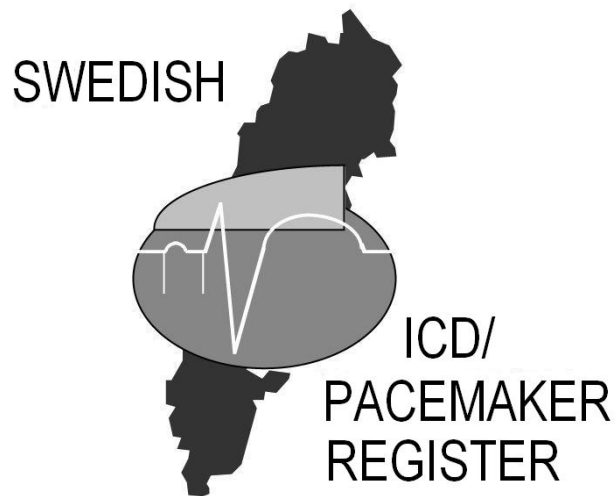


KAROLINSKA HOSPITAL
DEPARTMENT OF CARDIOLOGY
SWEDEN

ANNUAL STATISTICAL REPORT 2005

SWEDISH PACEMAKER REGISTER



STATISTICAL REPORT SWEDISH PACEMAKER REGISTRY 2005

The 2005 report from Swedish Pacemaker and ICD registry contains several new features.

We have specifically monitored the increase of use of ICD and CRT therapy in Sweden. The ICD usage is rapidly increasing with an average of 38/million inhabitants in 2004 to 55/million in 2005. The usage is also more evenly spread throughout Sweden this year. Primary prevention is still a minor indication with only 8% of implanted ICDs.

CRT therapy is also increasing over Sweden but is still concentrated to major implanting centres and there is a considerable regional difference.

We have included both new CRT implants and specifically looked at upgrades in this year's report. For the first time complications are shown for each individual participating hospital. Hospitals that have registered a complication rate below 2 % have been considered as not fully reporting and are thus not included in the statistics. There is a considerable variation in complications and one major factor behind this is probably a difference in registrations based on classification of complications. We hope to have a more uniform classification and registration in the future.

Fredrik Gadler, MD, PhD
Registry director

Anita Fredenson
Coordinator

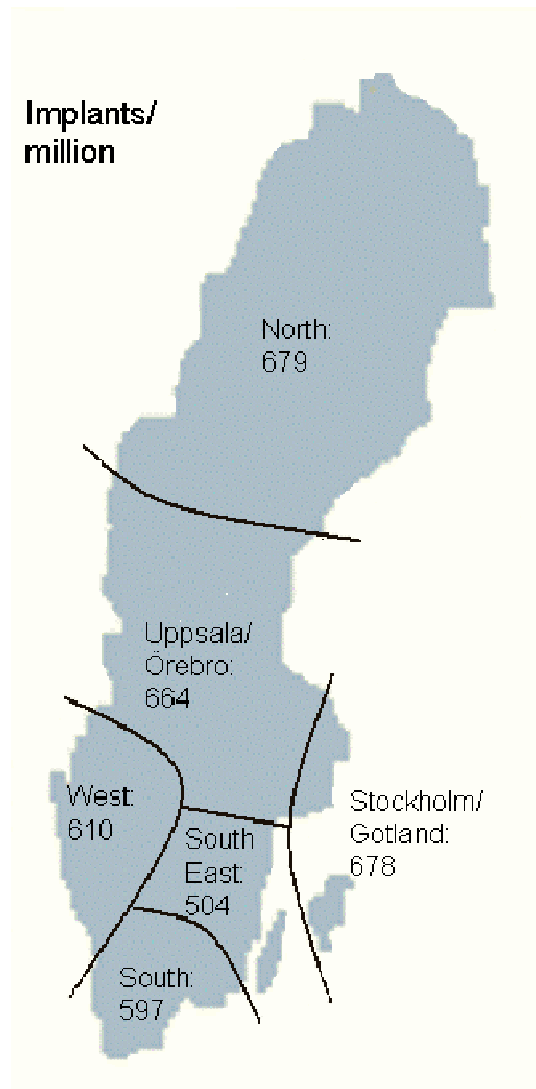
PACEMAKER IMPLANTING HOSPITALS / REGION 2005

Region	Hospitals and cities
STOCKHOLM/GOTLAND	Stockholm Karolinska Universitetssjukhuset Solna
	-"- Karolinska Universitetssjukhuset Huddinge
	-"- Danderyd
	-"- St. Göran
	-"- Södersjukhuset
	Visby
WESTERN SWEDEN	Borås
	Gothenburg Sahlgrenska hospital
	-"- Östra hospital
	Kungälv
	Skövde
	Trollhättan
	Uddevalla
Varberg	
NORTHERN SWEDEN	Kalix
	Luleå
	Piteå
	Skellefteå
	Sollefteå
	Sundsvall
	Umeå
	Örnsköldsvik
	Östersund
SOUTHERN SWEDEN	Halmstad
	Karlskrona
	Lund
	Malmö
	Växjö
UPPSALA/ÖREBRO	Arvika
	Bollnäs
	Eskilstuna
	Gävle
	Falun
	Hudiksvall
	Karlstad
	Uppsala
	Västerås
	Örebro
SOUTH-EAST SWEDEN	Jönköping
	Kalmar
	Linköping
	Norrköping
	Oskarshamn
	Västervik

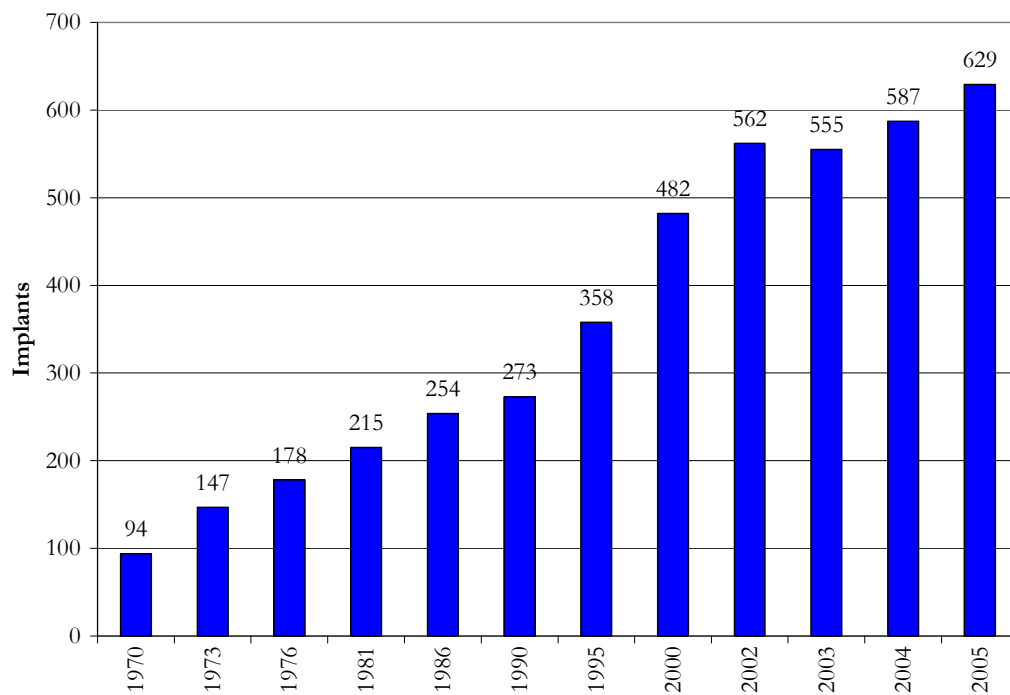
ANNUAL IMPLANTATION RATE

NUMBER OF IMPLANTS LISTED PER REGION

Region	Population	No of first implants	No / million	% BiV
Stockholm/Gotland	1 947 433	1 321	678	8,0
Western Sweden	1 692 694	1 033	610	1,5
Northern Sweden	880 156	598	679	12,0
Southern Sweden	1 620 232	968	597	6,1
Uppsala/Örebro	1 926 811	1 280	664	3,9
Southeast Sweden	980 426	495	504	3,2
Total	9 047 752	5 695	629	5,6



