower (103.7% vs. 74.0%), presumably due to problems of the procedural code for pacemakers (ICPM-code): Until 2005, the ICPM-code for some of the reoperations could not differentiate whether it dealt with an implantable cardioverter defibrillator (ICD) or a pacemaker. As a consequence, ICD-interventions were erroneously recorded in the nominal statistics as well.

data base 2003	expected	received	%
number of hopitals reporting	870	907	104.3
interventions			
- 09/1 initial implants	50,366	51,904	103.1
- 09/2 pulse generator replacement	9,232	12,484	135.2
- 09/3 reoperations	3,899	4,042	103.7

Table 3: Completeness of the data base as well as the hopitals reporting in 2003

data base 2004	expected	received	%
number of hopitals reporting	1,054	989	93.8
interventions			
- 09/1 initial implants	65,332	62,382	95.5
- 09/2 pulse generator replacement	14,616	14,622	100.0
- 09/3 reoperations	12,493	9,248	74.0

Table 4: Completeness of the data base as well as the hopitals reporting in 2004

Demographic data

In the demographic data given in **Table 5**, there are only marginal changes to be observed. As aforementioned, the number of new implantations, pulse generator replacements and reoperations per hospital increased in the last years. The reduction in the median stay in the hospital may be reflective of the general developments associated with the increasing economization of the health care system. Details concerning the age distribution are to be

seen in **Appendix Table 2**. Surprising, however, is the fact that the proportion of patients dependent on their pacemakers is apparently decreasing (from 26.8% in 2002 to 24.9% in 2004).

	2002	2003	2004
new implantations	28,763	51,904	62,382
mean per institution	46.2	57.8	63.3
gender			
male	51,6%	51,7%	51.9%
female	48,4%	48,3%	48.1%
mean age (years)			
males	73	73	73.3
females	76.9	76.8	77.1
patients < 60-years-old	6.5%	6.5%	6.2%
proportion of patients dependent on PM	26.8%	25.1%	24.9%
average length of stay in the hospital (days)	7.1	7.2	6.4
pulse generator replacements	6,553	12,484	14,622
Mean per institution	11.9	15.8	16.0
mean age (years)			
males	75.3	74.7	75.0
females	77.7	77.7	78.5
time between implantation and exchange (years):	8.5	8.5	8.5
proportion of patients dependent on PM	40.5%	38.7%	37.6%
average length of stay in the hospital (days)	4.5	4.3	3.5
reoperations	1,496	4,042	9,248
mean per institution	4.8	6.7	10.5
gender			
males	51.6%	53.7%	55.1%
females	48.4%	46.3%	44.9%
mean age (years)			
males	72.4	71.3	70.8
females	75.1	74.0	73.9
proportion of patients dependent on PM	35.5%	37.3%	30.8%
average length of stay in hospital (days)	7.4	6.3	6.1

Table 5: Demographic data concerning new implantations, pulse generator exchanges and reoperations

New implantations

ECG indications for pacemaker implantation

Although there were changes in the absolute figures, the distribution of indications for pacemaker implantation (see

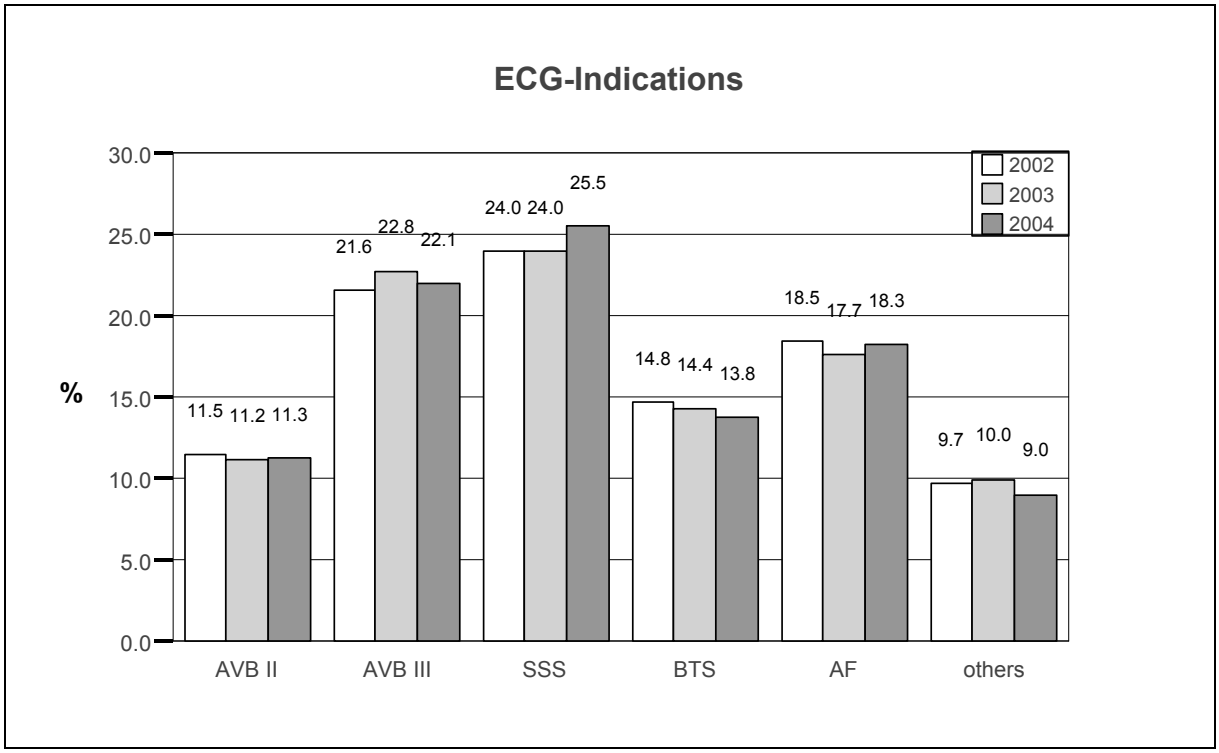

Figure 2, Appendix Table 3) showed only minor changes since 2002.

The indications followed the guidelines in an exceptional rate of > 95% of the cases (see **Appendix Table 4**). Only the small group of "other" indications is below average (71.2%). However, this low number rather indicates problems of the guidelines than problems with adherence to guidelines. The new guideline (2) will (hopefully) solve this problem.

ECG-Indication	2002	2003	2004
AV block II	3,296	5,807	7,058
AV block III	6,219	11,836	13,761
SSS	6,894	12,447	15,930
BTS	4,243	7,451	8,586
AF+ bradycardia	5,309	9,175	11,403
other	2,802	5,188	5,644
total	**28,763**	**51,904**	**62,382**

Table 6: ECG indications for PM implantation in comparison (SSS = sick sinus syndrome, BTS = bradycardia-tachycardia syndrome, AF+bradycardia = atrial fibrillation with bradycardia, other = no predominant ECG finding, carotid sinus syndrome, vasovagal syndrome, bifascicular block, AV block I, binodal disease, other predominant ECG finding)

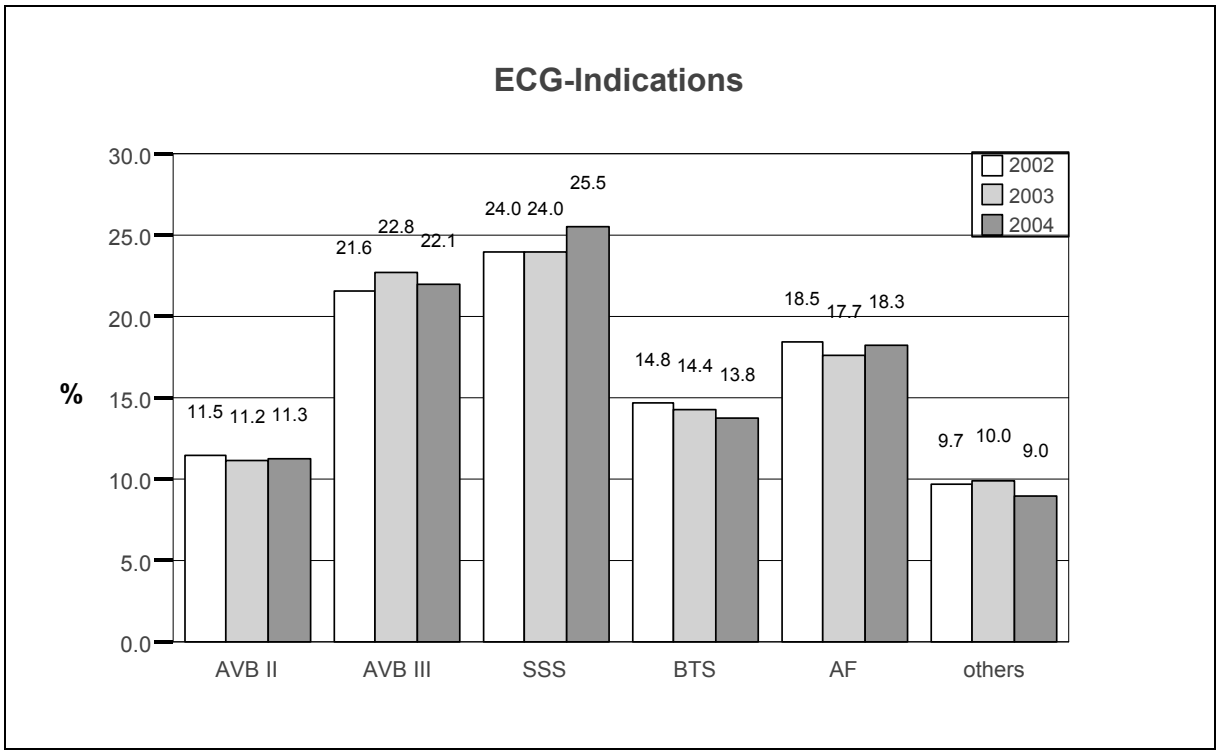

Figure 2 Distribution of the ECG indications for new implantations (AVB = AV block, SSS = sick sinus syndrome, BTS = bradycardia-tachycardia syndrome, AF = atrial fibrillation with bradycardia)

For a more detailed analysis of the indications and symptoms, see **Appendix, Table 4**.

Selection of pacing mode

As in 2003, the trend in the selection of pacing mode continues to favor atrial based pacing. This is not only the case for an overall review of all indications (see

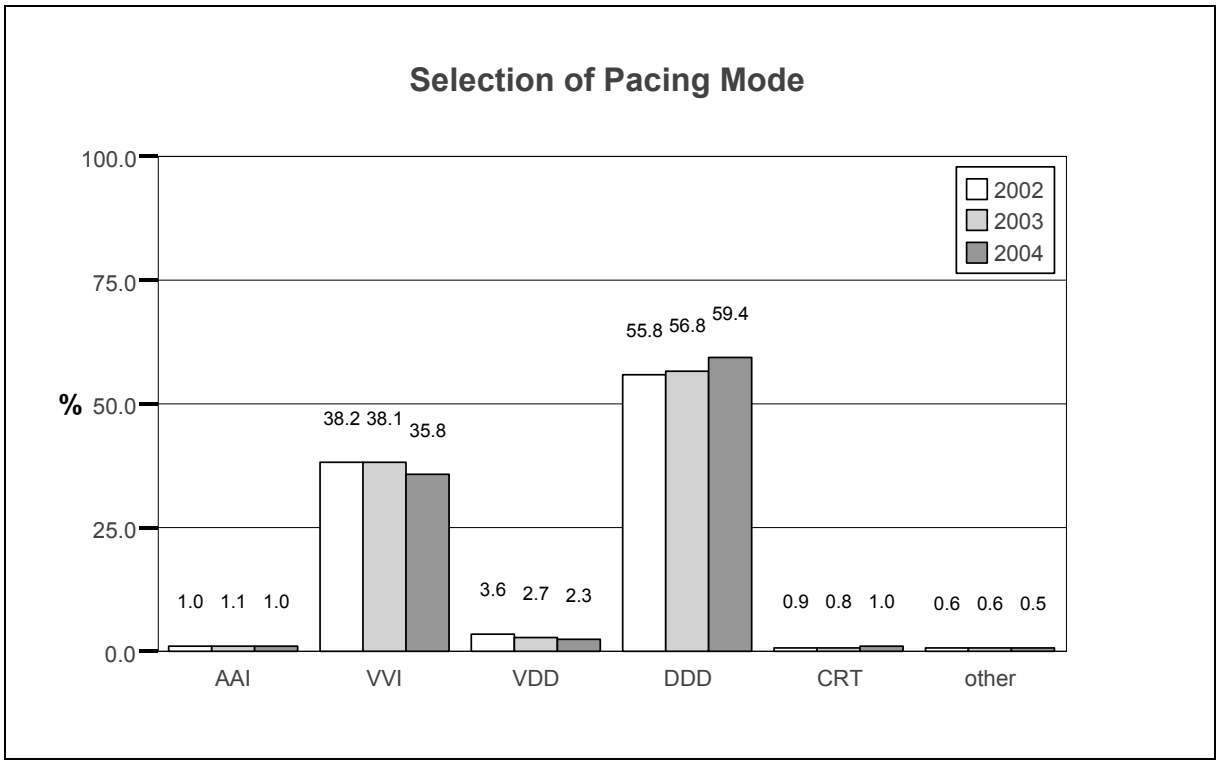

Figure 3), but also for the individual types of rhythmic disorders (see **Figure 4** to **Figure 7**). For slow atrial fibrillation, as expected, the changes merely appear to be quite small (see **Figure 7**).

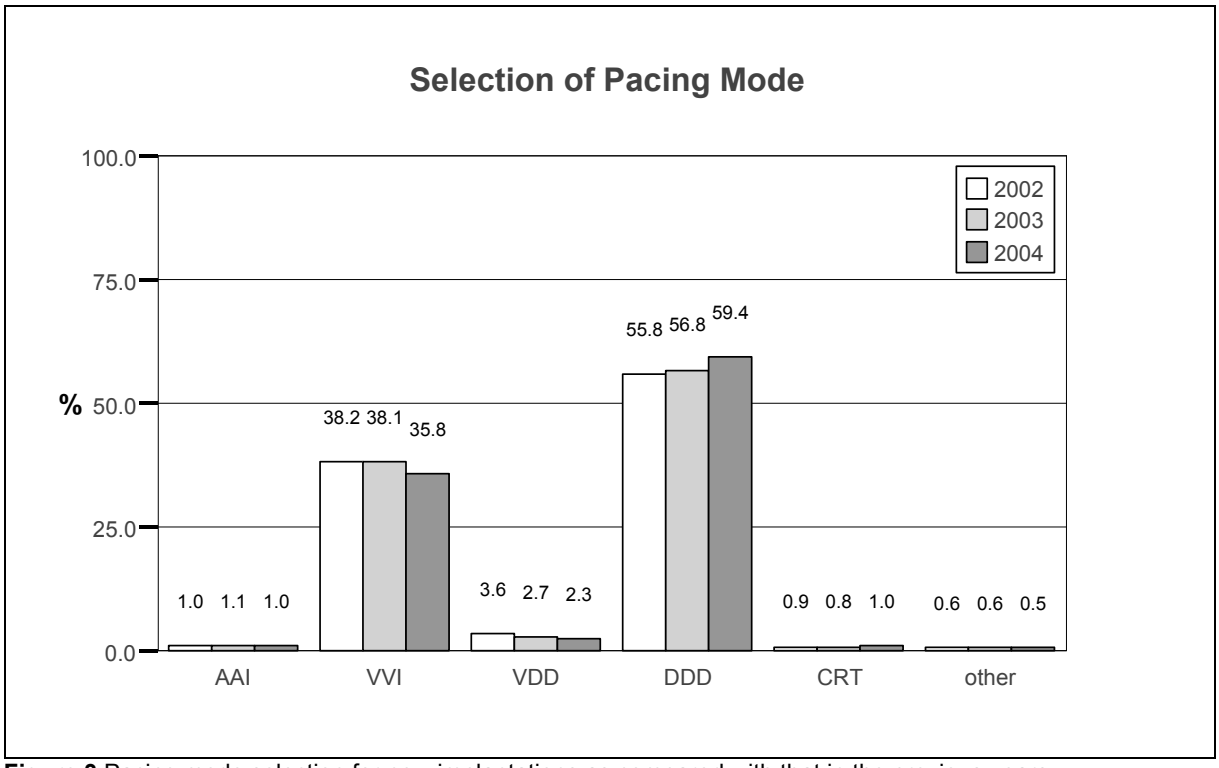

Figure 3 Pacing mode selection for new implantations as compared with that in the previous years

The reader can obtain more detailed information from the tables in the **Appendix Table 5 to Table 9**.

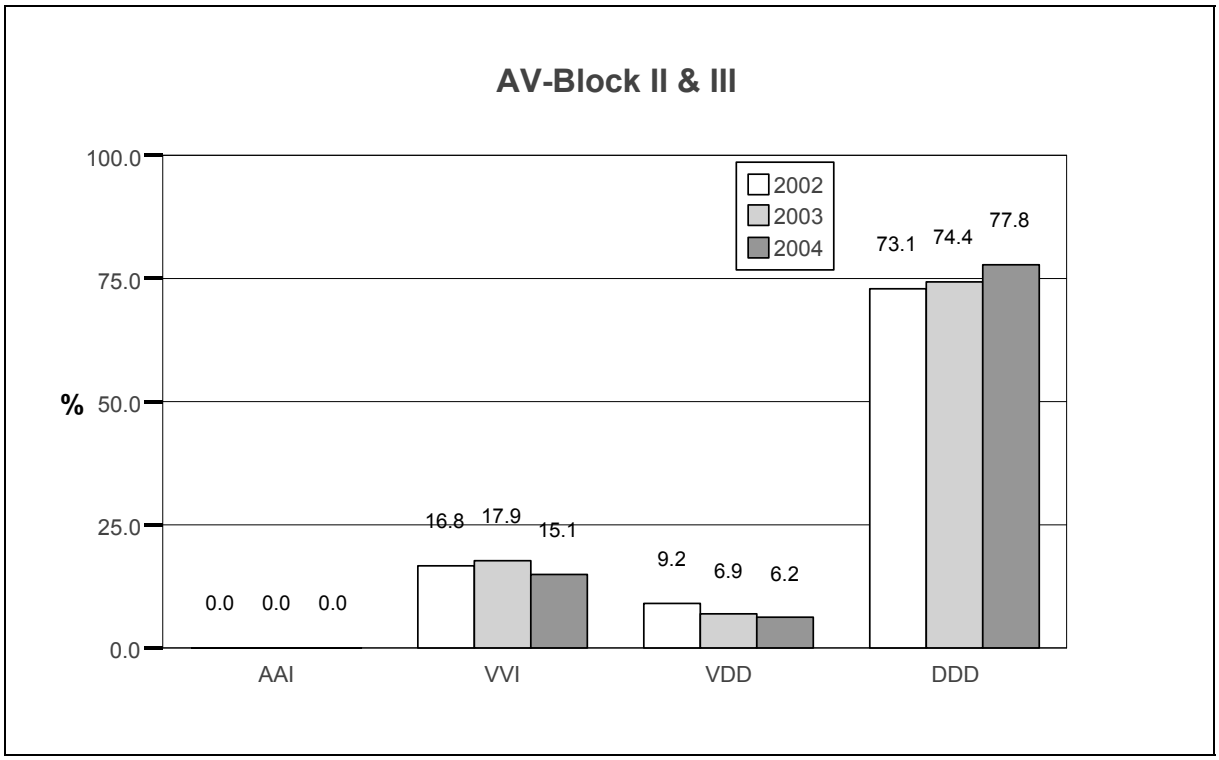

Figure 4: Pacing mode selection for AV block II & III as compared with the previous years (CRT systems and others were not recorded and have therefore not been included here)

