Danish Pacemaker and ICD Register
Annual report
2015

Preface

The Danish Pacemaker Register was founded in 1982 by physicians from all Danish hospitals where pacemakers were implanted. When the first implantable cardioverter defibrillator (ICD) was implanted in 1989, these devices were also included in the register as well as cardiac resynchronization therapy pacemakers and ICDs (CRT-P and CRT-D). The register have since the very start in 1982 recorded details on implant and explant including hardware and survival status of the patients and an annual report have been published. The register holds data on 94181 pacemaker- and 18887 ICD implants as of 31. December 2015.

Data collection and reporting have since 2007 been based on online reporting from all the implanting hospitals. The last printed annual report was issued in 2012, but despite that all data are accessible online, there is still a need for a commented report, which this collection of data represents.

Odense, May-2017

On behalf of the steering committee

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Danish Pacemaker and ICD Register

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Content

1 Introduction

1.1 Organisation

The register has previously been a private research database, but is now an official clinical quality database and part of the Danish Clinical Registries (RKKP). The steering committee consists of a physician from all implanting hospitals and is rooted in the Danish Society of Cardiology working group for cardiac arrhythmias and device treatment. The daily management of the register is located at Department of Cardiology, Odense University Hospital, by physician Ole Dan Jørgensen (management and development of database), nurse-technician Lisbeth Skov Nielsen (data entry and support), engineer Roy Guldberg (issuing pacemaker ID cards) and physician Jens Brock Johansen (chairman).

The steering committee consists of (as of May 2017):

- Søren Højbjerg, Bispebjerg Hospital, Copenhagen
- Ulrik Hintze, South-West Jutland Hospital, Esbjerg
- Jens Harboe, Gentofte Hospital, Copenhagen
- Jerzy Malczinsky, Regional Hospital West Jutland, Herning
- Michael Dilou, Nordsjællands Hospital, Hillerød
- Jens Brock Johansen, Odense University Hospital, Odense
- Berit Philbert, Rigshospitalet, Copenhagen
- Thomas Melchior, Roskilde Hospital, Roskilde
- Thomas Fischer, Hospital Little Belt, Vejle
- Per Dahl Christensen, Regional Hospital of Viborg, Viborg
- Lene Svendstrup, South Jutland Hospital, Aabenraa
- Sam Riahi, Aalborg University Hospital, Ålborg
- Jens Cosedis Nielsen, Aarhus University Hospital, Aarhus.

All device manufacturers on the Danish market funds the activities of the register by a fee for each sold device and lead, and they have access to aggregated anonymous data in the register.

Data are entered online by the treating physician at implant and explant. Survival status is checked in the civil registration system and users have access to all data in a web based format at the URL address www.icddata.dk. Data is also provided for research purposes after approval of the steering committee and The Danish Clinical Registries (RKKP).

Data are regularly audited by a senior consultant, Regitze Videbæk, who has visited all sites for systematic review of data entry with a special focus on complication and quality.

1.2 Comments on implant activity in Denmark 2015

Pacemaker and ICD implantation in Denmark is done in 14 public hospitals and one private hospital (Varde).

Institution	Pacemaker	CRT-P	ICD (VVI/DDD)	CRT-D	Lead extraction	Pediatrics GUCH
Bispebjerg	X					
Esbjerg	X					
Gentofte	X	X	X	X		
Herning	X					
Hillerød	X					
Nuuk	X*					
Odense	X	X	X	X	X	
Rigshospitalet	X	X	X	X	X	X
Roskilde	X		X			
Varde	X					
Vejle	X					
Viborg	X					
Aabenraa	X					
Ålborg	X	X	X	X	X	
Aarhus	X	X	X	X	X	X

Table 1.1 Pacemaker and ICD implantation in Danish hospitals 2015
*Only VVI pacemakers.

The vast majority of institutions were high volume centers except for Nuuk and Varde. The intention is to aim for at least 50 device implants per year per operator.

1.2.1 Pacemaker

The majority of first pacemaker implants was dual chamber (n=2805, 69.4%) and about one quarter was single chamber right ventricle pacemakers (n=1005, 24.9%). A small number (n=27) of the single chamber right ventricle were lead-less Micra pacemakers. Biventricular pacemakers were implanted in a smaller percentage (n=250, 6.2%) and an even smaller number (n=9, 0.2%) were single chamber atrial pacemakers (See Table 2.1).
The pacemaker replacements and system up-/downgrades took up 23.2% of the total number of implants in 2015 (See Table 2.2 and Table 2.3).

1.2.2 ICD

The predominant pacing mode in first ICD implants was VVI (n=694, 63.8%) while DDD (n=178, 16.4%) and CRT-D (n=219, 19.9%) was only used in a smaller number. Total subcutaneous ICD was implanted in 13 cases (See Table 2.4). The ICD replacements and system up-/downgrades took up 38.1% of the total number of ICD implants in 2015 (See Table 2.5 and Table 2.6).

The indication for first ICD implant was primary prophylactic in 45.5% in all first implants (See Table 2.12 and Figure 2.5), and the predominant etiology for ICD implant was ischemic heart disease (76.1%) (See Table 2.14 and Figure 2.6).

1.2.3 Leads

All low voltage leads for atrial and right ventricle were bipolar active fixation leads. Of n=739 low voltage leads for left ventricular pacing, n=632 (86%) were quadripolar and n=107 (14%) bipolar (See Table 2.9).

Similarly all high voltage leads (except for a small number of leads used for subcutaneous defibrillation) were active fixation leads. Of n=1363 right ventricular leads n=801 (59%) were single coil leads and n=562 (41%) were dual coil leads (See Table 2.10).

1.3 Comments on pacemaker and ICD patients

The majority of patients for first pacemaker implant were between 75-79 years of age for DDD pacemakers and 85-89 years for VVI pacemakers (see Table 3.1 and Figure 3.1). Female patients consisted of 39.7% of all first pacemaker patients (See Table 3.2).

For ICD patients, the largest group was 65-75 years of age, with only a limited number above 80 years of age at time of implant (n=51, 4.7%) (See Table 3.3 and Figure 3.3). Male patients were dominating in first ICD implants (n=909, 83.5%) (See Table 3.4 and Figure 3.4).

At the end of 2015 27397 pacemaker- and 9317 ICD patients were in treatment and alive (See Table 3.5 and Table 3.6).

1.4 Comments on trends in implant activity 2000-2015

1.4.1 Number of implants

The number of first pacemaker implants has increased from 440 per million citizens in 2000 to 714 per million citizens in 2015. Currently, this increase does not seem to reach a plateau (See Table 4.1 and Figure 4.1). On the other hand, first ICD implants increased dramatically from 43 per million citizens in 2000 to 219 per million citizens in 2012, but has now decreased slightly to 192 per million citizens in 2015 (See Table 4.2 and Figure 4.2). In this context, it is important to recognize that primary prophylactic indication in ischemic heart disease was endorsed in Denmark in 2006.

There seems to be only minor regional differences in number of implants with The North Denmark Region implanting 167 ICDs per million citizens and The Region of Southern Denmark 212 per million citizens (See Table 4.3).

1.4.2 Pacing modes

In first pacemaker implants DDD pacing mode was used in 62.2% in 2000 but this has increased to 69.4% in 2015. Single lead atrial pacing (AAI) has almost disappeared, whereas VVI pacing has remained virtually unchained from 22.8% in 2000 to 24.2 in 2015 (See Table 4.4 and Figure 4.3).

In first ICD implants VVI pacing mode was used in 61.3% in 2000 and is almost unchanged to 63.8% in 2015. CRT-D and DDD-ICD were more often implanted previously (highest in 2011), but after a decrease they now constitute 19.9% (CRT-D) 16.4% (DDD-ICD) of all first implants (See Table 4.5 and Figure 4.4).