ANNUAL IMPLANTATION RATE

NUMBER OF IMPLANTS / MILLION INHABITANTS 1970-2005

DISTRIBUTION OF MANUFACTURERS

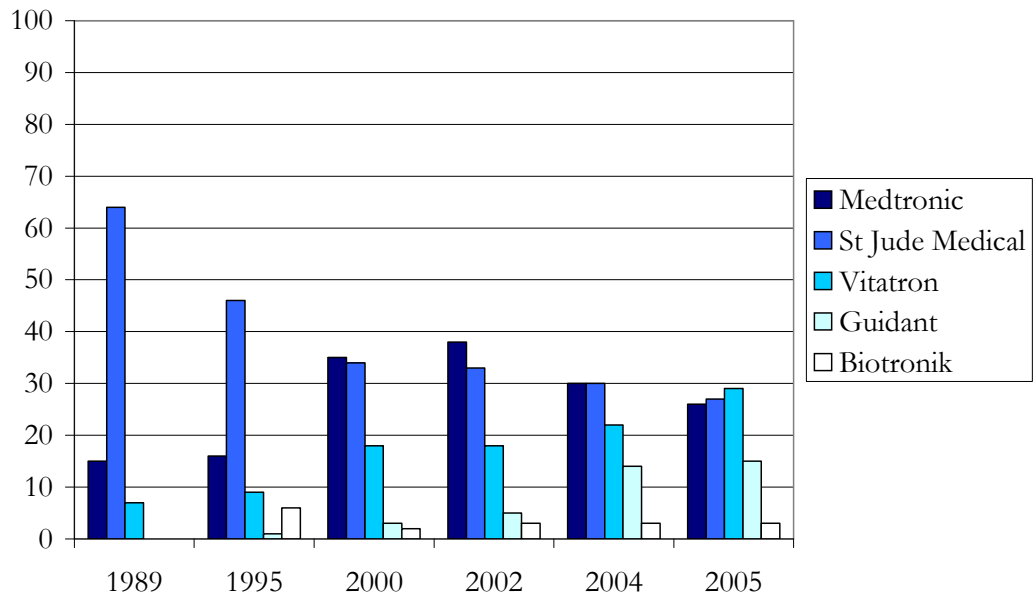
PACEMAKERS (% OF TOTAL)

	1989 n=2833	1995 n=4075	2000 n=5555	2002 n=6182	2004 n=6827	2005 n=7555
Medtronic	15	16	35	38	30	26
St Jude Medical	64	46	34	33	30	27
Vitatron	7	9	18	18	22	29
Guidant	-	1	3	5	14	15
Biotronik	-	6	2	3	3	3
ELA	-	2	8	3	<1	<1
Intermedics	3	6	<1	-	-	-
Telectronics	11	14	-	-	-	-

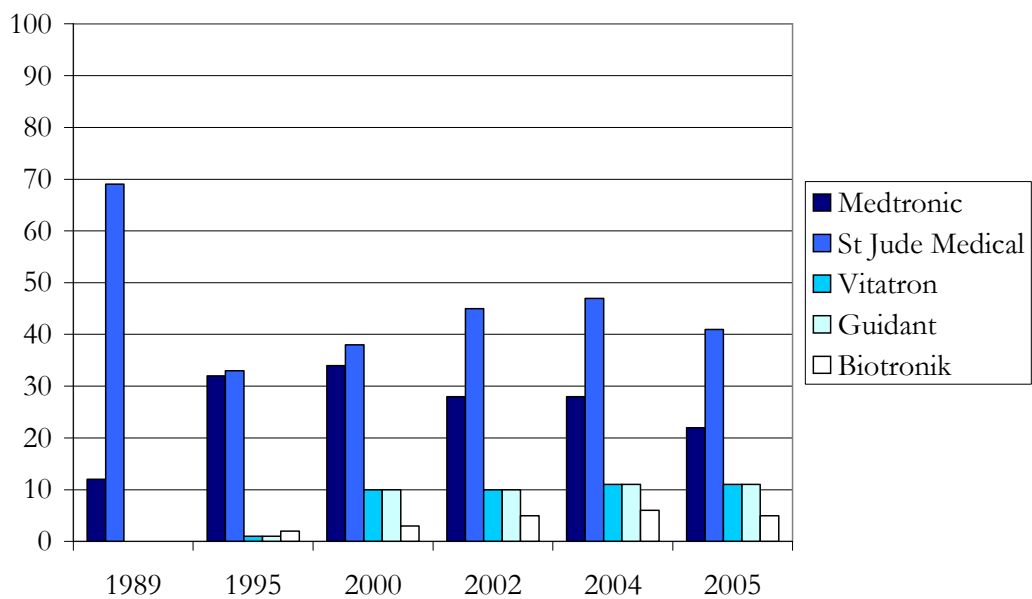
LEADS (% OF TOTAL)

	1989 n=2718	1995 n=5155	2000 n=7482	2002 n=8301	2004 n=9514	2005 n=10317
St Jude Medical	69	33	38	45	47	41
Medtronic	12	32	34	28	28	22
Vitatron	1	2	10	12	8	21
Guidant	-	1	10	10	11	11
Biotronik	-	2	3	5	6	5
ELA	-	-	1	-	-	-
Intermedics	4	4	3	-	-	-
Telectronics	7	15	-	-	-	-
Osypka	-	4	1	-	-	-
Stöckert	1	4	-	-	-	-
Sorin	<1	<1	-	-	-	-
Uns	5	3	<1	-	-	-

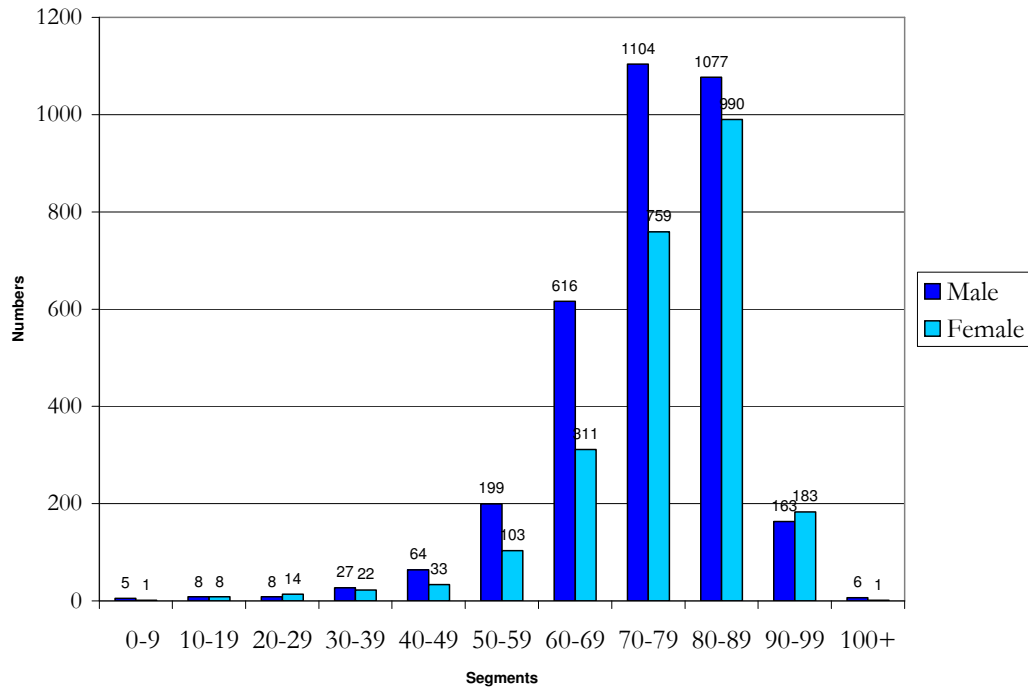
Pacemaker Market Share Development 1989-2005