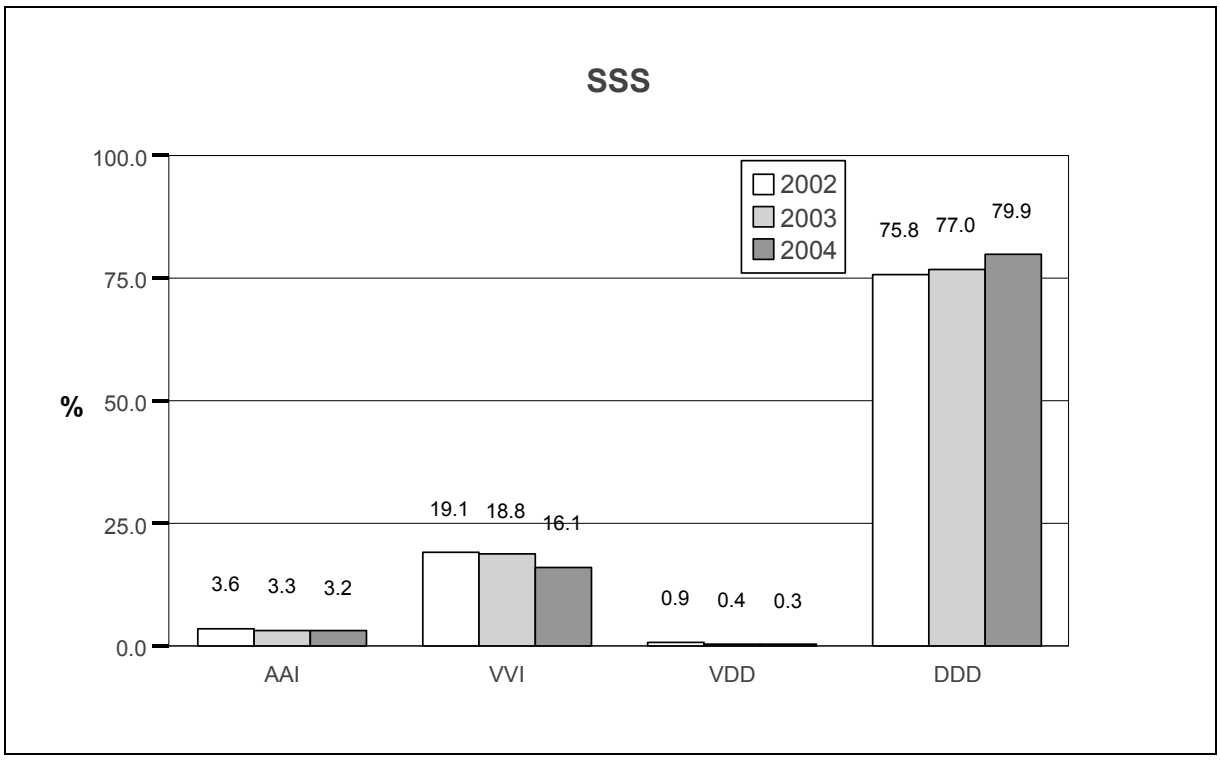

Figure 5: Pacing mode selection for sick sinus syndrome (SSS) as compared with the previous years (CRT systems and others were not recorded and have therefore not been included here)

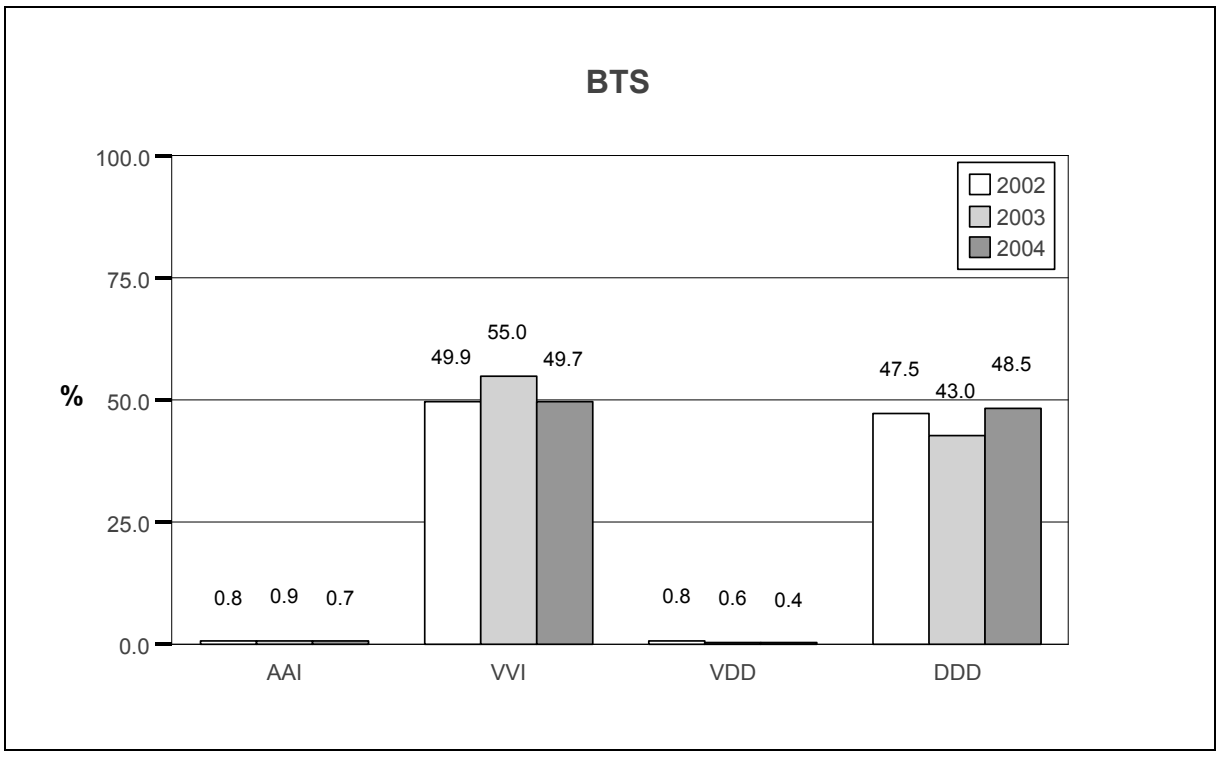

Figure 6: Pacing mode selection for the bradycardia-tachycardia syndrome (BTS) as compared with the previous years (CRT systems and others were not recorded and have therefore not been included here)

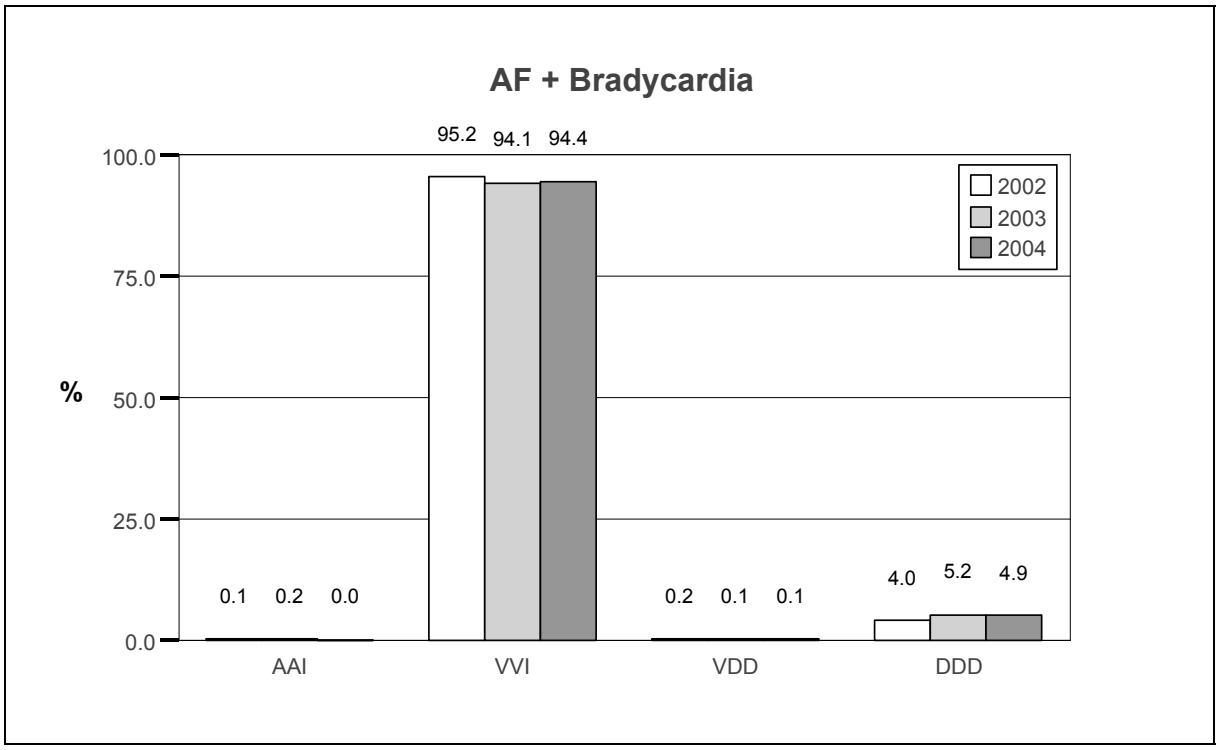

Figure 7: Pacing mode selection for bradycardial atrial fibrillation as compared with the previous years (CRT systems and others were not recorded and have therefore not been included here)

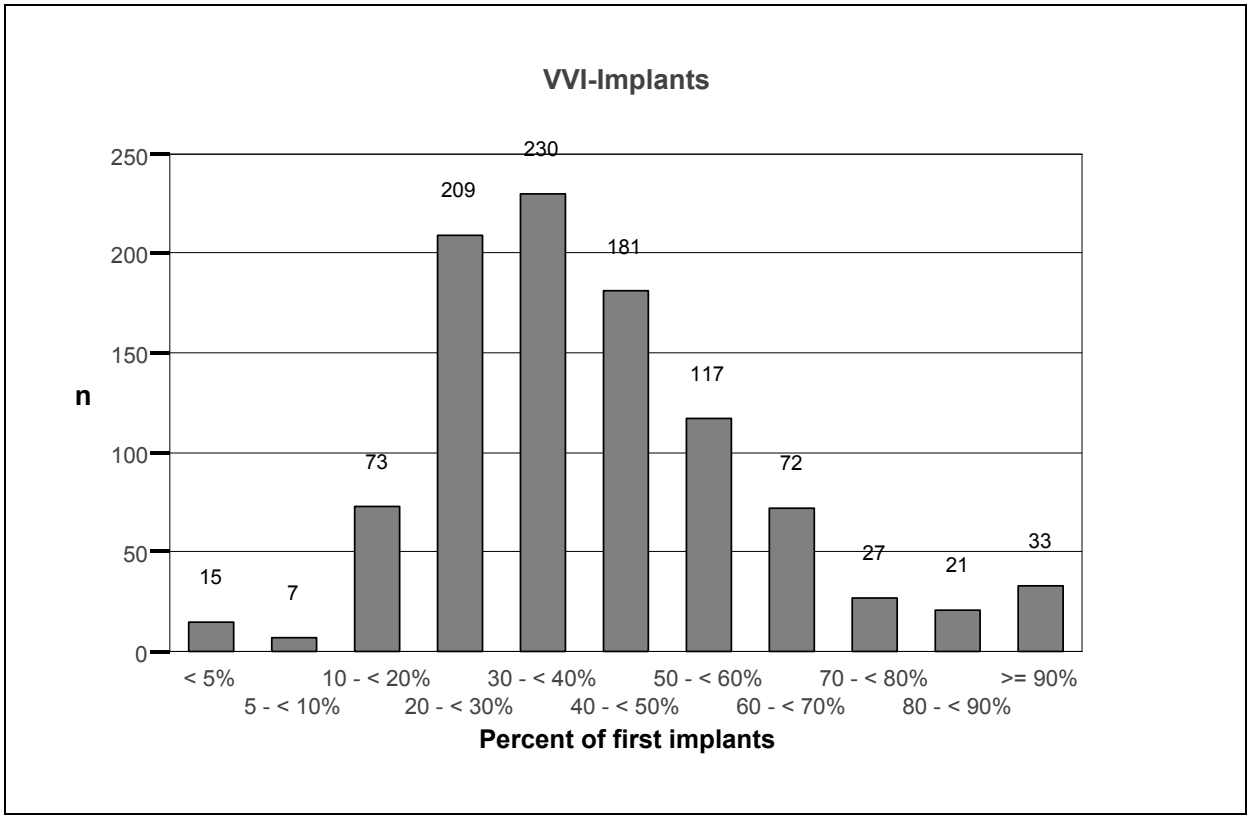

Figure 8: Distribution of the usage of VVI systems during initial implantations (to be read as follows, for instance: 15 hospitals used VVI systems in fewer than 5% of the cases)

Figure 8 reveals the wide distribution of usage between the various hospitals for the selection of pacemaker systems. Similar to that seen in previous years, the physicians of 270

hospitals (27.4%) implanted VVI systems in at least 50% of the cases. In 54 hospitals (5.5%) they even implanted VVI systems in at least 80% of the cases.

The distribution of manufacturers is to be found in **Appendix, Table 10**. Here, an error in the 2003 report must also be noted: The figures for the manufacturers Implantronik and Intermedics were cited incorrectly, and are presented here in this report once again, in the correct form.

Surprising is the fact that pulse generators from Intermedics, Siemens and Telectronics are still to be found in the implantation reports, although these companies are parts of another manufacturer since many years.

Lead selection

Discussions concerning the selection of suitable leads have been carried out in previous reports so that a repetition of the respective arguments appears to be pointless.

2004	Atrium		Ventricle	
polarity	**n**	**%**	**n**	**%**
unipolar	449	1.2	9,992	16.2
bipolar	38,009	98.0	50,766	82.4
multipolar	335	0.9	824	1.3
fixation mechanism				
active	31,999	82.5	8,335	13.5
passive	5,819	15.0	51,782	84.1
none	957	2.5	1,463	2.4
isolation material				
polyurethane	5,499	14.2	9,743	15.8
silicone rubber	27,873	71.9	41,917	68.1
dual	5,394	13.9	9,918	16.1
lead tip				
steroid	31,137	80.3	44,332	72.0
non-steroid	343	0.9	780	1.3
none	7,286	18.8	16,468	26.7

Table 7 Polarity, fixation mechanism, isolation material and type of lead tip in 2004 (percentage as related to the specific type of lead

In practice, the predominant use of bipolar leads with active fixation mechanism in the atrium and tined, bipolar leads in the ventricle (see **Table 7**) has demonstrated only minor changes as compared with the previous years. The proportion of bipolar leads, however, has increased in both chambers (see **Table 8** and **Figure 9**). According to the opinion of the author, there continues to be no evidence of any superiority for a particular, principal type of lead construction.

	2002	2003	2004
stimulation site	**%**	**%**	**%**
atrium			
unipolar	2.9	1.5	1.2
bipolar	96.6	97.5	98.0
multipolar	0.5	1.0	0.9
ventricle			
unipolar	37.1	25.0	16.2
bipolar	61.9	73.6	82.4
multipolar	1.0	1.4	1.3

Table 8: Lead polarity as compared with previous years (percentage as related to the specific type of lead

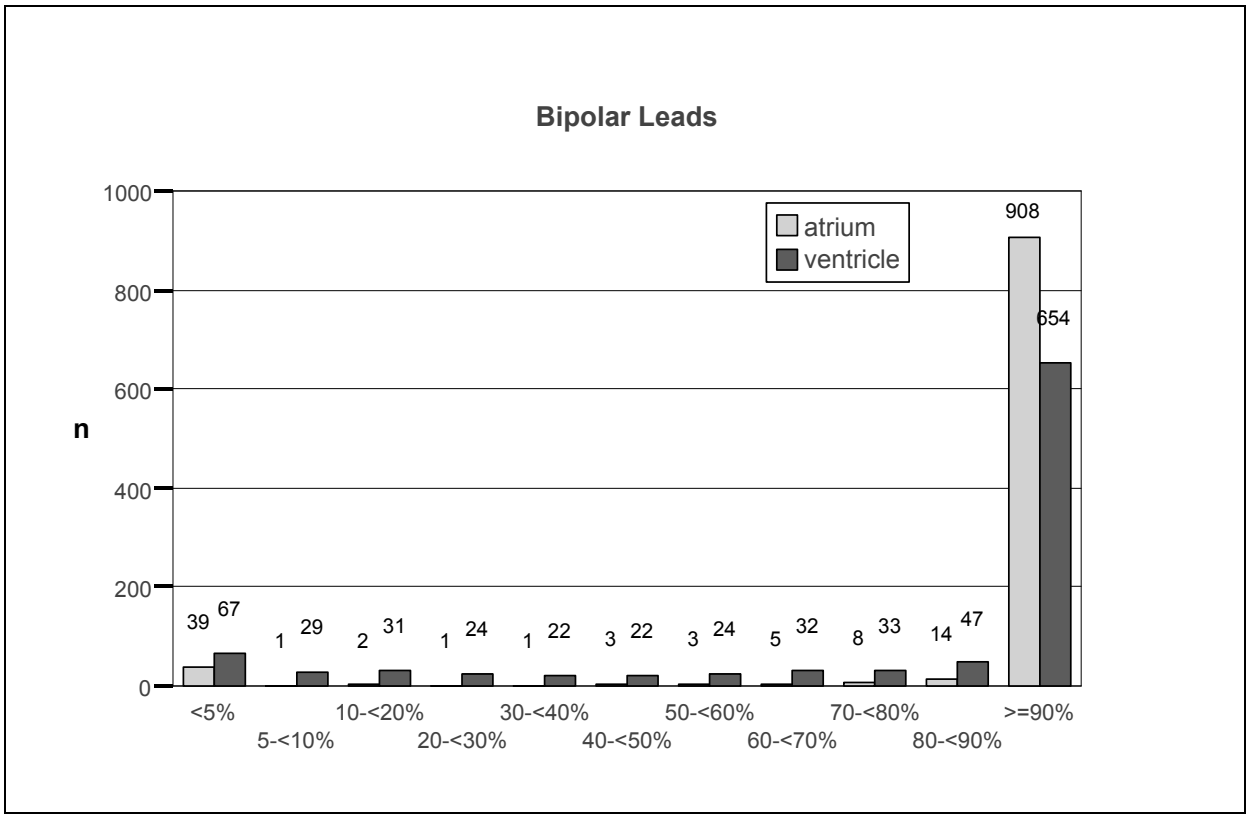

Figure 9: Distribution of bipolar leads used in German hospitals in 2004 (to be read as follows, for instance: 39 hospitals used bipolar leads in the atrium in less than 5% of the cases)

Operative data

As compared with the previous years, the form of anesthesia, the venous access used, as well as the preferred site of implantation, only demonstrated marginal changes (see **Table 9**).

	2004		2003
form of anesthesia	**n**	**%**	**%**
local anesthesia	58,660	94.0	93.7%
general anesthesia	3,722	6.0	6.3%
venous access			
cephalic vein	31,985	51.3	51.1%
subclavian vein	33,892	54.3	53.4%
other	1,048	1.7	2.0%
implantation site			
left	17,349	27.8	27.1%
right	45,273	72.6	73.2%

Table 9: Operative data for reoperations in 2004 as compared with the previous year

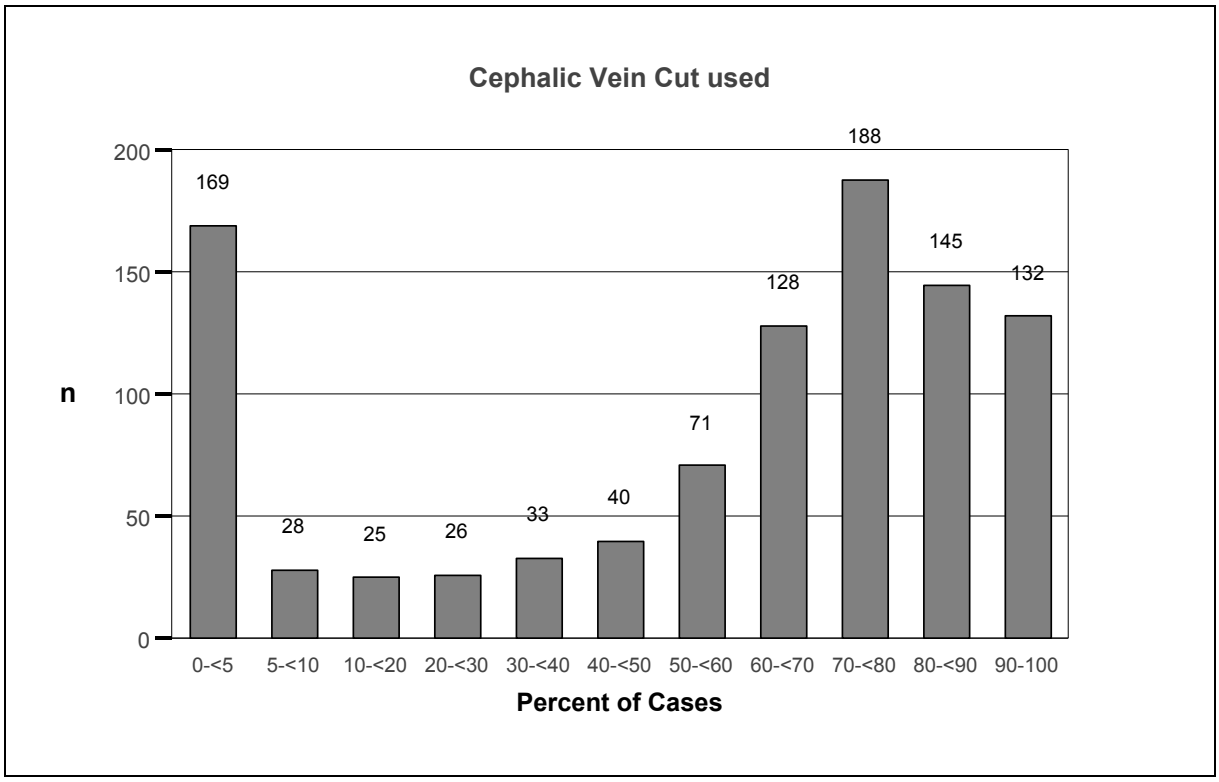

Figure 10: Distribution of the rate of using cephalic vein cut down for lead implantation (to be read as follows, for instance: in 26 hospitals, the proportion of patients in which a cephalic vein cut down had been used was between 20 and 30%)

Once again, it is hard to understand, why only one fifth of the hospitals (197 of 985), represented by the two columns to the left in **Figure 10**, used the cephalic vein for the implantation of leads in <10% of their cases. This applies in particular when considering the aspect that a subclavian puncture is associated with a significantly higher rate of complications (see **Table 14**).

