German Pacemaker Register

Report 2003

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

In the year 2003, more than 900 institutions submitted 68,430 reports (see **Table 1**). The German Pacemaker Register (1) has thereby impressively fulfilled its claimed goal of being, by far, the most extensive pacemaker (PM) registry in the world.

Data basis

As can be seen in **Table 1,** the number of reporting institutions and the number of individual reports for all types of surgical pacemaker interventions have increased substantially. It is somewhat surprising that only two third of the institutions in which implantations are performed carry out reoperations as well. Fewer than 90% of the institutions in which implantations are performed carry out pulse generator replacements. On the other hand some single institutions perform no new implantations, although they carry out generator replacements and/or reoperations.

data base	**2001**	**2002**	**2003**
hospitals reporting	**544**	**632**	09/1: 898
			09/2: 792
			09/3: 601
			Total: 907
new implantations	20,927	28,763	51,904
pulse generator exchanges	4,163*	6,553**	12,484
reoperations	1,567	1,496	4,042
total	**26,657**	**36,812**	**68,430**

Table 1: Data basis 2003 in comparison with the previous years (*replacement of generator and leads, **only generator replacement)

With the number of individual reports, the volume of pacemaker surgery in the institutions increased as well, as is to be seen in **Table 2** and **Figure 1**. The reader will find even more detailed information in **Appendix 1, Table 1.**

Number of pacemaker operations reported	**2001**		**2002**		**2003**	
	n	%	n	%	n	%
<20	200	37.2	176	27.9	162	18.0
20-49	157	29.2	209	33.1	275	30.6
50-99	118	21.9	146	23.1	255	28.3
100-199	50	9.3	82	13.0	160	17.8
200-299	10	1.9	13	2.1	35	3.9
≥ 300	3	0.6	5	0.8	13	1.4
total	**538**	**100**	**631**	**100**	**900**	**100**

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

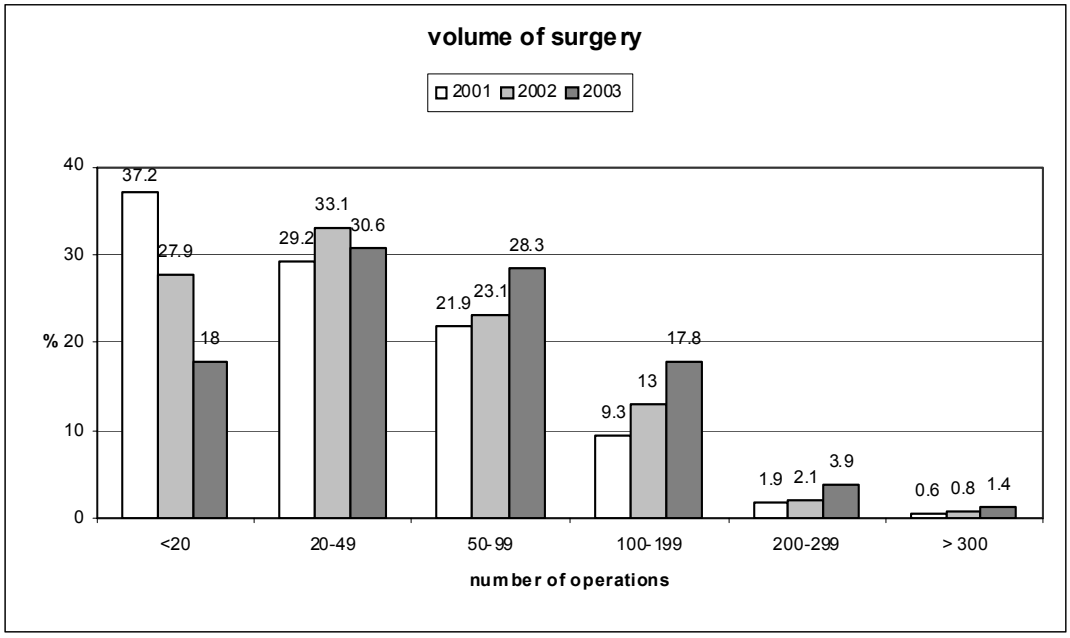


Figure 1: Distribution of the volume of surgery in the individual institutions (guide to interpretation: in the year 2001, 37.2% of the institutions carried out < 20 PM operations, in 2002 this was reduced to 27.9% and to 18% in the year 2003)

In 2002, 71.7% of the data expected were actually reported (range: 59.2% to 81.5% for the individual rates of surgical interventions (see **Table 3**) This rate has increased to 104% in all areas (see **Table 4**). It remains unclear, why so many more replacements than expected were reported.

data base 2002	expected	observed	%
hospitals reporting	881	632	71.7
- new implantations	48,571	28,763	59.2
- replacement surgery	8,040	6,553	81.5

Table 3: Data base in 2002

data base 2003	expected	observed	%
hospitals reporting	870	907	104
- new implantations	50,366	51,904	103.1
- replacement surgery	9,232	12,484	135.2
- explantation/revision surgery	3,899	4,042	103.7

Table 4: Data base in 2003

However, using the number of pacemakers sold in Germany in the year 2003 (n=87,287) as a basis – an information for which the authors extend their thanks to the Bundesverband Medizintechnologie e.V. (BV Med - German society of medical technology) - completeness of data is reduced to 72.7%, thereby being less complete than that of the previous model, but

nevertheless substantially better than the results of the previous year. As long as data of PM surgery on an outpatient basis are lacking, a 100% completeness remains a dream. However, through changing both the trigger for documentation and the measure for its completeness in 2004 by the use of procedural codes (ICPM-Codes) instead of administrative data, the completeness of the data reported will hopefully increase even further.

Demographic data

Table 5 reveals that - aside from the increasing number of reports - little has changed. Nevertheless, the relative increase in replacements is somewhat surprising: Whereas the number of new implantations (20,927) was seen to be five times greater than replacements (4,163) in 2001, this factor declined to 4.2 (51,904/12,484) in 2003.

51,904 new pacemaker implantations in Germany are equivalent to a rate of new implantations of 629 per 1 million inhabitants, which is presumedly one of the highest rates in the world. A reason for this could be the increasing proportion of older patients over the last years. A look at **Appendix 1, Table 2**, however, shows that little has changed with regard to age since 2001. This implies a high probababilty that the rate of implantations recorded in the past years was too low. So, the high rate of implantation deserves a detailed discussion, which can be read in the comment section of this report.

	2001	2002	2003
new implantations	20,927	28,763	51,904
mean per institution	38.5	46.2	57.8
gender			
male	51.9%	51.6%	51.7%
female	48.1%	48.4%	48.3%
mean age (years)			
males	73.3	73	73
females	77.1	76.9	76.8
patients < 60-years-old	6.4%		6.5%
proportion of patients dependent on PM	26.9%	26.8%	25.1%
average length of stay in the hospital (days)		7.1	7.2
pulse generator replacements	4,163	6,553	12,484
mean per institution	7.9	11.9	15.8
mean age (years)			
males	74.2	75.3	74.7
females	77.3	77.7	77.7
time between implantation and exchange (years):	8.7	8.5	8.5
proportion of patients dependent on PM	40.3%	40.5%	38.7%
average length of stay in the hospital (days)		4.5	4.3
reoperations		1,496	4,042
mean per institution		4.8	6.7
gender			
male		51.6%	53.7%
female		48.4%	46.3%
mean age (years)			
males		72.4	71.3
females		75.1	74.0
patients < 60-years-old			
proportion of patients dependent on PM		35.5%	37.3%
average length of stay in the hospital (days)		7.4	6.3

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

New implantations

ECG indications for pacemaker implantation

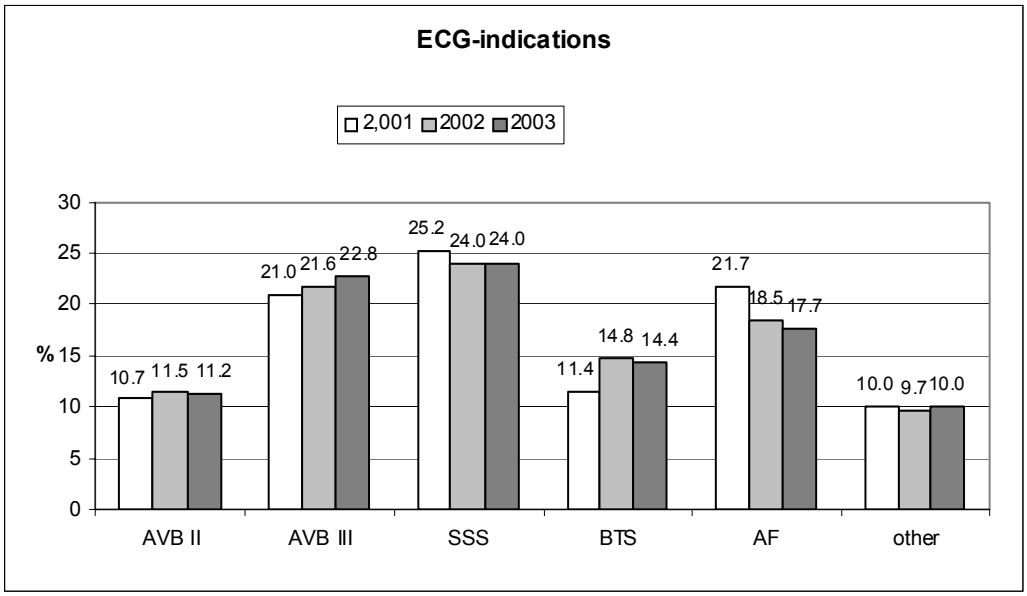
Table 6 and **Figure 2** reveal the ECG indications over the course of the years 2001 – 2003. There are no larger changes to be observed, the tendency of a reduction in the diagnosis of bradycardia-tachycardia syndrome (BTS) in favor of atrial fibrillation with slow ventricular response continued in 2003.

In the future, patients with a classical BTS, i.e. episodes of sinus bradycardia, sinus node arrest and/or sinoatrial block combined with episodes of supraventricular tachycardia or paroxysmal atrial fibrillation, have to be recorded as sick-sinus syndrome. This may help to avoid confusing BTS with atrial fibrillation with slow ventricular response, which can also be considered a BTS in the broadest sense of the term.

Detailed information concerning the ECG indications is to be found in **Appendix 1, Table 3**.

ECG indication	2001	2002	2003
AV-block II	1,650	3,296	5,807
AV-block III	3,225	6,219	11,836
SSS	3,867	6,894	12,447
BTS	1,747	4,243	7,451
AF+bradycardia	3,332	5,309	9,175
other	1,108	2,009	5,188
total	**15,365**	**28,763**	**51,904**

Table 6: ECG indications for PM implantation in comparison
(SSS = sick-sinus syndrome, BTS = bradycardia-tachycardia syndrome, AF+bradycardia = slow atrial fibrillation,



Other = carotid sinus syndrome, vasovagal syndrome, bundle branch block, AV block I, binodal disease)

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)

Symptoms

Whereas the absolute number of symptoms reported increased substantially, no substantial changes in the relative numbers could be detected. Detailed information is to be found in **Appendix 1, Table 4**.

Selection of pacing mode

Figure 3 shows that there are no changes as compared to previous years. As in the past, the rate of VVI implantations continues to be nearly 40%.

Figure 4, Figure 5, Figure 6 and **Figure 7** reveal the development for the four, most frequent types of bradycardia.

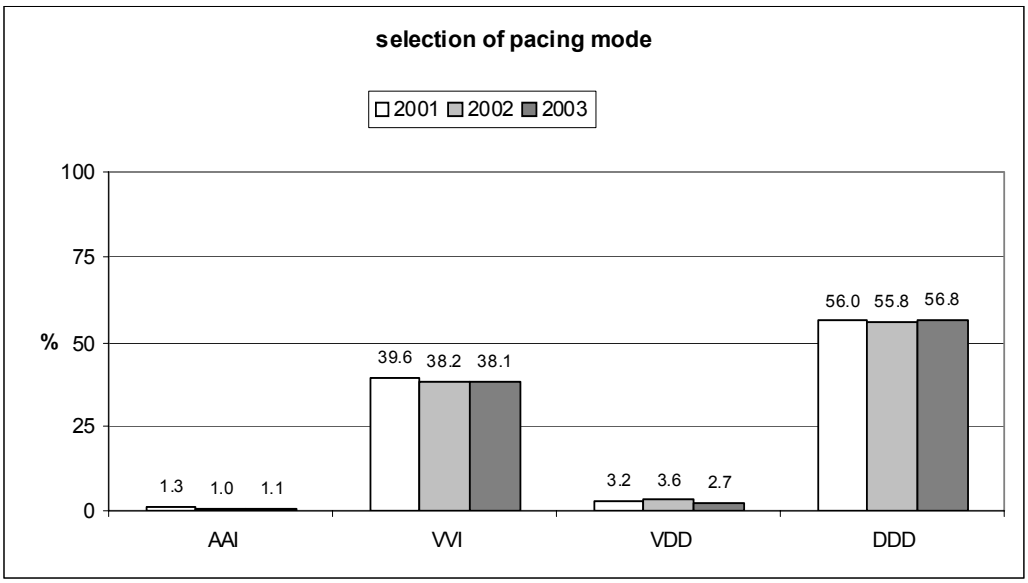


Figure 3: pacing mode selection as compared with that in the previous years (CRT systems were not recorded in the previous years and have therefore not been included here)

It is clear that there has been nearly no change in 2003 as compared with 2002 or 2001. The proportion of non-physiological VVI systems continues to be over 38% and even increased in type II and III AV block (see **Figure 4**) as well as in BTS (see **Figure 6**). With regard to the latter, however, it must be mentioned that a substantial proportion of institutions may have included patients with slow atrial fibrillation resulting in a limited significance of **Figure 6**