1.5 Comments Quality in device treatment 2015

Complications related to all device implantations within 120 days after implant were categorized according to a previous work from the register (Kirkfeldt et al EHJ 2013) and divided in major and minor complications, where “major” either have major clinical impact or results in reoperation. Only major complications are reported. Across all institutions, there seems to be an equal distribution of complications. However, the number of complications in each institution is too small for statistical comparison. In total, there were 281 major complications in 7028 device implants (4.0%). (See Table 5.1). First implant had a higher risk of major complication (4.4%) compared to device replacement (1.7%) but up-/downgrade had an even higher risk (6.6%) (See Table 5.2).
It is important to recognize that these numbers don’t take late infections into account.

Lead access via puncture of the subclavian vein is related to pneumothorax, and it is thus recommended to use the cephalic cut-down technique. This is well taken at all institutions but with some variations between hospitals (See Table 5.3 and Figure 5.1).

2 Implant activity in Denmark 2015

2.1 Pacemaker

2.1.1 First pacemaker implantation: (Institution|pacing mode)

	Procedure	Actual Device				
	First Implant					First Implant Total
Institution	PM-AAI	PM-VVI	PM-VVI leadless	PM-DDD	CRT-P	
Bispebjerg	1	78		274		353
Esbjerg	1	26		171		198
Gentofte	3	177	3	284	31	498
Herning		66		166		232
Hillerød		58		144		202
Nuuk		19				19
Odense		47	5	237	87	376
Rigshospitalet	1	33	4	130	60	228
Roskilde		173		379		552
Varde				3		3
Vejle		58		152		210
Viborg		36		104		140
Aabenraa		23		108		131
Ålborg	2	85		286	20	393
Aarhus	1	72	15	367	52	507
Grand Total	9	978	27	2805	250	4042

Table 2.1 First pacemaker implantations in Denmark 2015 for each institution and pacing mode

2.1.2 Pacemaker replacement: (Institution|pacing mode)

	Procedure	Actual Device					
	Replacement						Replacement Total
Institution	PM-AAI	PM-VVI	PM-VVI leadless	PM-VDD	PM-DDD	CRT-P	
Bispebjerg	7	22			44		73
Esbjerg		16			28	2	46
Gentofte	6	16		8	54	8	92
Herning	3	2			48		53
Hillerød	7	15		1	33		56
Nuuk		4					4
Odense	3	21	2		76	19	121
Rigshospitalet	2	14			45	14	75
Roskilde	19	26			71		116
Vejle	10	17			23		50
Viborg	2	6			29	4	41
Aabenraa	4	8			23		35
Ålborg	5	18			68	9	100
Aarhus	4	15	1		74	30	124
Grand Total	72	203	3	9	616	86	986

Table 2.2 Pacemaker replacements in Denmark 2015 for each institution and pacing mode

2.1.3 Pacemaker Up-/downgrade: (Institution|pacing mode)

	Procedure	Actual Device			
	Up-/Downgrade				Up-/Downgrade Total
Institution	PM-AAI	PM-VVI	PM-DDD	CRT-P	
Bispebjerg		2	1		3
Esbjerg		3	5	1	9
Gentofte		9	5	9	23
Herning		6	1		7
Hillerød		9	2		11
Odense		8	9	25	42
Rigshospitalet		5	5	16	26
Roskilde		14	9		23
Vejle		6	1		7
Viborg		6		2	8
Aabenraa		6			6
Ålborg		10	7	6	23
Aarhus	2	12	12	27	53
Grand Total	2	96	57	86	241

Table 2.3 Pacemaker up-/downgrades in Denmark 2015 for each institution and pacing mode

2.2 ICD

2.2.1 First ICD implantation (Institution|pacing mode)

	Procedure	Actual Device		
	First Implant			First Implant Total
Institution	ICD-VVI*	ICD-DDD	CRT-D	
Gentofte	102	20	21	143
Odense	176	11	70	257
Rigshospitalet	156	34	63	253
Roskilde	64	36		100
Ålborg	61	26	11	98
Aarhus	135	51	51	236
Grand Total	694	178	216	1088

Table 2.4 First ICD implantations in Denmark 2015 for each institution and pacing mode
*Of 694 VVI-ICD 13 (1.9%) were subcutaneous ICD, 1 imanted at Gentofte, 8 at Odense and 4 at Rigshospitalet.

2.2.2 ICD replacement: (Institution|pacing mode)

	Procedure	Actual Device		
	Replacement			Replacement Total
Institution	ICD-VVI*	ICD-DDD	CRT-D	
Gentofte	26	4	23	53
Odense	35	7	30	72
Rigshospitalet	84	24	49	157
Roskilde	5	3		8
Ålborg	24	10	26	60
Aarhus	47	24	66	137
Grand Total	221	72	194	487

Table 2.5 ICD replacements in Denmark 2015 for each institution and pacing mode
*Of 221 VVI-ICD 2 (0.9%) were subcutaneous ICD, 1 imanted at Odense and 1 at Rigshospitalet.

2.2.3 ICD Up-/downgrade: (Institution|pacing mode)

	Procedure	Actual Device		
	Up-/Downgrade			Up-/Downgrade Total
Institution	ICD-VVI	ICD-DDD	CRT-D	
Gentofte		7	23	30
Odense	2	5	41	48
Rigshospitalet	5	11	31	47
Roskilde	2	3		5
Ålborg	3	1	7	11
Aarhus		15	26	41
Grand Total	12	42	128	182

Table 2.6 ICD up-/downgrade in Denmark 2015 for each institution and pacing mode

2.3 Manufacturer

2.3.1 Pacemaker (manufacturer|pacing mode)

	Actual Device						
Manufacturer	PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P	Grand Total	Percent [%]
Biotronik	5	178		452	7	642	12.2
Boston Scientific	14	114	10	319	82	539	10.2
Medtronic	46	540		1137	13	1736	33.0
Pacesetter		5				5	0.1
Sorin	3	88		145		236	4.5
St. Jude Medical	15	342		1431	320	2108	40.0
Grand Total	83	1267	10	3484	422	5266	100.0

Table 2.7 Manufacturer of pacemakers implanted in Denmark 2015 for each pacing mode