PM device	mean 2003	mean 2004	SD	median	75th percentile
AAI (n=604)	50.4	49.1	25.0	45.0	59.8
VVI (n=22,309)	45.4	44.9	28.5	40.0	54.0
VDD (n=1,441)	50.6	49.9	27.6	45.0	60.0
DDD (n=37,055)	64.3	62.7	31.6	57.0	75.0
CRT (n=635)	155.5	135.7	78.3	120.0	160.0
other (n=338)	78.8	79.1	51.7	61.5	92.5
total (n=62,382)	**57.4**	**56.7**	**33.5**	**50.0**	**69.0**

Table 10: Duration of surgery (in minutes) for new implantations performed in 2004 (related to all cases for which valid information concerning the duration of the procedure had been provided, SD = standard deviation)

For the duration of the operation and the fluoroscopic time (see **Table 10** and **Table 11**) larger changes were only observed for the CRT devices: With no major change in fluoroscopic times, they were seen to be implanted within a time period requiring 20 minutes less. As a consequence, only the CRT devices revealed a substantial change for the 75th percentile, the benchmark above which one can expect to observe an increased incidence of wound infections.

PM device	mean 2003	mean 2004	SD	median
AAI (n=604)	5.5	4.5	7.6	2.5
VVI (n=22,309)	5.6	4.5	11.2	3.0
VDD (n=1,441)	5.3	4.5	5.5	3.0
DDD (n=37,055)	8.4	7.3	18.3	5.0
CRT (n=635)	26.1	25.6	22.9	21.0
other (n=338)	11.5	13.1	36.4	5.0
total (n=62,382)	**7.4**	**6.4**	**16.2**	**4.0**

Table 11: Fluoroscopic time for new implantations in 2004 (related to all cases for which valid information concerning the fluoroscopic time has been provided, SD = standard deviation

The distribution of operation times related either to initial implants (see **Figure 11** for AAI and VVI and

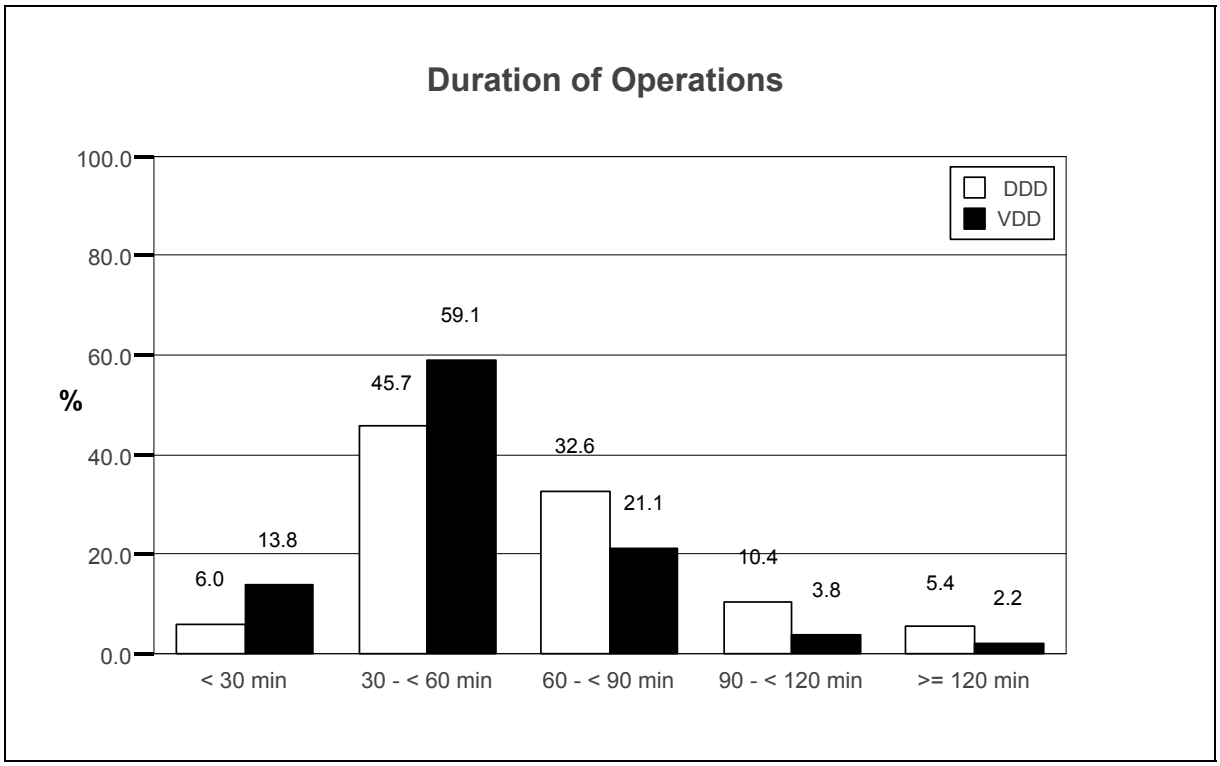

Figure 12 for DDD and VDD) or to the mean values of individual hospitals (see **Figure 13** for AAI and VVI and **Figure 14** for DDD and VDD), reveals only slight changes as compared to previous years.

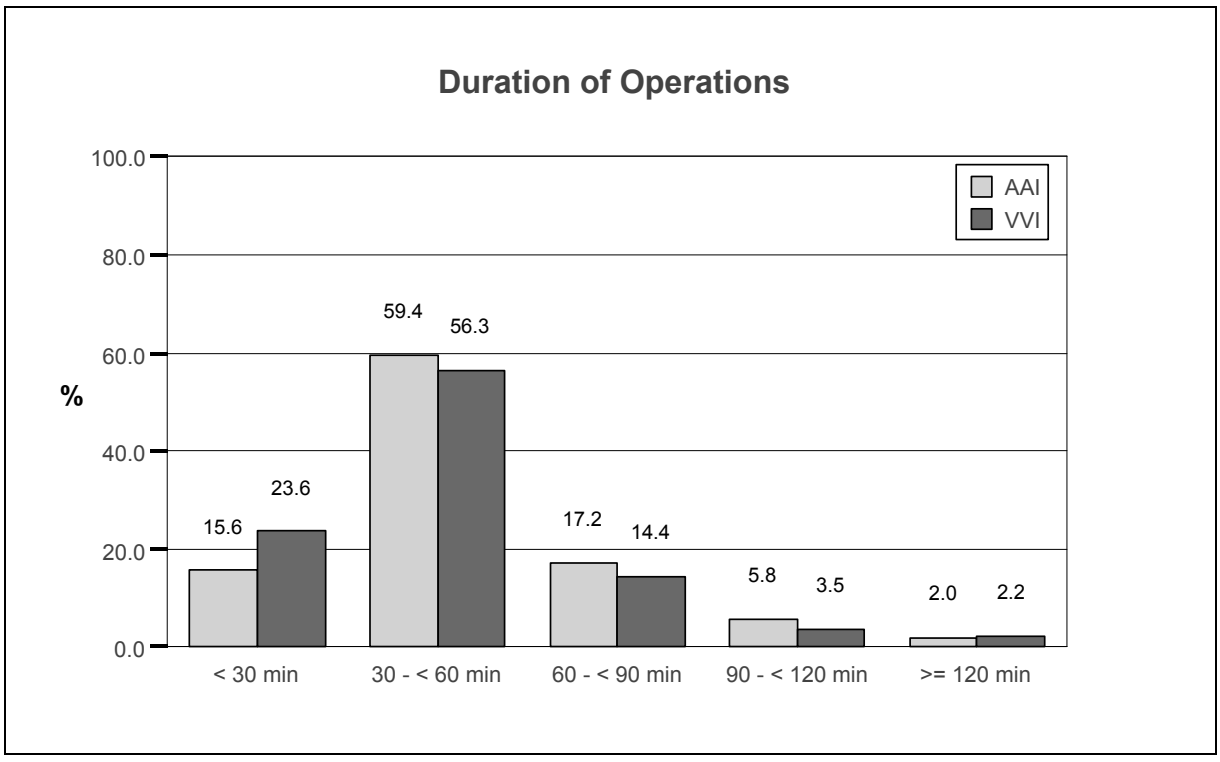

Figure 11: Distribution of the mean values for the duration of surgery during implantation of single-chamber devices related to all of the new implantations (to be read as follows, for instance: 15.6% of the AAI devices were implanted in less than 30 minutes)

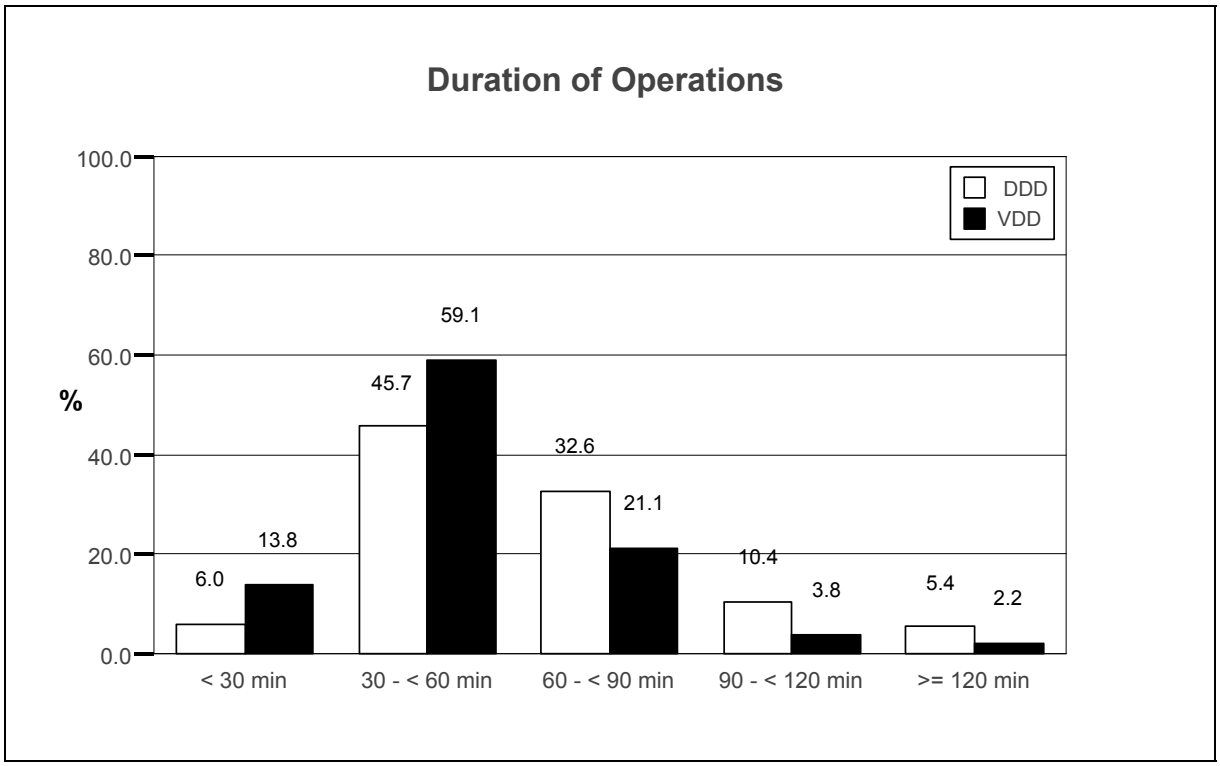

Figure 12: Distribution of the mean values for the duration of surgery during implantation of dual-chamber devices related to all of the new implantations (to be read as follows, for instance: 6.0% of the VDD devices were implanted in less than 30 minutes)

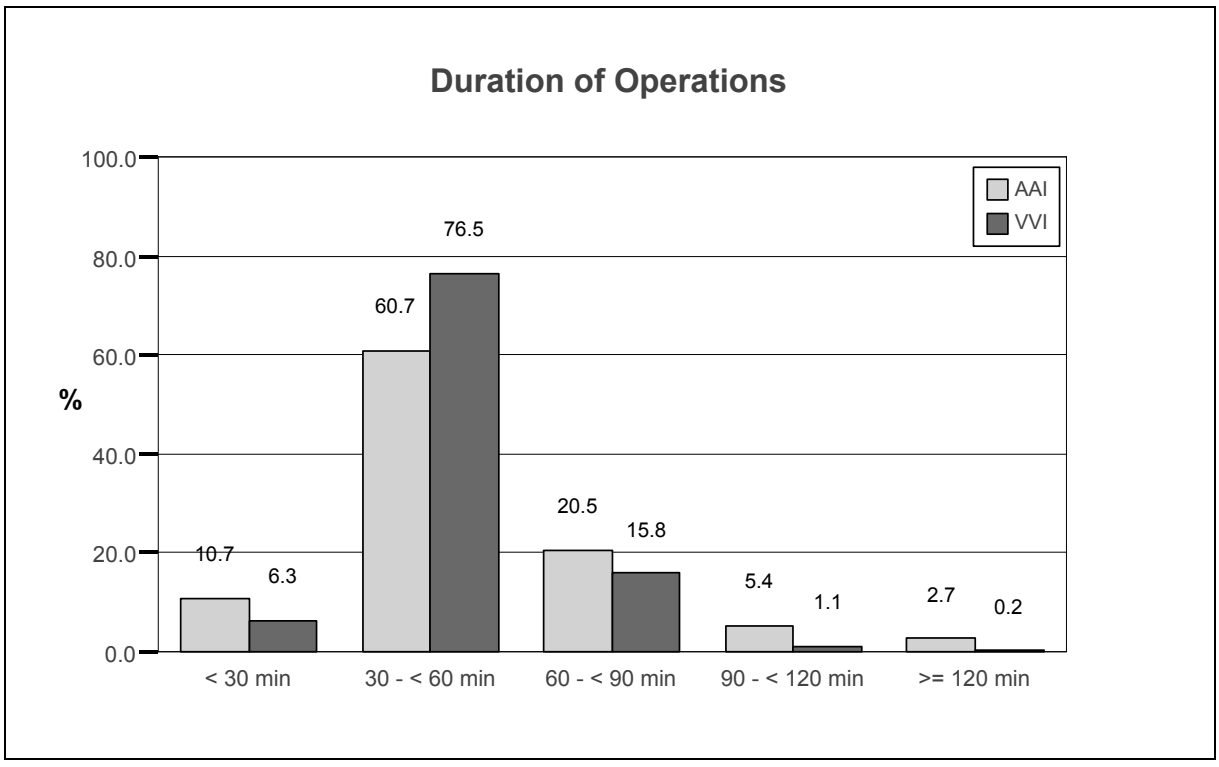

Figure 13: Distribution of the mean values for the duration of surgery during implantation of single-chamber devices as related to the mean values of the hospitals (for instance, 9.0% of all hospitals had a mean value of less than 30 minutes for implantation of an AAI device)

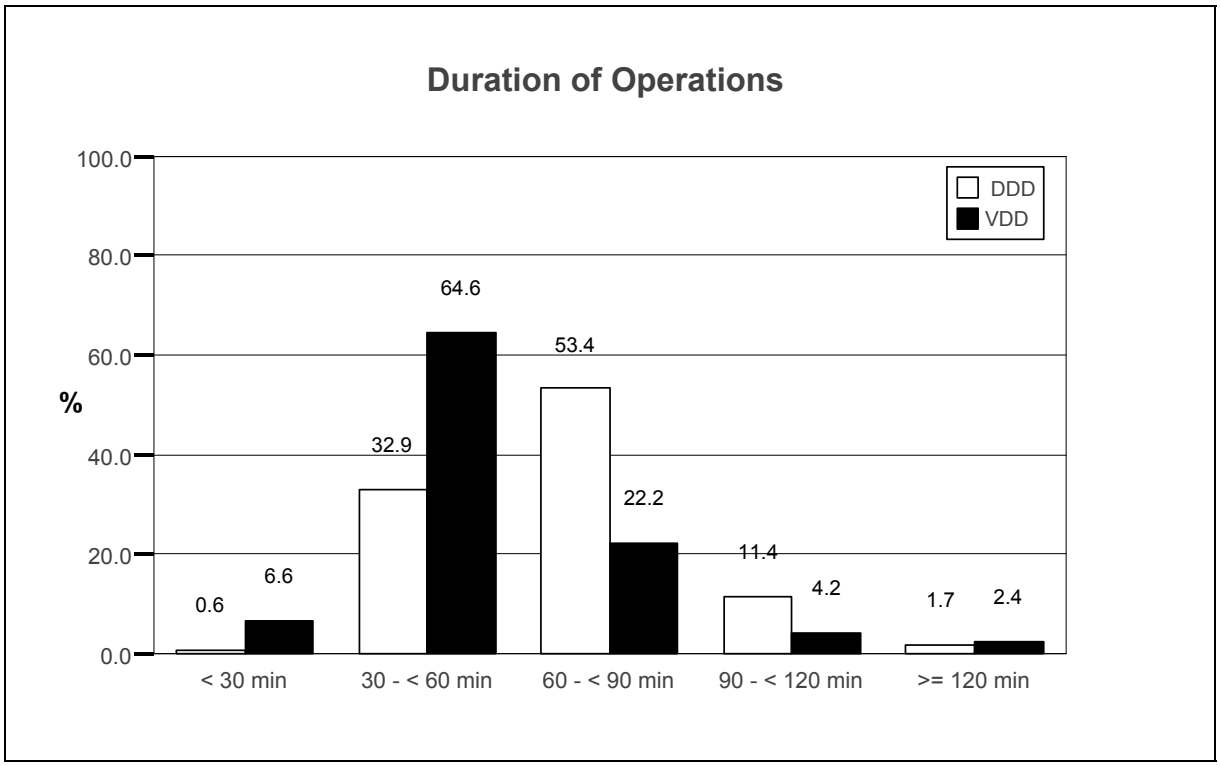

Figure 14: Distribution of the mean values for the duration of surgery during implantation of dual-chamber devices as related to the mean values of the hospitals (for instance, 0.7% of all hospitals had a mean value of less than 30 minutes for implantation of a DDD device)

The intraoperative measurements made in 2004, as compared with those from the previous years, reveal almost identical results (see **Table 12**).

atrium	**n**	**Mean**	**SD**	**Median**
pacing threshold	35,921	0.8	0.5	0.7
P-wave	37,940	3.1	1.7	2.8
ventricle	**n**	**mean**	**SD**	**median**
pacing threshold	61,049	0.5	0.4	0.4
R-wave	59,643	13.1	5.4	12.1
coronary sinus (LV) lead	**n**	**mean**	**SD**	**median**
pacing threshold	647	1.1	0.8	0.9
R-wave	625	14.6	7.2	13.0