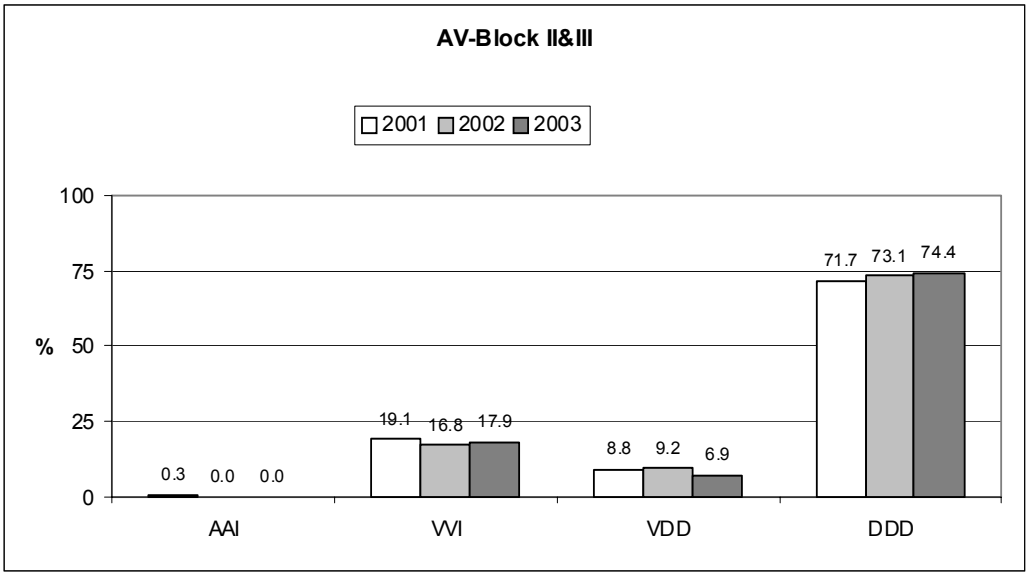


Figure 4: pacing modes used for patients with AV block II & III as compared with the previous years

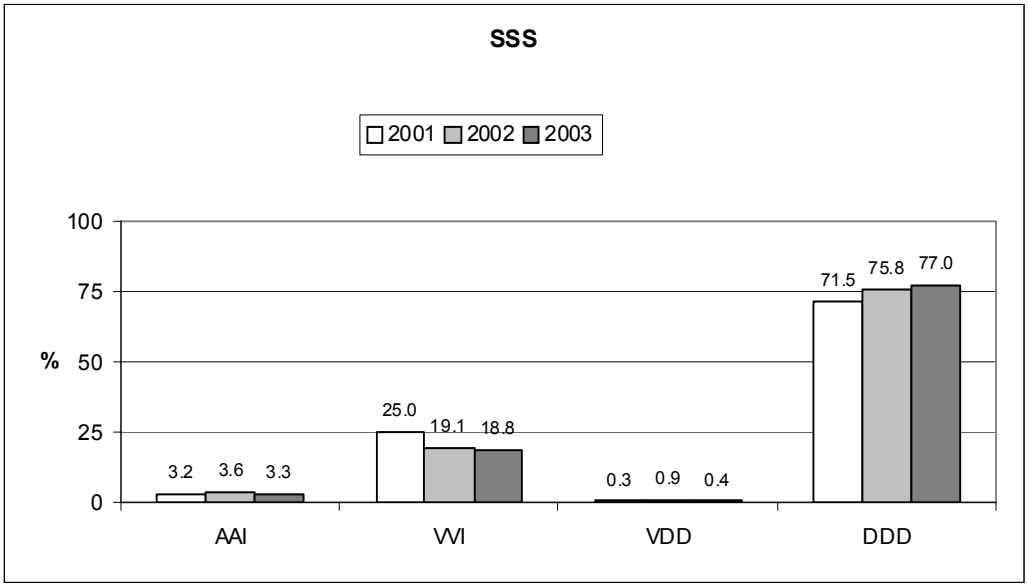


Figure 5: pacing modes used for patients with sick-sinus syndrome (SSS) as compared with the previous years

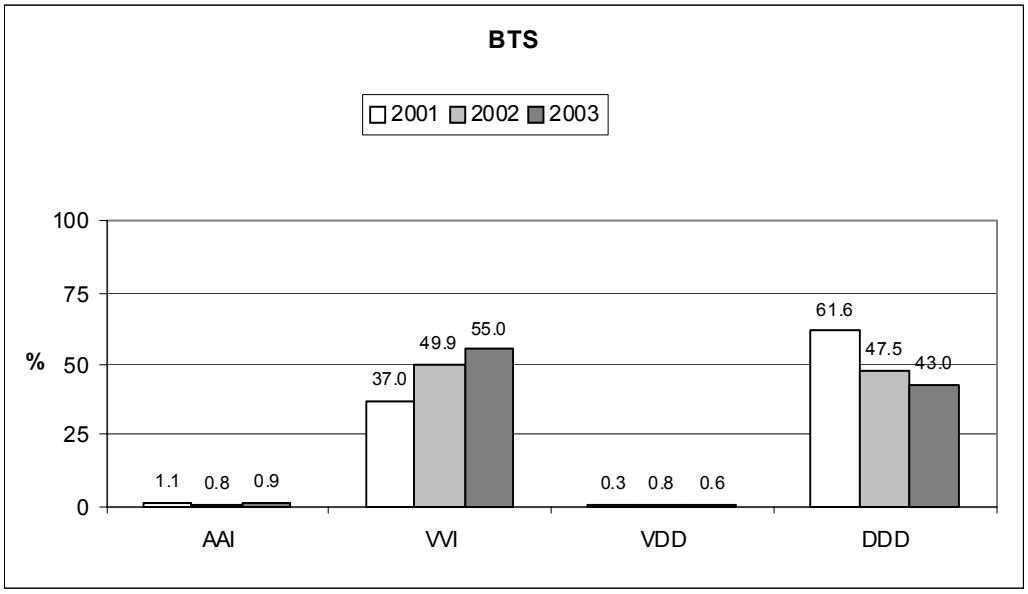


Figure 6: pacing modes used for patients with bradycardia-tachycardia syndrome (BTS) as compared with the previous years

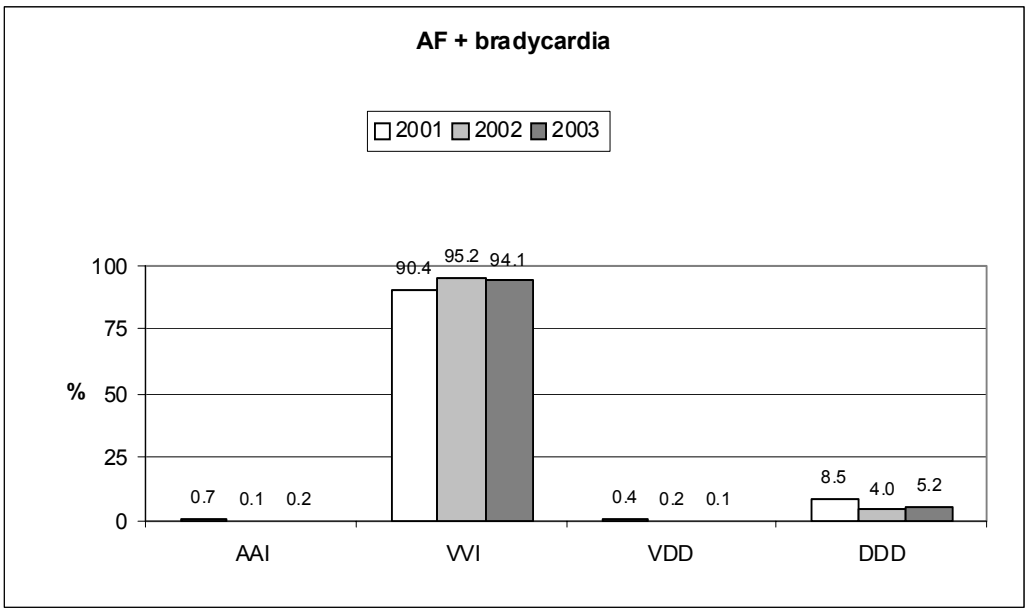


Figure 7: pacing modes used for patients with atrial fibrillation (AF) with slow ventricular response as compared with the previous years

Further details can be taken from **Appendix 1, Table 6, Appendix 1, Table 7** and **Appendix 1, Table 9.**

However, the high variability among the hospitals concerning the use of pacing modes is somewhat surprising (see **Appendix 1, Table 9**).

As a part of the whole, the distribution of VVI systems is depicted in **Figure 8**.

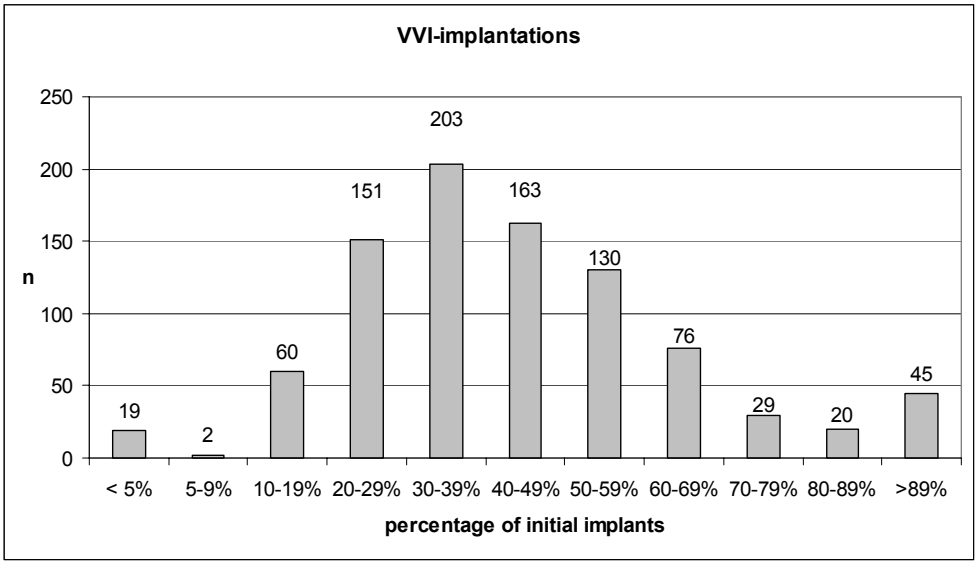


Figure 8: Distribution of the usage of VVI systems during initial implantations (to be read as follows, for instance: 19 hospitals used VVI systems in fewer than 5% of the cases)

In 2003, again more than 10% (n=94) of the hospitals were seen to have implanted VVI systems in over 70% of the cases. This result cannot be explained with the information available, since it neither corresponds to existing guidelines nor to the evidence from literature.

In comparison to 2002, the minor alterations in this distribution show that the results of the German Pacemaker Register in previous years, although not complete, were a representative sampling.

The manufacturers are to be observed in **Appendix 1, Table 10**.

Lead selection

Only few changes have been observed for the leads as well, as is to be seen in **Table 7**, **Table 8** and **Figure 9.**

2003	Atrium		Ventricle	
polarity	**n**	**%**	**n**	**%**
unipolar	461	1.5	12,811	25.03
bipolar	30,171	97.5	37,663	73.58
multipolar	314	1.0	707	1.38
fixation mechanism				
active	24,820	80.2	6,540	12.8
passive	5,214	16.9	43,053	84.1
none	910	2.9	1,588	3.1
isolation material				
polyurethane	5,005	16.2	8,912	17.4
silicone rubber	21,677	70.0	33,836	66.1
dual	4,252	13.7	8,429	16.5
lead tip				
steroid	23,212	75.0	33,891	66.2
none-steroid	300	1.0	629	1.2
none	7,420	23.4	16,659	32.6

Table 7: Polarity, fixation mechanism, isolation material and type of lead tip in 2003 (percentage as related to the specific type of lead)

	2001	2002	2003
stimulation site	**%**	**%**	**%**
atrium			
unipolar	4.9	2.9	1.5
bipolar	95.1	96.6	97.5
multipolar		0.5	1.0
ventricle			
unipolar	38.0	37.1	25.0
bipolar	62.0	61.9	73.6
multipolar		1.0	1.4

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

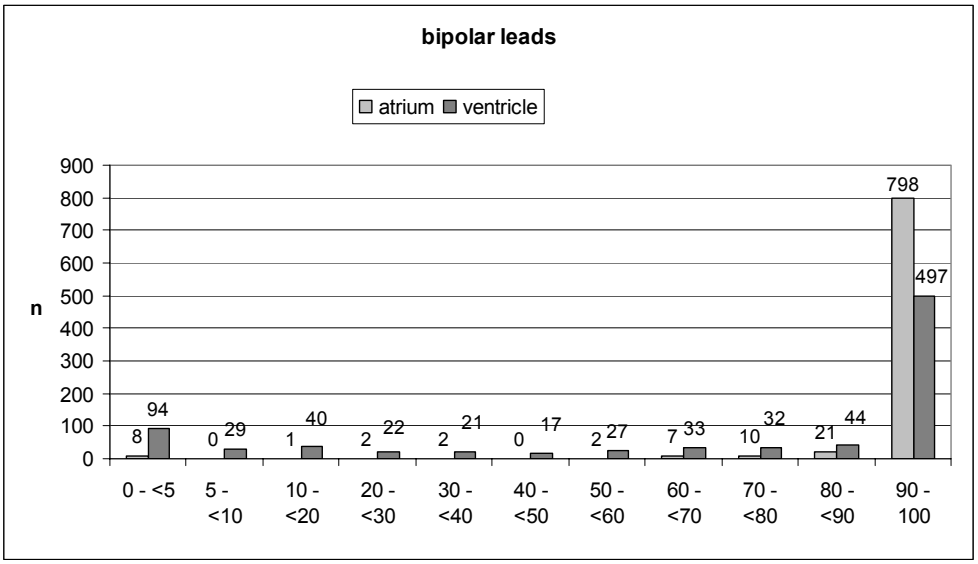


Figure 9: Distribution of bipolar leads used in German hospitals in 2003 (to be read as follows, for instance: 8 hospitals used bipolar leads in the atrium in fewer than 5% of the cases and 94 hospitals used bipolar leads in the ventricle in fewer than 5% of the cases)

The preference for bipolar leads, particularly in the atrium, is obvoius and supported by the new guidelines of the Working Group for Cardiac Pacing of the German Cardiac Society. However, seen from the viewpoint of a surgeon having more than 20 years experience in this field, the evidence that the advantages of bipolar leads outweigh the disadvantages of these leads could be somewhat more convincing.

As in the past, the atrial leads are primarily implanted using active fixation, silicon-isolated, and steroid-eluting leads, findings which, aside from the specific mode of fixation, are also valid for the ventricular leads: In the ventricle, tined leads are generally preferred.