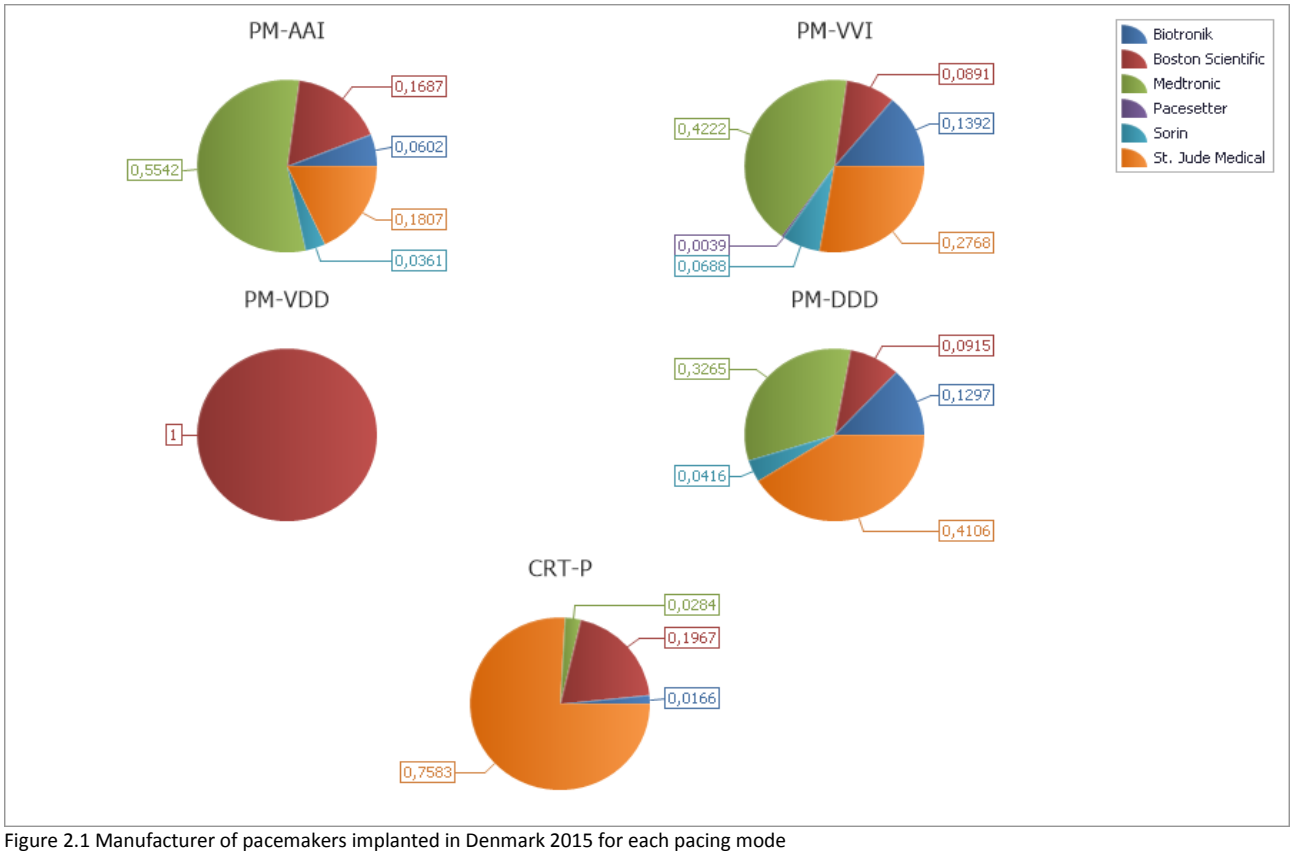

Figure 2.1 Manufacturer of pacemakers implanted in Denmark 2015 for each pacing mode

2.3.2 ICD (manufacturer|pacing mode)

	Actual Device				
Manufacturer	ICD-VVI	ICD-DDD	CRT-D	Grand Total	Percent [%]
Biotronik	95	48	51	194	11.0
Boston Scientific	202	48	55	305	17.3
Cameron Health	3			3	0.2
Medtronic	404	114	204	722	41.0
St. Jude Medical	225	82	231	538	30.5
Grand Total	929	292	541	1762	100.0

Table 2.8 Manufacturer of ICD´s implanted in Denmark 2015 for each pacing mode

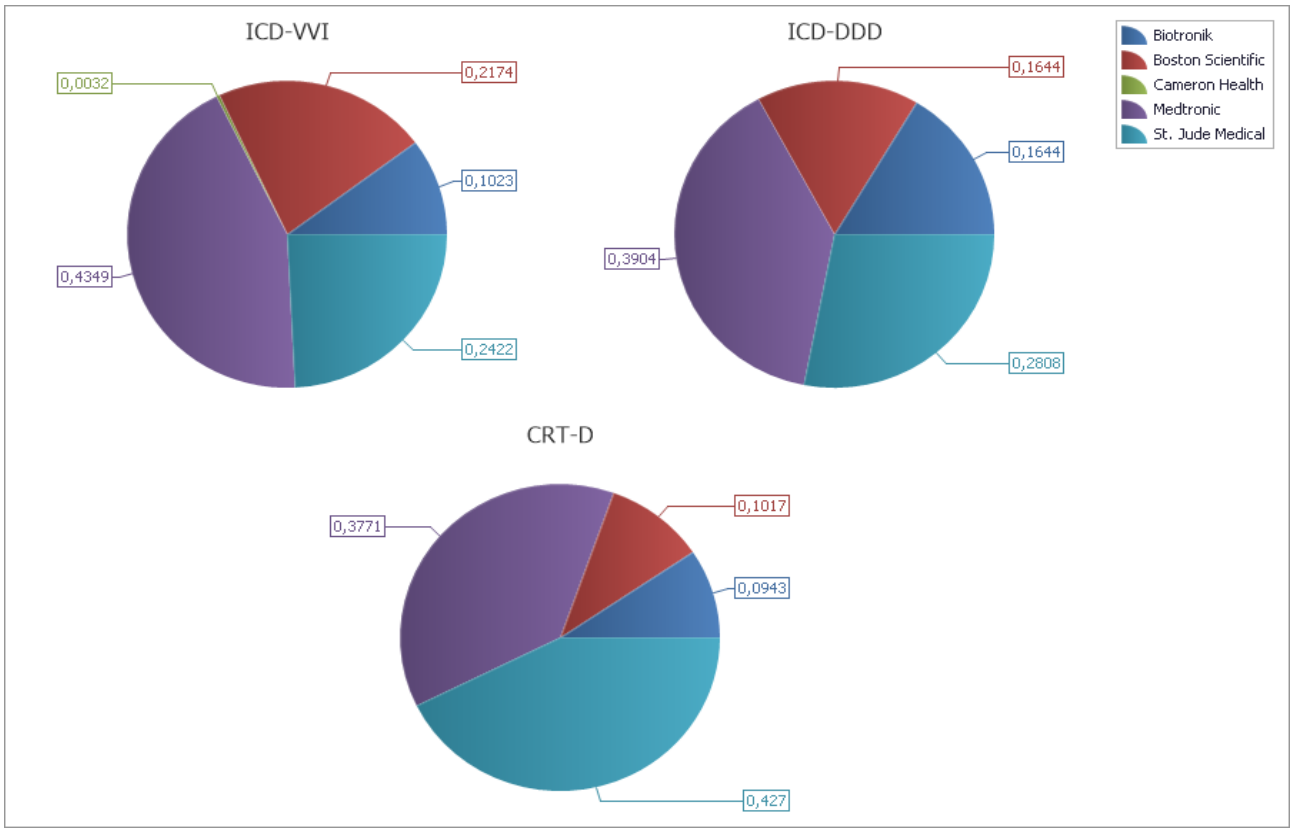

Figure 2.2 Manufacturer of ICD´s implanted in Denmark 2015 for each pacing mode

2.4 Leads

2.4.1 Low voltage leads (atrial, left ventricular, suppl. right ventricular pace/sense | manufacturer)

	Atrial	Left ventricular*	Right ventricular	Suppl. RV pace/sense	Grand Total	Percent [%]
Biotronik	220	19	673		912	10.5
Boston Scientific	279	27	252		558	6.4
Medtronic	24	50	24	2	100	1.2
Sorin	4		5		9	0.1
St. Jude Medical	3137	643	3302	7	7089	81.8
Grand Total	3664	739	4256	9	8668	100.0

Table 2.9 Manufacturer of low voltage leads implanted in Denmark 2015
*Of 739 low voltage leads for left ventricular pacing, 632 (86%) were quadripolar and 107 (14%) bipolar.