Lead Market Share Development 1989-2005



AGE DISTRIBUTION - FIRST IMPLANT

AGE DISTRIBUTION FOR MALES, FEMALES 2005


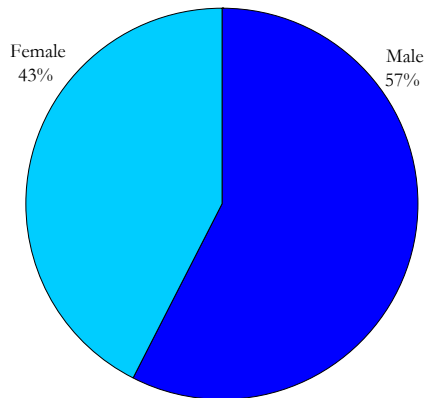
Total number of implants 5702

Age (Years)	Total no	%	Male	Female
0-9	6	0,1	5	1
10-19	16	0,3	8	8
20-29	22	0,4	8	14
30-39	49	0,9	27	22
40-49	97	1,7	64	33
50-59	302	5,3	199	103
60-69	927	16,3	616	311
70-79	1863	32,7	1104	759
80-89	2067	36,3	1077	990
90-99	346	6,1	163	183
100+	7	0,1	6	1
average	75,9		75,0	77,2

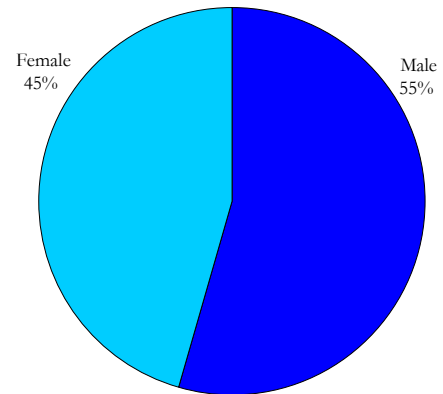
NUMBER OF IMPLANTS

	Total no	Male	Female
First implant	5702	3274	2428
	75,5%	57,4%	42,6%
Replacement	1853	1011	842
	24,5%	54,6%	45,4%

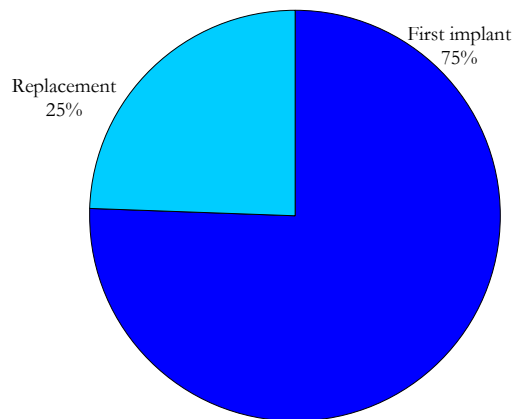
First implant



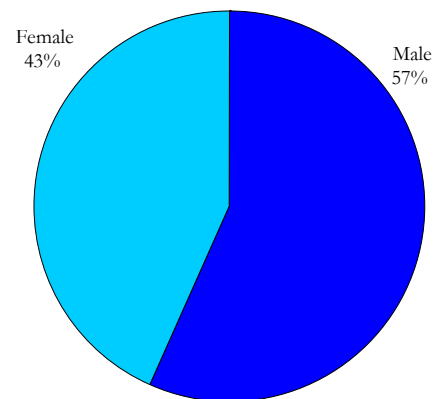
Replacement



Replacement ratio



All Implants - Sex

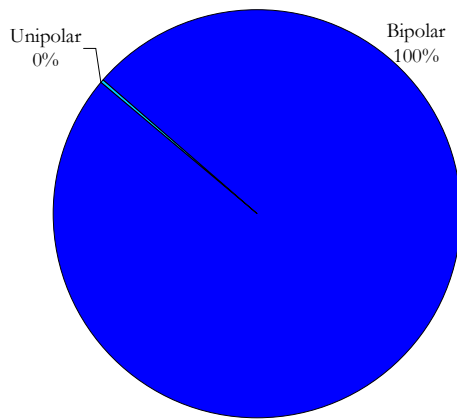


LEADS

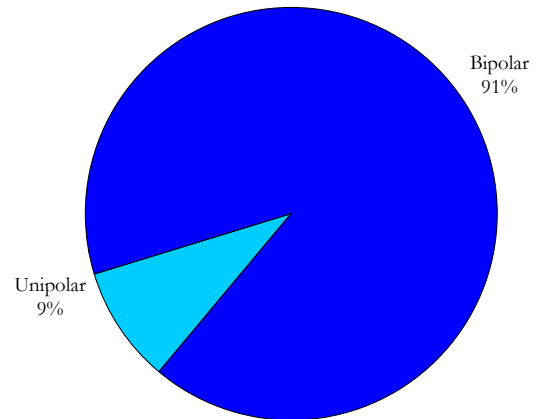
Total no of leads: 10317

	ATRIAL (n=3921)		VENTRICULAR (n=5362)	
	no	%	no	%
Unipolar	12	0,3	531	9,2
Bipolar	4224	99,7	5215	90,8
Passive fixation	226	5,3	3670	63,9
Active fixation	4010	94,7	2076	36,1
Sinus Coronarius BiV			335	* 5,8
				* of total