Operative data

Operative data demonstrates no substantial changes, as can be seen in **Table 9**.
It is interesting, however, that more than 150 hospitals made use of the cephalic vein as venous access in fewer than 5% of the cases (see **Figure 10**).

form of anesthesia	n	%
local anesthesia	48,639	93.7
general anesthesia	3,265	6.3
venous access		
cephalic vein	26,535	51.1
subclavian vein	27,705	53.4
other	1,023	2.0
implantation site		
left	14,084	27.1
right	38,004	73.2

Table 9: Operative data for new implantations in 2003

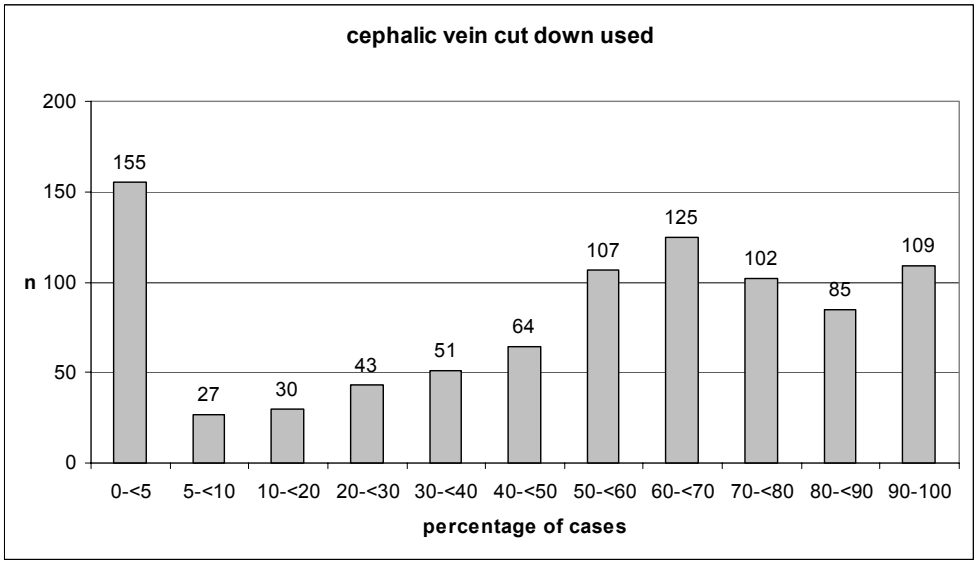


Figure 10: Distribution of the rate of using cephalic vein cut down for lead implantation (absolute figures cited by the hospitals)

The results of operation - and fluoroscopic times (see **Table 10** and **Table 11**) confirm the high standard reached. For CRT systems, the substantially shorter times may indicate the increasing experience obtained with implantation of these devices.

The 75th percentile of the operation times enables the surgeon to determine when he/she must expect a higher risk of surgical site infection during pacemaker surgery, i.e. whenever an operation time exceeds this 75th percentile (2,3,4). The background for this risk assessment is provided by the well accepted risk score for surgical site infections from the NNIS (National Nosocomial Infections Surveillance System). It includes the duration of surgery as well as the clinical state of the patients as (defined by the ASA classification) as risk factors.The available evidence suggests that both an excess of the 75th percentile in the

duration of surgery as well as an ASA score ≥ 3 increase the risk of a surgical site infection (2,3).

PM device	mean	SD	median	75th percentile
AAI (n=547)	50.4	28.7	45.0	60.0
VVI (n=19,762)	45.4	32.9	40.0	55.0
VDD (n=1,378)	50.6	31.5	45,0	60.0
DDD (n=29,441)	64.3	32.9	60	77.0
CRT (n=427)	155.5	93.9	135	180.0
other (n=314)	78.4	55.5	60	99.0
total (n=51,869)	**57.4**	**34.1**	**50**	**70.0**

Table 10: Duration of surgery for new implantations performed in 2003 (related to all cases for which valid information concerning the duration of the procedure had been provided, SD = standard deviation)

PM device	m	SD	median
AAI (n=542)	5.4	23.1	3.0
VVI (n=19,538)	5.5	20.4	3.0
VDD (n=1,375)	5.2	20.4	3.0
DDD (n= 29,364)	8.4	23.3	5.0
CRT (n=402)	24.6	21.6	21.0
other (n =314)	11.3	18.3	5.0
total (n =51,904)	**7.31**	**22.2**	**4.0**

Table 11: Fluoroscopic time for new implantations in 2003 (related to all cases for which valid information concerning the fluoroscopic time has been provided, SD = standard deviation)

Concerning the distribution of the times for surgery involving single-chamber and dual-chamber systems (see **Table 11** and **Figure 12**), a comparison with the previous year reveals a tendency toward more rapid surgical procedures.

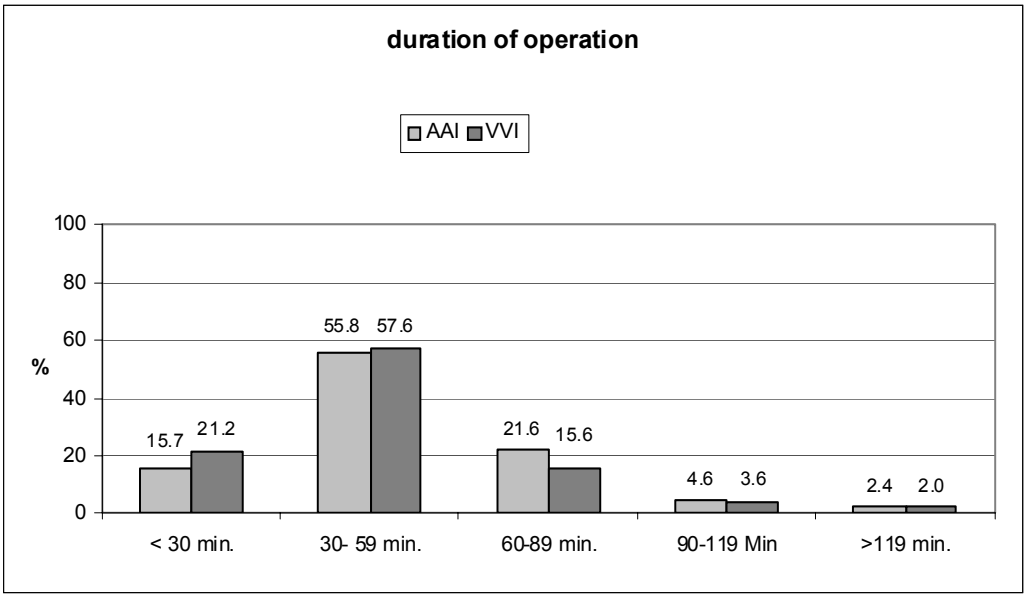


Figure 11: Distribution of the mean values for the duration of surgery during implantation of single-chamber devices related to all of the new implantations

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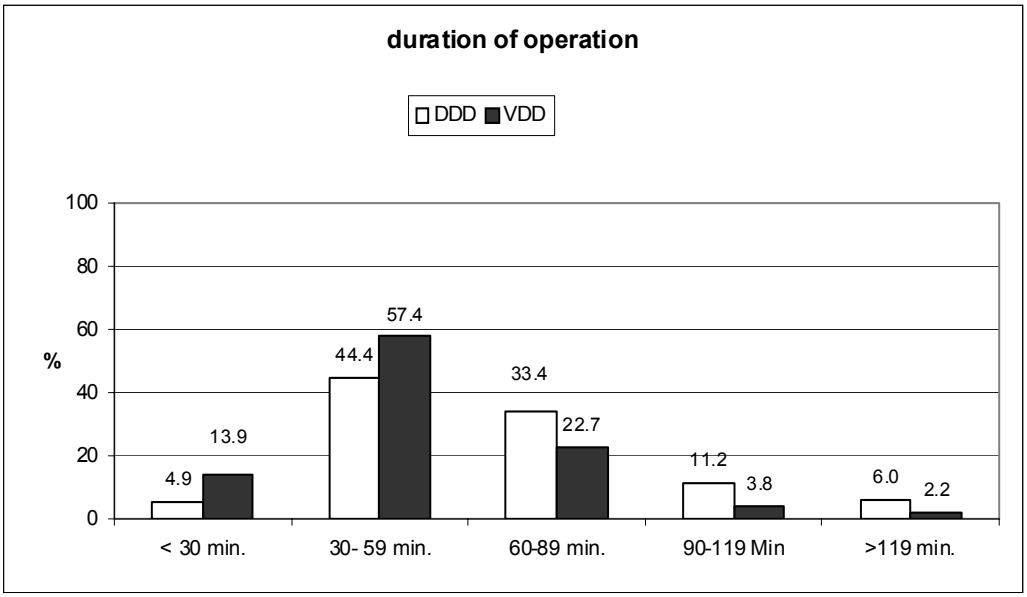

Gelöscht: ¶

Figure 12: Distribution of the mean values for the duration of surgery during implantation of dual-chamber devices as related to all of the new implantations

The 75th percentile (**Figure 11** and **Figure 12**), however, is exceeded in approximately 28% of the AAI implantations, 21% of the VVI implantations, 29% of the VDD implantations and in a minimum of at least 17% of the DDD implantations (operations ≥ 90 minutes in duration).

A look at the duration of operation as related to the mean values of the individual hospitals (see **Figure 13** and **Figure 14**) reveals a somewhat different picture:

Hereby, 34% of the hospitals documented mean values of the time of operation for AAI implantations that exceed the 75th percentile , about 18% for VVI implantations, 29% for VDD implantations and at least 15% for DDD implantations.

These results might indicate that the implantation of an atrial lead causes more difficulties for an individiual hospital than would be expected from the distribution of the time of operation related to the number of cases. This impression is intensified even further when you compare the number of ***hospitals*** where the average time of operation was under 30 minutes with the number of ***cases*** in which the time of surgery was shorter than 30 minutes

Further details can be derived from **Appendix 1 Table 11**.

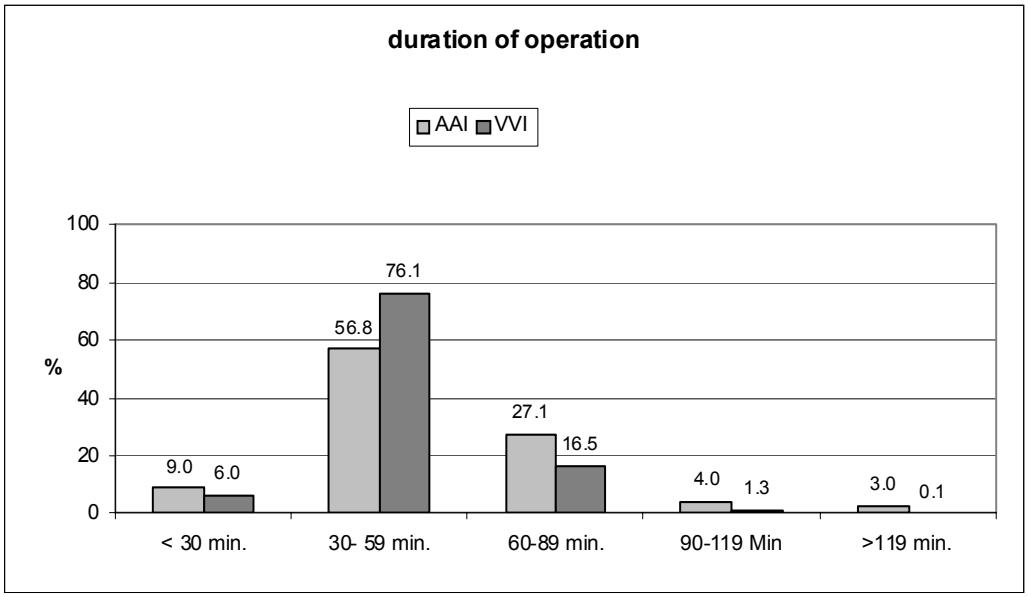

Figure 13: Distribution of the mean values for the duration of surgery during implantation of single-chamber devices related to the mean values of the hospitals (for instance, 9% of all hospitals had a mean value of under 30 minutes for implantation of an AAI device)

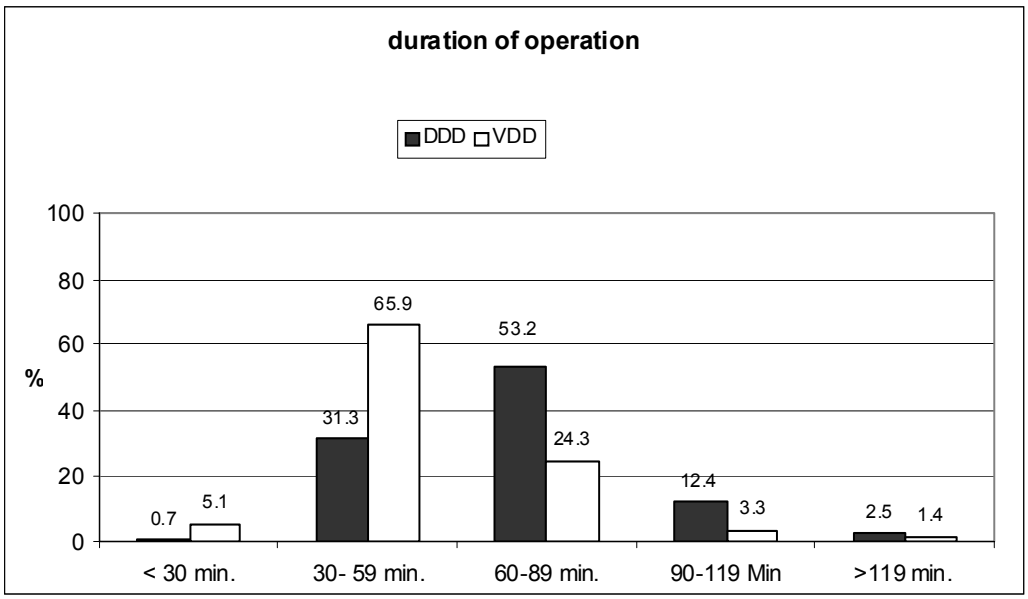

Figure 14: Distribution of the mean values for the duration of surgery during implantation of dual-chamber devices as related to the mean values of the hospitals (for instance, 0.7% of all hospitals had a mean value of under 30 minutes for implantation of a DDD device)

Intraoperative measurements

The intraoperative measurements made in 2003, as compared with those from 2002 (1), reveal almost identical results (see **Table 12**).

atrium	**n**	**mean**	**sd**	**median**
pacing threshold	28,660	0.8	0.6	0.7
P-wave	30,194	3.1	1.8	2.8
ventricle	**n**	**mean**	**sd**	**median**
pacing threshold	50,647	0.5	0.5	0.4
R-wave	49,543	12.9	5.4	12.0
coronary sinus (lv) lead	**n**	**mean**	**sd**	**median**
pacing threshold	413	1.1	0.9	0.8
R-wave	408	14.2	7.3	13.0

Table 12: Results of intraoperative measurements during new implantations in 2003 (only cases with valid information; SD = standard deviation, LV = left-ventricular)

Complications

As already discussed in the previous year, nobody likes to talk about problems. Complications, however, represent a parameter which is an extremely suitable indicator for the quality of a procedure and as well a significant target for improvement. **Figure 15** provides an overview about the most important complications, while **Table 13** enumerates the respective details.