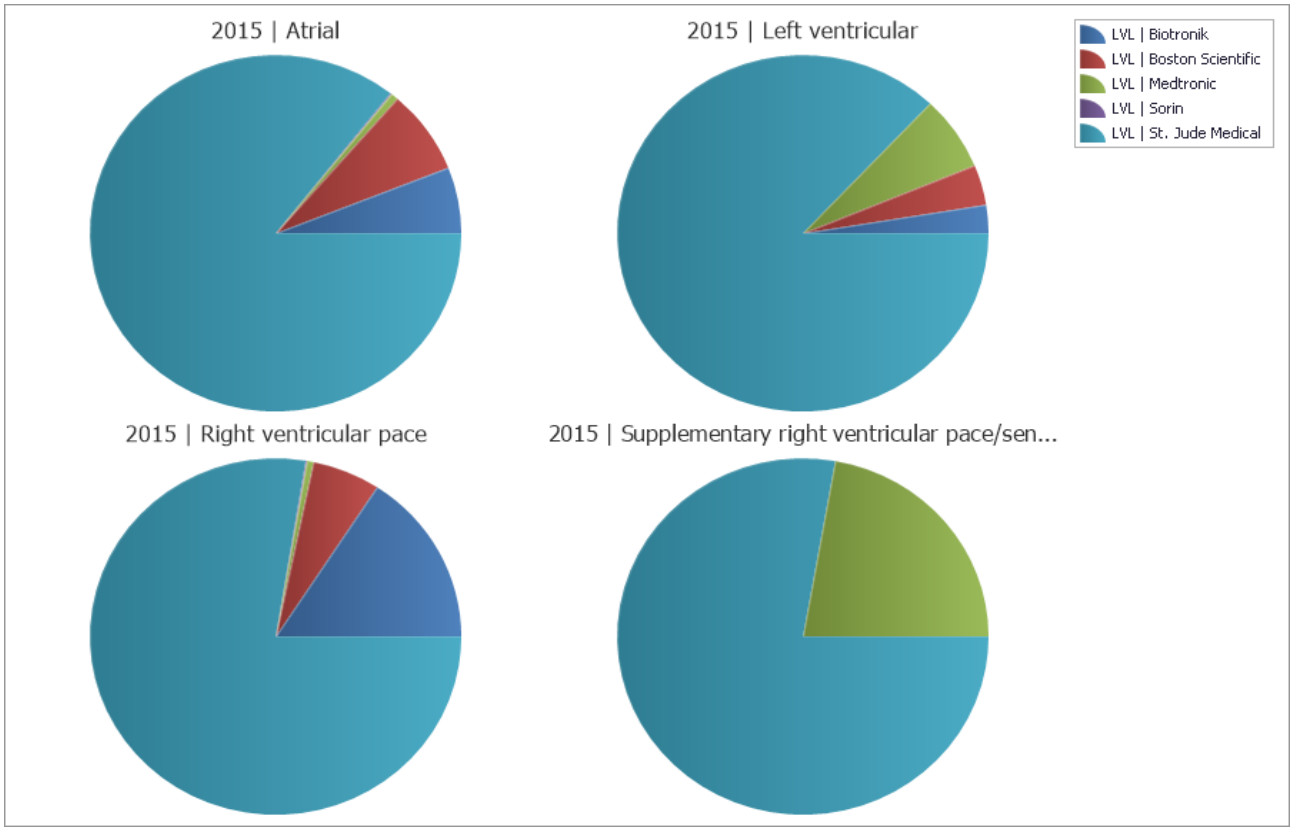

Figure 2.3 Manufacturer of low voltage leads implanted in Denmark 2015

2.4.2 High voltage leads (Right ventricular defibrillation, supplementary defibrillation|manufacturer)

	Right ventricular defibrillation	Supplementary defibrillation	Grand Total	Percent [%]
Biotronik	214		214	15.6
Boston Scientific	248		248	18.0
Cameron Health	12		12	0.9
Medtronic	348	11	359	26.1
St. Jude Medical	541	1	541	39.4
Grand Total	1363*	12	1375	100.0

Table 2.10 Manufacturer of high voltage leads implanted in Denmark 2015
*Of 1363 right ventricular leads 801 (59%) were single coil leads and 562 (41%) were dual coil leads.

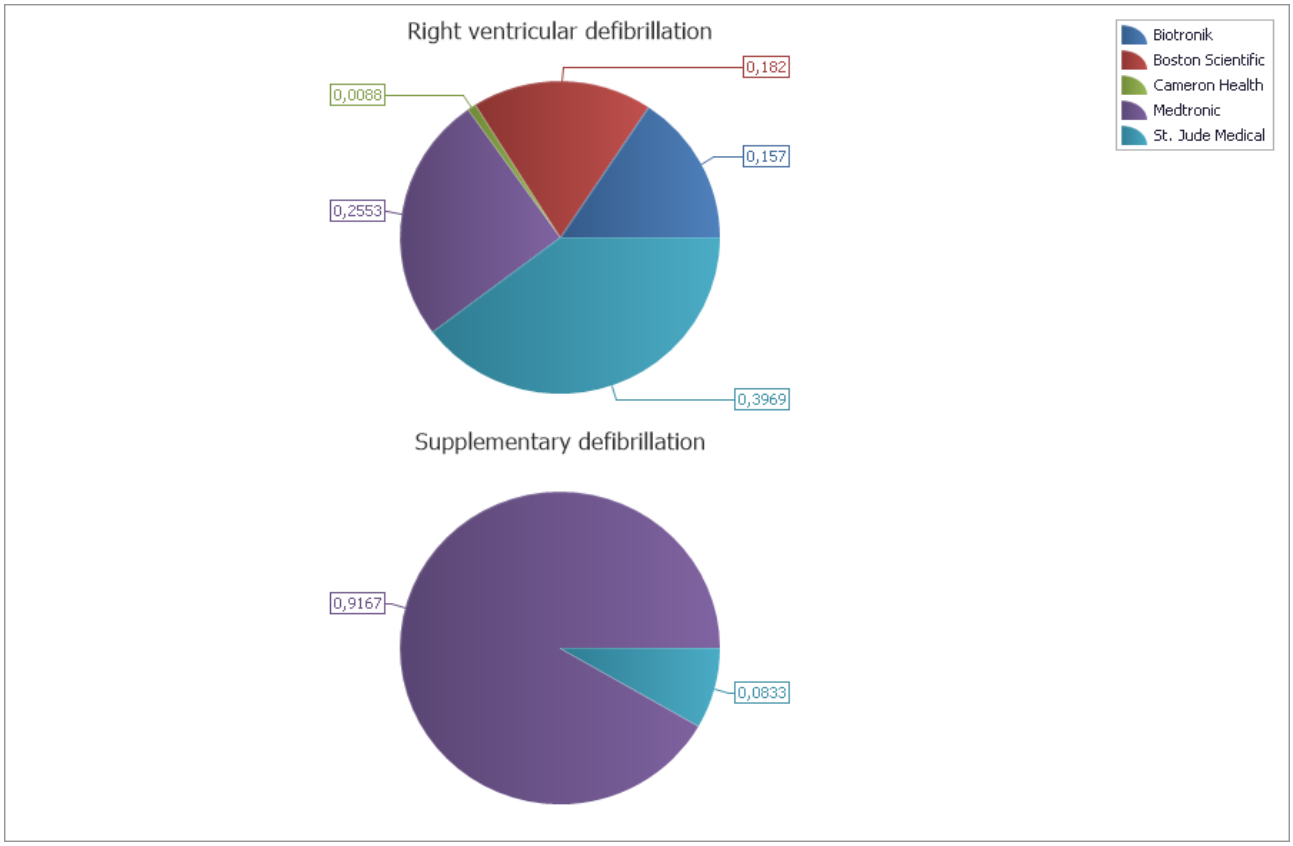

Figure 2.4 Manufacturer of high voltage leads implanted in Denmark 2015

2.5 Indication

2.5.1 Pacemaker (First implant|Indication)

	Procedure	
Indication	First Implant	Percent [%]
Arrhythmia not documented	13	0.3
Atrial arrhythmias without sinus dysfunction	14	0.3
AV block - 1°	24	0.6
AV block - 2:1	97	2.4
AV block - 2° . advanced type	137	3.4
AV block - 2° type I	36	0.9
AV block - 2° type II	236	5.8
AV block - 3°	1327	32.9
AV conduction impaired - status unknown	28	0.7
Bradycardia - Tachycardia syndrome	498	12.3
Bundle branch block, unspecified	72	1.8
Chronic atrial fibrillation & AV block - 3°	165	4.1
Chronic atrial fibrillation & bradycardia	263	6.5
Left bundle branch block	159	3.9
Other	37	0.9
Polymorphic VT /Torsades des pointes	6	0.1
Right bundle branch block	39	1.0
Sinus node dysfunction unspec. + imp. AV conduction	27	0.7
Sinus node dysfunction unspecified	34	0.8
Sinus node dysfunction with pause	636	15.7
Sinus node dysfunction without pause	121	3.0
Unknown	70	1.7
Grand Total	4039	100.0