Table 12: Results of intraoperative measurements during new implantations in 2004 (only cases with valid information; SD = standard deviation, lv = left-ventricular**)**

Complications

Among the perioperative complications, the absolute and relative number of pocket hematomas decreased (see

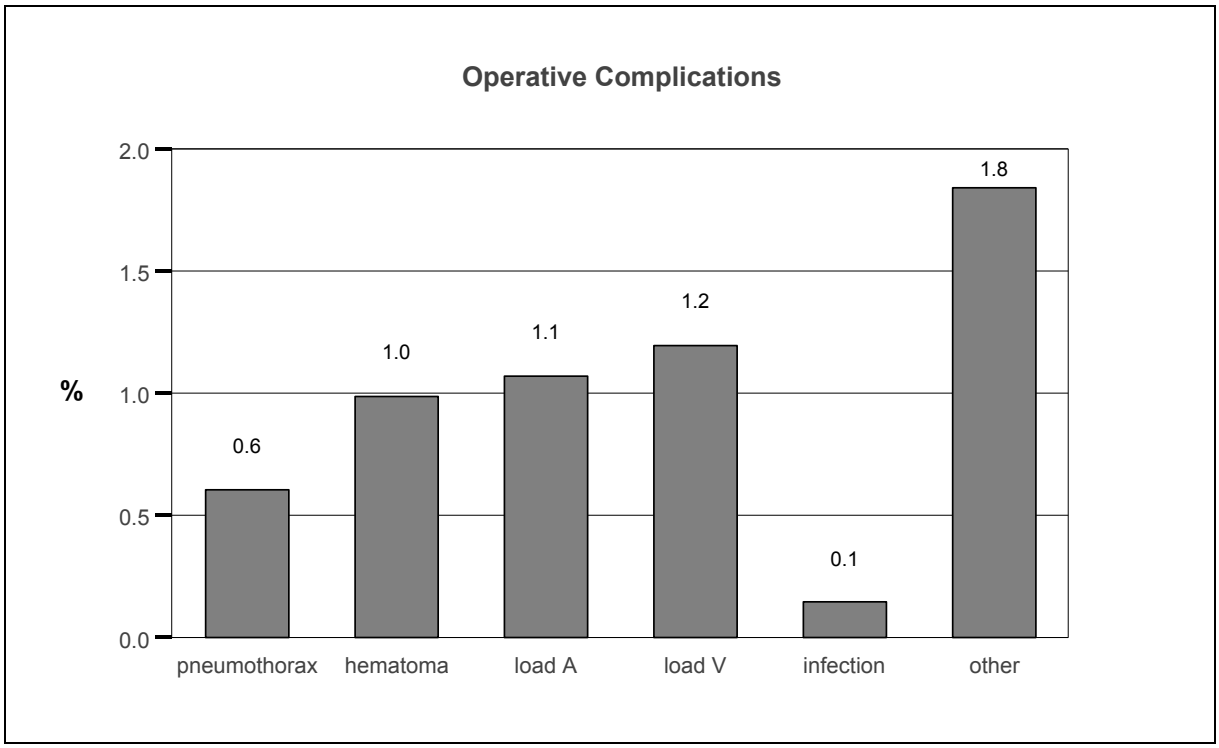

Figure 15 and **Table 13**), while all other problems were still observed nearly as often as before.

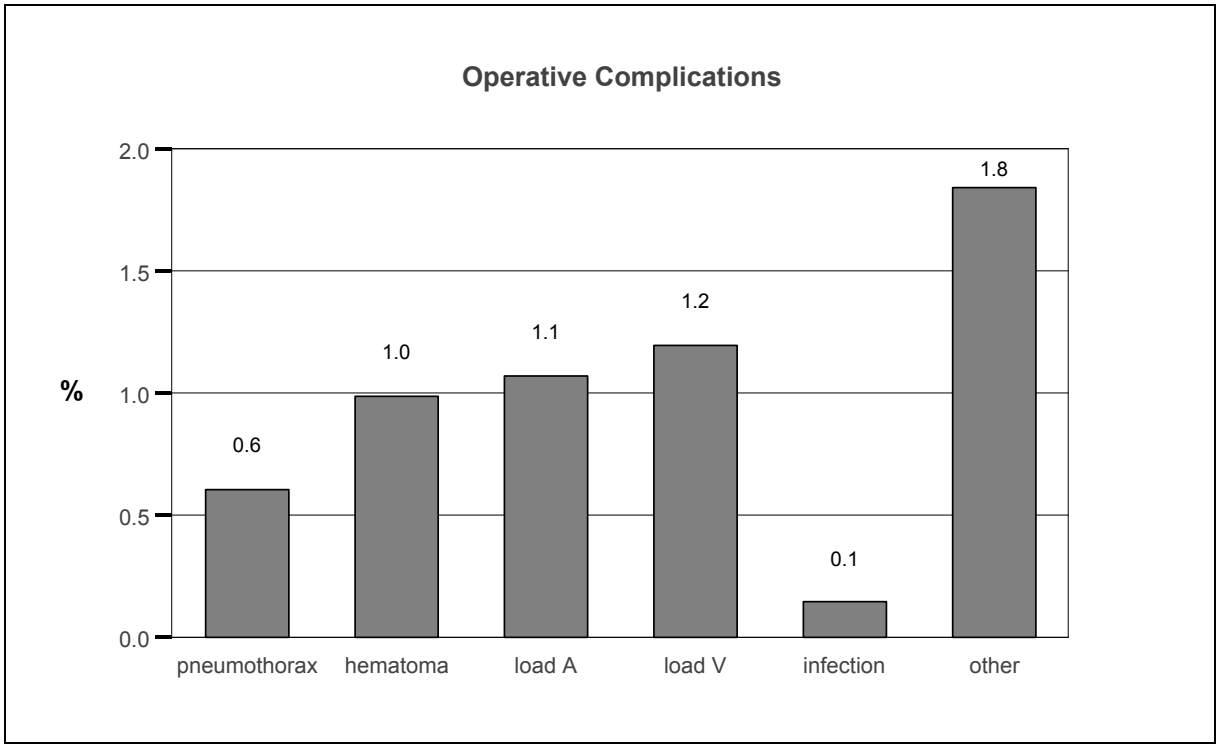

Figure 15: Operative complications following initial implantations (lead A = dislocation of atrial lead, lead V = dislocation of ventricular lead, infection = surgical site infection, other = cases with at least one of the following complications: Asystole, ventricular fibrillation, atrial fibrillation, pericardial tamponade, hematothorax, or classified as unspecified)

The infection rate of only 0.1% appears to be exceptionally low. However, this may be only the "tip of the iceberg", because the average observation period was 6.4 days only.

According to the current classification, all pocket infections within the first year after pacemaker surgery are considered to be nosocomial infections related to the procedure. So, the infection rate associated with a stay in an institution truly has very little to say.

complications	2004		2003
	n	%	
asystole	198	0.3%	0.3%
ventricular fibrillation	66	0.1%	0.1%
atrial fibrillation	417	0.7%	0.7%
pneumothorax	379	0.6%	0.6%
cardiac tamponade	62	0.1%	0.1%
pocket hematoma	619	1.0%	1.3%
hematothorax	43	0.1%	0.1%
wound infection	91	0.1%	0.2%
other	423	0.7%	0.7%
lead dislocation			
as related to all patients	1,357	2.2%	2.2%
- only of the atrial lead	608	1.0%	1.0%
- only of the ventricular lead	686	1.1%	1.1%
- of both leads	63	0.1%	0.1%
lead dislocation			
atrial leads (as related to all patients with implanted atrial leads)	650 / 38,797	1.7%	1.8%
ventricular leads (as related to all patients with implanted ventricular leads)	746 / 61,584	1.2%	1.2%
at least 1 perioperstivre complication	3,362	5.4%	5.7%

Table 13: Perioperative complications during or after new implantations

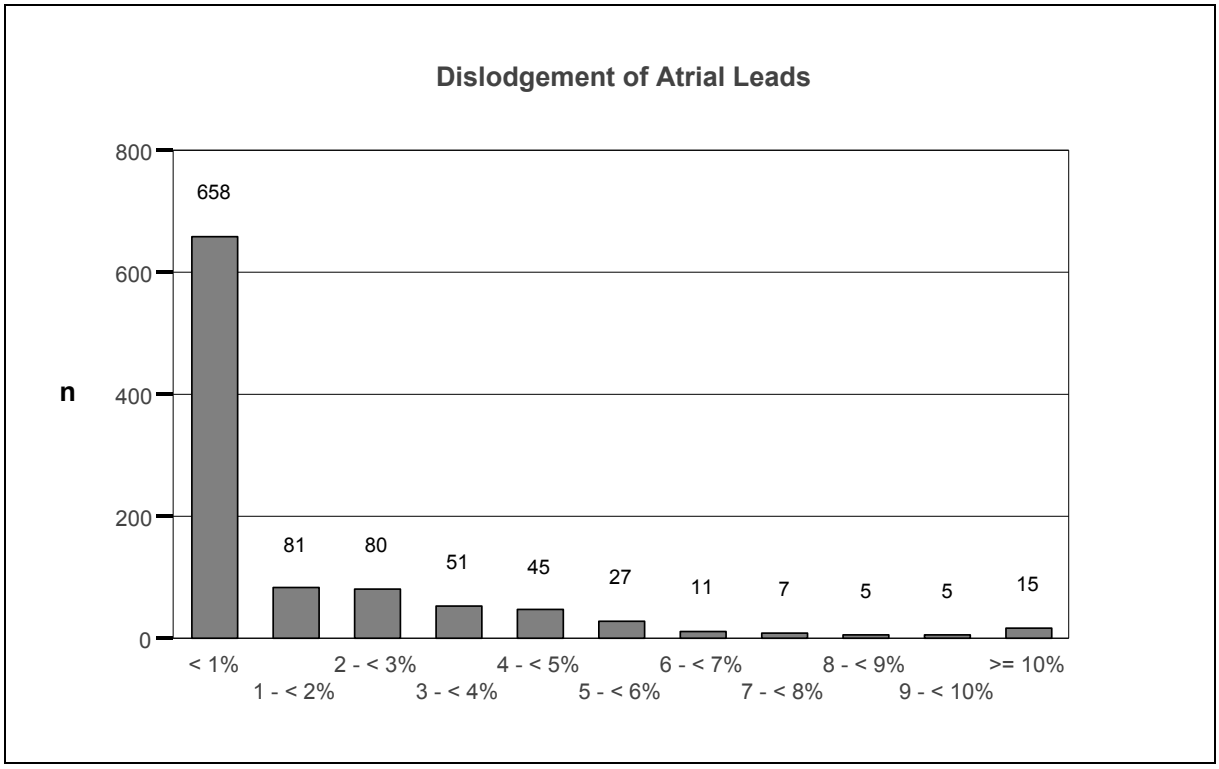

Figure 16: Distribution of rate of dislocations of the atrial lead per hospital following new implantations (to be read as follows: 658 hospitals reported an atrial dislocation in < 1% of their procedures)

The dislocation of an atrial lead is an indicator complication which is considered to indicate the technical quality of pacemaker implantation. The rate of the hospitals with this complication is fortunately lower as compared with 2003 (see **Table 13 and Figure 16**), both absolutely and relatively, although a substantial potential for improvements continues to exist.

The presence of potential improvements can also be seen in the detailed evaluation (see **Appendix, Table 12**). A pneumothorax, a pocket hematoma or a dislocation of atrial or ventricular leads have been seen to occur 60 times in more than 10% of the cases (whereby multiple citations were also possible). This must at least be considered unusual, whereby it must be taken into consideration that a low cumulative number of cases can be the reason for high rates of complications.

complications 2004	cephalic vein cut down	subclavian vein puncture	p value*
asystole	0.28%	0.33%	0.34
ventricular fibrillation	0.13%	0.09%	0.16
atrial fibrillation	0.58%	0.69%	0.09
pneumothorax	0.15%	0.94%	<0.001
cardiac tamponade	0.09%	0.08%	0.80
pocket hematoma	1.13%	0.92%	0.01
hematothorax	0.04%	0.09%	0.02
lead dislocation	2.26%	1.98%	0.02
wound infection	0.15%	0.15%	0.91
other perioperative complication	0.63%	0.67%	0.58
CPR	0.11%	0.13%	0.42
at least 1 periop. complication	**5.1%**	**5.4%**	**0.04**

***** = two-sided chi²-test according to Pearson

Table 14: Perioperative complications as dependent on the site of venous access for the cardiac pacemaker lead (CPR = cardio-pulmonary resuscitation)

The rate of complications associated with subclavian vein puncture is significantly higher than with cephalic vein cut-down, predominantly due to the significantly higher rate of pneumothoraces. (see **Table 14**). However, in 2004, this effect is less substantial than in the previous year. The clinical relevance of the results has already been discussed in detail.

In 2004, 716 patients died following pacemaker implantations. There is a slightly lower percentage to be seen as compared with that observed in 2003 (see **Table 15**). Unfortunately, there is no data available concerning the various causes of death. In particular, in those 3 cases with a dysfunction of the pulse generator and/or the lead as a possible reason for death we would have liked to know much more.

	2004		2003
	n	%	%
Death	**716**	**1.15%**	**1.21%**
- in relation with the surgical intervention or the responsible bradycardia	41	0.07%	0.08%
- with PM or lead dysfunction	3	< 0.01%	0.01%

Table 15: Fatalities associated with new pacemaker implantations

Pulse generator replacements

The demographic data concerning these procedures have already been presented in Table 5. For the lifetime of the pulse generators, little has changed (see

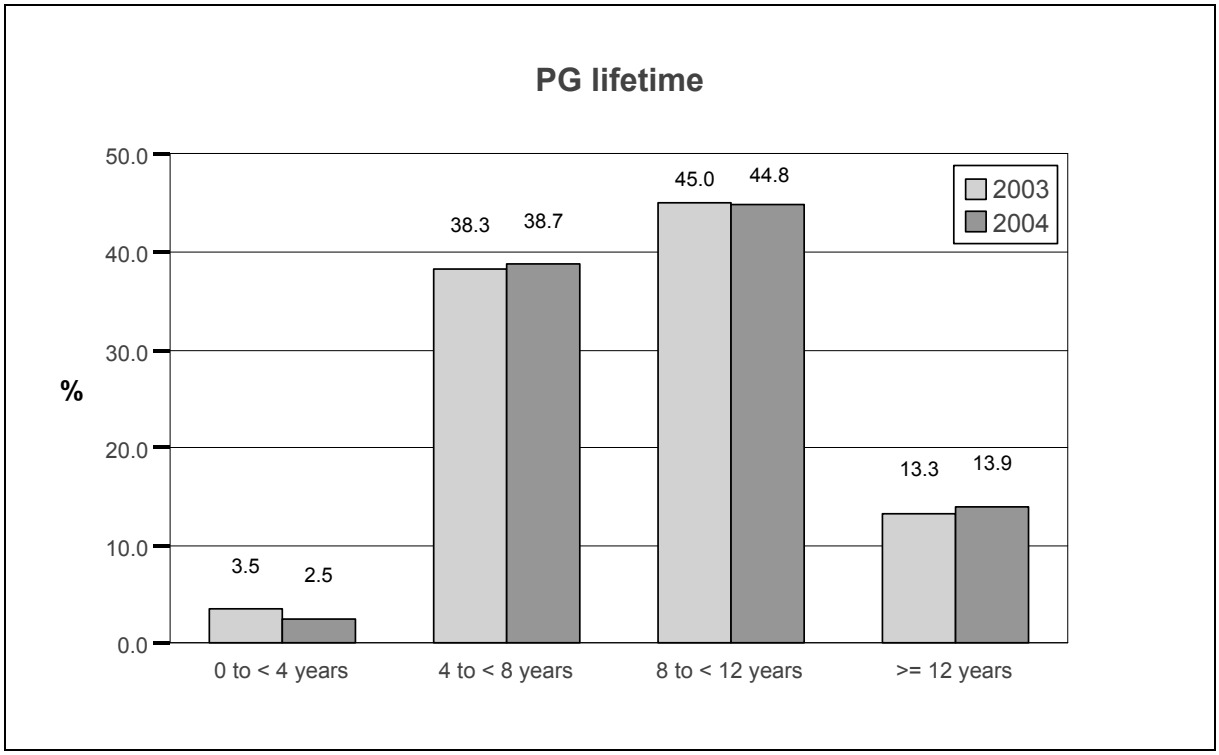

Figure 17). This can also seen in the detailed, manufacturer-related evaluation (see **Appendix, Table 13**).

However, the manufacturer of the pulse generator removed was recorded in only 8,706 of 14,622 cases (59.5%). Since the name of the manufacturer is generally clearly visible on the pulse generators, the cause for this extremely low rate of information remains unexplainable to the authors.

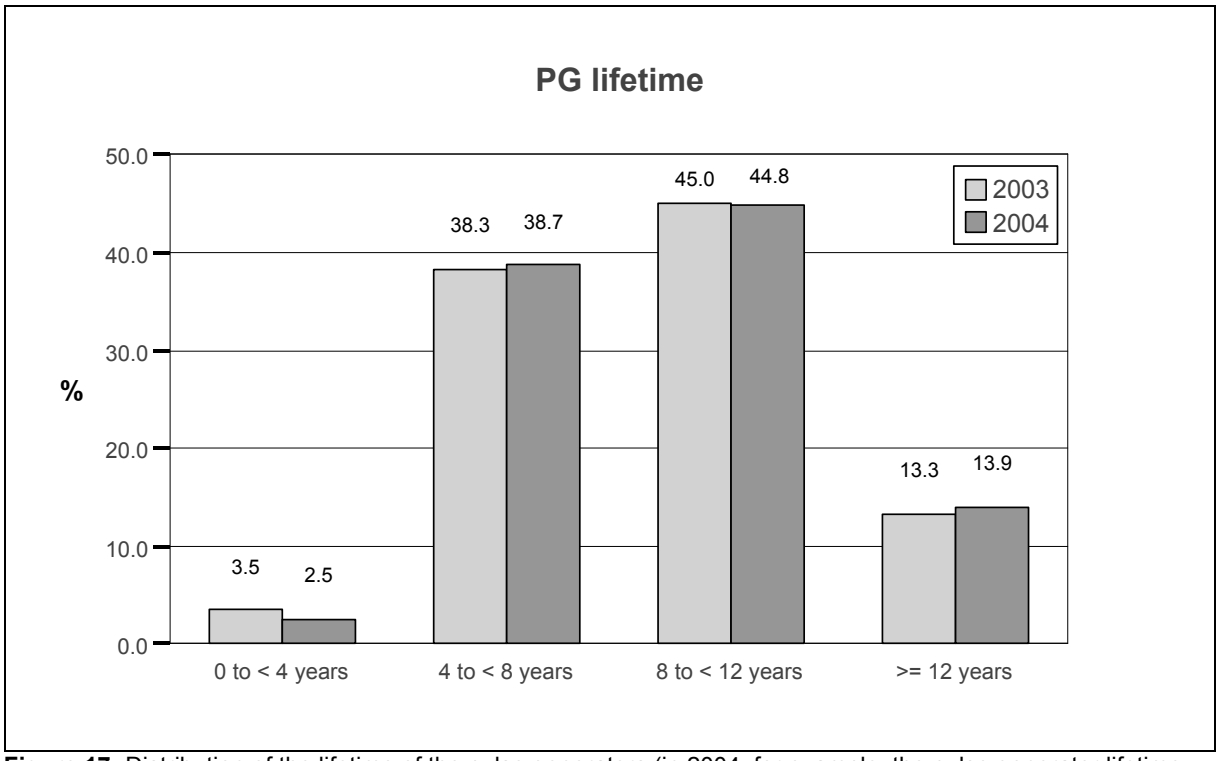

Figure 17: Distribution of the lifetime of the pulse generators (in 2004, for example, the pulse generator lifetime was cited as being between 8 and 12 years in 44.8% of the cases)

The differences in lifetime, when comparing single-chamber and dual-chamber devices, has remained unchanged, although we must report an error here concerning the last evaluation made in 2003: The figures reported for both the means and also the median values were too low, and have now been corrected in **Table 16**.

	n		mean (years)		SD (years)		median (years)	
year	2003	2004	2003	2004	2003	2004	2003	2004
AAI	248	208	9.0	9.1	3.0	3.2	9	9
VVI	3,408	3,494	9.6	9.9	3.8	3.7	9	9
DDD	4,236	5,009	7.7	7.7	2.7	2.6	7	7
VDD	366	452	7.1	7.6	2.0	2.4	7	8

Table 16: Lifetime of pulse generator as related to the pacing mode (only valid information considered

Reoperations

The demographic data concerning reoperations (redos) have already been presented in **Table 5**. It has already been pointed out that the number of revisions performed has more than doubled, possibly not alone through the changes made in the mode of registration. So, the relative frequency with which a problem in an individual hospital has to be solved by a reoperation has increased slightly, with 74.5% as compared to 71.6% in 2003 (see **Table 17**).