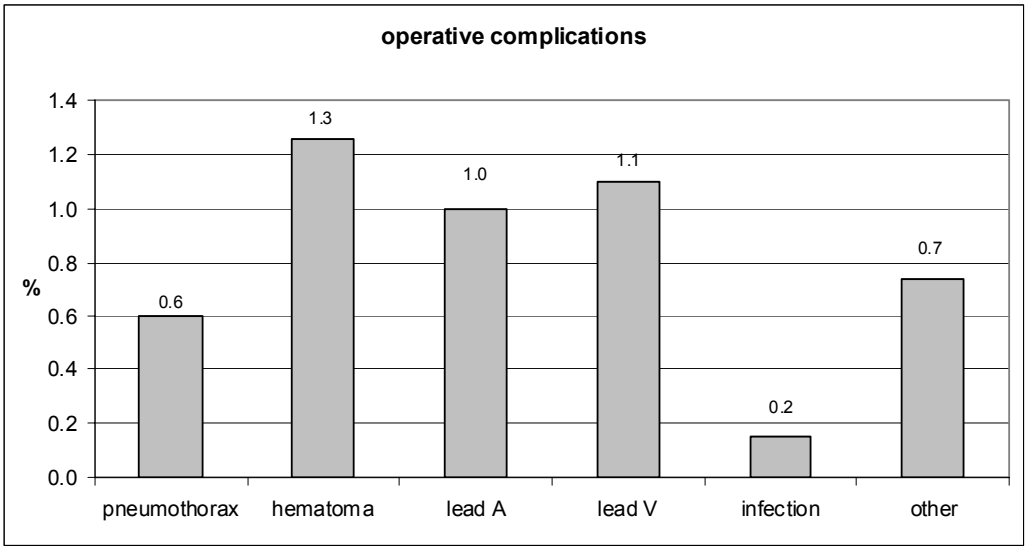

Figure 15: Operative complications following initial implantations
(lead A = dislocation of atrial lead, lead V = dislocation of ventricular lead, infection = surgical site infection, other = cases with at least one of the following complications: Asystole, ventricular fibrillation, atrial fibrillation,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

There are relatively few differences between the various types of complication, although the number of pocket hematomas continues to be relatively high, a finding that might indicate a

problem of the user understanding the corresponding item in the data set. Whereas only pocket hematomas that required any kind of operative intervention should have been documented as true complications, some larger bruises over the pocket may have been reported as well. This problem can be solved by an improvement of the item in the data set.
The exceptionally low rate of infections observed can be explained by the short observation period during the inhospital stay. In contrast, the international literature defines all surgical site infections which develop within the first year following implantation as nosocomial infection. So, this low rate of infection is unfortunately far from being representative.
For more detailed information, the reader is referred to **Appendix 1, Table 12**.

	n	%
asystole	158	0.3%
ventricular fibrillation	57	0.1%
atrial fibrillation	367	0.7%
pneumothorax	315	0.6%
pericardial tamponade	50	0.1%
pocket hematoma	653	1.3%
hematothorax	36	0.1%
wound infection	76	0.2%
other	383	0.7%
lead dislocation		
as related to all patients	1,143	2.2%
- only of the atrial lead	522	1.0%
- only of the ventricular lead	560	1.1%
- of both leads	61	0.1%
lead dislocation		
atrial leads (as related to all patients with implanted atrial leads)	583 / 30,956	1.9%
ventricular leads (as related to all patients with implanted ventricular leads)	621 / 51,187	1.2%
at least 1 perioperative complication	**2,969**	**5.7%**

Table 13: Perioperative complications during or after new implantations

The dislocation of an atrial lead can be seen as some kind of indicative complication, the resulting picture is known from the previous year (see **Figure 16**).
A great majority of the hospitals (n=612 = 68.2%) demonstrate rates of lead dislocation of < 1%. Nevertheless, dislocation rates of ≥ 5% were observed in 76 institutions (8.5%) and a fortunately quite small group of 22 of the reporting hospitals (2.4%) demonstrate lead dislocations in the atrium in over 10% of the cases.

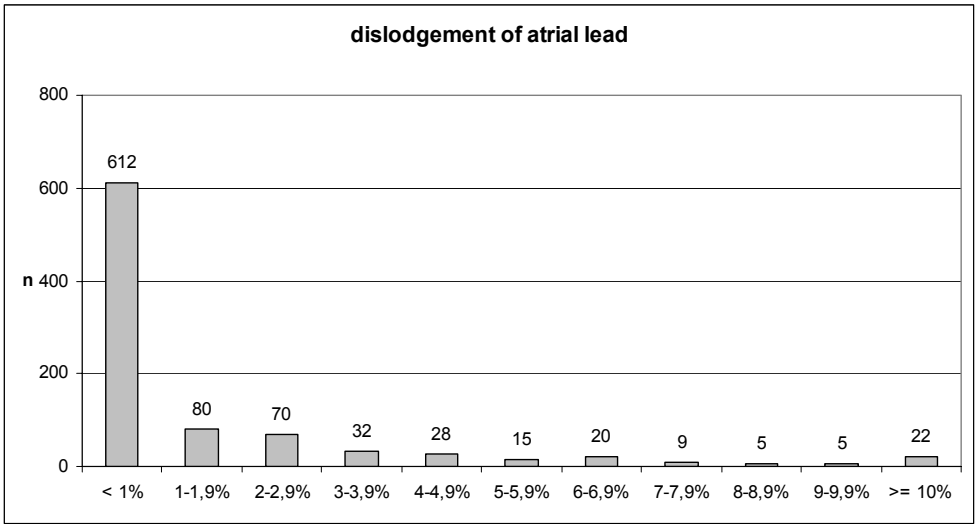

Figure 16: Distribution of rate of dislocations of the atrial lead per hospital following new implantations (to be read as follows: 612 hospitals reported an atrial dislocation in < 1% of their procedures)

As in 2002 (1), the correlation between the rate of complications on one hand and the chosen technique (cephalic vein cut down vs. subclavian puncture) on the other hand was analysed in 2003(see **Table 14**). Statistical differences between these two techniques are solely due to the larger number of pneumothoraces associated with subclavian puncture. This fact highlights the central role of subclavian puncture mishaps among operative complications.

complications 2003	cephalic vein cut down	subclavian vein puncture	p value*
asystole	0.26%	0.31%	0.28
ventricular fibrillation	0.10%	0.11%	0.60
atrial fibrillation	0.60%	0.61%	0.90
pneumothorax	0.17%	0.93%	<0.001
pericardial tamponade	0.10%	0.10%	0.67
pocket hematoma	1.20%	1.31%	0.27
hematothorax	0.04%	0.08%	0.06
lead dislocation	2.25%	2.03%	0.10
wound infection	0.15%	0.14%	0.58
other perioperative complication	0.62%	0.73%	0.14
CPR	0.12%	0.17%	0.22
at least 1 periop. complication	**5.1%**	**5.8%**	**<0.001**

***** = 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).

Since the register report from 2002, we know that fatalities are to be observed following pacemaker implantations.

2003	n	%
death	**626**	**1.21%**
- in relation with the surgical intervention or the responsible bradycardia	43	0.08%
- with PM or lead dysfunction	6	0.01%

Table 15: Fatalities associated with new pacemaker implantations

Table 15 shows that, with regard to the incidence of death, no differences are to be seen in comparison with the previous year (1) As in the past, one would like to have more detailed information regarding these patients. This applies in particular to the 6 patients who demonstrated a dysfunction of some parts of the pacemaker device. We have attempted to obtain more detailed information concerning every individual case of fatalities, but the results are not yet available.

Pulse generator replacements

The demographic data concerning these procedures have already been presented in **Table 5** (see above).

From the 12,484 pulse generator exchange operations, the great majority (n = 12,101, 96.9%) was carried out because of a regular battery depletion, while the remaining 383 cases (3.1%) involved a premature depletion of the battery.

For 8,770 generators, the time interval between implantation and replacement could be determined: According to this, the average lifetime of the pulse generators (mean: 8 years) remained nearly unchanged from that of the previous year (mean: 8.5 years). **Figure 17** reveals the distribution of lifetime.

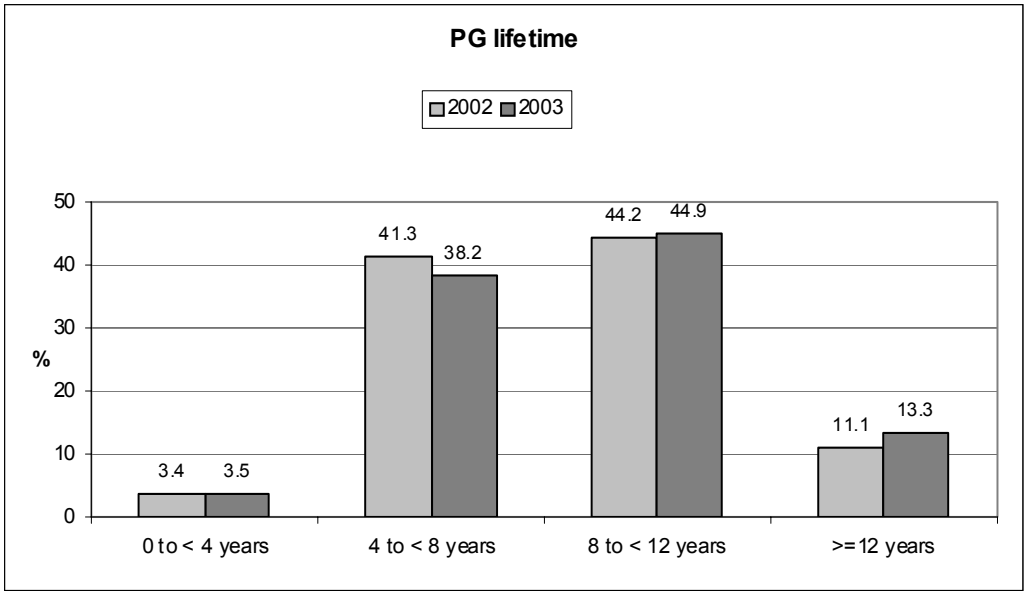

Figure 17: Distribution of the lifetime of the pulse generators (PG)

Unfortunately there were 3,540 cases (28.6%) in which it seemed to be impossible for the documenting surgeon to identify, to record or to report the year of implantation.

On one hand, **Figure 17** shows that more than half of the generators had a lifetime of at least 8 years. This result might be considered as quite satisfactory, especially with regard to the miniaturization of pacemakers which is primarily gained by reducing the size and thereby the capacity of the battery.

On the other hand, the observation derived from **Table 16** is somewhat alarming. It shows that there is a reduction in the mean lifetime in all pacemaker systems compared to 2002, with the exception of the VDD systems. For the most frequently used VVI and DDD

generators, the median lifetime decreased by 1 year. In times at which the resources are considered to be or are actually quite poor, it would be worth discussing whether one could improve this situation by an increased demand for generators with a lifetime of over 10 years with 100% stimulation, an output of 2.5 V / 0.4 msec in both chambers and an impedance in the range of 500 Ω. On the other hand, the price level for cardiac devices in Germany has meanwhile reached such a low point that one must ask, how the companies can satisfy their shareholders.

	n		m (years)		SD (years)		median (years)	
year	**2002**	**2003**	**2002**	**2003**	**2002**	**2003**	**2002**	**2003**
AAI	171	236	9	8.3	3.1	3.9	8	8
VVI	1,768	3,959	9.7	8.6	4.9	3.8	9	8
DDD	1,734	4,240	7.4	6.7	2.6	2.8	7	6
VDD	138	335	6.2	6.4	3.6	3	6	6

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

Not included in the table are the lifetimes of the 33 CRT systems which had been replaced as well as the 79 so called 'other' systems

The lifetimes of the generators in respect to the individual manufacturers are displayed in **Appendix 1, Table 13**.

Reoperations

The demographic data concerning reoperations (redos) have already been presented in **Table 5** (see above). Making up 5.9% of all pacemaker operations, the reoperation rate has increased in comparison with 2002. At that time, reoperations represented 4.1% of all surgical interventions; however, the incomplete data collection in 2002 must be taken into account.

As in the previous year (1), the great majority of the surgical procedures preceding the 4,042 redos had been performed in the same institutions, i.e. those who did the reoperation. (see **Table 17**).

site of the last intervention in 2003	number	%
same institution	2,893	71.6%
other institution	1,149	28.4%
total	**4,042**	**100**

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

The indications for the 4,042 reoperative procedures are presented in **Table 18**. The varying sums observed as compared with **Table 17** are due to the fact that more than one indication could be reported.

indication for reoperation in 2003	number	%
generator problems	1,951	48.3%
lead problems	2,584	63.9%
other	430	10.6%

Table 18: Indications for reoperation (multiple citations were possible)

Once again, it can be seen that problems or complications with the leads and/or generators represent the most frequent cause for a reoperation. This is not really surprising, but it calls for a more detailed investigation of these problems.

Table 19 shows that the regular depletion of the battery continues to be the most frequent cause for revisions involving problems with the generator or with pockets, while a suspected pulse generator dysfunction or the replacement of a generator due to a recall were observed very rarely.

generator problems			
	number	% of all revisions (n = 4,042)	% of the generator problems (n = 1,951)
depletion of battery	1,193	29.5%	61.1%
- premature	98	2.4%	5.0%
- regular	1,095	27.1%	56.1%
PG dysfunction suspected	122	3.0%	6.3%
PG dysfunction with recall	5	0.1%	0.3%
up-, side- downgrading	575	14.2%	29.5%
- between different PM systems	563	13.9%	28.9%
- between PM and ICD	12	0.3%	0.6%
twitching of the pectoralis muscle	48	1.2%	2.5%
pocket hematoma	30	0.7%	1.5%
infection	231	5.7%	11.8%
other problems with the pocket	88	2.2%	4.5%
generator perforation	88	2.2%	4.5%
other indications	219	5.4%	11.2%
at least 1 generator problem	**1,951**	**48.3%**	**100%**

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

More serious complications such as infections or perforations were observed rather seldom in relationship to the over 50,000 new implantations. However, we still do not know exactly, if these figures really reflect the true image of PM-therapy in Germany, since an audit must be carried out in order to ensure that the documented data do indeed reflect reality.