Table 2.11 ECG indication, first pacemaker implantation Denmark 2015

2.5.2 ICD (First implant|Indication)

	Procedure	
Indication	First Implant	Percent [%]
Other	3	0.3
Prophylactic (none documented / induced)	497	45.5
Syncope with inducible VT or VF	22	2.0
Unknown	16	1.5
Ventricular Fibrillation	309	28.3
VT - monomorphic Non-sustained	66	6.0
VT - monomorphic Sustained	161	14.7
VT - Polymorhic w. long QT (Torsades des pointes)	11	1.0
VT - polymorphic (with normal QT interval)	8	0.7
Grand Total	1093	100.0

Table 2.12 ECG indication, first ICD implantation Denmark 2015

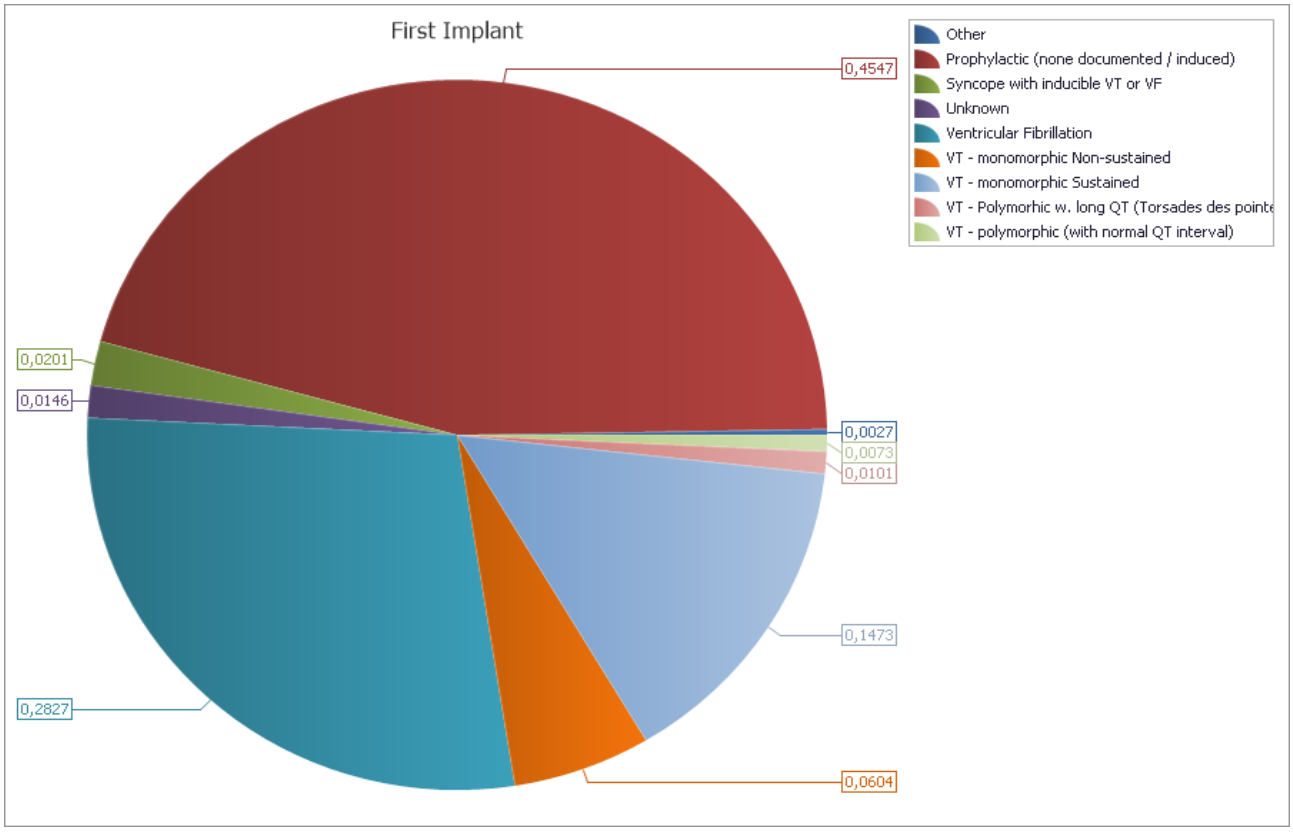

Figure 2.5 ECG indication, first ICD implantation Denmark 2015

2.6 Etiology

2.6.1 Pacemaker (First implant|Indication)

	Procedure	
Diagnosis	First Implant	Percent [%]
Autonomic dysfunction, other	3	0.1
AV node ablation, complication	4	0.1
AV node ablation, therapeutic	24	0.6
Cardiomyopathy - dilated	136	3.4
Cardiomyopathy - hypertrophic	5	0.1
Cardiomyopathy - other	18	0.4
Carotid sinus syndrome	99	2.4
Conduction tissue disease	2340	57.8
Congenital AV block	9	0.2
Conginetal heart disease	5	0.1
Drug induced	13	0.3
Endocarditis	2	0.0
Heart transplant	1	0.0
Ischaemic heart disease	197	4.9
Myocarditis	1	0.0
Other	142	3.5
Primary electrical disease - other	2	0.0
Surgical complication	89	2.2
Surgical therapeutic	4	0.1
Unknown	892	22.0
Valvular heart disease	49	1.2
Vasovagal syncope	16	0.4
Grand Total	4051	100.0

Table 2.13 Etiology, first pacemaker implantation Denmark 2015

2.6.2 ICD (First implant|Indication)

	Procedure	
Diagnosis	First Implant	Percent [%]
Arrhythmogenic right ventricle	6	0.5
Brugada syndrome	8	0.7
Cardiomyopathy - dilated	71	6.5
Cardiomyopathy - hypertrophic	26	2.4
Cardiomyopathy - other	32	2.9
Congenital heart disease	4	0.4
Congenital long QT	10	0.9
Idiopathic ventricular fibrillation	31	2.8
Ischaemic heart disease	832	76.1
Other	12	1.1
Primary electrical disease - other	12	1.1
Unknown	36	3.3
Valvular heart disease	13	1.2
Grand Total	1093	100.0