	2004		2003
preceding intervention in 2004	**number**	**%**	**%**
same institution	6,891	74.5%	71.6%
other institution	2,357	25.5%	28.4%
total	**9,248**	**100**	**100**

Table 17: Site at which the intervention prior to the reoperation had been performed

Only few changes were observed in the distribution of indications for redos (see **Table 18**).

	2004		2003
indication for reoperation	**number**	**%**	**%**
generator problems	3,924	42.4%	48.3%
lead problems	6,423	69.5%	63.9%
other	1,420	15.4%	10.6%

Table 18: indications for reoperation (multiple citations were possible

In the detailed analysis of the problems associated with pacemaker pulse generators (see **Table 19**), it is to be noted that an expected battery depletion, as well as up-, side- or downgrading of a pacemaker system, were less frequently observed as an indication (with a reduction of 4.4% and 6.1%, respectively), while other problems involving pockets have increased by 3.4% in comparison with the previous year.

pacemaker pocket and/or pulse generator problems	**number**	**% of all revisions**	**% of the generator problems**	
			2004	**2003**
depletion of battery	2,225	24.1%	56.7%	61.1%
- premature	182	2.0%	4.6%	5.0%
- regular	2,043	22.1%	52.1%	56.1%
PG dysfunction suspected	176	1.9%	4.5%	6.3%
PG dysfunction with recall	13	0.1%	0.3%	0.3%
up-, side-,downgrading	917	9.9%	23.4%	29.5%
- between different PM systems	853	9.2%	21.7%	28.9%
- between PM and ICD	64	0.7%	1.6%	0.6%
twitching of the pectoralis muscle	65	0.7%	1.7%	2.5%
pocket hematoma	78	0.8%	2.0%	1.5%
infection	549	5.9%	14.0%	11.8%
other problems with the pocket	311	3.4%	7.9%	4.5%
generator perforation	253	2.7%	6.4%	4.5%
other indications	381	4.1%	9.7%	11.2%
at least 1 generator problem	**3,924**	**42.4%**	**100%**	**100%**

Table 19 Indications for reoperations involving problems with the generator or pocket (multiple citations are also possible)

For the detailed analysis of the problems with leads (see **Table 20**), there are more unusual findings to be observed. Here, the problems with the atrial leads, especially those involving dislocation, have increased substantially (by about 8.6%), whereas lead fracture and the loss of stimulation, in comparison, have become rarer.

It remains unclear, however, why the absolute number of dislocations, with 2,476, is more than three-fold than that seen 2003, when only 772 were recorded.

lead problems	number	% of all revisions	% of the problems with leads	
			2004	2003
site of the problem				
atrium	1,619	17.5%	25.2%	23.8%
ventricle	3,077	33.3%	47.9%	47.7%
both	749	8.1%	11.7%	12.8%
dislocation	2,476	26.8%	38.5%	29.9%
lead fracture	434	4.7%	6.8%	8.9%
insulation breakdown	409	4.4%	6.4%	7.7%
defective connector	115	1.2%	1.8%	2.2%
diaphragmatic stimulation	144	1.6%	2.2%	2.5%
oversensing	65	0.7%	1.0%	1.4%
loss of sensing	783	8.5%	12.2%	13.5%
loss of capture	2,105	22.8%	32.8%	38.0%
infection	408	4.4%	6.4%	7.1%
perforation	161	1.7%	2.5%	3.0%
other	502	5.4%	7.8%	9.4%
at least 1 lead problem	**6,423**	**69.5%**	**100%**	**100%**

Table 20: Indications for reoperations associated with problems involving the lead (multiple citations were possible)

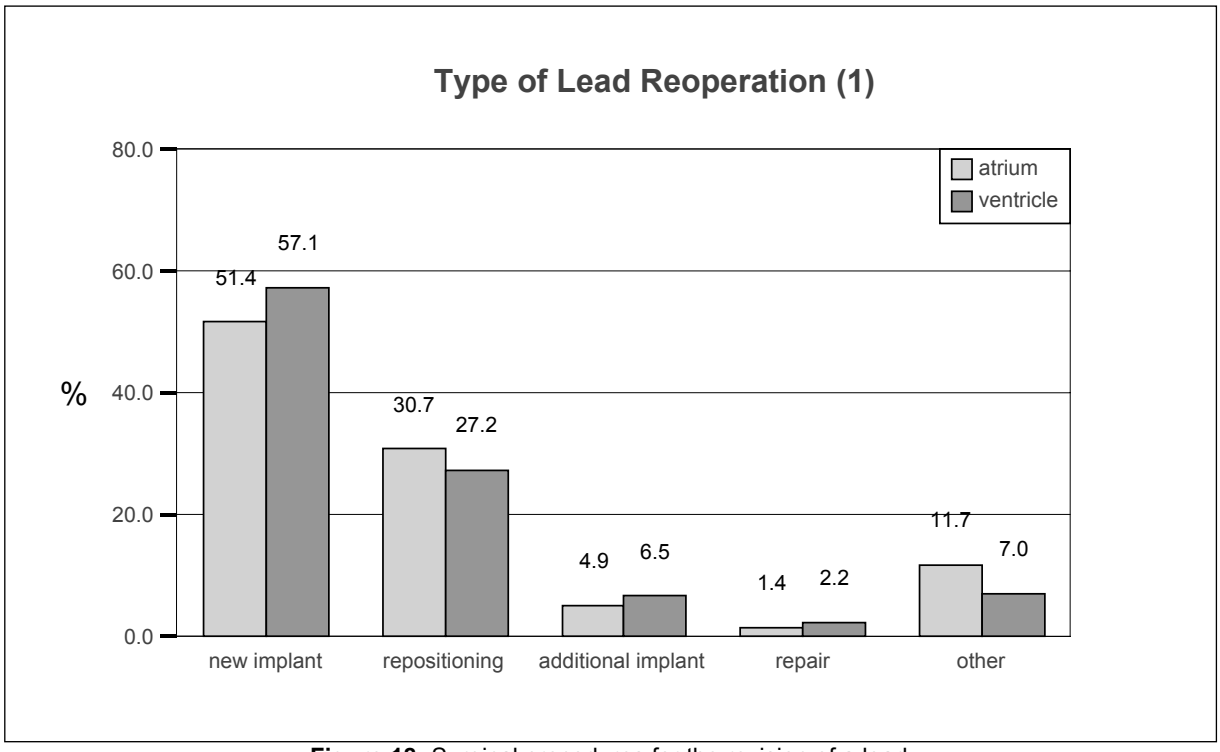

Figure 18: Surgical procedures for the revision of a lead

Due to the increased rate of dislocation, the rate of new lead implantations has been reduced and the rate of repositioning has increased (see **Figure 18** and **Appendix, Table 14**).

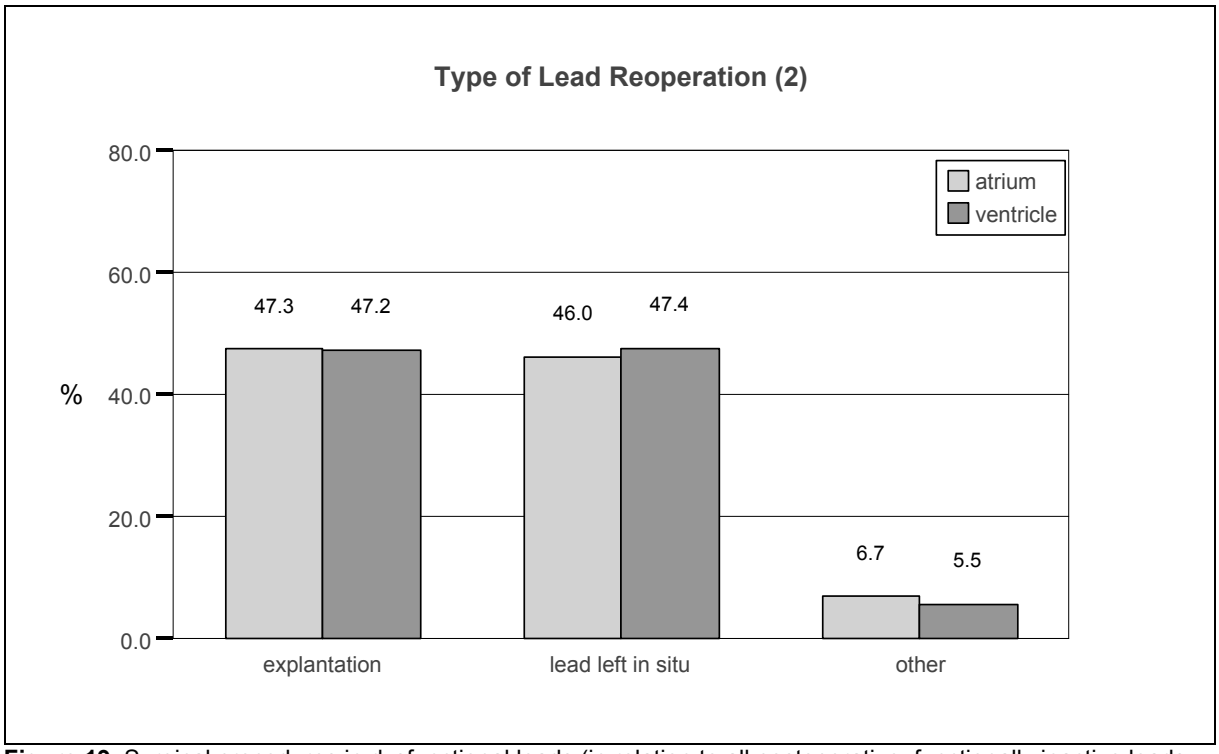

Figure 19: Surgical procedures in dysfunctional leads (in relation to all postoperative, functionally inactive leads (initial lead) for which the type of procedure has been documented)

The increased rate of repositioning may indicate as well that many dislodgements occurred early during the postoperative course. The surgical handling of dysfunctional leads (see **Figure 19** and **Appendix, Table 15**) reflects a trend toward more explantations with leaving fewer leads having been left in situ.

Complications associated with PG replacements and reoperations

The rate of perioperative complications associated with replacements or redos (see **Table 21**) has remained nearly identical since 2003.

	replacements		reoperations	
complications	n	% *	n	% **
asystole	41	0.28% (0.47%)	41	0.44% (0.49%)
ventricular fibrillation	5	0.03%(0.06%)	8	0.09% (0.17%)
atrial fibrillation	41	0.28% (0.30%)	24	0.26% (0.89%)
pneumothorax:			41	0.44% (0.64%)
drainage required			33	0.36% (0.40%)
pericardial tamponade			8	0.09% (0.25%)
pocket hematoma	117	0.80% (0.83%)	84	0.91% (1.24%)
hematothorax			8	0.09% (0.12%)
lead dislocation			145	1.57% (1.78%)
- atrium			54	0.58% (0.92%)
- ventricle			85	0.92% (0.84%)
- both			6	0.06% (0.02%)
wound infection	22	0.15% (0.14%)	36	0.39% (0.52%)
- wound infection: revision required	14	0.10% (0.11%)	21	0.23%(0.37%)
other	84	0.57% (0.79%)	57	0.62% (0.96%)

CPR required	3	0.02% (0.08%)	13	0.14% (0.22%)
at least 1 operative complication	**299**	**2.04% (2.41%)**	**415**	**4.49% (6.36%)**

*= related to PG replacements, ** = related to all reoperations
values from the previous year are in parentheses

Table 21: Complications associated with replacements and reoperations

The number of deaths following the replacement of pulse generators has been reduced, while it increased following reoperations (see **Table 22**); the rate of fatalities in relation to the individual intervention or to the responsible rhythmic disorder, as well as the number of fatalities based on pacemaker or lead dysfunction, has remained at a level seen previously.

	replacements		reoperations	
2004	**n**	**%**	**n**	**%**
death	35	0.24% (0.36%)	100	1.08% (0.64%)
- in relation with the surgical intervention or the responsible bradycardia	1	0.01% (0.01%)	11	0.12% (0.10%)
- with PM or lead dysfunction	0	0 (0)	2	0.02% (0)

Table 22: Fatalities in relationship to replacements and reoperations

Comment

As in the previous years, a comparison is made with other European registries which have a (nearly) complete data recording and who publish their results in either English or German. The reports of the Danish, Swiss and Swedish pacemaker registers present the basis for the following discussion (3,4,5).

Data basis

Few changes were observed for the respective data bases (see **Table 23**). Now, as in the past, the rate of implantations per institution among our Scandinavian neighbors is substantially higher than in Switzerland and Germany. The relationship of new implantations to subsequent interventions may be of limited significance, since the other registries probably do not include all subsequent interventions.

	Denmark	Switzerland	Sweden	Germany
reporting institutions	14	60	44	989
implanting institutions	14	62	44	?
new implantations	2,635	3,346	5,298	62,382
- mean per institution	188.2	55.8	120.4	63.3
- new implantations/one million inhabitants	514	451	587	756.1
reoperations	786	1,053	1,528	23,870
relationship of first implantations to reoperations	3.35	3.18	3.47	2.61

total	**3,421**	**4,399**	**6,826**	**86,252**

Table 23: Data basis in comparison

A point which was already discussed in detail in the report from 2003 is the rate of initial implantations per 1 million inhabitants in Germany. This rate (756) has been seen to increase once again. Germany, in a comparison of the 4 registries, continues to be the uncontested leader (see **figure 20**), a fact which cannot be explained as being related to the age distribution (see **figure 21**). It must be emphasized, however, that the implantation rate in Belgium is even higher, namely 1,120 per 1 million inhabitants (6).

How can we explain the high implantation rate in Germany? As we were unable to find a solution last year in the international comparison, we have investigated a different aspect more precisely this year, that involving the regional variations.

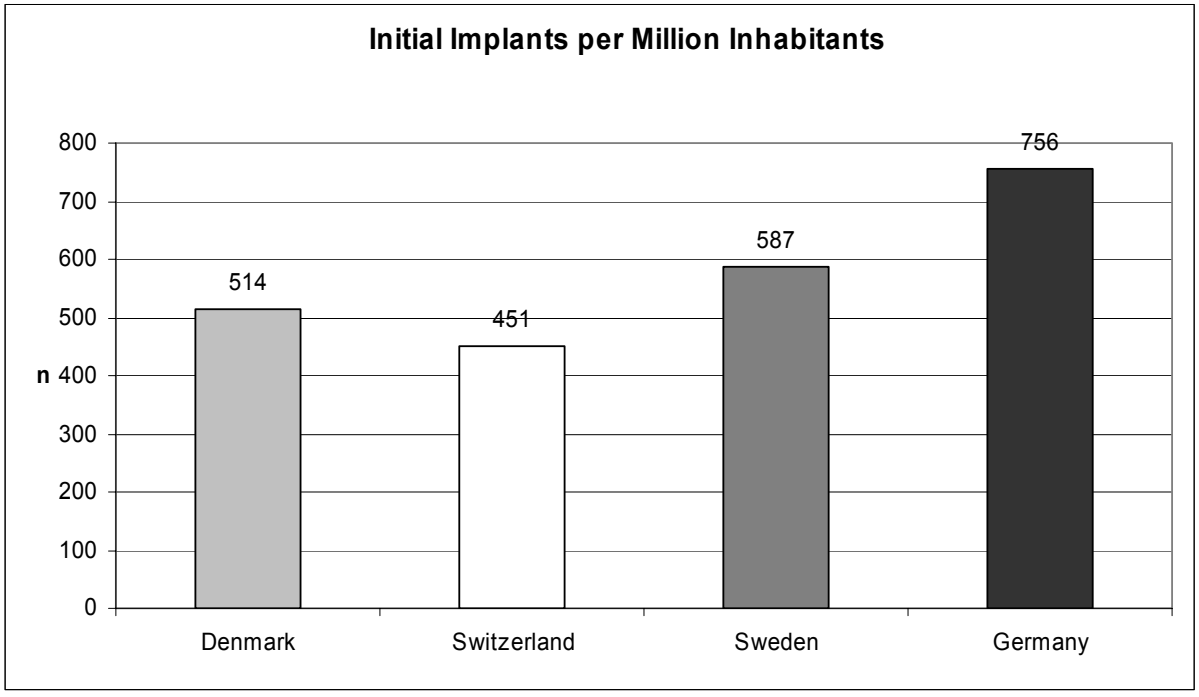

Figure 20: New implantations per 1 million inhabitants, in comparison

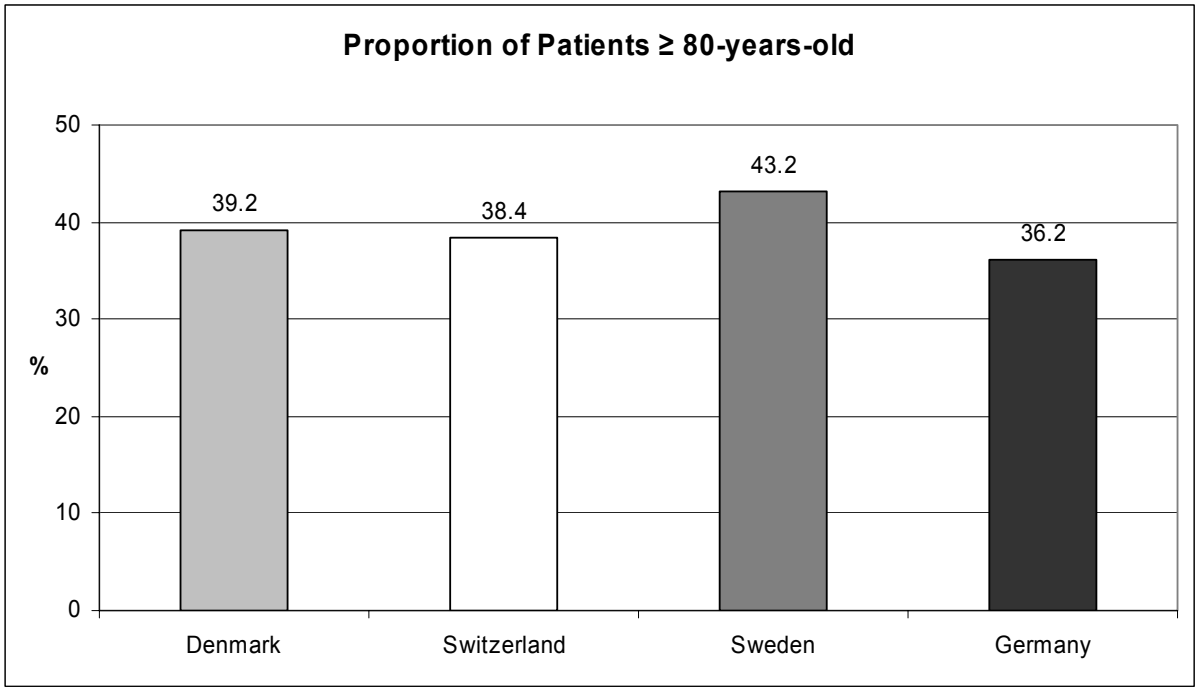

Figure 21: Proportion of patients ≥ 80-years-old of the entire patient population in whom a pacemaker had been implanted, in comparison

Initially, it can be seen that there are substantial differences between the implantation rates of the individual federal states (see **Figure 22**). Clearly the greatest number of pacemakers per 1 million inhabitants was implanted in Saxony and Thuringia, while the fewest was implanted in Baden-Württemberg and in Bavaria. Even more notable is the substantially improved data completeness to be observed in the Eastern federal states. This is especially notable in Saxony and Thuringia and thereby provides a benchmark which has not yet been achieved elsewhere.