ATRIAL



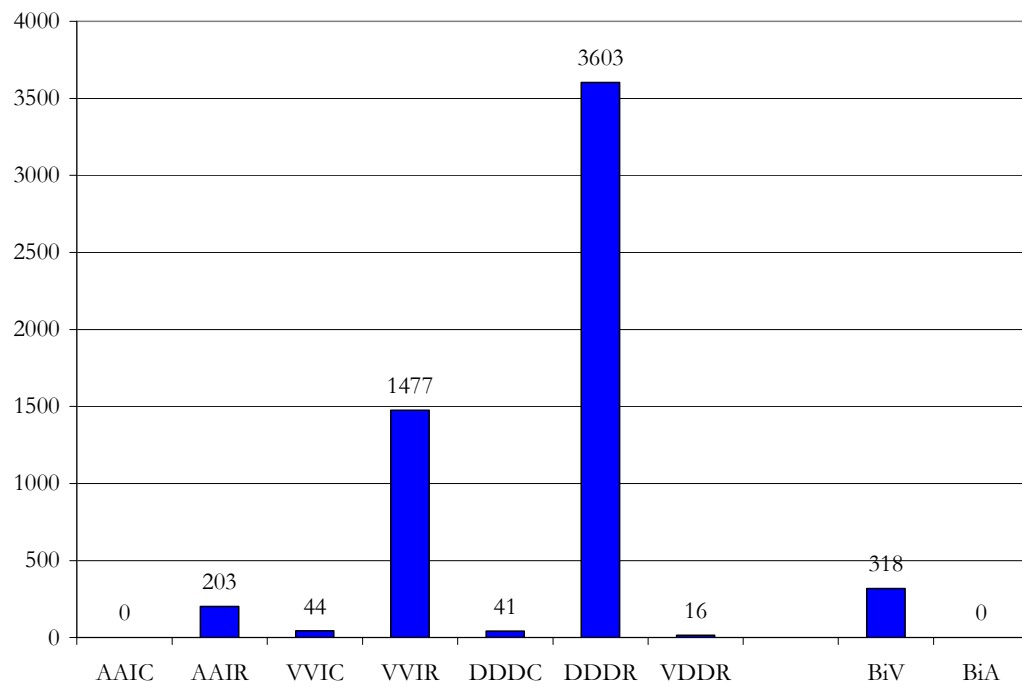
VENTRICULAR



PACING MODE FIRST IMPLANT

Total number of implants 5702

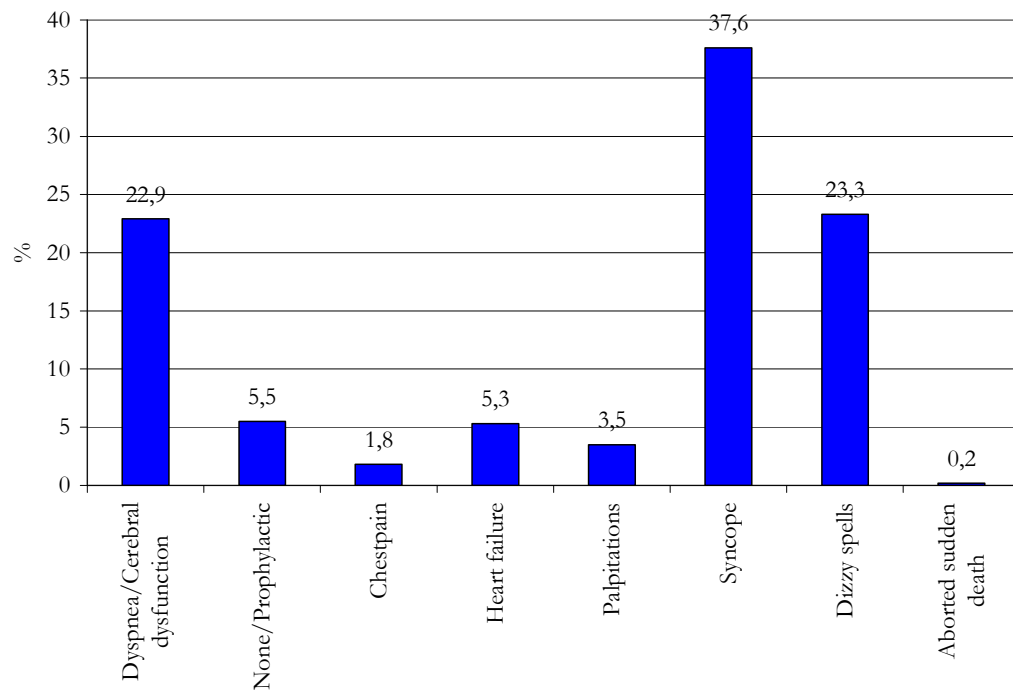
Mode	%	No
AAIC	-	-
AAIR	3,5	203
VVIC	0,8	44
VVIR	25,9	1477
DDDC	0,7	41
DDDR	63,2	3603
VDDR	0,3	16
BiV	5,6	318
BiA	-	-



CLINICAL INDICATIONS - FIRST IMPLANT

Total number of implants 5702

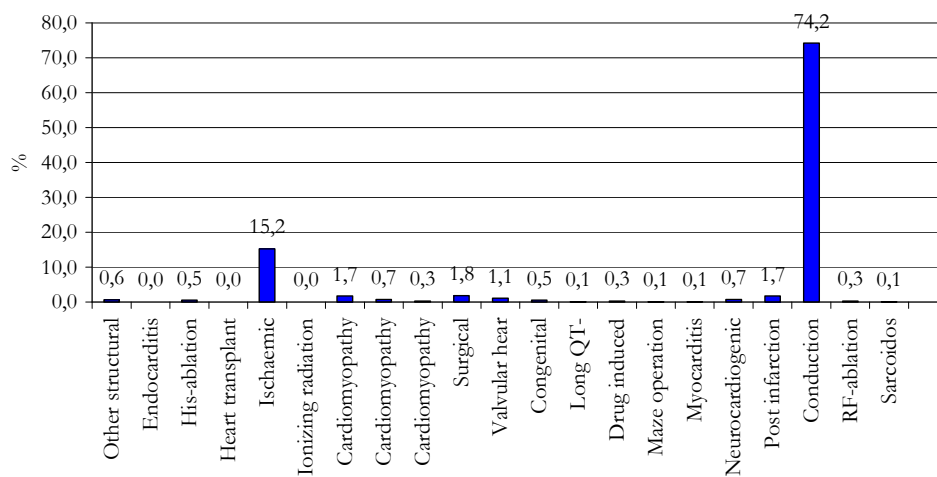
Indication	%
Dyspnea/Cerebral dysfunction	22,9
None/Prophylactic	5,5
Chestpain	1,8
Heart failure	5,3
Palpitations	3,5
Syncope	37,6
Dizzy spells	23,3
Aborted sudden death	0,2



AETIOLOGY - FIRST IMPLANT

Total number of implants 5702

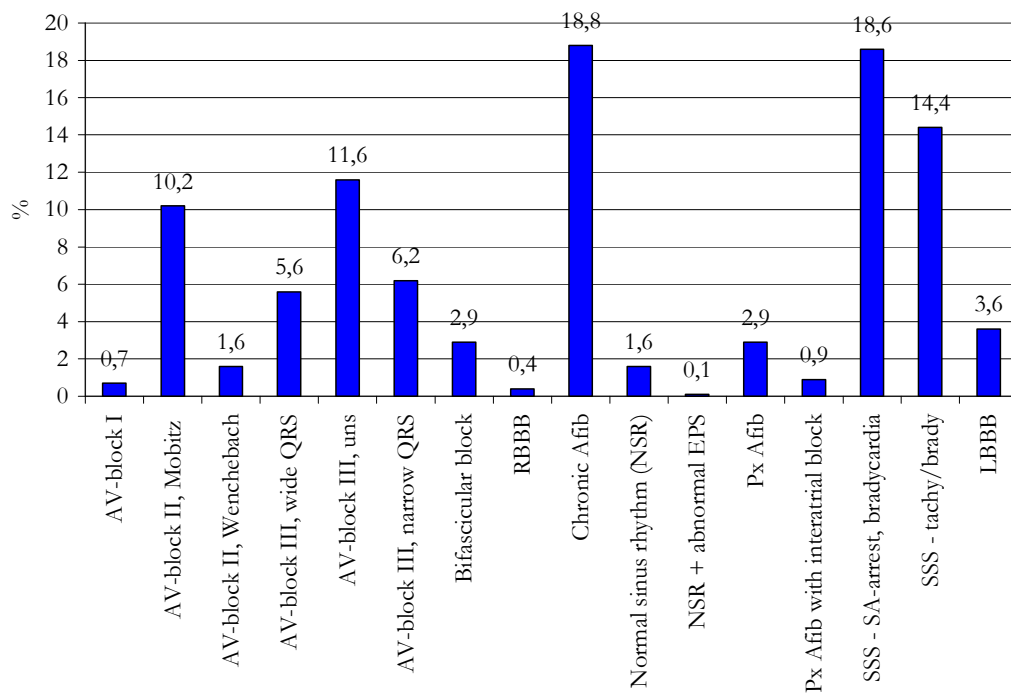
Aetiology	%
Other structural heart disease	0,6
Endocarditis	0,0
His-ablation	0,5
Heart transplant	0,0
Ischaemic	15,2
Ionizing radiation	0,0
Cardiomyopathy dilated	1,7
Cardiomyopathy hypertrophic	0,7
Cardiomyopathy ischaemic	0,3
Surgical complication	1,8
Valvular hear disease	1,1
Congenital	0,5
Long QT-syndrome	0,1
Drug induced	0,3
Maze operation	0,1
Myocarditis	0,1
Neurocardiogenic syncope	0,7
Post infarction	1,7
Conduction tissue fibrosis	74,2
RF-ablation	0,3
Sarcoidos	0,1