Table 2.14 Etiology, first ICD implantation, Denmark 2015

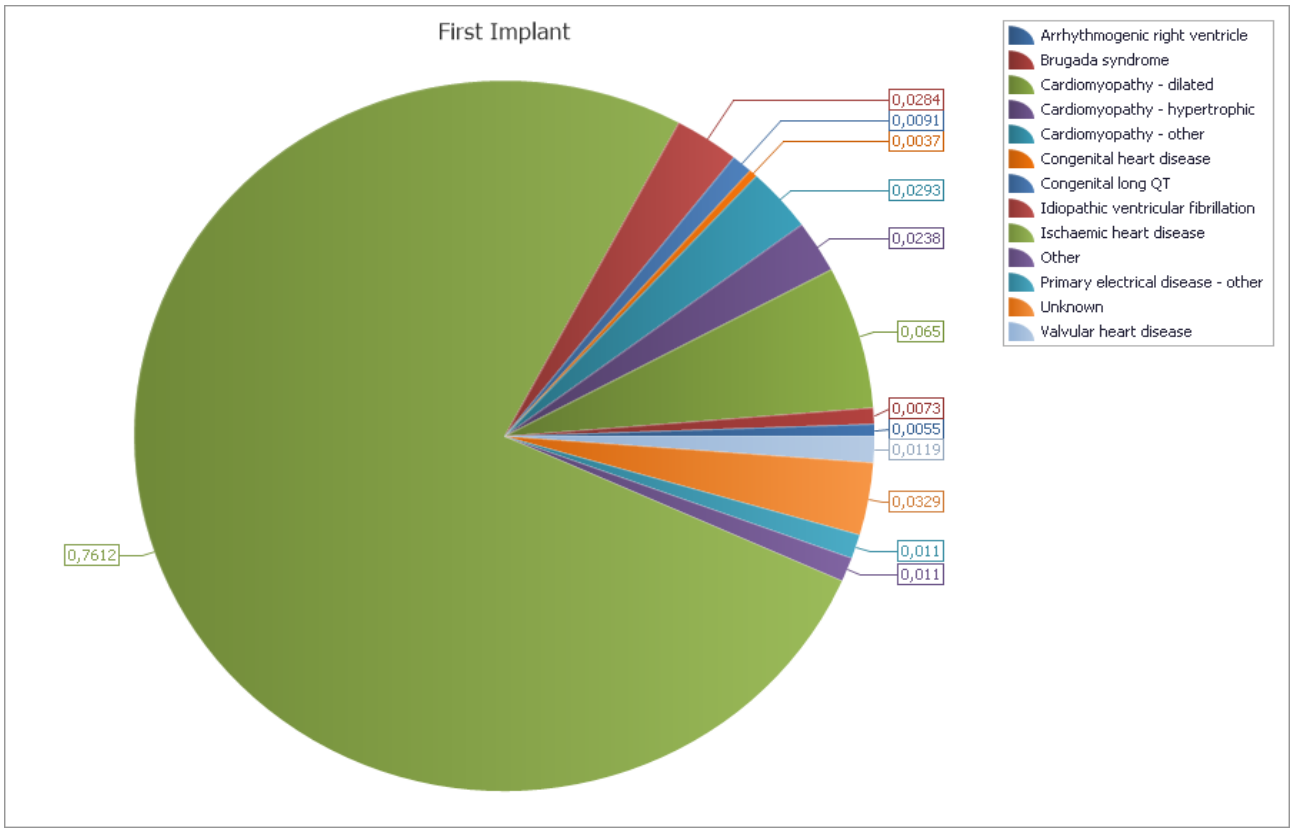

Figure 2.6 Etiology, first ICD implantation, Denmark 2015

3 Patients

3.1 Age and sex

3.1.1 First pacemaker implant (Age group|pacing mode)

	Age Implant																				
Actual Device	0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	95-99	100-104	Grand Total
PM-AAI										1	1	1			2	2	1	1				9
PM-VVI	1	1		3		1	1				6	14	15	65	107	157	187	230	145	40	5	978
PM-DDD	3	1	1	5	4	4	8	13	31	30	51	123	162	327	492	562	491	361	113	23		2805
CRT-P					1			1	4	9	18	27	25	22	46	48	37	9	2	1		250
Grand Total	4	2	1	8	5	5	9	14	35	40	76	165	202	414	647	769	716	601	260	64	5	4042

Table 3.1 Age group in first pacemaker implantation, Denmark 2015

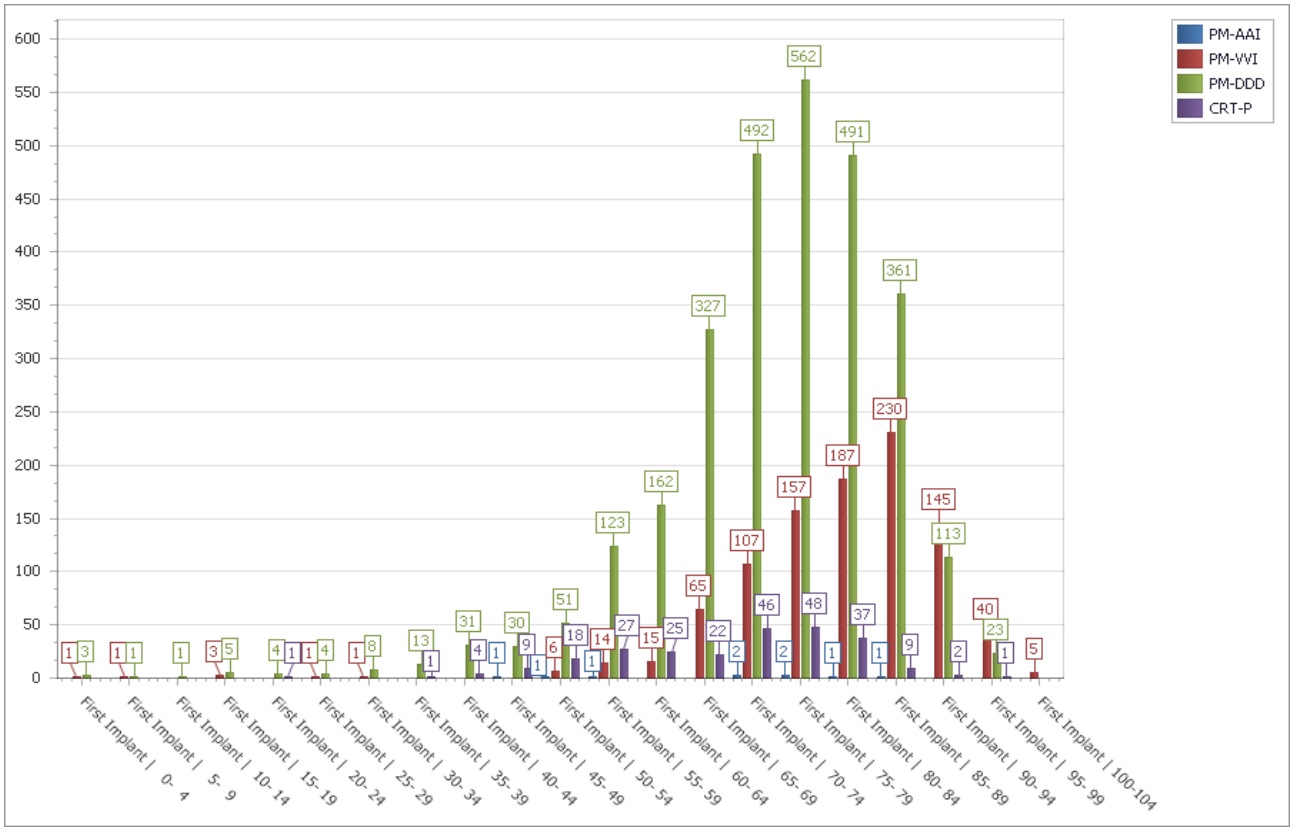

Figure 3.1 Age group in first pacemaker implantation, Denmark 2015

3.1.2 First pacemaker implant (Sex|pacing mode)

	Sex		
Actual Device	Female	Male	Grand Total
PM-AAI	1 (11.1%)	8 (88.9%)	9
PM-VVI	383 (39.2%)	595 (60.8%)	978
PM-DDD	1151 (41.0%)	1654 (59.9%)	2805
CRT-P	69 (27.6%)	181 (72.4%)	250
Grand Total	1604 (39.7%)	2438 (60.3%)	4042

Table 3.2 Gender in first pacemaker implantation in each pacing mode, Denmark 2015