Table 20 reveals the indications for the lead-reoperations. A loss of capture and/or sensing, and dislocations of a lead make up 2/3 of the lead complications. As in the past, we only know that problems with the leads occur after an average of 5.8 years (median: 6 years)

following initial implantation. As mentioned in the previous year, it would be interesting to know at which point of time after the implantation of a lead such problems occur, especially dislocations and the rare infections. In the case of early dislocations within the first 3-6 months, as well as in infections occurring within the first year, more intensive considerations about the performance of the preceding procedure might be appropriate. All other complications involving the leads are based upon problems with a multifactorial genesis and might probably only be improved in a few individual cases.

lead problems			
	number	**% of all revisions (4,042)**	**% of the problems with leads (2,584)**
site of the problem			
atrium	615	15.2%	23.8%
ventricle	1,232	30.5%	47.7%
both	330	8.2%	12.8%
dislocation	772	19.1%	29.9%
lead fracture	230	5.7%	8.9%
insulation breakdown	200	4.9%	7.7%
defective connector	58	1.4%	2.2%
diaphragmatic stimulation	65	1.6%	2.5%
oversensing	37	0.9%	1.4%
loss of sensing	350	8.7%	13.5%
loss of capture	983	24.3%	38.0%
infection	183	4.5%	7.1%
perforation	77	1.9%	3.0%
other	243	1.9%	9.4%
at least 1 lead problem	**2,584**	**63.9%**	**100%**

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

Problems with ventricular leads occur twice as often as those involving atrial leads. This fact, together with the respective data of **Table 13**, indicates that the common belief that atrial leads cause more problems than ventricular leads is only true for the perioperative phase, but is not for the long-term outcome.

From a surgical viewpoint, it is rather interesting to see what kind of reoperation was performed to fix the problem (see **Appendix 1, Table 14** and **Figure 18**).

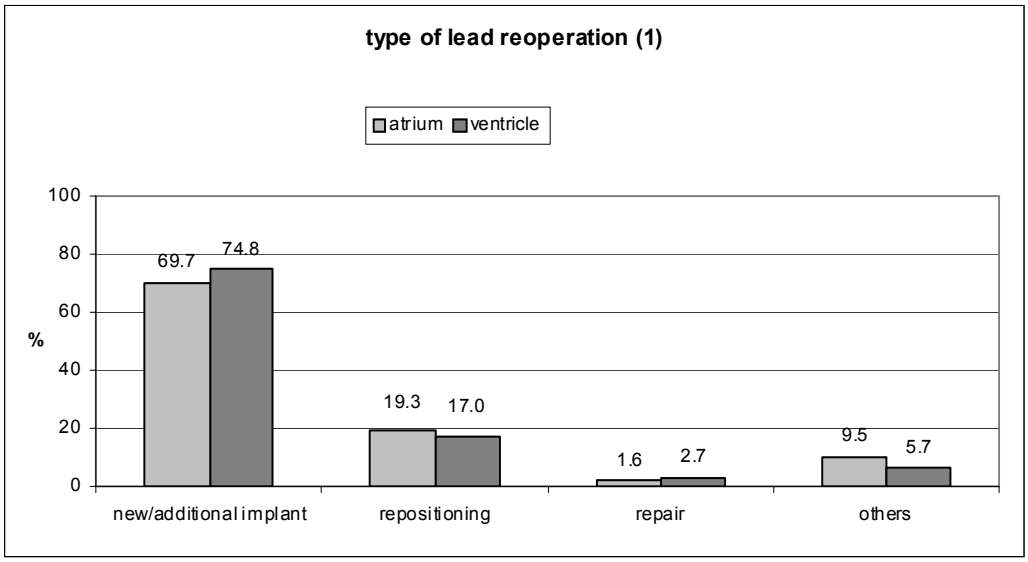

Figure 18: Surgical procedures for the revision of a lead

Another important surgical question - what happens with the dysfunctional leads - is answered in **Appendix 1, Table 15** and **Figure 19**.

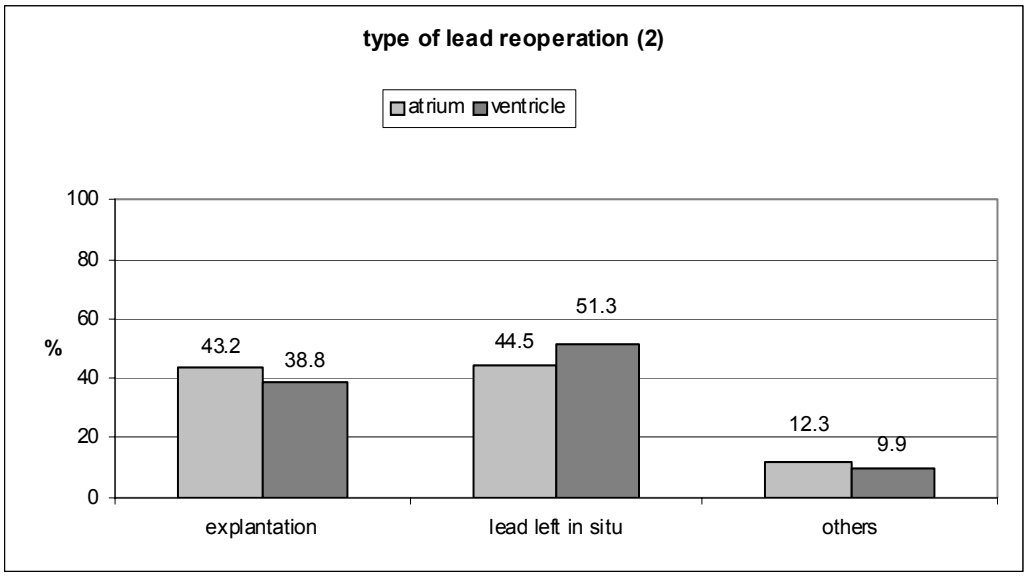

Figure 19: Surgical procedures in dysfunctional leads (in relation to all postoperative, functionally inactive leads (initial lead) for which the type of procedure has been documented)

Even more than in 2002, most surgeons clearly preferred a risk-free abandoning of the lead while leaving it *in situ*: This procedure is justified in all situations where there is no clear-cut indication for lead explantation (5). However, knowing the indications for explantation of leads, which has meanwhile become somewhat rarer, would be interesting, but such data is unfortunately not available.

Complications associated with PG relacements and reoperations

As expected, PG exchange operation is only associated with a few complications, whereas the rate of complications in reoperative surgery is related to new implantations (see **Table 21** and, in comparison, **Table 13**).

	replacements		**reoperations**	
	n	% *	n	% **
asystole	59	0.5%	20	0.5%
ventricular fibrillation	8	0.06%	7	0.2%
atrial fibrillation	37	0.3%	36	0.9%
pneumothorax			26	0.6%
pneumothorax: drainage required			16	0.4%
pericardial tamponade			10	0.3%
pocket hematoma	104	0.8%	50	1.2%
hematothorax			5	0.1%
lead dislocation			72	1.8%
- atrium			37	0.9%
- ventricle			34	0.8%
wound infection	18	0.1%	21	0.5%
- wound infection: Revision required			15	0.4%
other	98	0.8%	39	1.0%
CPR required	10	0.08%	9	0.2%
at least 1 operative complication	**301**	**2.4%**	**257**	**6.4%**

*= related to PG replacements, ** = related to all reoperations

Table 21:Complications associated with replacements and reoperations

The incidence of pocket hematomas associated with replacements and reoperations is high with the limitations cited above for first implantations being valid again. The rate of lead dislocations following reoperations has remained at the level already seen in 2002 (1).

Fatalities as a result of replacements or reoperative procedures occurred in nearly the identical, relative frequency as in 2002 (1) (see **Table 22**).

	replacements		reoperations	
2003	**n**	**%**	**n**	**%**
death	45	0.36%	26	0.64%
- in relation with the surgical intervention or the responsible bradycardia	1	0.01%	4	0.10%
- with PM or lead dysfunction	0	0	0	0

Table 22: Fatalities in relationship to replacements and reoperations

Comment

The 2003 report of the German Pacemaker Register is based upon an impressing number of reports from more than 68,000 PM-operations. The observation that nearly no changes are seen in the relative frequencies is encouraging, so that the previous reports starting in 1982 can also be estimated as being representative

One specific number may confuse people from outside the medical community, the rate of new implantations of 629 per 1 million citizens which appears to be rather high.

For detailed analysis, once again a comparison with other European registries may seem sound. To the best of our knowledge, there are 3 European registries which have recorded data of more than 95% of all PM implantations and replacements and publish these results either in German or in English: the pacemaker registries from Denmark (6), Switzerland (7), and Sweden (8). The report in 2003 of the respective pacemaker registries presents the basis for the following discussion (9,10,11).

Data basis

Table 23 shows that the number of institutions in which PM surgery is performed is known in Denmark, in Switzerland and in Sweden and that (nearly) all of the institutions take part in a national register. The number of implantations and replacements reported is substantially smaller because of the smaller population in these countries. For the purpose of more easily comparing the data, pulse generator replacements as well as other reoperations in Germany were summarized in the table as reoperations, since these two types of intervention were summarized in Denmark and Switzerland as well. The Swedish register has not yet provided information about reoperations.

	Denmark	Switzerland	Sweden	Germany
reporting institutions	14	63	44	898
implanting institutions	14	64	44	?
new implantations	2,582	3,238	4,989	51,904
- mean per institution	184.4	50.6	113.4	57.8
- new implantations/one million inhabitants	503	439	555	629
reoperations	705	1,001	not indicated	16,526
relationship of first implantations to reoperations	3.66	3.23	not indicated	3.14
total	**3,287**	**4,239**	**4,989**	**68,430**

Table 23: Data basis in comparison

There are more new implantations carried out per institution in the two Scandinavian countries than in Switzerland or Germany. As a consequence, the two countries cited first

can serve as a model for high-volume PM surgery, whereas the latter countries may represent low-volume PM surgery.

In Denmark, Sweden and Switzerland the number of PM per million inhabitants is substantially smaller than in Germany, as is to be seen in **Figure 20**. The question is: why ?

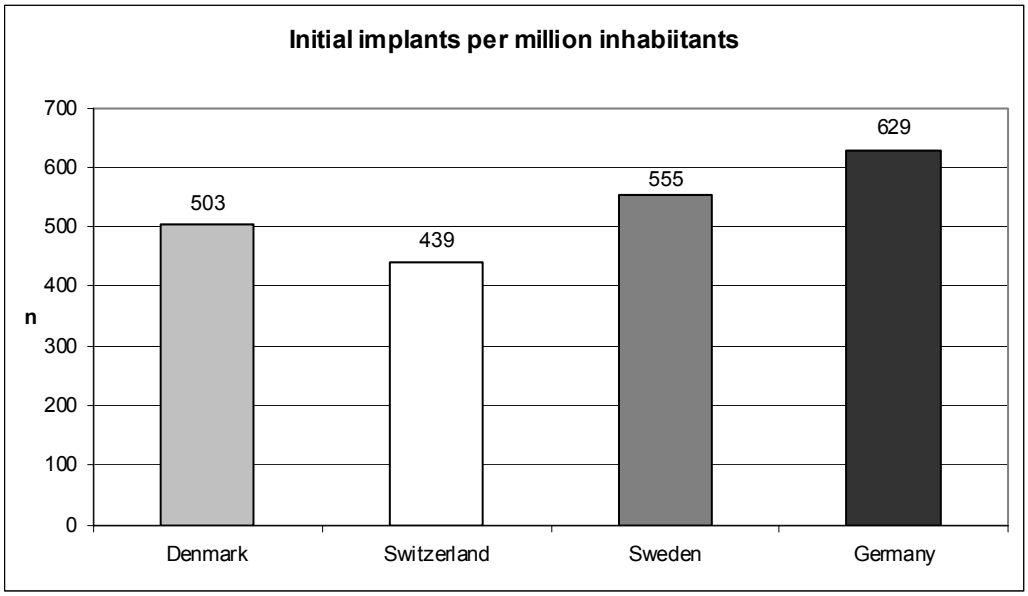

Figure 20: New implantations per 1 million inhabitants, in comparison

There are a number of possible answers to this question:

1. There may be less money available for the health-care system.
2. The patients in Germany are substantially older than those in the other countries, so that the increased rate of implantations can be explained biologically.
3. The Germans do not follow the guidelines and implant too many pacemakers.
4. A combination of the answers is true.
5. No satisfactory answer can be given on the basis of the available data.

Let us take a detailed look at each of the possible answers.

1.: The amount of money available is higher in the health-care system of Switzerland and lower in Denmark and Sweden as compared to Germany (12). The differences, however, are rather small. So, a lack of money cannot be considered to be the cause for a lower implantation-rate in the Scandinavian countries. In addition, the country with the highest relative expenditure, Switzerland, demonstrates the lowest rate of implantation of all 4 countries.

2.: The proportion of patients in the respective countries who are 80-years-old and over is presented graphically in **Figure 21.**

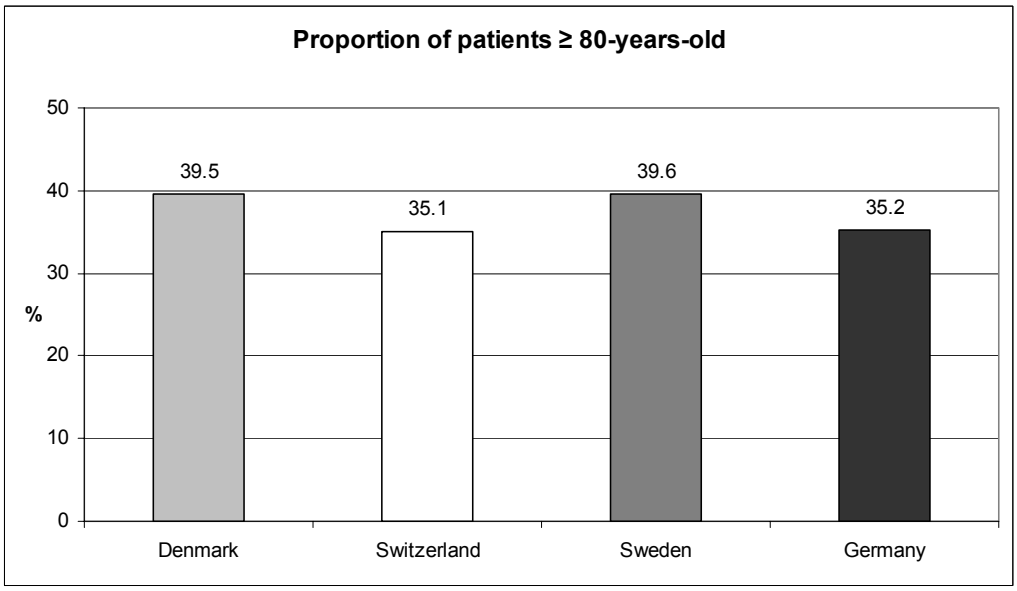

Figure 21: Proportion of patients ≥ 80-years-old of the entire patient population in whom a pacemaker had been implanted, in comparison

It is obvious that this answer is also invalid. One may understand why fewer pacemakers were implanted in Switzerland, but not why such a high number had been performed in our country.