ECG INDICATIONS - FIRST IMPLANT

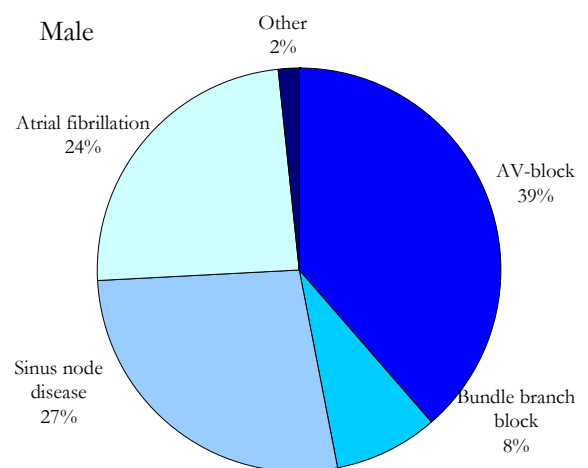
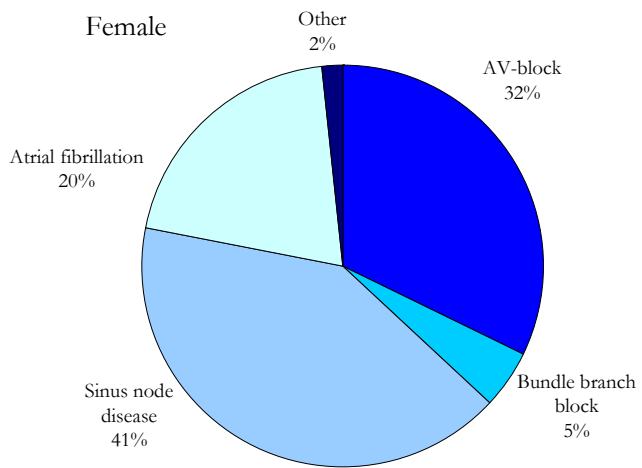
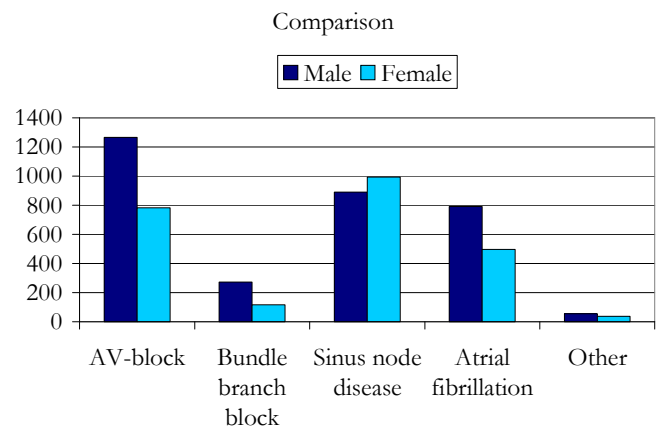
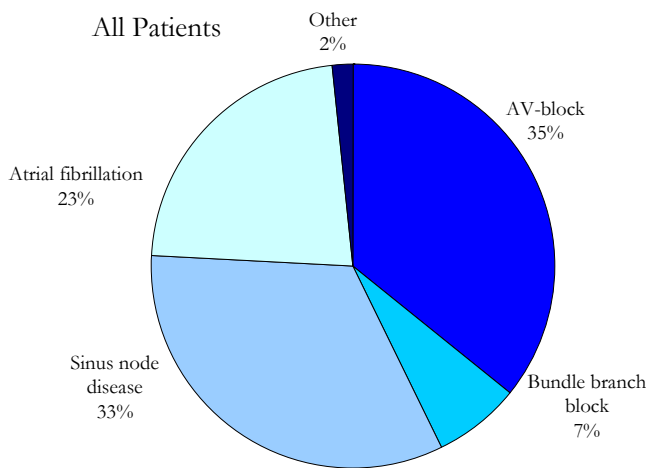
Total number of implants 5702

indication	%
AV-block I	0,7
AV-block II, Mobitz	10,2
AV-block II, Wenchebach	1,6
AV-block III, wide QRS	5,6
AV-block III, uns	11,6
AV-block III, narrow QRS	6,2
Bifascicular block	2,9
RBBB	0,4
Chronic Afib	18,8
Normal sinus rhythm (NSR)	1,6
NSR + abnormal EPS	0,1
Px Afib	2,9
Px Afib with interatrial block	0,9
SSS - SA-arrest, bradycardia	18,6
SSS - tachy/brady	14,4
LBBB	3,6



PREPACING ECG – FIRST IMPLANT – SEX

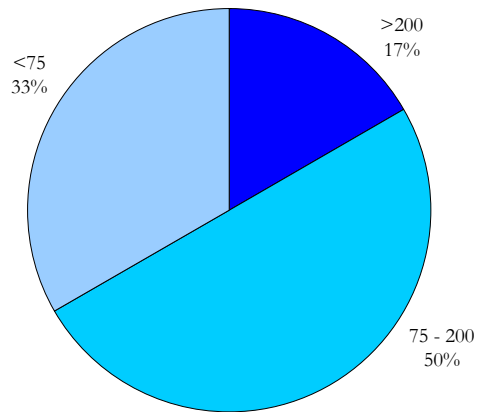
Prepacing ECG	No	%	Male	Female
AV-block	2048	35,9	1266	782
Bundle branch block	391	6,8	273	118
Sinus node disease	1881	33	889	992
Atrial fibrillation	1287	22,6	790	497
Other	95	1,7	56	39



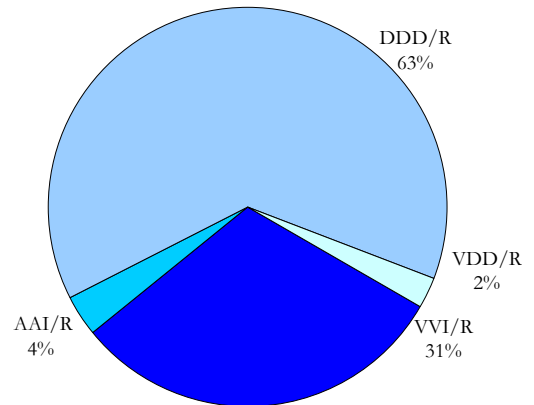
USE OF PACING MODES FOR FIRST IMPLANT

Implants / year	Hospitals	VVI/R	AAI/R	DDD/R	VDD/R
>200	7	22,1	4,2	73,7	-
75 - 200	21	29,4	3,0	67,6	-
<75	14	30,7	3,6	63,3	2,4
Total	42				

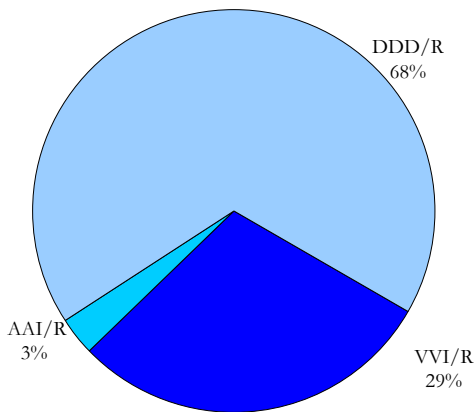
Hospitals and number of implants per year



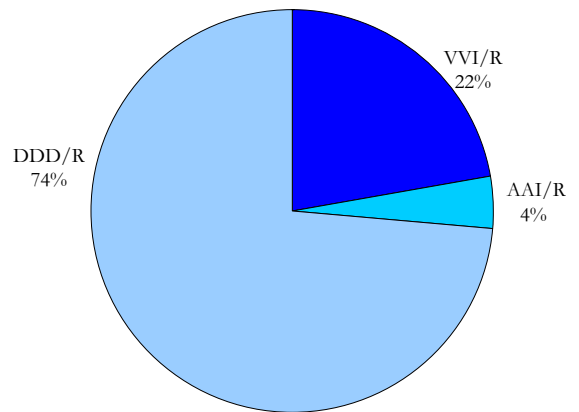
Hospitals with less than 75 implants per year



Hospitals with 75-200 implants per year



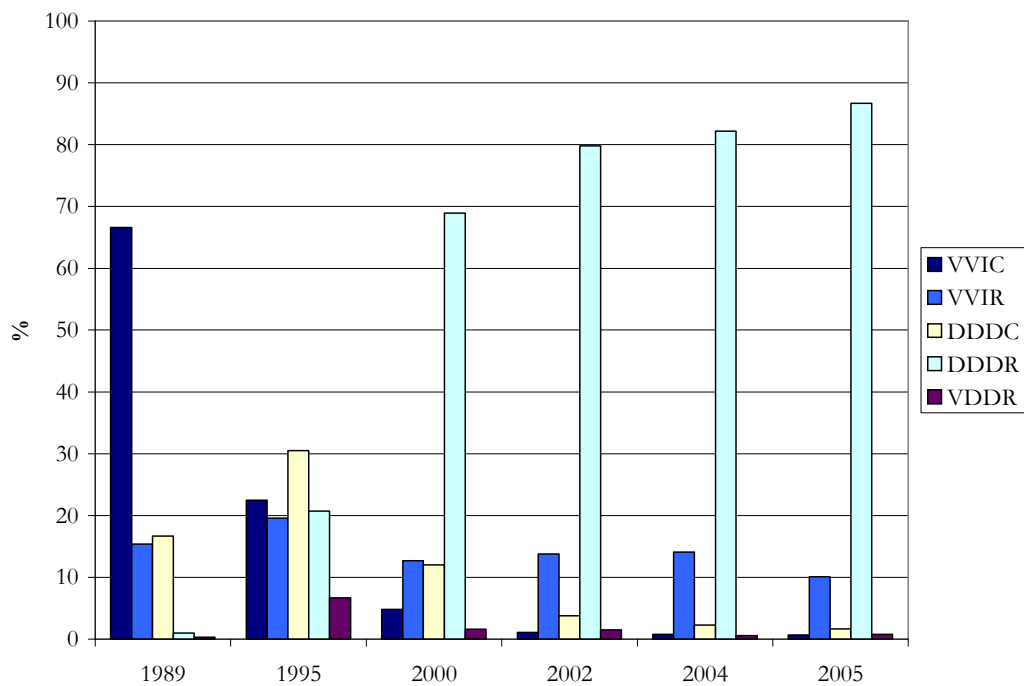
Hospitals with more than 200 implants per year