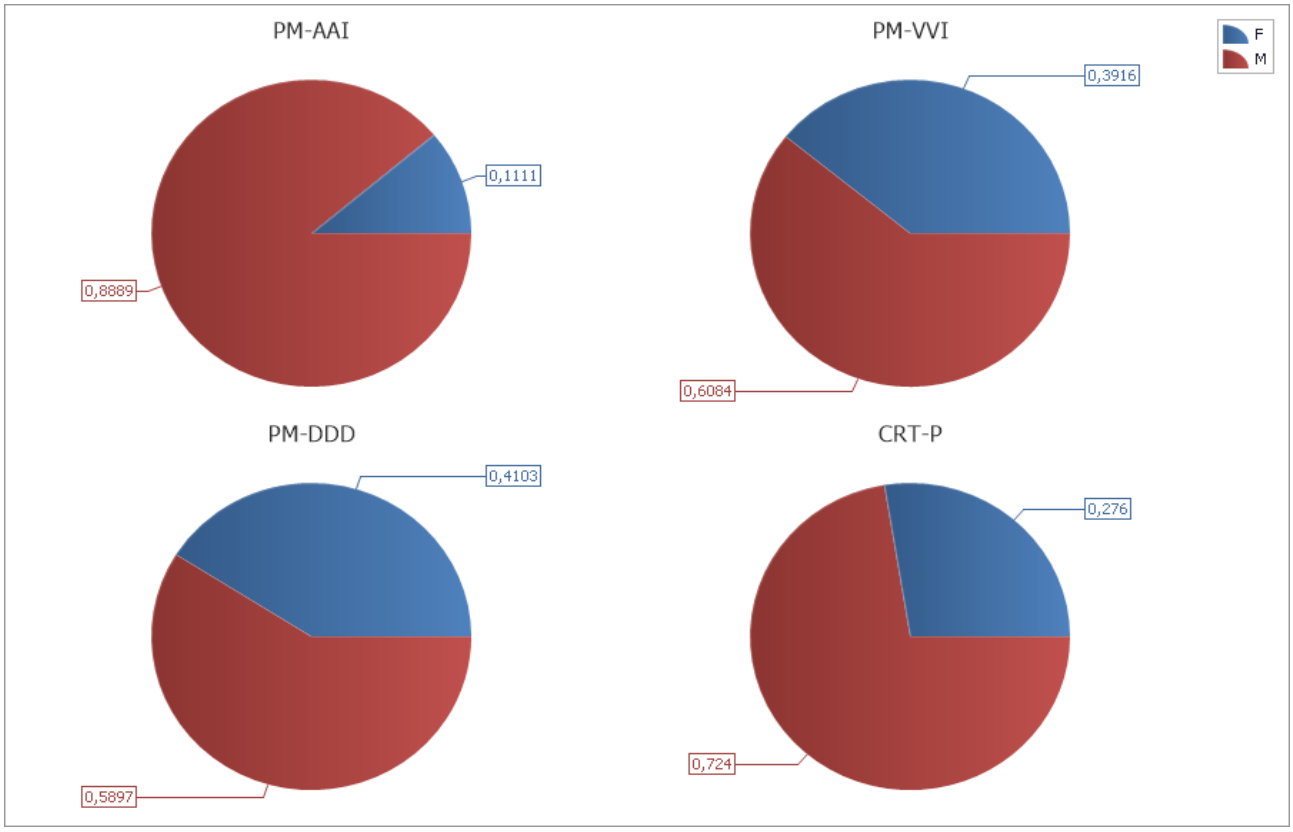

Figure 3.2 Gender in first pacemaker implantation in each pacing mode, Denmark 2015

3.1.3 First ICD implant (Age group | pacing mode)

	Age Implant																		
Actual Device	0-4	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	Grand Total
ICD-VVI	1	4	6	2	7	7	11	15	42	57	83	99	129	129	75	23	3	1	694
ICD-DDD				2	1	1	2	4	7	7	17	26	39	26	35	11			178
CRT-D							1	2	11	8	19	27	41	50	44	11	2		216
Grand Total	1	4	6	4	8	8	14	21	60	72	119	152	209	205	154	45	5	1	1088

Table 3.3 Age group in first ICD implantation, Denmark 2015

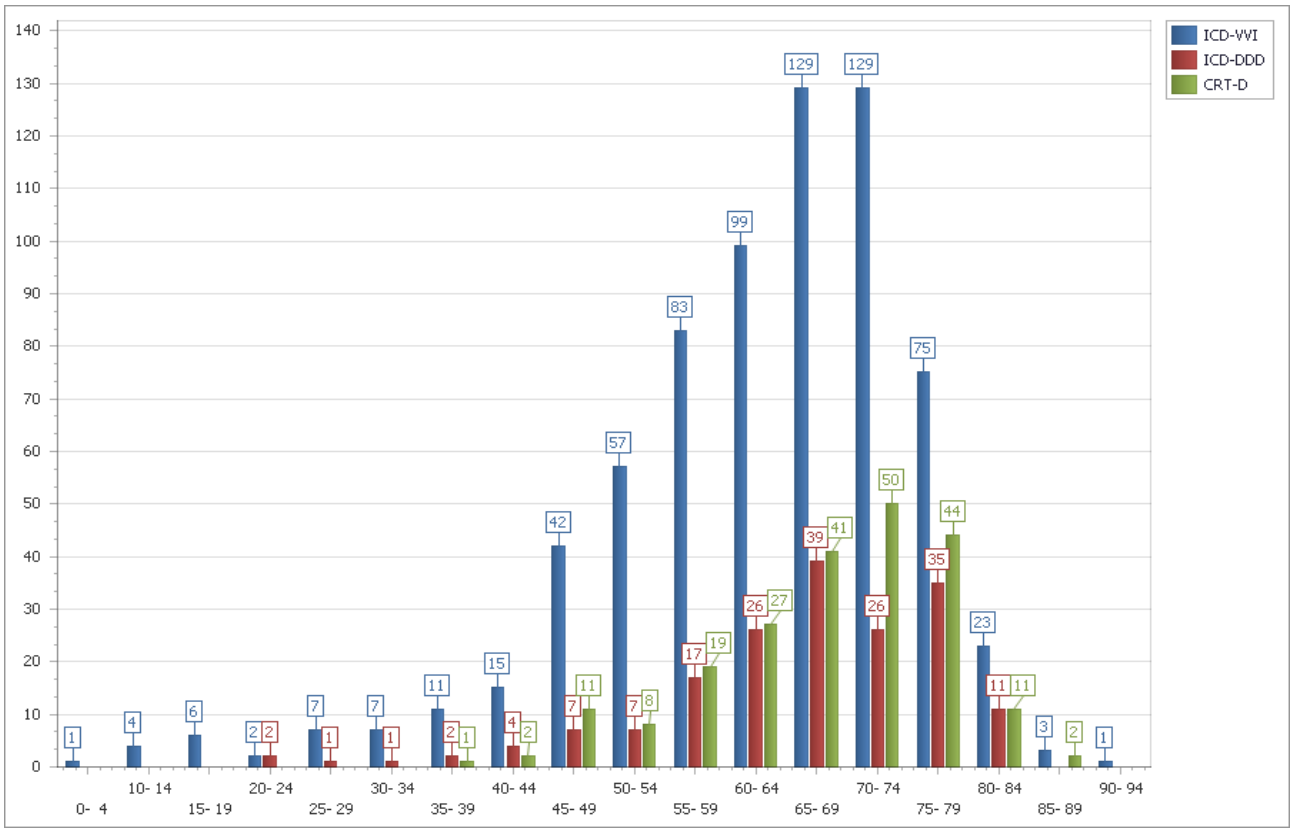

Figure 3.3 Age group in first ICD implantation, Denmark 2015

3.1.4 First ICD implant (Sex|pacing mode)

	Sex		
Actual Device	Female	Male	Grand Total
ICD-VVI	116 (16.7%)	578 (83.3%)	694
ICD-DDD	34 (19.1%)	144 (80.9%)	178
CRT-D	29 (13.4%)	187 (89.6%)	216
Grand Total	179 (16.5%)	909 (83.5%)	1088