3.: The question, whether current guidelines are followed in Germany, is portrayed in **Figure 22**.

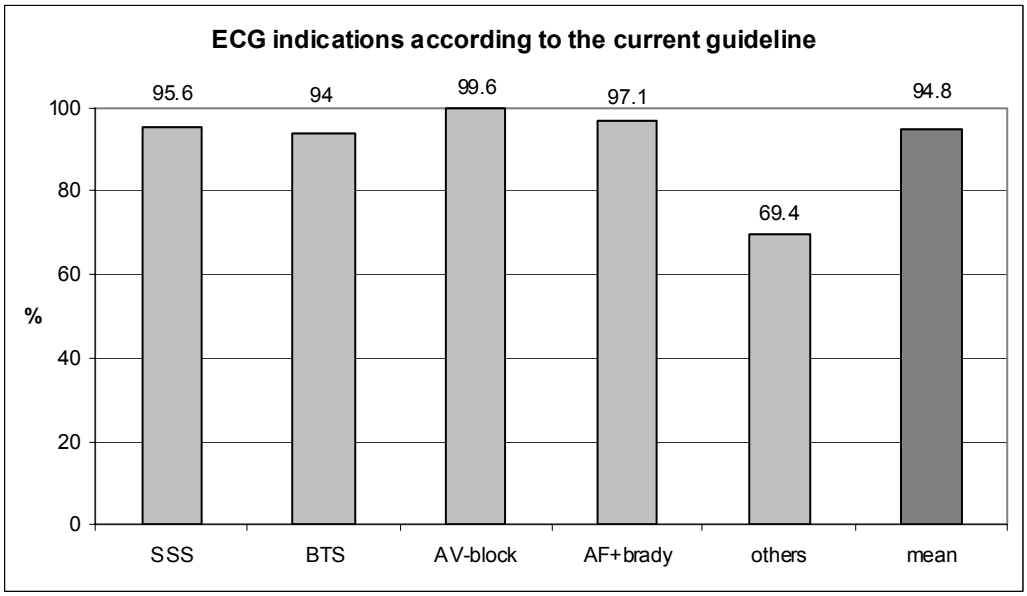

Figure 22: ECG indications according to the current national guideline in Germany 2003 (SSS=sick-sinus syndrome, BTS=bradycardia-tachycardia syndrome, AF+brady=atrial fibrillation with bradycardia, Other = carotid sinus syndrome, vasovagal syndrome, bundle branch block, binodal disease)

The results are self-explaining; rates of more than 90% of indications following the existing national guideline can be considered an excellent result.
Since none of the possible answers is seen to be valid so far, answer 4 must also be considered invalid and we must, in conformity with possibility 5, admit to being unable to answer the question, why the implantation rate in Germany is higher than in other countries.

As in the previous years, we would like to briefly present and compare some of the essential points like the indications for pacemaker therapy, the selection of pacing mode, some surgical data and the perioperative complications.

ECG indications for cardiac pacemaker therapy

Figure 23 points out that there are only marginal differences comparing the ECG indications in the different countries. The most frequent indication is the type II and III AV block in all countries, followed by the sick-sinus syndrome, even if one now considers the bradycardia-tachycardia syndrome to be a type of sick-sinus syndrome and no longer as a separate entity (as has been done by the German Cardiac Society (DGK) in the latest guidelines by the Working Group for Cardiac Pacing, for instance).

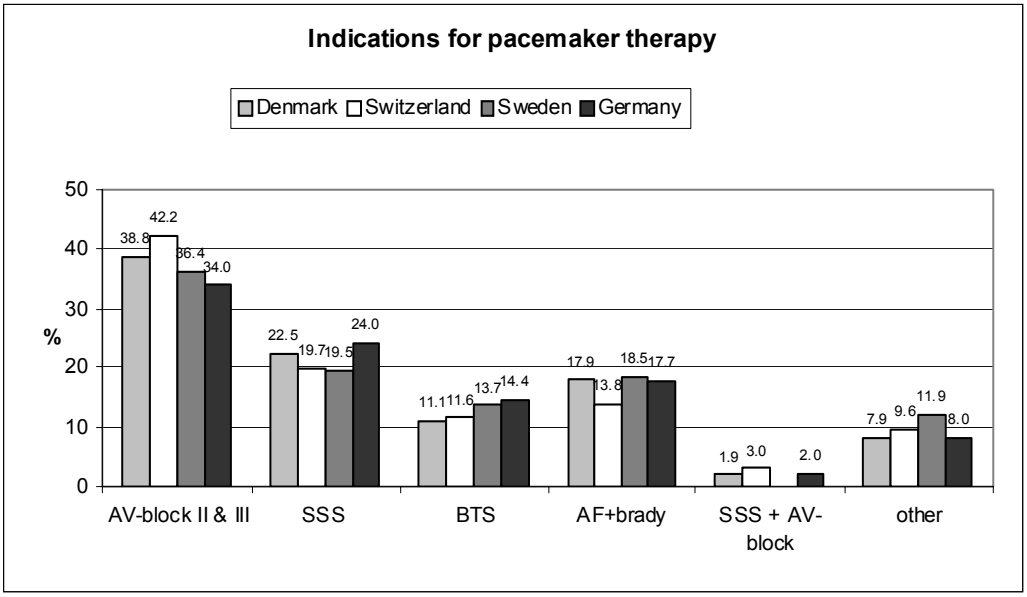

Figure 23: ECG indications in comparison

In addition to **Figure 23** absolute and relative values are presented once again in **Appendix 2, Table 1**.

Selection of pacing mode

Figure 24 shows that the proportion of "non-physiological" VVI systems in the Scandinavian countries is more than 10% lower than in Switzerland and Germany, in spite of nearly identical ECG indications. The absolute figures are to be found in **Appendix 2, Table 2**. Whether this reflects an overuse of VVI-mode in the German-speaking countries or whether the Scandinavians made too frequent use of implanting atrial or dual chamber PM systems, the reader will have to decide for him/herself. Data, which permit more than a speculation, however, are not available.

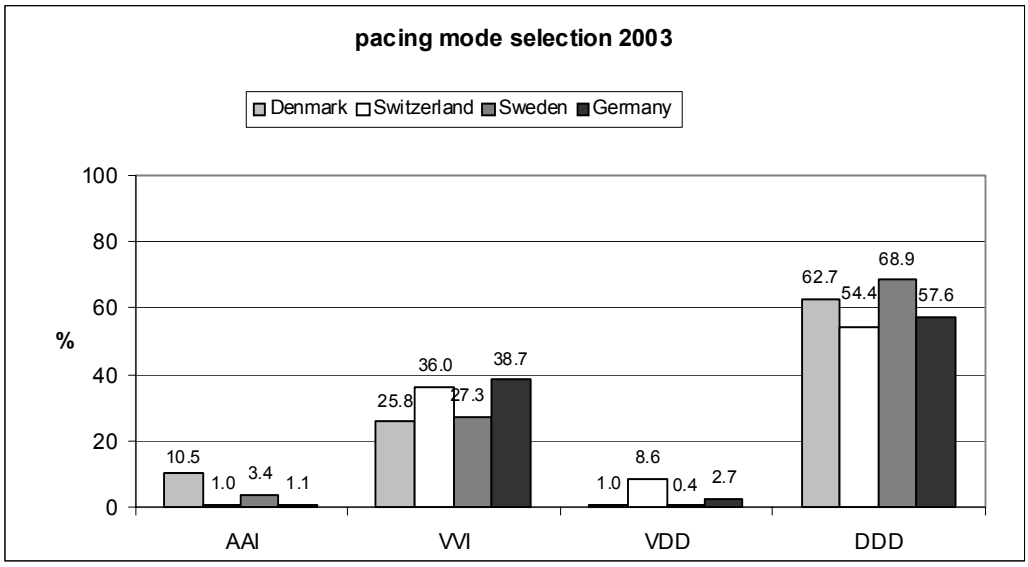

Figure 24: selection of pacing mode in comparison

Figure 25 and **Figure 26** underline what has been stated above. In addition, the great preference of the Danish collegues for AAI devices is obvious, an attitude which is clearly not shared by their Swedish neighbours to the same extent (see **Figure 24**).

The observation made by the Swedish registry that the number of VVI systems implanted is inversely proportional to the number of new implantations in the individual centers awaits confirmation by others but may fuel the discussion about volume and outcome.

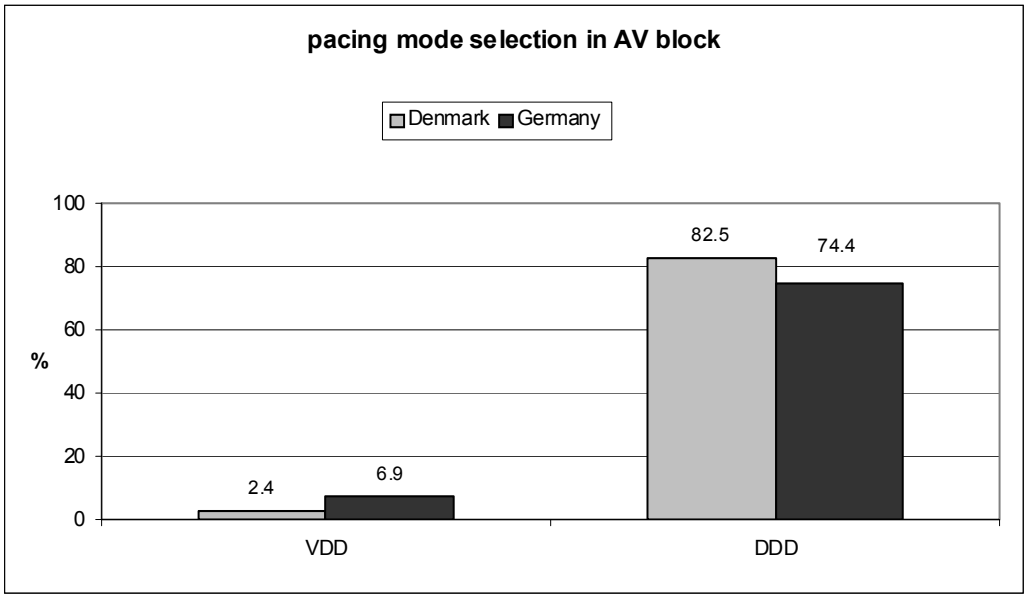

Figure 25: Selection of pacing mode for AV block, in comparison

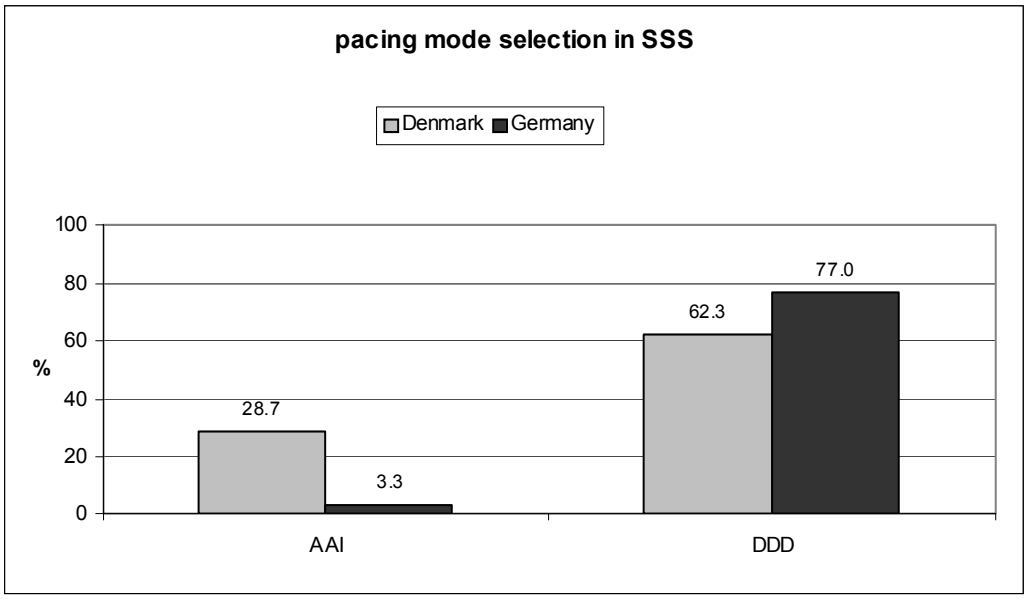

Figure 26: Selection of pacing mode for sick-sinus syndrome (SSS), in comparison

Surgical data

The results of comparing surgical data between Germany, Denmark and Switzerland are the same as in 2002. This is true for the venous access, the implantation site (see **Table 24**), the duration of surgery for the various PM systems (see **Figure 27**) and for the characteristics of atrial and ventricular leads (see **Figure 28** and **Figure 29**).