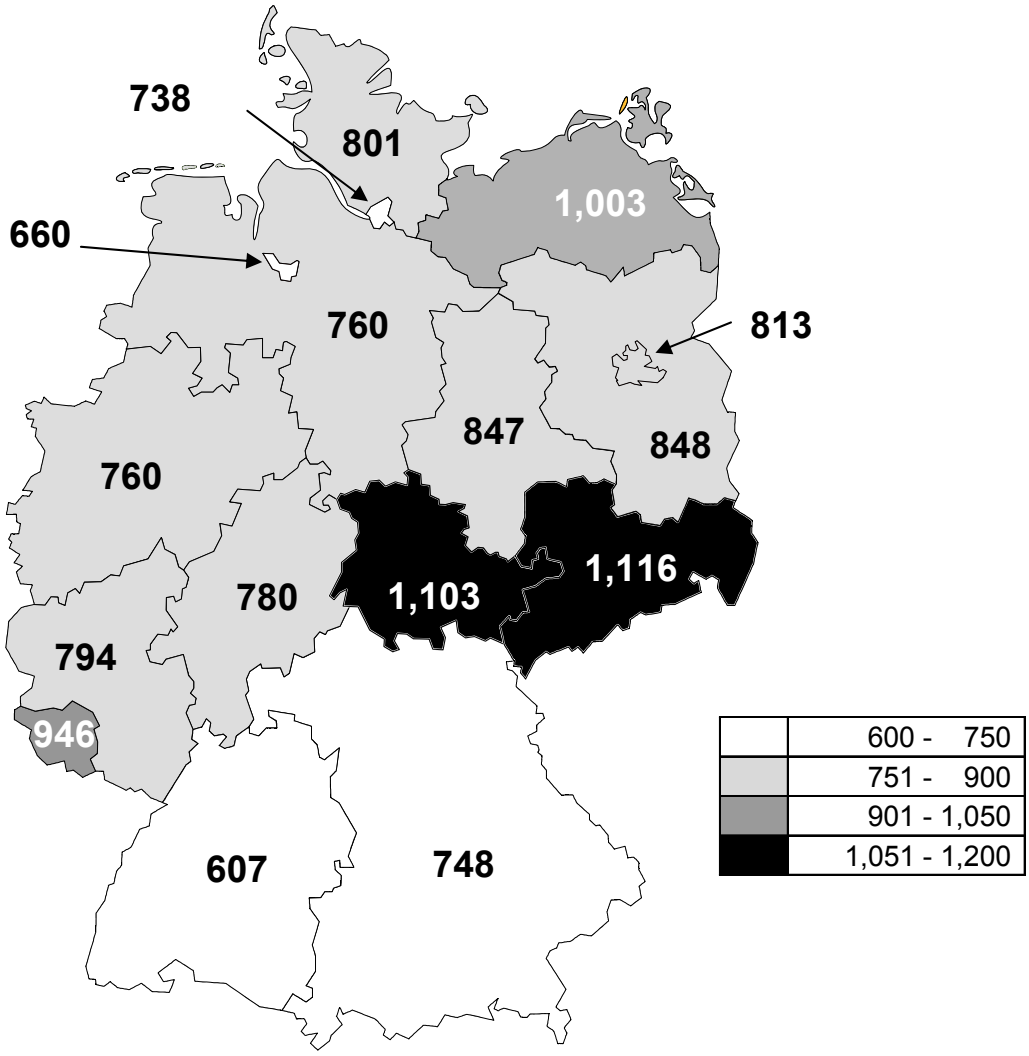

Figure 22: Implantation rate per 1 million inhabitants in the individual German federal states

The reason for these differences could be due to a somewhat poorer adherence to existing guidelines in the southernmost of the federal states in our republic. However, by looking more closely at the available data, it shows that this speculation does not meet reality (see **Figure 23**).

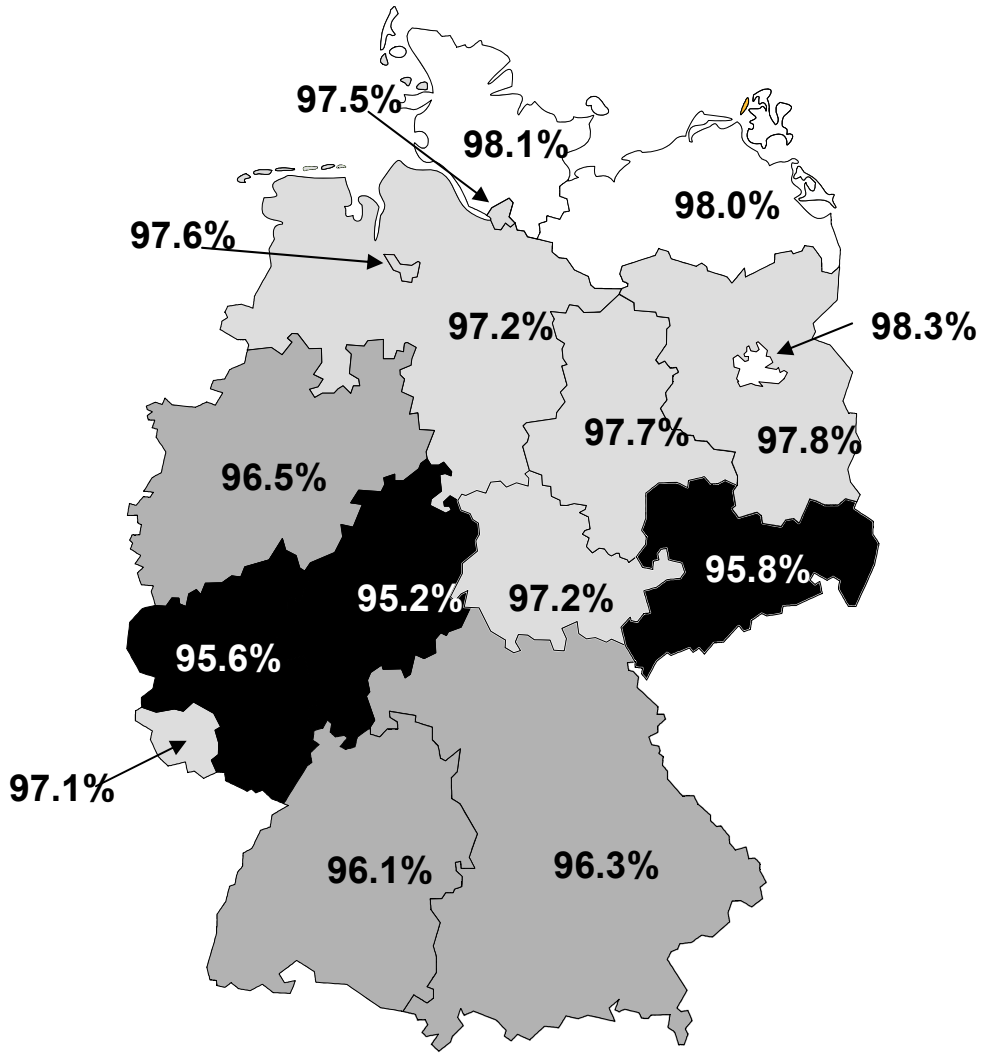

Figure 23: Percentage of indications following the guidelines in the individual federal states of Germany

In all of the German federal states, the indications for pacemaker implantation followed the guidelines in > 95% of the cases. The physicians in the northernmost federal states and in the capital were seen to adhere especially well to the guidelines.

The most important possible reason for the differences in the implantation rate is shown in **Figure 24**: In the federal states with the lowest or the highest rates of implantation, for instance, the average age is also seen to be the lowest or the highest, respectively. If the implantation rates were determined by the average age alone, even higher rates of implantation would have been expected in Brandenburgia, Bremen, the Saarland and in Sachsen-Anhalt; only in Berlin the average age of the population is lower as expected from the rate of implantation.

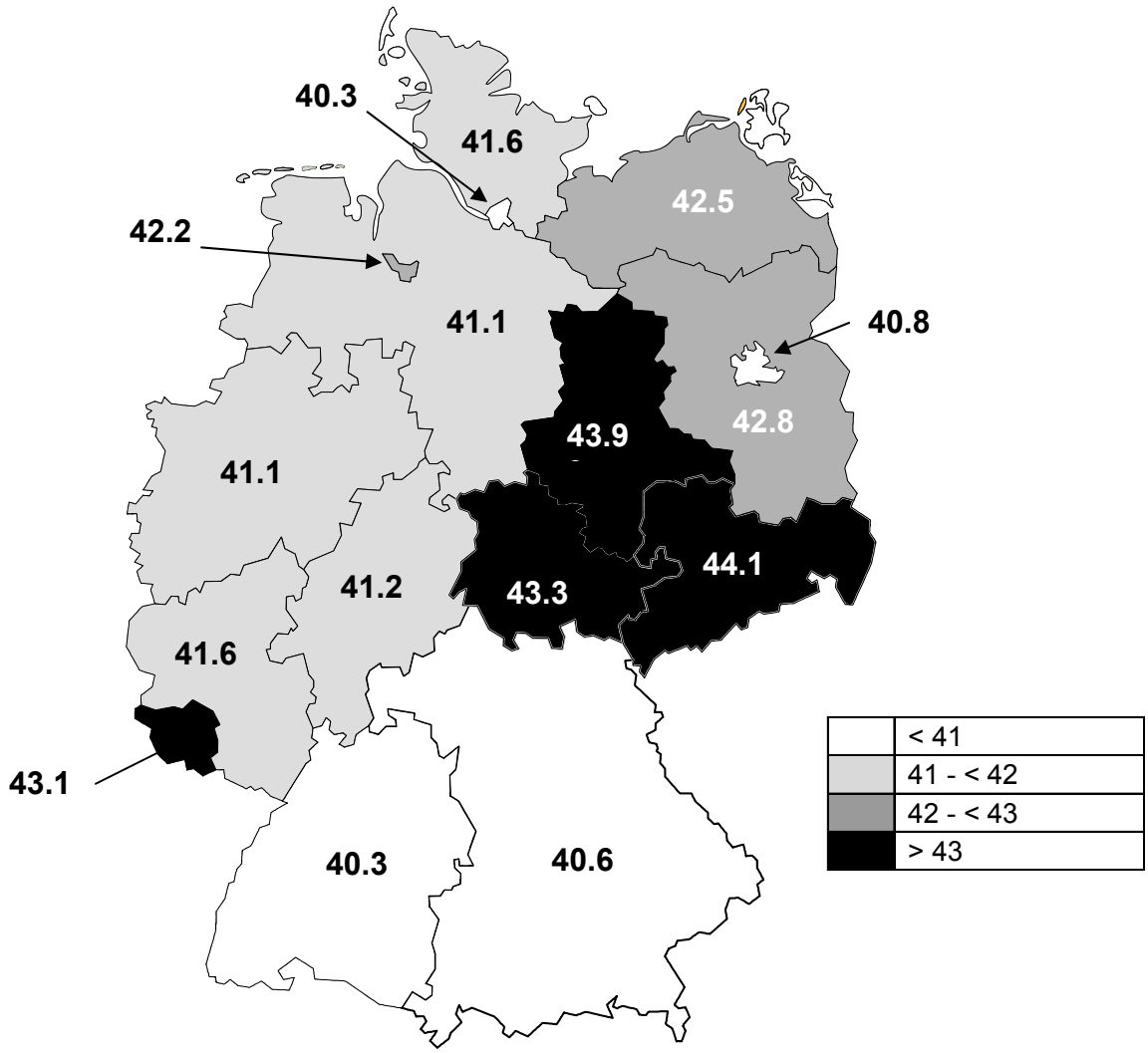

Figure 24: Average age in the individual German federal states

Consequently, it must once again be realized, that we are still unable to determine the reason for the documented high rates of implantations. In addition, however, it must be emphasized that the available information provides no indication for an overusage of pacemaker therapy in Germany.

ECG indications for pacemaker therapies

In comparsion to the previous year, neither the ECG indications (see **Figure 6** and **Figure 25**) nor the selection of pacemaker systems (see **Figure 7** and **Figure 26**) provide any substantially newer information in comparison with the other registries.

In Germany, AV block II and III continue to be under-represented and sick sinus syndrome is over-represented. However, the opposite could be true as well with AV block being over-represented and sick sinus syndrome under-represented in the other registries.

In the Scandinavian countries, the almost 10% higher rate of so-called physiological, i.e. atrial based pacemaker systems, has (unfortunately) demonstrated no changes either.
In comparison with Denmark, there are hardly any differences to be seen concerning selection of the pacing mode for AV block (see **Figure 8**), while the differences concerning sick sinus syndrome are quite evident (see **Figure 9**).

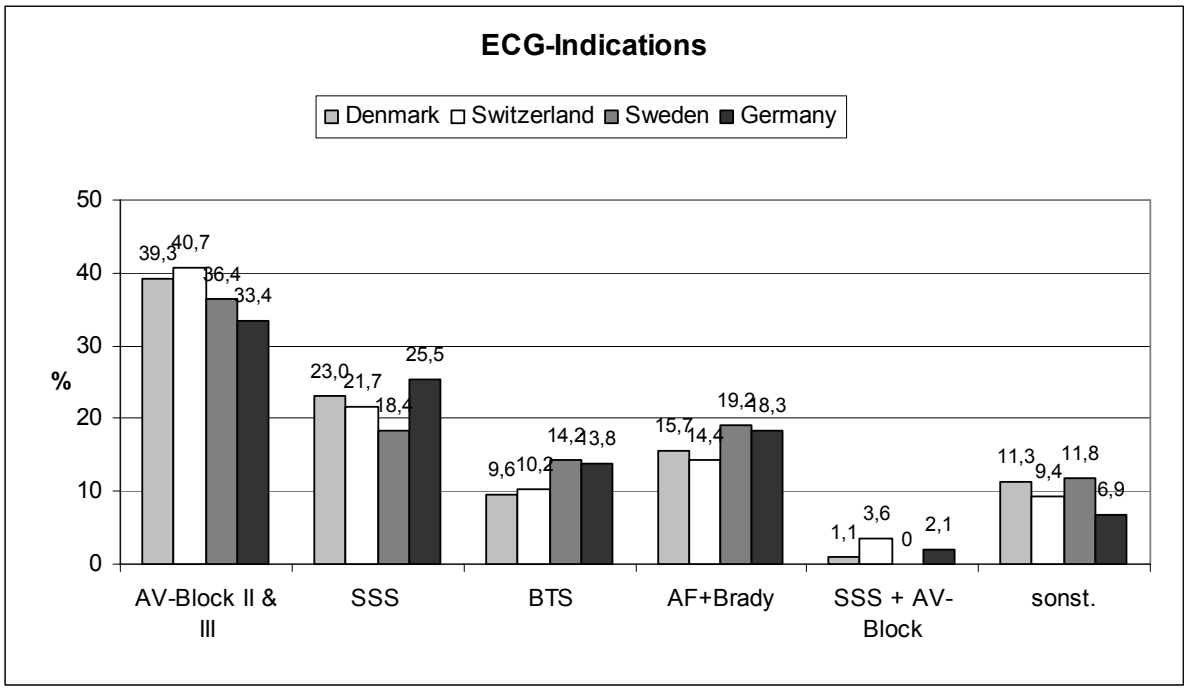

Figure 25: ECG indications, in comparison

Selection of pacemaker systems

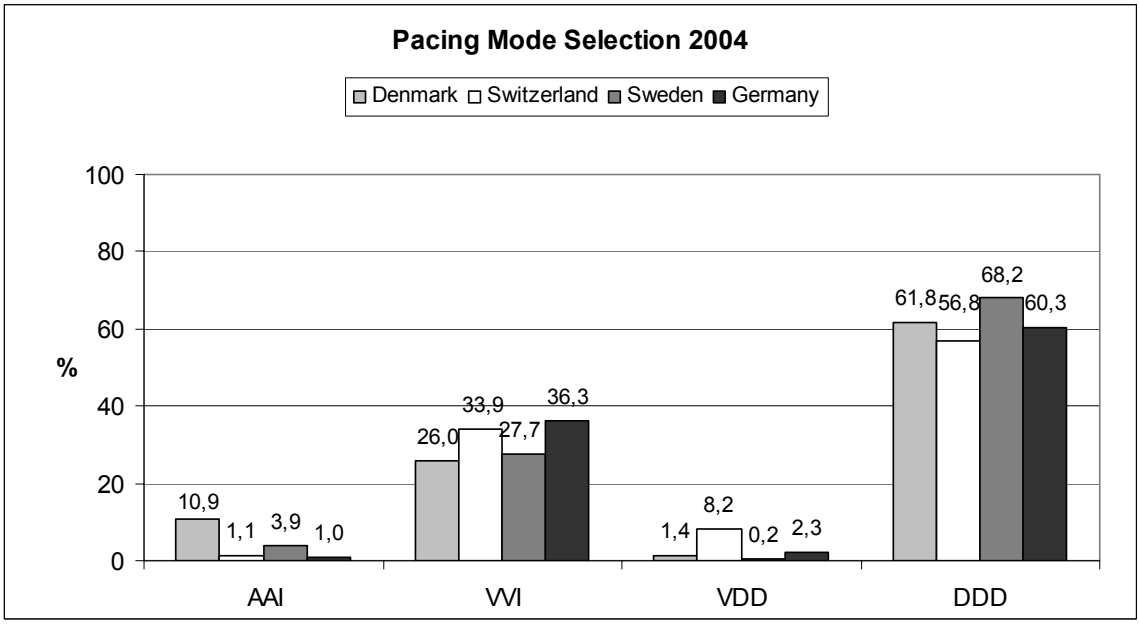

Figure 26: Selection of pacing mode, in comparison

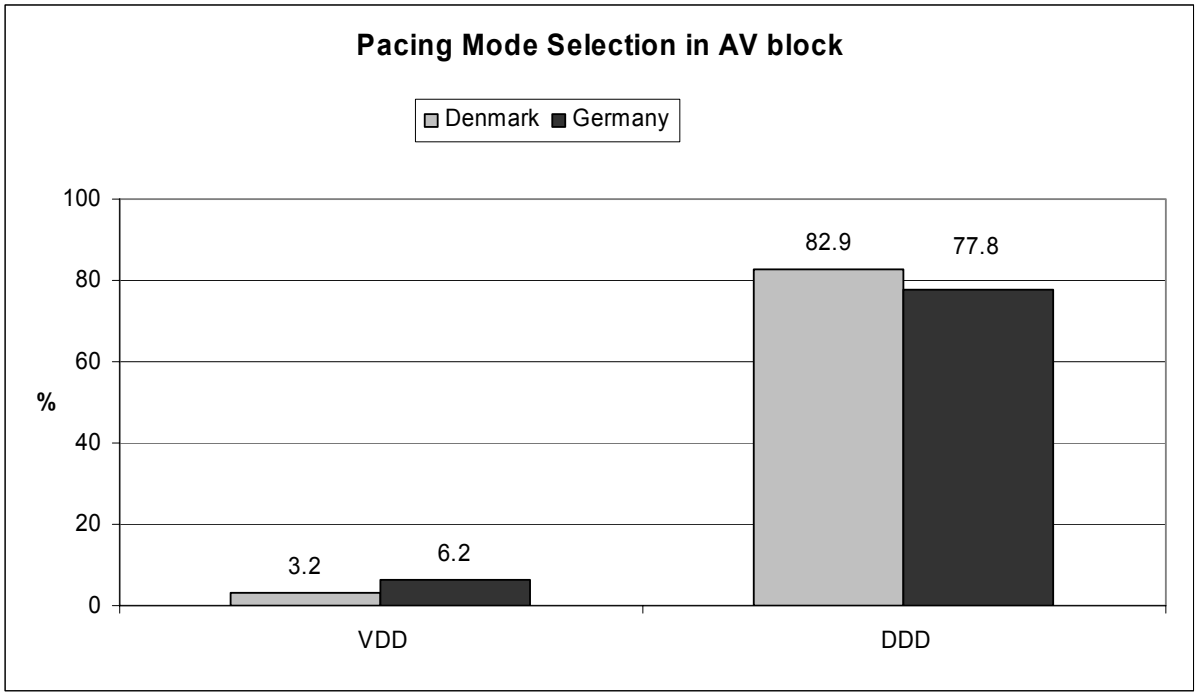

Figure 27: Selection of pacing mode for AV block, in comparison

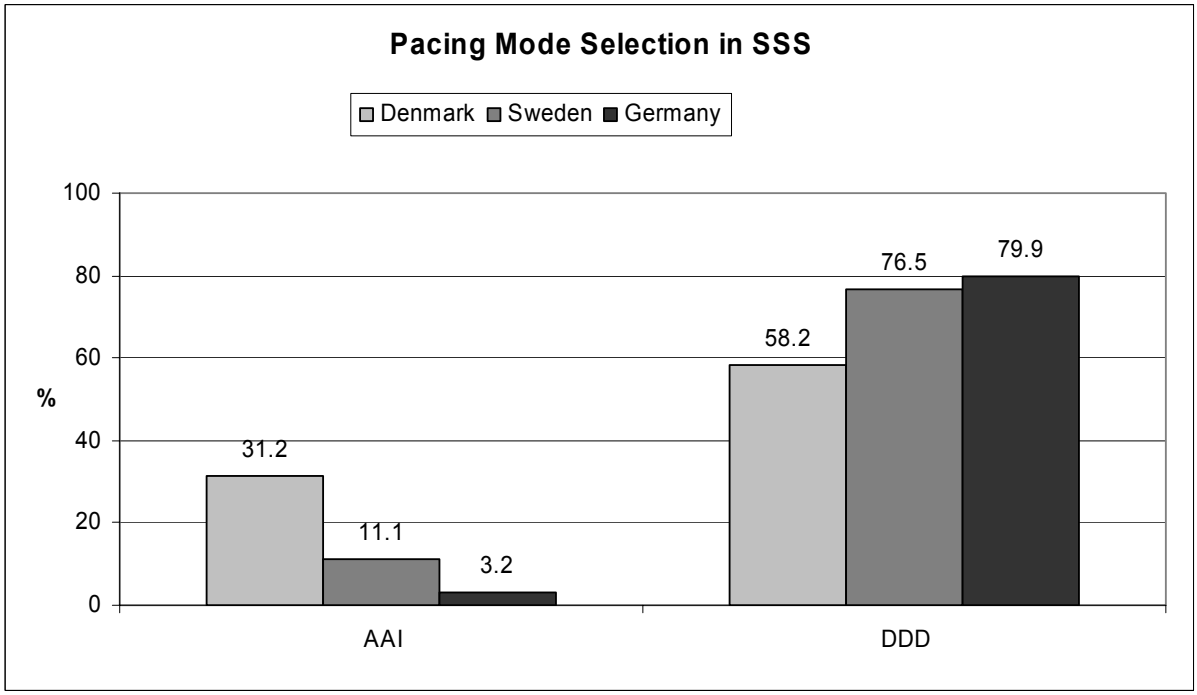

Figure 28: Selection of pacing mode for sick sinus syndrome (SSS), in comparison

Especially the Danes, but also the Swedes, use single-chamber atrial devices much more frequently than German physicians. German physicians prefer dual-chamber devices, but their totals (83.1%) are lower than the implantation rates observed for atrial pacemaker devices in Denmark (89.4%) and Sweden (87.6%). In the previous years, however, this was not seen to be any different either.