HIGH DEGREE AV-BLOCK FIRST IMPLANT

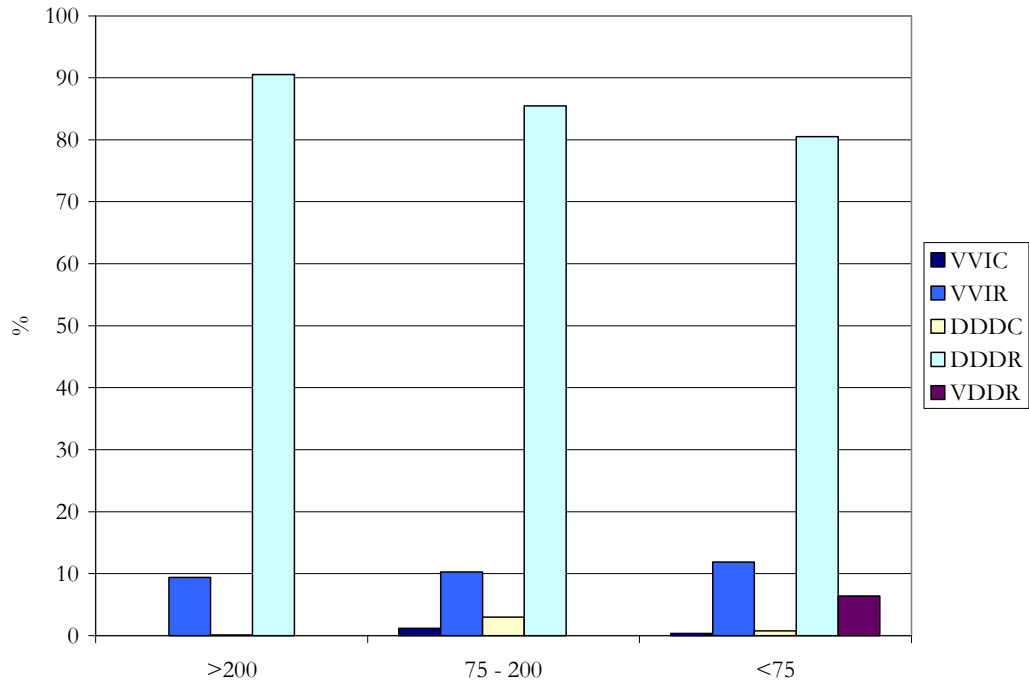
MODES USED, HISTORICAL DATA

Mode	1989	1995	2000	2002	2004	2005
VVIC	66,6	22,5	4,8	1,1	0,8	0,7
VVIR	15,4	19,6	12,7	13,8	14,1	10,1
DDDC	16,7	30,5	12,0	3,8	2,3	1,7
DDDR	1,0	20,7	68,9	79,8	82,2	86,7
VDDR	0,3	6,7	1,6	1,5	0,6	0,8



AV-BLOCK, MODES USED PER HOSPITAL, ORDERED BY SIZE

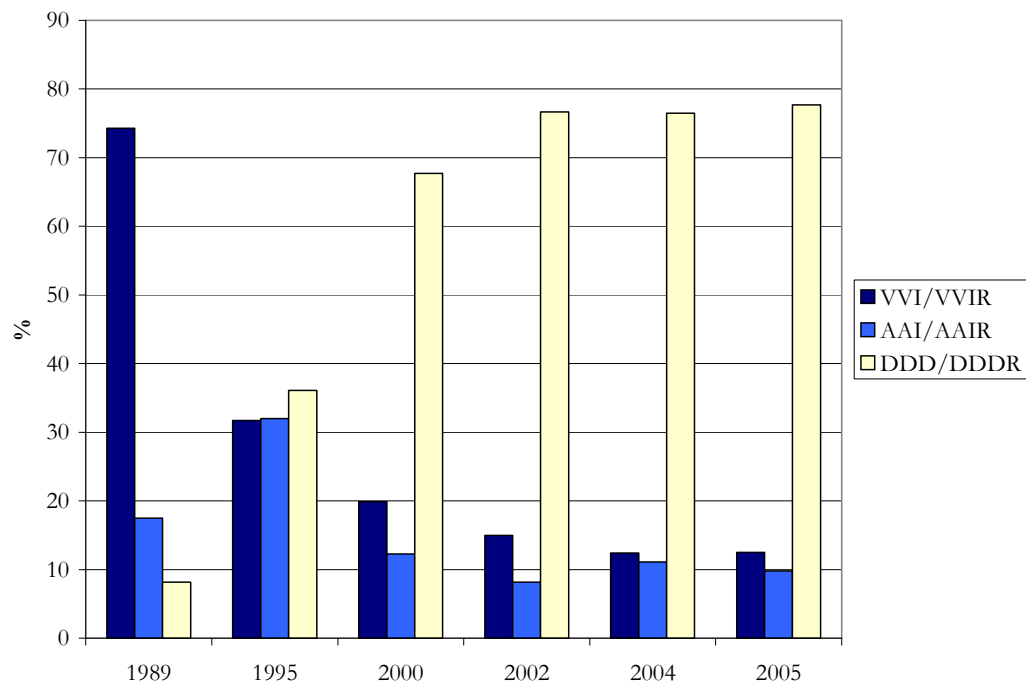
Mode	All hospitals	>200	75 - 200	<75
VVIC	0,7	-	1,2	0,4
VVIR	10,1	9,4	10,3	11,9
DDDC	1,7	0,1	3,0	0,8
DDDR	86,7	90,5	85,5	80,5
VDDR	0,8	-	-	6,4



SINUS NODE DYSFUNCTION FIRST IMPLANT

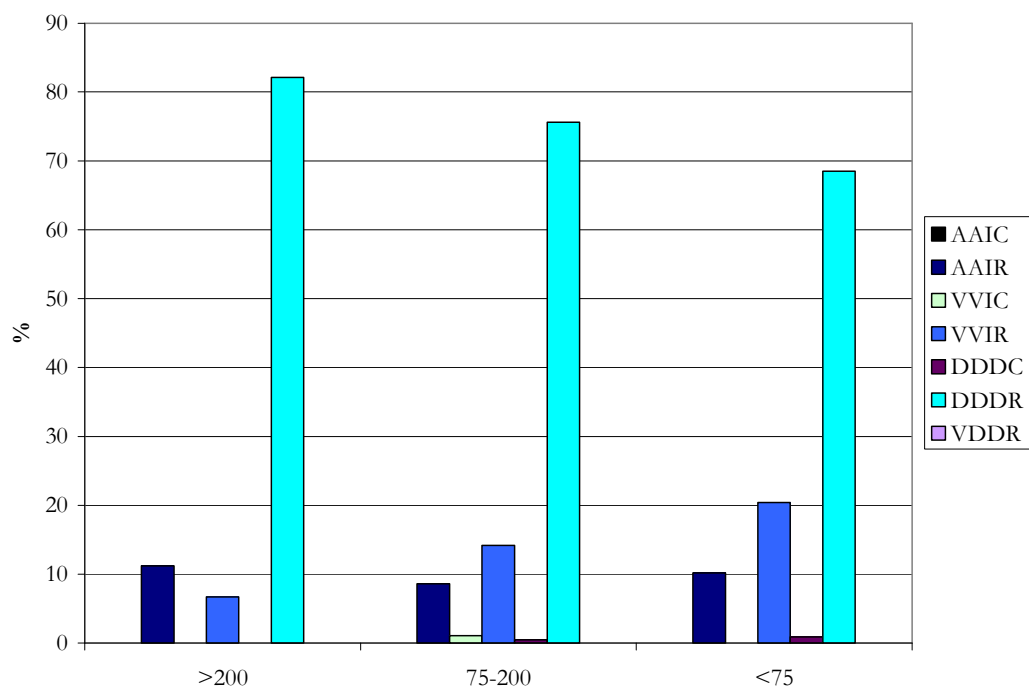
MODES USED, HISTORICAL DATA, %

Mode	1989	1995	2000	2002	2004	2005
VVI/VVIR	74,3	31,7	19,9	15	12,4	12,5
AAI/AAIR	17,5	32	12,3	8,2	11,1	9,8
DDD/DDDR	8,2	36,1	67,7	76,7	76,5	77,7
VDD/VDDR	-	0,2	<0,1	0,1	-	-