	Denmark	Switzerland	Germany
cephalic vein	50.7	30.0	51.1
subclavian vein	47.6	58.5	53.4
other	1.8	11.5	2.0
left	not indicated	20.2	27.0
right	not indicated	69.3	73.0
other (not indicated, sternotomy, etc.)	not indicated	10.5	not indicated

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

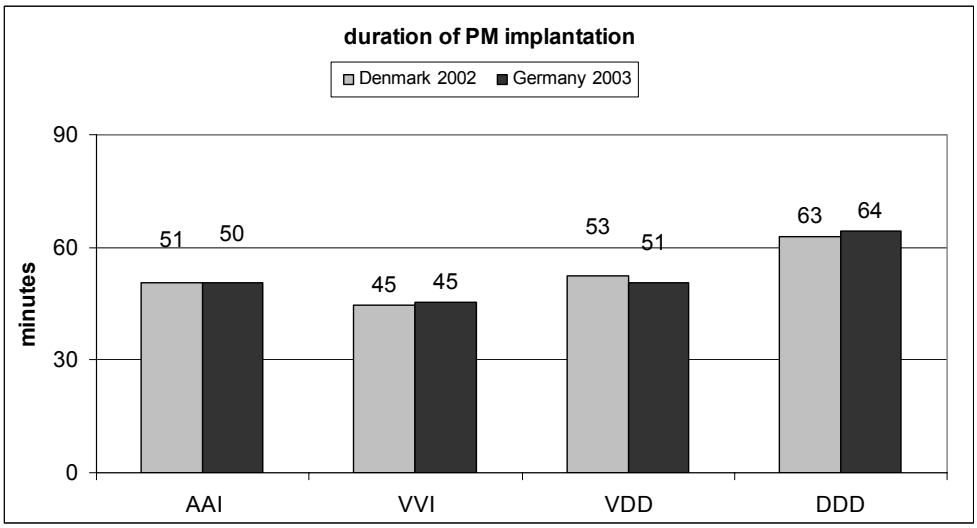

Figure 27: Comparison of the duration of PM implantation with regard to the pacing mode

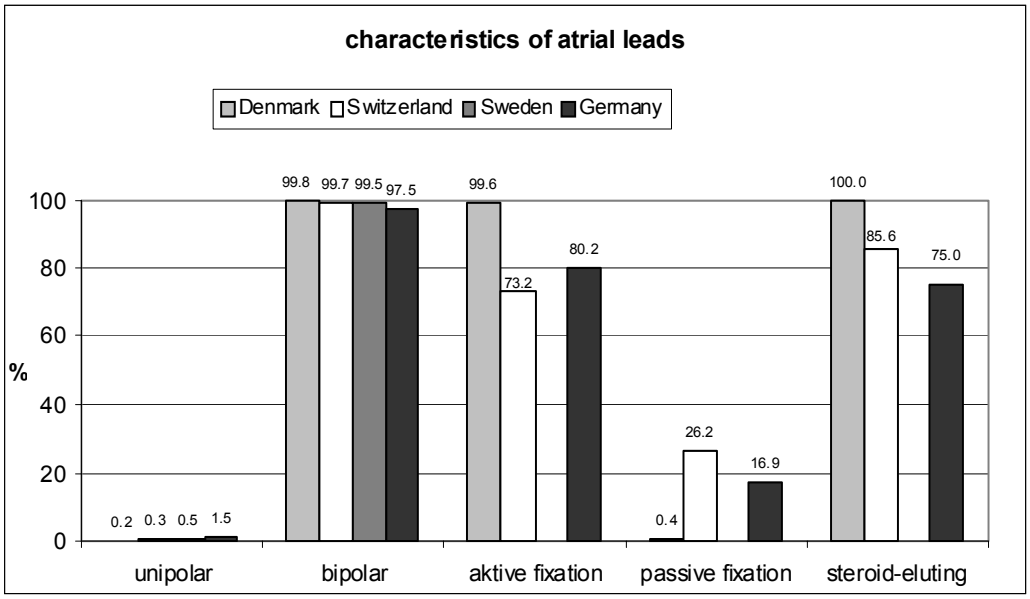

Figure 28: Comparison of the characteristics of atrial leads

Once again, the homogeneity of the types of leads used in Denmark has to be emphasized. Everything else about the advantages and disadvantages of the different types of leads has already been extensively discussed.

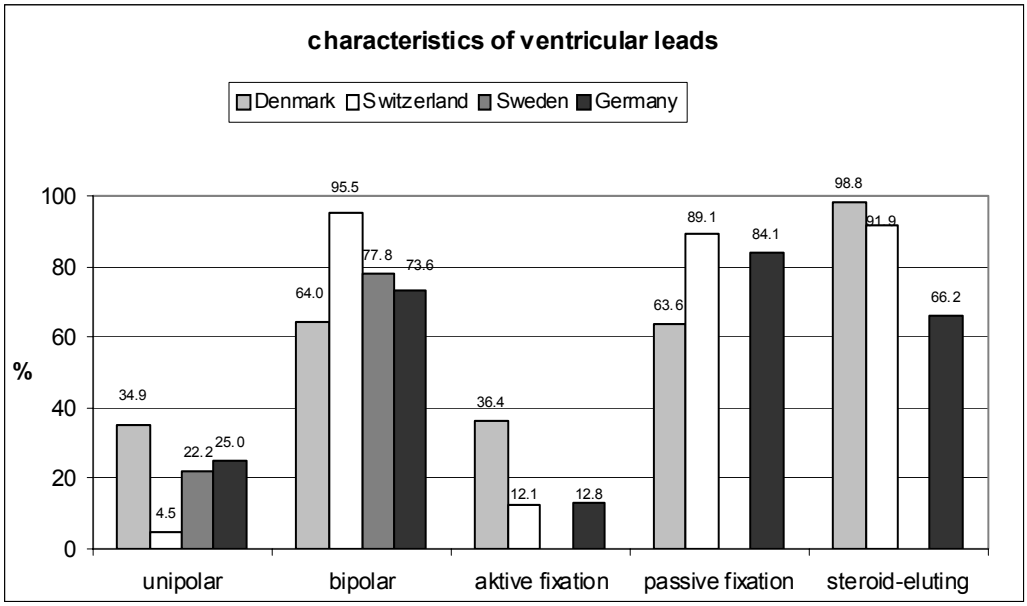

Figure 29: Comparison of the characteristics of the ventricular leads

Complications with new implantations

Only few changes have occurred in 2003 (see **Figure 30**). The possible reasons for the high incidence of pocket hematomas seen in Germany have already been discussed in detail above.

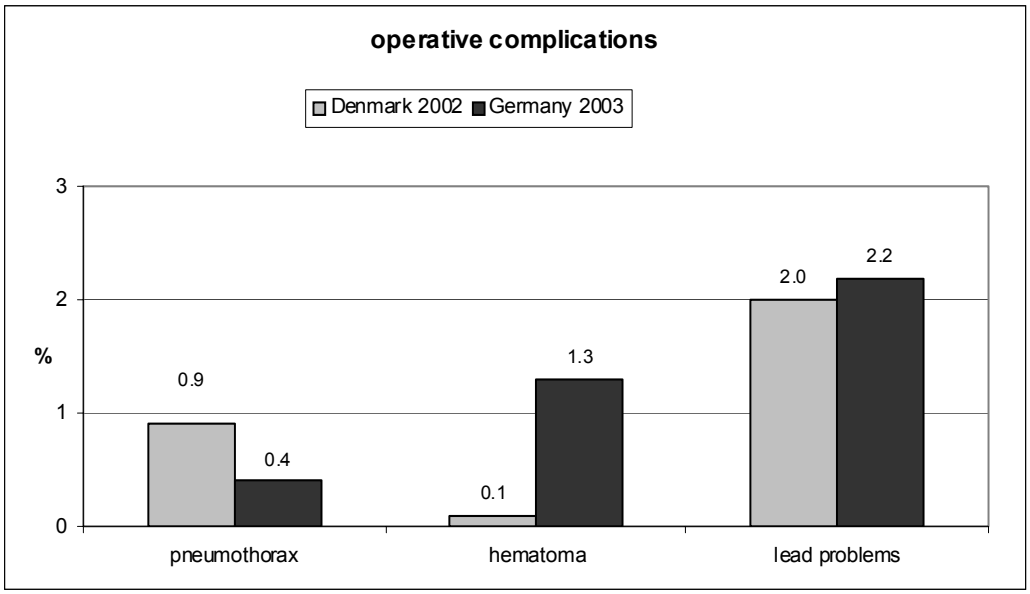

Figure 30: Occurrence of specific operative complications associated with new implantations, in comparison. For the pneumothoraces, only those requiring chest tube insertion have been included

The low rate of pneumothoraces and problems associated with leads continues to be very encouraging, especially considering the fact that Danish institutions have a substantially higher volume of operations as compared to those in Germany and that a higher volume is said to be associated with a better outcome and quality of the procedures.

Summary and outlook

The report from the German Pacemaker Register for the year 2003 demonstrates three peculiarities:

1. It is published too late due to the high workflow of the institutions and individuals involved in completing this report. Hopefully, we can improve this.
2. It is based on the largest amount of PM data records which has ever been published. There was a remarkable accordance to the German PM reports published in the previous years, which included only about half of the PM operations. ,
3. It demonstrates that Germany has one of the world's highest rate of implantations. In the synopsis of the available data, this fact reflects the high quality of PM-therapy in our country.

In 2006, the items of the data set will be optimised. It remains to be hoped for that these changes will help to improve the quality of the information in the reports.

As a final point: many thanks to those who have returned their reports. The author of this report knows, from his own experience, how much time is required today for non-medical activities. This report may hopefully make somewhat more sense of the these activities.

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10. http://www.pacemaker.ch/de/statistik/statistik_2003.asp

11. http://www.pacemakerregistret.se/icdpmr/annualReport/2003/annualReport_2003_v1_0.pdf

12. http://www.oecd.org/dataoecd/13/13/31963469.xls

Appendix 1: Detailed tables for Germany

Volume of surgery in 2003		
new implantations	**no. of institutions**	**%**
n <20	192	21.4
n = 20-49	334	37.2
n = 50-99	225	25.1
n > 100	147	16.4
total	**898**	**100**
pulse generator replacements	**no. of institutions**	**%**
n <20	596	75.3
n = 20-49	153	19.3
n = 50-99	38	4.8
n > 100	5	0.6
total	**792**	**100**
reoperations	**no. of institutions**	**%**
n <20	561	93.3
n = 20-49	32	5.3
= 50-99	6	1.0
n > 100	2	0.3
total	**601**	**100**

Appendix 1, Table 1: Volume of pacemaker surgery in Germany in 2003

age (years)	2001		2002		2003	
	n	**%**	**n**	**%**	**n**	**%**
0-9 -	78	0.3	10	0.04	86	0.2
10-19	59	0.2	18	0.1	74	0.1
20-29	62	0.2	67	0.2	119	0.2
30-39	137	0.5	131	0.5	287	0.6
40-49	347	1.4	362	1.3	702	1.4
50-59	973	3.9	1,244	4.3	2,118	4.1
60-69	4,125	16.4	5,379	18.7	9,745	18.8
70-79	10,196	40.6	11,466	39.9	20,600	39.7
80-89	7,737	30.8	8,696	30.3	15,714	30.3
≥ 90	1,370	5.5	1,357	4.7	2,449	4.7
total	**25,084**	**100**	**28,730**	**100**	**51,894**	**100**

Appendix 1, Table 2: Age distribution of the patients with new implantations in Germany for 2001, 2002 and 2003 (only those cases with valid age data)

ECG indications	2002		2003	
	n	%	n	%
rhythm uncoded	178	0.6	524	1.0
AV-block I	165	0.6	314	0.6
AV-block II,1	500	1.7	877	1.7
AV-block II,2	2,796	9.7	4,930	9.5
AV-block III	6,219	21.6	11,836	22.8
BBB	335	1.2	591	1.1
SSS	6,894	24	12,447	24.0
BTS	4,243	14.8	7,451	14.4
AF + brady	5,309	18.5	9,175	17.7
CSS	657	2.3	1,149	2.2
VVS	73	0.3	110	21.0
SSS + AV block	628	2.2	1,060	2.0
other	766	2.7	1,440	2.8
total	**28,763**	**100**	**51,904**	**100**

Appendix 1, Table 3: ECG indications for pacemaker implantations in 2002/2003 (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	171	125	166	78	2	35	156	**733**
AV-block I	130	104	121	83	2	24	45	**509**
AV-block II,1	293	458	304	261	6	53	89	**1,464**
AV-block II,2	1,732	2,739	1,630	1,488	18	259	306	**8,172**
AV-block III	5,702	5,098	4,379	4,110	171	345	1,040	**20,845**
BBB	321	192	291	132	2	34	42	**1,014**
SSS	5,149	6,886	3,774	3,177	55	410	937	**20,388**
BTS	2,446	4,190	2,946	2,299	111	360	653	**13,005**
AF + brady	2,753	4,888	3,590	4,642	28	277	572	**16,750**
CSS	910	396	300	178	0	12	54	**1,850**
VVS	93	42	16	8	1	5	9	**174**
SSS + AV block	399	622	403	319	5	39	100	**1,887**
other	499	494	582	311	45	73	313	**2,317**
total	**20,598**	**26,234**	**18,502**	**17,086**	**446**	**1,926**	**4,316**	**89,108**
column percentages (%)	syncope	presyncope	CHF	CHF due to bradycardia	ablation	prophylactic indications	other	**total**
rhythm uncoded	0.8	0.5	0.9	0.5	0.4	1.8	3.6	**0.8**
AV-block I	0.6	0.5	0.7	0.5	0.4	1.2	1.0	**0.6**
AV-block II,1	1.4	1.7	1.6	1.5	1.3	2.8	2.1	**1.6**
AV-block II,2	8.4	10.4	8.8	8.7	4.0	13.4	7.1	**9.2**
AV-block III	27.7	19.4	23.7	24.1	38.3	17.9	24.1	**23.4**
BBB	1.6	0.7	1.6	0.8	0.4	1.8	1.0	**1.1**
SSS	25.0	26.2	20.4	18.6	12.3	21.3	21.7	**22.9**
BTS	11.9	16.0	15.9	13.5	24.9	18.7	15.1	**14.6**
AF + brady	13.4	18.6	19.4	27.2	6.3	14.4	13.3	**18.8**
CSS	4.4	1.5	1.6	1.0	0.0	0.6	1.3	**2.1**
VVS	0.5	0.2	0.1	0.0	0.2	0.3	0.2	**0.2**
SSS + AV block	1.9	2.4	2.2	1.9	1.1	2.0	2.3	**2.1**
other	2.4	1.9	3.1	1.8	10.1	3.8	7.3	**2.6**
total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
line percentages (%)	syncope	presyncope	CHF	CHF due to bradycardia	ablation	prophylactic indications	other	
rhythm uncoded	32.6	23.9	31.7	14.9	0.4	6.7	29.8	
AV-block I	41.4	33.1	38.5	26.4	0.6	7.6	14.3	
AV-block II,1	33.4	52.2	34.7	29.8	0.7	6.0	10.1	
AV-block II,2	35.1	55.6	33.1	30.2	0.4	5.3	6.2	
AV-block III	48.2	43.1	37.0	34.7	1.4	2.9	8.8	
BBB	54.3	32.5	49.2	22.3	0.3	5.8	7.1	
SSS	41.4	55.3	30.3	25.5	0.4	3.3	7.5	
BTS	32.8	56.2	39.5	30.9	1.5	4.8	8.8	
AF + brady	30.0	53.3	39.1	50.6	0.3	3.0	6.2	
CSS	79.2	34.5	26.1	15.5	0.0	1.0	4.7	
VVS	84.5	38.2	14.5	7.3	0.9	4.5	8.2	
SSS + AV block	37.6	58.7	38.0	30.1	0.5	3.7	9.4	
other	34.7	34.3	40.4	21.6	3.1	5.1	21.7	