Surgical data

As in the past, the Danes continue to perform more implantations using cephalic vein cut down than do the Germans or the Swiss, while the later, in comparison, perform subclavian vein puncture most frequently (see **Table 24**). The times required for surgery have remained nearly unchanged (see **Figure 10**).

	Denmark	Switzerland	Germany
cephalic vein	51.4	33.5	47.8
subclavian vein	45.5	58.0	50.6
other	3.2	8.5	1.6

Table 24: Percentual distribution of the sites of venous access and the implantation sites, in comparison

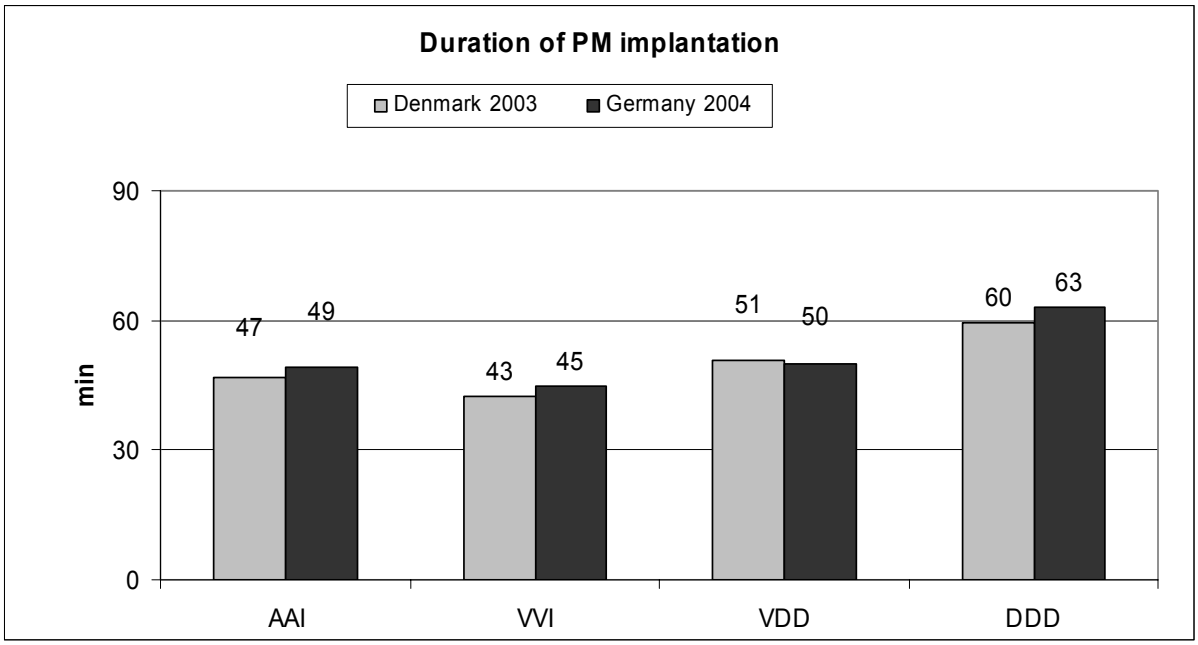

Figure 29: Comparison of the duration of PM implantation with regard to the pacing mode

Bipolar, steroid-eluting leads with active fixation mechanisms tips have proved to be the most frequently selected atrial leads (see **Figure 31**). To be noted is the extremely homogeneous selection of atrial leads in Denmark, as well as the relatively high rate of tined leads used in Switzerland.

For the ventricular leads, however, the picture is somewhat less uniform (see **Figure 32**). In the ventricles, bipolar, steroid-eluting leads are preferred. As fixation-mechanism, the Scandinavians favor screw-in leads much more frequently than do the Swiss or the Germans.

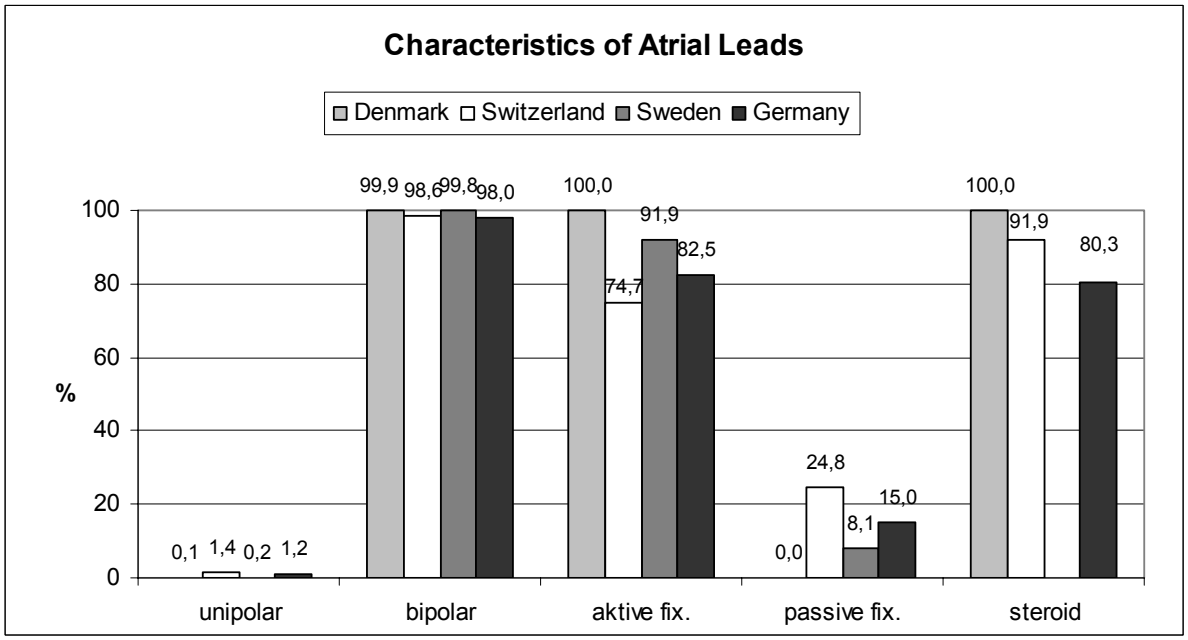

Figure 30: Comparison of the characteristics of atrial leads used (fix. = fixation mechanism, steroid = steroid-eluting)

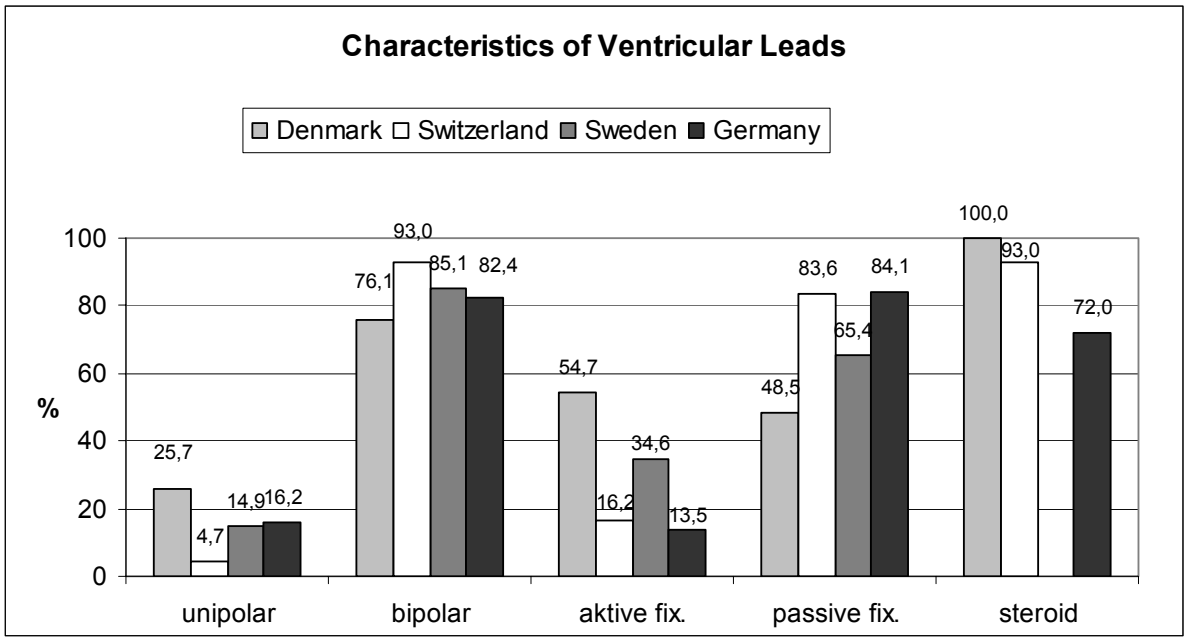

Figure 31: Comparison of the characteristics of the ventricular leads used (fix = fixation mechanism, steroid = steroid-eluting)

Complications associated with new implantations

As compared with the previous year, the changes in Denmark are more substantial than those observed in Germany (see **Figure 32**): the rate of pneumothoraces is seen to be reduced, while the rate of complications related to leads has increased substantially.

Somewhat strange is the high rate of pocket hematomas in Germany, although this has become less.

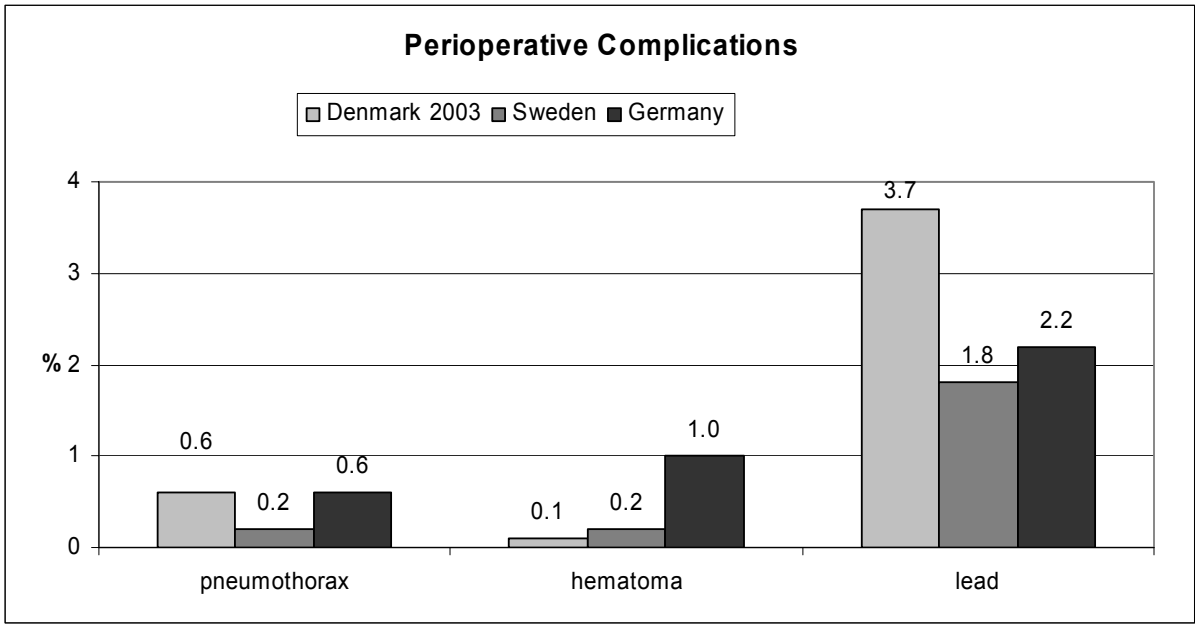

Figure 32: Occurrence of specific perioperative complications associated with new implantations, in comparison. The pneumothoraces recorded involve only those requiring thorax drainage

To summarize, the German results are comparable with those found in other European countries. However, this applies only in part for the selection of pacing mode. Here, Germany, in comparison with the four registries cited, continues to demonstrate the lowest rate of implantations atrail based pacing devices.

Summary and outlook

As already in the past years, it must be noted for 2004 that only few changes have occurred in the relative frequency of all parameters. This may be considered positively, since it shows, that the preceding reports may be considered representative in spite of the substantially reduced number of data sets seen in the past. One may note, however, somewhat less positively, that all attempts made at altering the behavior of users, whether through external or possibly even internal quality assurance, have apparently had little effect on changing this behavior.

Not without consideration, the reports from this registry always take 3 specific points in a more detailed fashion:

1. the implantation rates for VVI devices,
2. the use of the cephalic vein for insertion of the lead and
3. the rate of dislocation of atrial leads.

Considering these 3 points over the course of years, the following relationships are to be found (see **Table 25)**.

	2002		2003		2004	
	number		number		number	
Hospitals	**622**		**898**		**985**	
	n	%	n	%	n	%
selection of a VVI device in > 80%	39	6.3	65	7.2	54	5.5
use of the cephalic vein in < 10%	118	19.0	171	19.0	197	20.0
dislocation of the atrial lead in > 5%	45	7.2	76	8.5	70	7.1

Table 25: Behavior of the hospitals in the selection of a PM device, the preferred venous access as well as the dislocation of atrial leads in the individual hospitals comparing the years 2002, 2003 and 2004

The number of hospitals in which more than 80% of the cases receive VVI devices (which appears to be too frequent) is seen to be reduced relatively as well as also absolutely in the year 2004. Here, the optimist will note that this fact indicates an increased adherence to the guidelines. In contrast, the pessimist may argue that one must wait and see whether this trend from 2004 or another trend from 2003, where the numbers increased both relatively and absolutely, will be observed to continue.

Few changes have been observed involving the use of the cephalic vein. As in the past, this venous access site is hardly ever used in about one fifth of the hospitals. This is most probably due to the fact that those who have performed the implantations have remained unchanged, and that an implanter who has always used the subclavian vein as an access site will continue to do so in the future as well. This may be adequate, as long as it does not result in a significantly higher perioperative rate of complications as compared to cephalic vein cut down. This, however, is what we have always observed in this registry.

The dislocation rate of atrial leads demonstrates only little dynamic. The number of hospitals in which the patients suffer from this complication in more than 5% of its cases (and thus too frequently) has no true tendency toward improvement.

It is not the primary goal of this registry to draw conclusions or to promote suggestions from these results. On the other hand, it is also well known that most physicians would prefer to be able to spend less time with bureaucracy and more with their patients, and the collection of this data is one of these bureaucratic activities. So, it may possibly be somewhat too utopic to wish that the analysis and interpretation of the data would result in recognizable improvements in the practices of all individuals involved. This author, however, would definitely consider this development to be wonderful, if it came true.