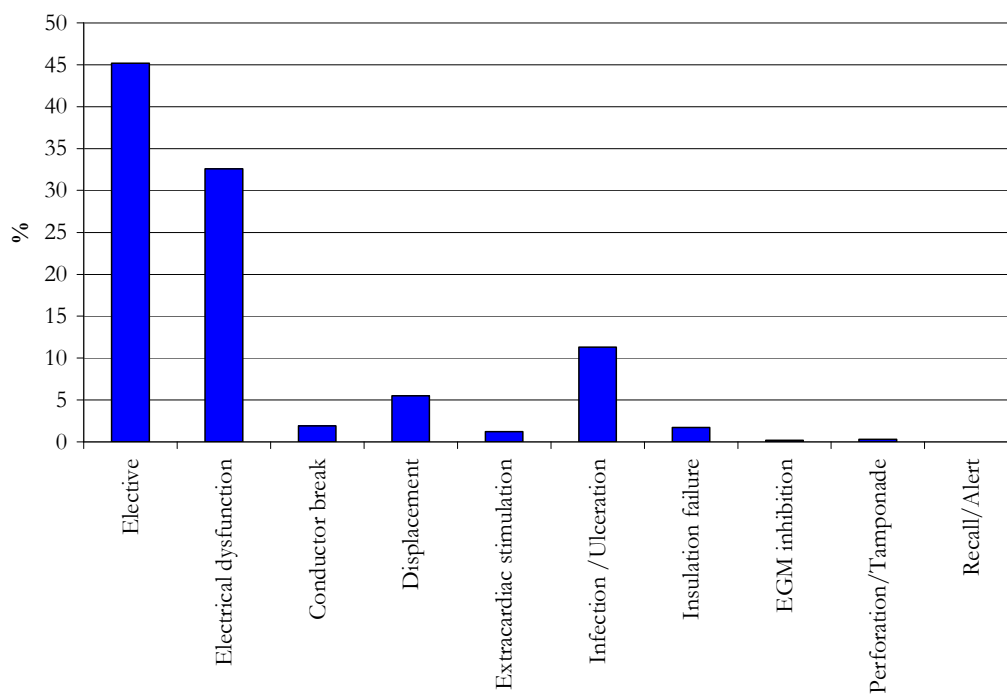
SND MODES USED PER HOSPITAL ORDERED BY SIZE, %

Mode	All hospitals	>200	75-200	<75
AAIC	-	-	-	-
AAIR	9,9	11,2	8,6	10,2
VVIC	0,5	-	1,1	-
VVIR	11,9	6,7	14,2	20,4
DDDC	0,3	-	0,5	0,9
DDDR	77,4	82,1	75,6	68,5
VDDR	-	-	-	-



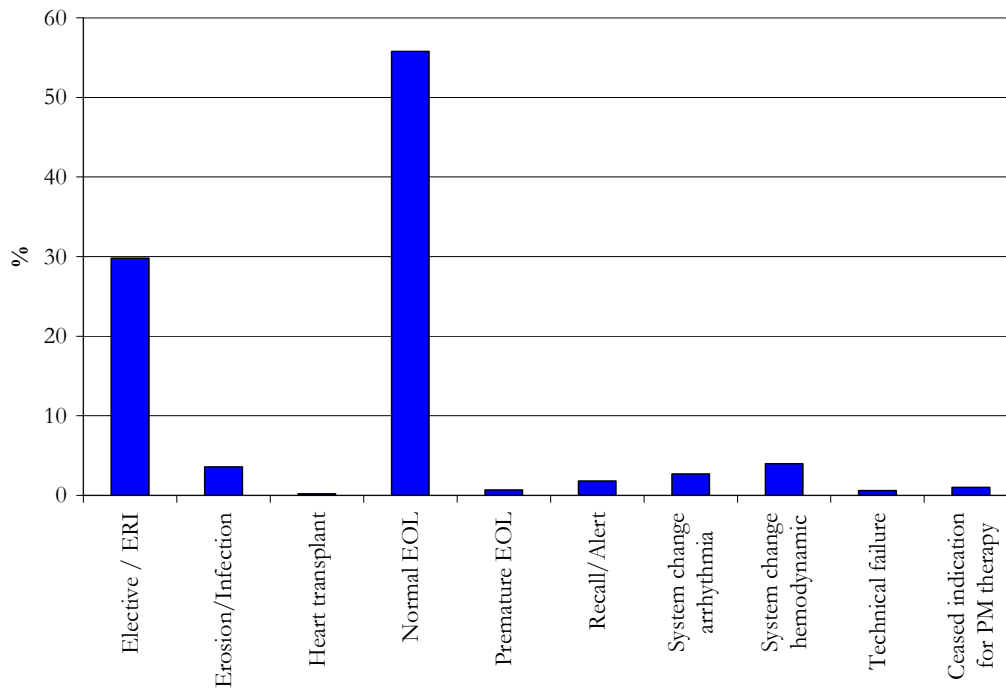
REASON FOR LEAD REPLACEMENT %

Reason	All hospitals	>200	75 - 200	<75
Elective	45,2	54,3	38,5	39,1
Electrical dysfunction	32,6	17,7	42,4	50
Conductor break	1,9	2,5	1,7	-
Displacement	5,5	4,9	6,3	4,3
Extracardiac stimulation	1,2	2,1	0,7	-
Infection /Ulceration	11,3	16	8,7	2,2
Insulation failure	1,7	2,5	1	2,2
EGM inhibition	0,2	-	-	2,2
Perforation/Tamponade	0,3	-	0,7	-
Recall/Alert	-	-	-	-