Appendix 1, Table 4: Symptoms (multiple citations possible) and ECG indications for new implants performed in Germany in 2003 (CHF = congestive heart failure)

indications according to current national guidelines in %	2002	2003
SSS	95.5	95.6
BTS	93.4	94.0
AV block	97.7	99.6
AF+bradycardia	97.1	97.1
other	84.1	69.4
average	**96.3**	**94.8**

Appendix 1, 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	3,161	1,209	13,123	50	93	17,643
SSS	410	2,342	54	9,581	17	43	12,447
BTS	66	4,099	41	3,205	15	25	7,451
SSS + AV block	0	129	10	888	14	19	1,060
AF + bradycardia	14	8,635	9	473	20	24	9,175
other	50	1,411	55	2,190	312	110	4,128
total	547	19,777	1,378	29,460	428	314	51,904
%	**AAI**	**VVI**	**VDD**	**DDD**	**CRT**	**other**	
AV block II&III	1.3%	16.0%	87.7%	44.5%	11.7%	29.6%	34.0%
SSS	75.0%	11.8%	3.9%	32.5%	4.0%	13.7%	24.0%
BTS	12.1%	20.7%	3.0%	10.9%	3.5%	8.0%	14.4%
SSS + AV block	0.0%	0.7%	0.7%	3.0%	3.3%	6.1%	2.0%
AF + bradycardia	2.6%	43.7%	0.7%	1.6%	4.7%	7.6%	17.7%
other	9.1%	7.1%	4.0%	7.4%	72.9%	35.0%	8.0%
total	100%	100%	100%	100%	100%	100%	100%

Appendix 1, 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	410	66	0	14	50	547
VVI	3,161	2,342	4,099	129	8,635	1,411	19,777
VDD	1,209	54	41	10	9	55	1,378
DDD	13,123	9,581	3,205	888	473	2,190	29,460
CRT	50	17	15	14	20	312	428
other	93	43	25	19	24	110	314
total	17,643	12,447	7,451	1,060	9,175	4,128	51,904
%	**AV block II&III**	**SSS**	**BTS**	**SSS + AV block**	**AF + bradycardia**	**other**	**total**
AAI	0.0%	3.3%	0.9%	0.0%	0.2%	1.2%	1.1%
VVI	17.9%	18.8%	55.0%	12.2%	94.1%	34.2%	38.1%
VDD	6.9%	0.4%	0.6%	0.9%	0.1%	1.3%	2.7%
DDD	74.4%	77.0%	43.0%	83.8%	5.2%	53.1%	56.8%
CRT	0.3%	0.1%	0.2%	1.3%	0.2%	7.6%	0.8%
other	0.5%	0.3%	0.3%	1.8%	0.3%	2.7%	0.6%
total	100%	100%	100%	100%	100%	100%	100%

Appendix 1, Table 7: Distribution of pacing modes for initial implants in Germany in 2003 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			
	2001	2002	2003
AAI	0.3	< 0.1	0.0
VVI	19.1	16.8	17.9
VDD	8.8	9.2	6.9
DDD	71.7	73.1	74.4
SSS			
	2001	2002	2003
AAI	3.2	3.6	3.3
VVI	25.0	19.1	18.8
VDD	0.3	0.9	0.4
DDD	71.5	75.8	77.0
BTS			
	2001	2002	2003
AAI	1.1	0.8	0.9
VVI	37.0	49.9	55.0
VDD	0.3	0.8	0.6
DDD	61.6	47.5	43.0
SSS + AV block			
	2001	2002	2003
AAI	0.0	0.2	0.0
VVI	17.9	15.3	12.2
VDD	0.6	1.0	0.9
DDD	81.4	80.6	83.8
AF + bradycardia			
	2001	2002	2003
AAI	0.7	0.1	0.2
VVI	90.4	95.2	94.1
VDD	0.4	0.2	0.1
DDD	8.5	4.0	5.2
other			
	2001	2002	2003
AAI	1.2	0.7	1.2
VVI	39.6	36.2	34.2
VDD	1.7	2.2	1.3
DDD	57.4	51.7	53.1
total			
	2001	2002	2003
AAI	1.3	1.0	1.1
VVI	39.6	38.2	38.1
VDD	3.2	3.6	2.7
DDD	56.0	55.8	56.8

Appendix 1, Table 8: Percentual distribution of stimulation mode for initial implants in Germany in 2003 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%	835	19	727	51	883
5 to < 10%	42	2	75	8	11
10 to < 20%	16	60	58	34	3
20 to < 30%	4	151	21	52	1
30 to < 40%	0	203	11	86	0
40 to < 50%	0	163	3	110	0
50 to < 60%	0	130	1	201	0
60 to < 70%	0	76	1	187	0
70 to < 80%	0	29	0	120	0
80 to < 90%	0	20	0	34	0
≥ 90%	1	45	1	15	0
total	**898**	**898**	**898**	**898**	**898**
percent (%)	**AAI**	**VVI**	**VDD**	**DDD**	**CRT**
0 to < 5%	93.0%	2.1%	81.0%	5.7%	98.3%
5 to < 10%	4.7%	0.2%	8.4%	0.9%	1.2%
10 to < 20%	1.8%	6.7%	6.5%	3.8%	0.3%
20 to < 30%	0.4%	16.8%	2.3%	5.8%	0.1%
30 to < 40%	0.0%	22.6%	1.2%	9.6%	0.0%
40 to < 50%	0.0%	18.2%	0.3%	12.2%	0.0%
50 to < 60%	0.0%	14.5%	0.1%	22.4%	0.0%
60 to < 70%	0.0%	8.5%	0.1%	20.8%	0.0%
70 to < 80%	0.0%	3.2%	0.0%	13.4%	0.0%
80 to < 90%	0.0%	2.2%	0.0%	3.8%	0.0%
≥ 90%	0.1%	5.0%	0.1%	1.7%	0.0%
total	**100%**	**100%**	**100%**	**100%**	**100%**

Appendix 1, 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)

	2002		2003	
manufacturer	**n**	**%**	**n**	**%**
Biotronik	8,626	30	14,548	28
CCS	-	-	2	< 0.1
Cook	12	< 0.1	13	< 0.1
CPI/Guidant	2,111	7.3	4,170	8,0
ELA Medical	876	3	1,249	2.4
Implantronik	32	0.1	232	0.4
Intermedics/Guidant	3	< 0.1	6	< 0.1
Medtronic	8,978	31.2	15,769	30.4
Osypka	14	< 0.1	19	< 0.1
Pacesetter/St. Jude Medical	3,685	12.8	5,483	10.6
Siemens/St. Jude Medical	88	0.3	606	1.2
Sorin Biomedica	776	2.7	1,106	2.1
Stöckert	29	0.1	20	< 0.1
St. Jude Medical	-	-	2,115	4.1
Teletronics/St. Jude Medical	2	< 0.1	44	0.1
Vitatron	2,813	9.8	6,001	11.6
other	718	2.5	521	1,0
total	**28,763**	**100**	**51,904**	**100**

Appendix 1, Table 10: Distribution of the manufacturers of cardiac pacemakers in first implantations in Germany during the year 2003. 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 got used to these names during the years.

	AAI		VVI		DDD		VDD		CRT		not classifiable	
duration of operation	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
< 30 min	18	9.0%	47	5.3%	6	0.7%	14	5.1%	0	0.0%	4	6.5%
30- 59 min	112	56.3%	658	74.8%	248	29.2%	180	65.2%	3	3.5%	21	33.9%
60-89 min	54	27.1%	145	16.5%	444	52.2%	67	24.3%	14	16.3%	19	30.6%
90-119 min	8	4.0%	11	1.3%	105	12.4%	9	3.3%	13	15.1%	7	11.3%
>119 min	6	3.0%	1	0.1%	21	2.5%	4	1.4%	56	65.1%	11	17.7%
not available*	1	0.5%	18	2.0%	26	3.1%	2	0.7%	0	0.0%	0	0.0%
total	**199**	**100%**	**880**	**100%**	**850**	**100%**	**276**	**100%**	**86**	**100%**	**62**	**100%**
duration of fluoroscopy	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
< 30 min	123	61,8%	519	59.0%	159	18.7%	175	63.4%	4	4.7%	23	37.1%
30- 59 min	48	24,1%	286	32.5%	447	52.6%	74	26.8%	7	8.1%	15	24.2%
60-89 min	14	7,0%	34	3.9%	162	19.1%	14	5.1%	8	9.3%	6	9.7%
90-119 min	6	3,0%	18	2.0%	44	5.2%	8	2.9%	8	9.3%	4	6.5%
>119 min	8	4,0%	23	2.6%	38	4.5%	5	1.8%	59	68.6%	14	22.6%
not available*	0	0,0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
total	**199**	**100%**	**880**	**100%**	**850**	**100%**	**276**	**100%**	**86**	**100%**	**62**	**100%**

Appendix 1 Table 11: Distribution of the mean duration of surgery and of the fluoroscopy during initial implants in the institutions reporting (* = none or invalid information).

	at least 1 complication		pneumo-thorax		pocket hematoma		dislocation of atrial lead		dislocation of ventricular lead		surgical site infection with revision	
proportion of periopera-tive compli-cations	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0 to < 1%	212	23.6%	700	78.0%	561	62.5%	600	66.8%	561	62.5%	783	87.2%
1 to < 2%	0	0.0%	1	0.1%	1	0.1%	0	0.0%	2	0.2%	0	0.0%
2 to < 3%	1	0.1%	3	0.3%	1	0.1%	2	0.2%	3	0.3%	0	0.0%
3 to < 4%	3	0.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
4 to < 5%	7	0.8%	1	0.1%	4	0.5%	4	0.5%	4	0.5%	2	0.2%
5 to < 6%	6	0.7%	4	0.5%	4	0.5%	2	0.2%	2	0.2%	1	0.1%
6 to < 7%	2	0.2%	0	0.0%	1	0.1%	0	0.0%	2	0.2%	0	0.0%
7 to < 8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
8 to < 9%	5	0.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
9 to < 10%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
>= 10%	217	24.2%	5	0.6%	24	2.7%	18	2.0%	19	2.1%	15	1.7%
not indicated	445	49.6%	184	20.5%	302	33.6%	272	30.3%	305	34.0%	97	10.8%
total	**898**	**100%**	**898**	**100%**	**898**	**100%**	**898**	**100%**	**898**	**100%**	**898**	**100%**

Appendix 1, Table 12: Distribution of the complication-rate following initial implants in the institutions reporting. To be read as follows, for instance: 212 hospitals (23.6%) have demonstrated a complication in 0 to 1% of the cases.

single-chamber devices (AAI, VVI)				
manufacturer	**n**	**mean**	**SD**	**Median**
Biotronik	1,227	9.4	3.8	9
Cook	1	14.0	-	14
CPI/Guidant	238	7.7	3.9	7
ELA Medical	157	7.6	2.2	7
Implantronik	10	12.1	2.1	12
Intermedics/Guidant	240	9.4	4.1	9
Medtronic	629	9.4	3.6	9
Osypka	11	12.8	5.5	12
Pacesetter/St. Jude Medical	150	8.9	4.0	8
Siemens/St. Jude Medical	209	12.0	3.4	11
Sorin Biomedica	97	8.7	4.7	7
St. Jude Medical	1	0.0	-	0
Teletronics/St. Jude Medical	197	10.1	2.6	10
Vitatron	198	9.9	3.9	10
other	110	12.8	3.1	14
dual-chamber devices (DDD, VDD)				
manufacturer	**n**	**mean**	**SD**	**Median**
Biotronik	1,061	7.4	2.6	7
CCS	2	8.5	2.1	8.5
Cook	2	7.5	0.7	7.5
CPI/Guidant	404	6.5	2.2	6
ELA Medical	433	7.4	3.7	7
Implantronik	3	7.0	1.7	8
Intermedics/Guidant	492	7.6	1.8	7
Medico	1	5.0	-	5
Medtronic	782	8.1	2.5	8
Osypka	5	8.4	1.3	9
Pacesetter/St. Jude Medical	346	8.2	3.1	8
Siemens/St. Jude Medical	111	9.7	2.6	9
Sorin Biomedica	166	6.6	2.9	6
St. Jude Medical	11	4.6	3.3	6
Stöckert	2	8.0	2.8	8
Teletronics/St. Jude Medical	181	8.6	1.7	8
Vitatron	377	7.3	3.3	7
other	54	8.5	2.7	8

Appendix 1, Table 13: Lifetime in years of the pulse generators replaced (SD: standard deviation)

	2002		**2003**	
surgical procedure	**atrial lead**	**ventricular lead**	**atrial lead**	**ventricular lead**
new or addtitional implant	432	631	1,037	1,651
replacement	96	147	287	375
repair	12	45	24	59
other	41	43	141	125
total	**581**	**866**	**1,489**	**2,210**

Appendix 1, Table 14: type of lead reoperation

	2002		2003	
surgical procedure	**atrial lead**	**ventricular lead**	**atrial lead**	**ventricular lead**
explantation	164	194	420	589
left in situ	223	360	433	780
other	88	139	120	150
total	**475**	**693**	**973**	**1,519**

Appendix 1, Table 15: Procedure with dysfunctional leads

Appendix 2: Detailed tables
Comparison of Denmark - Switzerland - Sweden - Germany

ECG indications				
number (n)	**Denmark**	**Switzerland**	**Sweden**	**Germany**
AV block II&III	1,001	1,368	not available	17,643
SSS	580	638	not available	12,447
BTS	286	375	not available	7,451
AF + brady	461	448	not available	9,175
SSS + AV block	50	97	not available	1,060
other	204	312	not available	4,128
total	**2,582**	**3,238**	**not available**	**51,904**
percent (%)	**Denmark**	**Switzerland**	**Sweden**	**Germany**
AV block II&III	38.8	42.2	36.4	34.0
SSS	22.5	19.7	19.5	24.0
BTS	11.1	11.6	13.7	14.4
AF+brady	17.9	13.8	18.5	17.7
SSS + AV block	1.9	3.0	not available	2.0
other	7.9	9.6	11.9	8.0
total	**100**	**100**	**100**	**100**

Appendix 2, Table 1: ECG indications in comparison (Sweden only provided information with regard to the relative frequency)

pacing mode selection	Denmark	Switzerland	Sweden	Germany
AAI	270	30	171	547
VVI	666	1,164	1,361	19,777
VDD	26	279	21	1,378
DDD	1,620	1,761	3,436	29,460

Appendix 2, Table 2: pacing mode selection, in comparison