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Appendix: Detailed tables

Volume of Surgery in 2004		
new implantations	**number of institutions**	**%**
n <20	180	18.3
n = 20-49	344	34.9
n = 50-99	277	28.1
n > 100	184	18.7
total	**985**	**100**
pulse generator replacements	**no. of institutions**	**%**
n <20	667	73.0
n = 20-49	201	22.0
n = 50-99	41	4.5
n > 100	5	0.5
total	**914**	**100**
reoperations	**no. of institutions**	**%**
n <20	762	86.5
n = 20-49	95	10.8
n = 50-99	19	2.2
n > 100	5	0.6
total	**881**	**100**

Appendix, Table 1: Volume of pacemaker surgery in Germany in 2004

Age (years)	2002		2003		2004	
	number	**percentage**	**number**	**percentage**	**number**	**percentage**
0-9	40	0.1	86	0.2	107	0.2
10-19	18	0.1	74	0.1	95	0.2
20-29	67	0.2	119	0.2	131	0.2
30-39	131	0.5	287	0.6	290	0.5
40-49	362	1.3	702	1.4	829	1.3
50-59	1,244	4.3	2,118	4.1	2,413	3.9
60-69	5,379	18.7	9,745	18.8	11,276	18.1
70-79	11,466	39.9	20,600	39.7	24,628	39.5
80-89	8,696	30.3	15,714	30.3	19,540	31.3
≥ 90	1,357	4.7	2,449	4.7	3,073	4.9
total	**28,760**	**100**	**51,894**	**100**	**62,382**	**100**

Appendix, Table 2: Age distribution of the patients with new implantations in Germany for 2002, 2003 and 2004 (only cases with valid age data)

ECG indications	2003		2004	
	n	%	n	%
rhythm uncoded	524	1.0	369	0.6
AV block I	314	0.6	324	0.5
AV block II, 1	877	1.7	1,134	1.8
AV block II, 2	4,930	9.5	5,924	9.5
AV block III	11,836	22.8	13,761	22.1
BBB	591	1.1	731	1.2
SSS	12,447	24.0	15,930	25.5
BTS	7,451	14.4	8,586	13.8
AF + brady	9,175	17.7	11,403	18.3
CSS	1,149	2.2	1,170	1.9
VVS	110	0.2	98	0.2
SSS + AV block	1,060	2.0	1,280	2.1
other	1,440	2.8	1,672	2.7
total	**51,904**	**100**	**62,382**	**100**

Appendix, Table 3: ECG indications for pacemaker implantations in 2003/2004 (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)

number (n)	Syncope	Presyncope	CHF	CHF due to bradycardia	Ablation	Prophylactic indications	Other	**total**
rhythm uncoded	130	66	164	48	3	23	104	**538**
AV block I	160	119	103	77	2	11	38	**510**
AV block II,1	384	623	368	341	5	38	85	**1,844**
AV block II,2	2,074	3,313	1,812	1,627	21	273	324	**9,444**
AV block III	6,800	5,900	4,625	4,653	162	373	967	**23,480**
BBB	397	219	297	130	2	47	41	**1,133**
SSS	6,577	8,781	4,458	3,812	45	474	1,120	**25,267**
BTS	2,813	4,859	3,111	2,323	94	376	637	**14,213**
AF + bradycardia	3,654	6,111	4,320	5,355	51	304	628	**20,423**
CSS	936	365	314	133	2	12	51	**1,813**
VVS	87	28	11	8	0	1	7	**142**
SSS + AV block	556	709	422	309	6	38	92	**2,132**
other	600	553	762	344	41	82	393	**2,775**
total	**25,168**	**31,646**	**20,767**	**19,160**	**434**	**2,052**	**4,487**	**103,714**
column percentages (%)	Syncope	Presyncope	CHF	CHF due to bradycardia	Ablation	Prophylactic indications	Other	**total**
rhythm uncoded	0.5	0.2	0.8	0.3	0.7	1.1	2.3	**0.5**
AV block I	0.6	0.4	0.5	0.4	0.5	0.5	0.8	**0.5**
AV block II,1	1.5	2.0	1.8	1.8	1.2	1.9	1.9	**1.8**
AV block II,2	8.2	10.5	8.7	8.5	4.8	13.3	7.2	**9.1**
AV block III	27.0	18.6	22.3	24.3	37.3	18.2	21.6	**22.6**
BBB	1.6	0.7	1.4	0.7	0.5	2.3	0.9	**1.1**
SSS	26.1	27.7	21.5	19.9	10.4	23.1	25.0	**24.4**
BTS	11.2	15.4	15.0	12.1	21.7	18.3	14.2	**13.7**
AF + brady	14.5	19.3	20.8	27.9	11.8	14.8	14.0	**19.7**
CSS	3.7	1.2	1.5	0.7	0.5	0.6	1.1	**1.7**
VVS	0.3	0.1	0.1	0.0	0.0	0.0	0.2	**0.1**
SSS + AV block	2.2	2.2	2.0	1.6	1.4	1.9	2.1	**2.1**
other	2.4	1.7	3.7	1.8	9.4	4.0	8.8	**2.7**
total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
line percentages (%)	Syncope	Presyncope	CHF	CHF due to bradycardia	Ablation	Prophylactic indications	Other	
rhythm uncoded	35.2	17.9	44.4	13.0	0.8	6.2	28.2	
AV block I	49.4	36.7	31.8	23.8	0.6	3.4	11.7	
AV block II,1	33.9	54.9	32.5	30.1	0.4	3.4	7.5	
AV block II,2	35.0	55.9	30.6	27.5	0.4	4.6	5.5	
AV block III	49.4	42.9	33.6	33.8	1.2	2.7	7.0	
BBB	54.3	30.0	40.6	17.8	0.3	6.4	5.6	
SSS	41.3	55.1	28.0	23.9	0.3	3.0	7.0	
BTS	32.8	56.6	36.2	27.1	1.1	4.4	7.4	
AF + bradycardia	32.0	53.6	37.9	47.0	0.4	2.7	5.5	
CSS	80.0	31.2	26.8	11.4	0.2	1.0	4.4	
VVS	88.8	28.6	11.2	8.2	0.0	1.0	7.1	
SSS + AV block	43.4	55.4	33.0	24.1	0.5	3.0	7.2	
other	35.9	33.1	45.6	20.6	2.5	4.9	23.5	

Appendix, Table 4: Symptoms (multiple citations possible) and ECG indications for new implants performed in Germany in 2004 (CHF=congestive heart failure)

Indication according to current national Guidelines in %	2003	2004
SSS	95.6	96.2
BTS	94.0	94.8
AV block	99.6	99.6
AF + bradycardia	97.1	97.0
other	69.4	71.2
total	**95.9**	**96.4**

Appendix, Table 5: ECG indications: adherence to existing national guidelines (other = carotid sinus syndrome, vasovagal syndrome, bundle branch block, AV block I)

number	AAI	VVI	VDD	DDD	CRT	other	total
AV block II + III	7	3,149	1,296	16,195	81	91	20,819
SSS	502	2,564	55	12,722	29	58	15,930
BTS	61	4,266	34	4,168	21	36	8,586
SSS + AV block	1	122	1	1,116	18	22	1,280
AF + bradycardia	4	10,761	9	563	40	26	11,403
other	29	1,447	46	2,291	446	105	4,364
total	604	22,309	1,441	37,055	635	338	62,382
%	**AAI**	**VVI**	**VDD**	**DDD**	**CRT**	**other**	
AV block II + III	1.2%	14.1%	89.9%	43.7%	12.8%	26.9%	33.4%
SSS	83.1%	11.5%	3.8%	34.3%	4.6%	17.2%	25.5%
BTS	10.1%	19.1%	2.4%	11.2%	3.3%	10.7%	13.8%
SSS + AV block	0.2%	0.5%	0.1%	3.0%	2.8%	6.5%	2.1%
AF + bradycardia	0.7%	48.2%	0.6%	1.5%	6.3%	7.7%	18.3%
other	4.8%	6.5%	3.2%	6.2%	70.2%	31.1%	7.0%
total	100%	100%	100%	100%	100%	100%	100%

Appendix, Table 6: Selection of pacing mode for new implantations (CRT=cardiac resynchronization therapy, other = AV block I, carotid sinus syndrome, vasovagal syndrome, bundle branch block, rhythm not reported, other ECG finding)

number	AV block II + III	SSS	BTS	SSS + AV block	AF + bradycardia	other	total
AAI	7	502	61	1	4	29	**604**
VVI	3,149	2,564	4,266	122	10,761	1,447	**22,309**
VDD	1,296	55	34	1	9	46	**1441**
DDD	16,195	12,722	4,168	1,116	563	2,291	**37,055**
CRT	81	29	21	18	40	446	**635**
other	91	58	36	22	26	105	**338**
total	20,819	15,930	8,586	1,280	11,403	4,364	**62,382**
%	**AV block II + III**	**SSS**	**BTS**	**SSS + AV block**	**AF + bradycardia**	**other**	**total**
AAI	0.0%	3.2%	0.7%	0.1%	0.0%	0.7%	**1.0%**
VVI	15.1%	16.1%	49.7%	9.5%	94.4%	33.2%	**35.8%**
VDD	6.2%	0.3%	0.4%	0.1%	0.1%	1.1%	**2.3%**
DDD	77.8%	79.9%	48.5%	87.2%	4.9%	52.5%	**59.4%**
CRT	0.4%	0.2%	0.2%	1.4%	0.4%	10.2%	**1.0%**
other	0.4%	0.4%	0.4%	1.7%	0.2%	2.4%	**0.5%**
total	100%	100%	100%	100%	100%	100%	**100%**

Appendix, Table 7: Distribution of pacing modes for initial implants in Germany in 2004 related to the type of bradycardia (other = AV block I, carotid sinus syndrome, vasovagal syndrome, bundle branch block, rhythm not reported, other ECG finding)

AV block II&III			
	2002	2003	2004
AAI	< 0.1	0.0	0.0
VVI	16.8	17.9	15.1
VDD	9.2	6.9	6.2
DDD	73.1	74.4	77.8
SSS			
	2002	2003	2004
AAI	3.6	3.3	3.2
VVI	19.1	18.8	16.1
VDD	0.9	0.4	0.3
DDD	75.8	77.0	79.9
BTS			
	2002	2003	2004
AAI	0.8	0.9	0.7
VVI	49.9	55.0	49.7
VDD	0.8	0.6	0.4
DDD	47.5	43.0	48.5
SSS + AV block			
	2002	2003	2004
AAI	0.2	0.0	0.1
VVI	15.3	12.2	9.5
VDD	1.0	0.9	0.1
DDD	80.6	83.8	87.2
AF + bradycardia			
	2002	2003	2004
AAI	0.1	0.2	0.0
VVI	95.2	94.1	94.4
VDD	0.2	0.1	0.1
DDD	4.0	5.2	4.9
other			
	2002	2003	2004
AAI	0.7	1.2	0.7
VVI	36.2	34.2	33.2
VDD	2.2	1.3	1.1
DDD	51.7	53.1	52.5
total			
	2002	2003	2004
AAI	1.0	1.1	1.0
VVI	38.2	38.1	35.8
VDD	3.6	2.7	2.3
DDD	55.8	56.8	59.4

Appendix, Table 8: Percentual distribution of stimulation mode for initial implants in Germany in 2004 related to the type of bradycardia as compared to the previous years; CRT systems and others are not included because of the lacking chance for comparison.

number (n)	AAI	VVI	VDD	DDD	CRT
0 to < 5%	923	15	824	38	953
5 to < 10%	43	7	58	5	24
10 to < 20%	14	73	65	32	7
20 to < 30%	4	209	21	47	1
30 to < 40%	1	230	9	81	0
40 to < 50%	0	181	5	130	0
50 to < 60%	0	117	2	205	0
60 to < 70%	0	72	0	227	0
70 to < 80%	0	27	0	157	0
80 to < 90%	0	21	0	46	0
≥ 90%	0	33	1	17	0
total	**985**	**985**	**985**	**985**	**985**
percent (%)	**AAI**	**VVI**	**VDD**	**DDD**	**CRT**
0 to < 5%	93.7%	1.5%	83.7%	3.9%	96.8%
5 to < 10%	4.4%	0.7%	5.9%	0.5%	2.4%
10 to < 20%	1.4%	7.4%	6.6%	3.2%	0.7%
20 to < 30%	0.4%	21.2%	2.1%	4.8%	0.1%
30 to < 40%	0.1%	23.4%	0.9%	8.2%	0.0%
40 to < 50%	0.0%	18.4%	0.5%	13.2%	0.0%
50 to < 60%	0.0%	11.9%	0.2%	20.8%	0.0%
60 to < 70%	0.0%	7.3%	0.0%	23.0%	0.0%
70 to < 80%	0.0%	2.7%	0.0%	15.9%	0.0%
80 to < 90%	0.0%	2.1%	0.0%	4.7%	0.0%
≥ 90%	0.0%	3.4%	0.1%	1.7%	0.0%
total	100%	100%	100%	100%	100%

Appendix, Table 9: Distribution of the pacing modes for initial implants in the reporting institutions. Absolute figures from the institutions (upper part of table), proportion of institutions (lower part of table) (to be read as follows: 923 hospitals (93.7%) have implanted an AAI pacemaker in 0 to < 5% of their patients.

	2003		2004	
Manufacturer	**n**	**%**	**n**	**%**
Biotronik	14,548	28.0	18,279	29.3
Cardiac Impulse	0	0	9	< 0.1
CCS	2	< 0.1	0	0
Cook	13	< 0.1	25	< 0.1
CPI/Guidant	4,170	8.0	4,335	6.9
ELA Medical	1,249	2.4	1,405	2.3
Implantronik	6	< 0.1	4	< 0.1
Intermedics/Guidant	232	0.4	340	0.5
Medico	0	0	1	< 0.1
Medtronic	15,769	30.4	18,333	29.4
Osypka	19	< 0.1	25	< 0.1
Pacesetter/St. Jude Medical	5,483	10.6	5,727	9.2
Siemens/St. Jude Medical	606	1.2	568	0.9
Sorin Biomedica	1,106	2.1	996	1.6
St. Jude Medical	2,115	4.1	4,922	7.9
Stöckert	20	< 0.1	41	0.1
Telectronics/St. Jude Medical	44	0.1	99	0.2
Vitatron	6,001	11.6	7,108	11.4
other	521	1.0	165	0.3
total	**51,904**	**100**	**62,382**	**100**

Appendix, Table 10: Distribution of the manufacturers of cardiac pacemakers in first implantations in Germany during the year 2004. The authors are aware that specific companies have meanwhile been purchased from other companies, have undergone fusions or other cooperations. The way data is presented here was chosen, since many pacemaker specialists have gotten used to these names during the years.

	AAI		VVI		DDD		VDD		CRT		not classi-fiable	
Duration of operation	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
< 30 min	24	10.7%	61	6.3%	6	0.6%	19	6.6%	0	0.0%	7	9.0%
30- 59 min	136	60.7%	744	76.5%	313	32.9%	186	64.6%	4	3.2%	19	24.4%
60-89 min	46	20.5%	154	15.8%	507	53.4%	64	22.2%	11	8.8%	17	21.8%
90-119 min	12	5.4%	11	1.1%	108	11.4%	12	4.2%	33	26.4%	17	21.8%
>119 min	6	2.7%	2	0.2%	16	1.7%	7	2.4%	77	61.6%	18	23.1%
total	**224**	**100%**	**972**	**100%**	**950**	**100%**	**288**	**100%**	**125**	**100%**	**78**	**100%**
Duration of fluoroscopy	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
< 5 min	145	64.7%	619	63.7%	207	21.8%	181	62.8%	2	1.6%	21	26.9%
5 - < 10 min	49	21.9%	298	30.7%	528	55.6%	84	29.2%	10	8.0%	21	26.9%
10 - 15 min	20	8.9%	31	3.2%	157	16.5%	15	5.2%	11	8.8%	11	14.1%
> 15 min	10	4.5%	24	2.5%	58	6.1%	8	2.8%	102	81.6%	25	32.1%
total	**224**	**100%**	**972**	**100%**	**950**	**100%**	**288**	**100%**	**125**	**100%**	**78**	**100%**

Appendix, Table 11: Distribution of the mean duration of surgery and of the fluoroscopy during initial implants in the institutions reporting (all valid information over 0 minutes)

	At least 1 complication		Pneumo-thorax		Pocket hematoma		Dislocation of atrial lead		Dislocation of ventricular lead		Surgical site infection with revision	
Incidence of perioperative complications	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0 to < 1%	219	22.2%	800	81.2%	698	70.9%	658	66.8%	625	63.5%	939	95.3%
1 to < 2%	79	8.0%	76	7.7%	71	7.2%	81	8.2%	106	10.8%	20	2.0%
2 to < 3%	69	7.0%	47	4.8%	66	6.7%	80	8.1%	87	8.8%	13	1.3%
3 to < 4%	71	7.2%	22	2.2%	42	4.3%	51	5.2%	50	5.1%	2	0.2%
4 to < 5%	63	6.4%	13	1.3%	28	2.8%	45	4.6%	31	3.1%	4	0.4%
5 to < 6%	72	7.3%	8	0.8%	24	2.4%	27	2.7%	22	2.2%	2	0.2%
6 to < 7%	54	5.5%	4	0.4%	16	1.6%	11	1.1%	17	1.7%	1	0.1%
7 to < 8%	62	6.3%	4	0.4%	12	1.2%	7	0.7%	11	1.1%	1	0.1%
8 to < 9%	38	3.9%	3	0.3%	6	.6%	5	0.5%	7	0.7%	0	0.0%
9 to < 10%	29	2.9%	1	0.1%	9	0.9%	5	0.5%	4	0.4%	0	0.0%
>= 10%	229	23.2%	7	0.7%	13	1.3%	15	1.5%	25	2.5%	3	0.3%
total	**985**	**100%**	**985**	**100%**	**985**	**100%**	**985**	**100%**	**985**	**100%**	**985**	**100%**

Appendix, Table 12: Distribution of the complication rate following initial implants in the institutions reporting. To be read as follows, for instance: 219 hospitals (22.2%) had at least 1 complication in 0 to <1% of the cases.

Single-chamber devices (AAI, VVI)				
Manufacturer	**n**	**mean**	**SD**	**median**
Biotronik	1,210	9.7	3.2	9
Cardiac Impulse	0	-	-	-
CCS	1	7.0	-	7
Cook	0	-	-	-
CPI/Guidant	221	8.2	3.4	7
ELA Medical	171	8.0	2.0	8
Implantronik	3	11.3	2.3	10
Intermedics/Guidant	245	9.3	2.9	9
Medico	0	-	-	-
Medtronic	680	10.0	3.8	9
Osypka	16	10.8	3.4	10
Pacesetter/St. Jude Medical	134	9.7	4.1	9
Siemens/St. Jude Medical	228	12.2	3.3	11
Sorin Biomedica	107	7.9	3.0	8
St. Jude Medical	20	8.3	4.2	9
Stöckert	4	9.3	4.0	8
Telectronics/St. Jude Medical	173	10.9	3.1	10
Vitatron	180	10.4	4.3	10
other	97	13.9	4.6	15
Dual-chamber devices (DDD, VDD)				
Manufacturer	**n**	**mean**	**SD**	**median**
Biotronik	1,355	7.4	2.2	7
Cardiac Impulse	0	-	-	-
CCS	1	11.0	.	11
Cook	0	-	-	-
CPI/Guidant	360	7.1	2.4	7
ELA Medical	594	6.9	2.2	6
Implantronik	1	8.0	-	8
Intermedics/Guidant	569	7.7	2.4	8
Medico	0	-	-	-
Medtronic	919	8.3	3.0	8
Osypka	1	5.0	-	5
Pacesetter/St. Jude Medical	437	8.1	2.9	8
Siemens/St. Jude Medical	107	10.5	2.7	10
Sorin Biomedica	193	6.6	1.7	7
St. Jude Medical	35	6.8	4.2	7
Stöckert	3	3.3	3.1	4
Telectronics/St. Jude Medical	101	9.1	1.9	9
Vitatron	494	7.3	2.3	7
other	46	7.6	3.6	8

Appendix, Table 13: Lifetime in years of the pulse generators replaced for which the manufacturers and their lifetime are known (SD: standard deviation).

	2003		2004	
Surgical procedure	**Atrial lead**	**Ventricular lead**	**Atrial lead**	**Ventricular lead**
new or additional implant	954	1,462	1,516	2,542
replacement	287	375	904	1,209
repair	24	59	40	100
other	141	125	344	310
total	**1,489**	**2,210**	**2,948**	**4,450**

Appendix, Table 14: Type of lead reoperation

	2003		2004	
Surgical procedure	**Atrial lead**	**Ventricular lead**	**Atrial lead**	**Ventricular lead**
explantation	420	589	829	1,221
left in situ	433	780	807	1,225
other	120	150	118	141
total	**973**	**1,519**	**1,754**	**2,587**

Appendix, Table 15: Procedure with dysfunctional leads

Federal states	**PM implantations 2004**	**Population (in million) 2003**	**Implantation rate per 1 million 2004**	**Completeness 2004 (%)**	**Implantation rate per 1 million 2004** adjusted according to completeness
Baden-Württemberg	6,063	10.693	567	93.42	607
Bavaria	8,754	12.423	705	94.22	748
Berlin	2,654	3.388	783	96.33	813
Brandenburgia	2,146	2.575	833	98.31	848
Bremen	434	0.663	655	99.09	661
Hamburg	1,242	1.734	716	96.96	739
Hassia	4,456	6.089	732	93.77	780
Mecklenburg-Vorpommern	1,732	1.732	1,000	99.71	1,003
Lower Saxony	5,687	7.993	711	93.60	760
Nordrhine-Westphalia	13,905	18.080	769	97.48	789
Rhineland-Palatinate	2,894	4.059	713	89.79	794
Saarland	990	1.061	933	98.61	946
Saxony	4,856	4.321	1,124	100.71	1,116
Sachsen-Anhalt	1,978	2.523	784	92.56	847
Schleswig-Holstein	1,915	2.823	678	84.70	801
Thuringia	2,676	2.373	1,128	102.22	1,103
total	**62,382**	**82.532**	**756**	**95.48**	**792**
total in the western federal states	46,340	65.619	706	94.42	748
total in the eastern federal states (with Berlin)	16,042	16.912	949	98.71	961

Appendix, Table 16: Rate of pacemaker implantations per 1 million inhabitants, differentiated according to the individual federal states and adjusted according to the completeness of data collection

ECG indications 2004				
	Denmark	**Switzerland**	**Sweden**	**Germany**
AV block II&III	39.3	40.7	36.4	33.4
SSS	23.0	21.7	18.4	25.5
BTS	9.6	10.2	14.2	13.8
AF + bradycardia	15.7	14.4	19.2	18.3
SSS + AV block	1.1	3.6	k.A.	2.1
other	11.3	9.4	11.8	6.9
total	**100**	**100**	**100**	**100**

Appendix, Table 17: ECG indications in the 4 pacemaker registries, in comparison

Pacing mode selection	**Denmark**	**Switzerland**	**Sweden**	**Germany**
AAI	286	36	207	604
VVI	684	1,129	1,466	22,309
VDD	36	272	12	1,441
DDD	1,629	1,889	3,614	37,055

Appendix, Table 18: Pacing mode selection in the 4 pacemaker registries, in comparison