REASONS FOR LEAD REPLACEMENT - ALL HOSPITALS


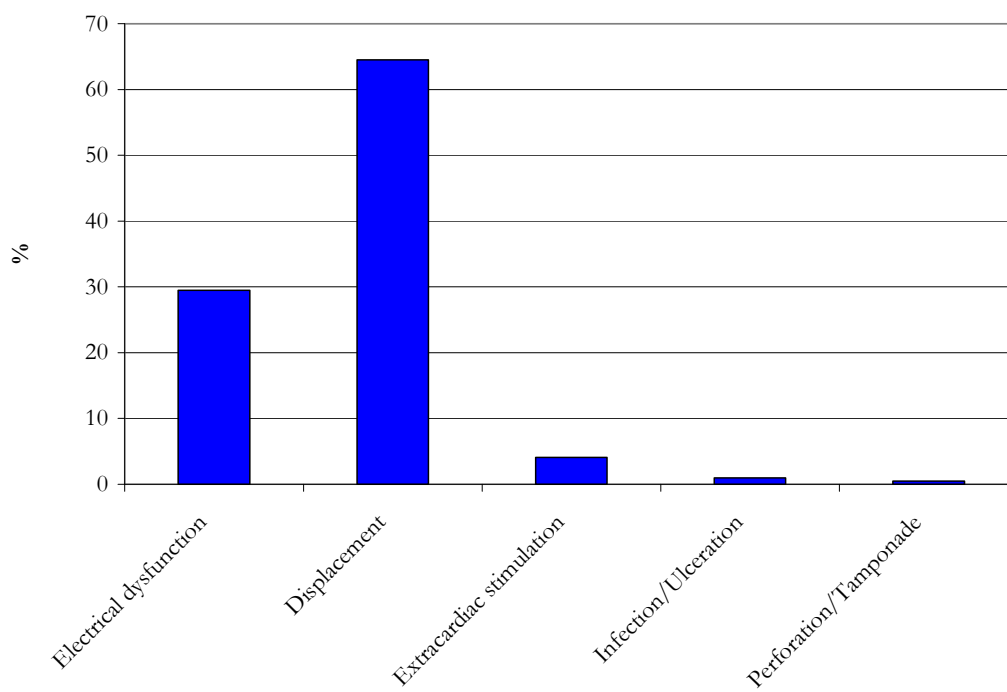
REASON FOR GENERATOR REPLACEMENT %

Reason	All hospitals %	>200	75 - 200	<75
Elective / ERI	29,8	28,6	32,6	21,2
Erosion/Infection	3,6	4	3,3	3
Heart transplant	0,2	0,3	-	0,6
Normal EOL	55,8	56,2	54,6	63,6
Premature EOL	0,7	0,2	1,2	-
Recall/Alert	1,8	0,9	1,7	7,3
System change arrhythmia	2,7	3,9	1,8	1,2
System change hemodynamic	4	5,4	3,2	1,8
Technical failure	0,6	0,5	0,6	0,6
Ceased indication for PM therapy	1	0,1	1	0,6

REASON FOR GENERATOR REPLACEMENT- ALL HOSPITALS


REASON FOR LEAD CORRECTION %

Reason	All hospital	>200	75 - 200	<75
Electrical dysfunction	29,5	32,9	29,7	18,2
Displacement	64,5	55,7	68,3	77,3
Extracardiac stimulation	4,1	8,6	2	-
Infection/Ulceration	1	1,4	-	4,5
Perforation/Tamponade	0,5	1,4	-	-

REASON FOR LEAD CORRECTION - ALL HOSPITALS


SYSTEM UPGRADE

VVI TO VVIR

	2002	2003	2004	2005
VVI to VVIR	38	77	64	50
(Elective/ERI)	15	25	19	7
(Hemodynamic)	3	1	2	0

VVI/VVIR TO DDD/DDDR

	2002	2003	2004	2005
VVI/VVIR to DDD/DDDR	39	57	59	75
(Elective/ERI)	14	15	19	14
(Hemodynamic)	18	27	30	27

VVI/VVIR/DDD/DDDR TO BiV

	2002	2003	2004	2005
VVI/VVIR/DDD/DDDR to BiV	26	25	45	63
(Elective/ERI)	4	3	12	10
(Hemodynamic)	20	19	29	47

COMPLICATIONS TOTAL

Based on 8133 (all implants) alternatively 6267
(first implants + lead replacement) validated events

COMPLICATION	%
Electrical dysfunction	1,5
Local bleeding	0,7
Perforation/Tamponad	0,2
Pneumothorax	0,4
Infection / Perforation	1,1
Electrode displacement	3,1
Other	1,6
Death	0
Total (607)	7,5

COMPLICATIONS TO INTERVENTIONS PER HOSPITAL

The following hospitals have 0 registered complications or incomplete registration (<2%) and are therefore not included in the tables below:

Arvika Sjukhus
Kalix Sjukhus
Sunderby Sjukhus
Universitetssjukhuset i Umeå.

Hospital	Electrical dysfunction	Local bleeding	Perforation/Tamponad	Pneumothorax
Akademiska sjukhuset	1,6	-	0,3	-
Blekinge sjukhuset	4,2	1,7	0,7	0,7
Bollnäs sjukhus	-	6,3	-	-
Borås lasarett	4,8	-	-	0,5
Centrallasarettet Västerås	0,9	-	0,9	-
Centralsjukhuset Karlstad	-	-	1,0	-
Centralsjukhuset Växjö	1,2	-	-	3,5
Danderyds sjukhus	1,0	1,3	-	-
Falu lasarett	1,0	0,7	0,5	-
Hudiksvalls sjukhus	2,8	3,7	-	-
Karolinska Universitetssjukhuset Huddinge	1,7	-	1,1	-
Karolinska Universitetssjukhuset Solna	0,4	-	-	-
Kungälv's sjukhus	1,0	2,4	-	-
Kärnsjukhuset Skövde	0,5	2,5	-	0,5
Linköpings Universitetssjukhuset	2,3	0,4	-	1,1
Länssjukhuset Gävle	0,6	3,2	-	-
Länssjukhuset Halmstad	-	-	-	-
Länssjukhuset Kalmar	-	-	-	2,0
Länssjukhuset Ryhov	1,7	1,3	-	2,9
Mälarsjukhuset	-	0,6	-	-
NÄL	2,6	-	-	-
Oskarshamns sjukhus	-	3,0	-	-
Sahlgrenska sjukhuset	0,6	-	-	-
Skellefteå lasarett	-	1,8	2,6	-
Sollefteå sjukhus	2,6	-	-	-
St Görans sjukhus	-	-	-	-
Sundsvalls sjukhus	1,9	-	-	-
Södersjukhuset	3,1	0,5	-	-
Uddevalla sjukhus	2,8	2,9	-	3,5
UMAS	5,5	-	-	-
Universitetssjukhuset Örebro	3,3	-	-	1,4
Universitetssjukhuset Lund	2,3	-	-	-
Varbergs sjukhus	-	2,5	1,1	2,3
Visby lasarett	-	11,1	-	5,9
Vrinnevisjukhuset	-	-	-	-
Västerviks sjukhus	4,0	-	-	-
Örnsköldsviks sjukhus	5,3	-	-	-
Östersunds sjukhus	1,5	2,3	1,5	-

Continues on next page.

COMPLICATIONS TO INTERVENTIONS PER HOSPITAL

Hospital	Infection/ Perforation	Electrode displacement	Other	Death
Akademiska sjukhuset	-	4,7	4,5	-
Blekinge sjukhuset	1,2	2,1	-	-
Bollnäs sjukhus	1,3	1,5	1,3	-
Borås lasarett	1,3	3,8	0,8	-
Centrallasarettet Västerås	1,4	1,9	0,7	-
Centralsjukhuset Karlstad	0,9	3,1	-	-
Centralsjukhuset Växjö	5,2	4,6	0,9	-
Danderyds sjukhus	0,4	4,1	0,6	-
Falu lasarett	2,3	5,3	0,7	-
Hudiksvalls sjukhus	-	4,2	1,2	-
Karolinska Universitetssjukhuset Huddinge	0,4	2,8	1,5	-
Karolinska Universitetssjukhuset Solna	1,3	3,6	0,8	-
Kungälv's sjukhus	-	6,0	-	-
Kärnsjukhuset Skövde	2,9	5,8	10,5	-
Linköpings Universitetssjukhuset	2,7	2,3	0,9	-
Länssjukhuset Gävle	2,7	0,6	6,9	-
Länssjukhuset Halmstad	2,1	1,3	6,2	-
Länssjukhuset Kalmar	-	5,9	-	-
Länssjukhuset Ryhov	1,3	9,8	0,4	-
Mälarsjukhuset	1,2	1,7	2,9	-
NÄL	-	7,9	1,0	-
Oskarshamns sjukhus	-	3,2	-	-
Sahlgrenska sjukhuset	0,4	-	1,7	-
Skellefteå lasarett	-	5,1	1,8	-
Sollefteå sjukhus	4,5	10,5	-	-
St Görans sjukhus	-	1,3	0,8	-
Sundsvalls sjukhus	-	3,8	0,9	-
Södersjukhuset	0,5	2,2	2	-
Uddevalla sjukhus	2,1	0,7	3,3	-
UMAS	0,4	-	-	-
Universitetssjukhuset Örebro	0,3	8,1	1,4	-
Universitetssjukhuset Lund	1,7	1,6	0,5	-
Varbergs sjukhus	0,8	6,8	-	-
Visby lasarett	6,7	5,9	8,9	-
Vrinnevisjukhuset	1,5	-	-	-
Västerviks sjukhus	-	-	-	-
Örnsköldsviks sjukhus	-	7,0	-	-
Östersunds sjukhus	3,5	4,5	-	-