Table 3.4 Gender in first ICD implantation in each pacing mode, Denmark 2015

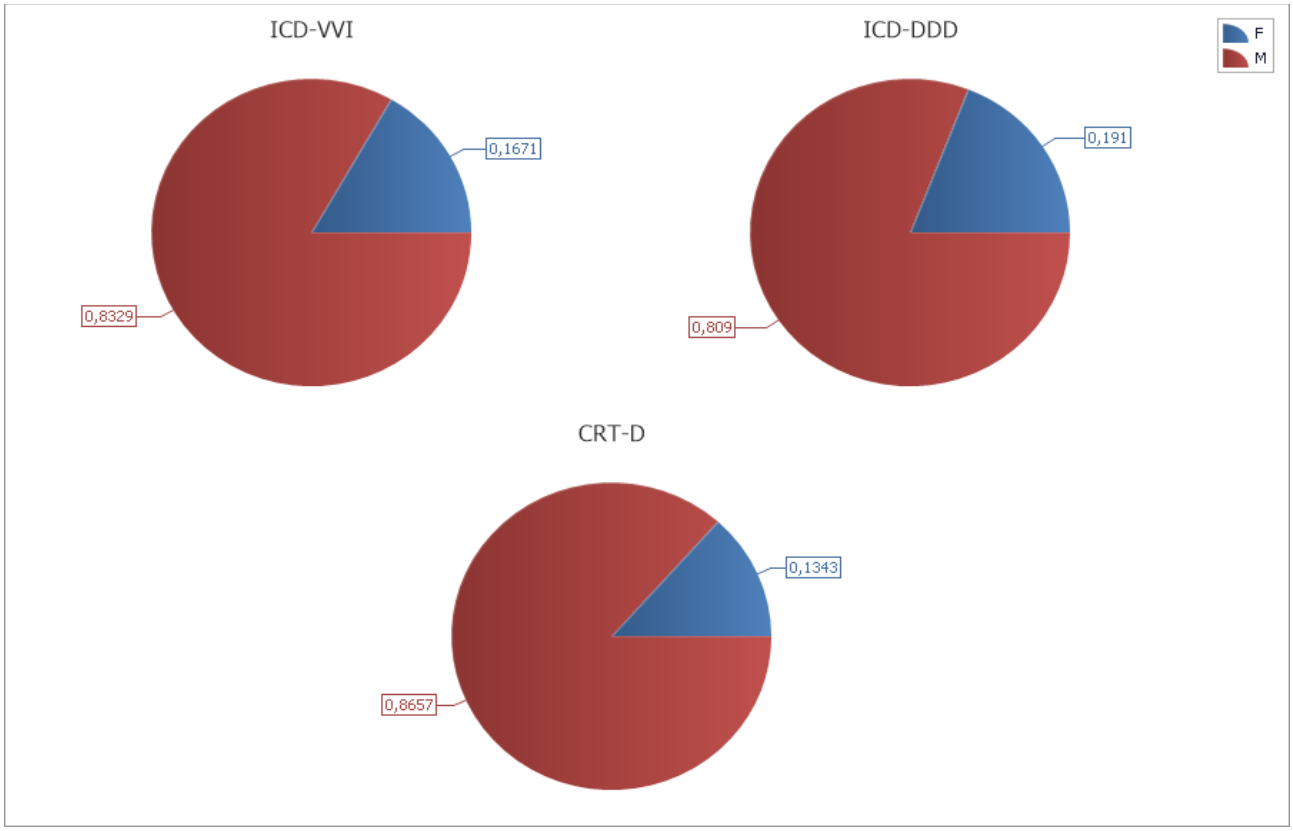

Figure 3.4 Gender in first ICD implantation in each pacing mode, Denmark 2015

3.2 Patients in treatment

3.2.1 All pacemaker patients in treatment and alive at 31. December 2015 according to last implant institution

		Actual Device					
Period	Last Institution	PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P	**Grand Total**
End 2015	Bispebjerg	48	409		1643		**2100**
	Esbjerg	23	147		841	28	**1039**
	Gentofte	119	723	65	2162	215	**3284**
	Herning	46	221		1137		**1404**
	Hillerød	82	372	2	1021		**1477**
	Odense	85	439	2	1886	350	**2762**
	Rigshospitalet	48	185		883	395	**1511**
	Roskilde	118	659	3	2291		**3071**
	Vejle	123	439		1264		**1826**
	Viborg	21	161		866	21	**1069**
	Aabenraa	45	211		846	1	**1103**
	Ålborg	91	412	1	2100	127	**2731**
	Aarhus	67	497	1	2961	494	**4020**
End 2015 Total		916	4875	74	19901	1631	**27397**

Table 3.5 All danish pacemaker patients in treatment and alive 31. December 2015 according to last implant institution

3.2.2 All ICD patients in treatment and alive at 31. December 2015 according to last implant institution

		Actual Device			
Period	Last Institution	ICD-VVI	ICD-DDD	CRT-D	Grand Total
End 2015	Gentofte	881	263	381	1525
	Odense	1130	284	494	1908
	Rigshospitalet	1406	477	587	2470
	Roskilde	202	101		303
	Ålborg	445	272	218	935
	Aarhus	1029	477	670	2176
End 2015 Total		5093	1874	2350	9317

Table 3.6 All danish ICD patients in treatment and alive 31. December 2015 according to last implant institution

4 Trends in implant activity 2000-2015

4.1 Total number of first implants and number of devices per million citizens

4.1.1 First pacemaker implants 2000-2015

Antal	Procedure																
	First Implant																First Implant Total
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	
Implants Total	2346	2449	2477	2605	2652	2883	2932	2780	3006	3080	3328	3386	3664	3733	3861	4042	49224
Implants per mill. citizens*	440	458	461	484	491	533	540	510	549	559	601	609	657	666	686	714	

Table 4.1 Number of first pacemaker implants in Denmark 2000-2015 and number of pacemakers per million citizens

*Data on population based on data from Statistics Denmark

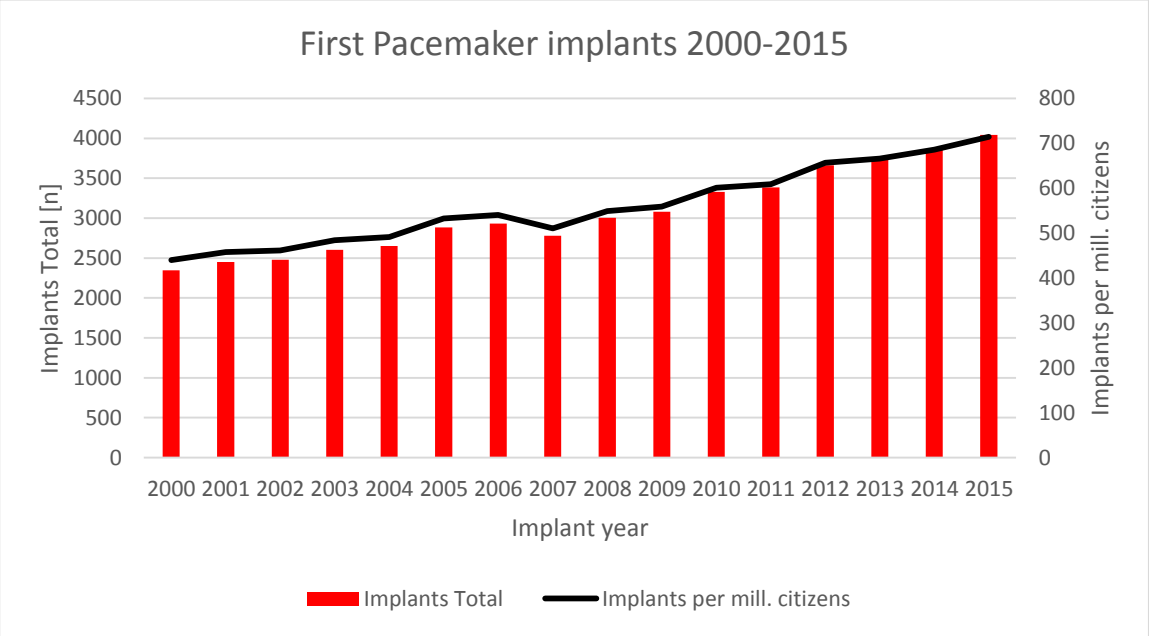

Figure 4.1 Number of first pacemaker implants in Denmark 2000-2015 and number of pacemakers per million citizens

4.1.2 First ICD implants 2000-2015

Antal	Procedure																
	First Implant																First Implant Total
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	
Implants Total	230	231	301	331	397	510	574	725	918	1013	1090	1160	1224	1180	1117	1088	12089
Implants per mill. citizens*	43	43	56	61	74	94	106	133	168	184	197	209	219	211	198	192	

Table 4.2 Number of first ICDs implants in Denmark 2000-2015 and number of ICDs per million citizens

*Data on population based on data from Statistics Denmark

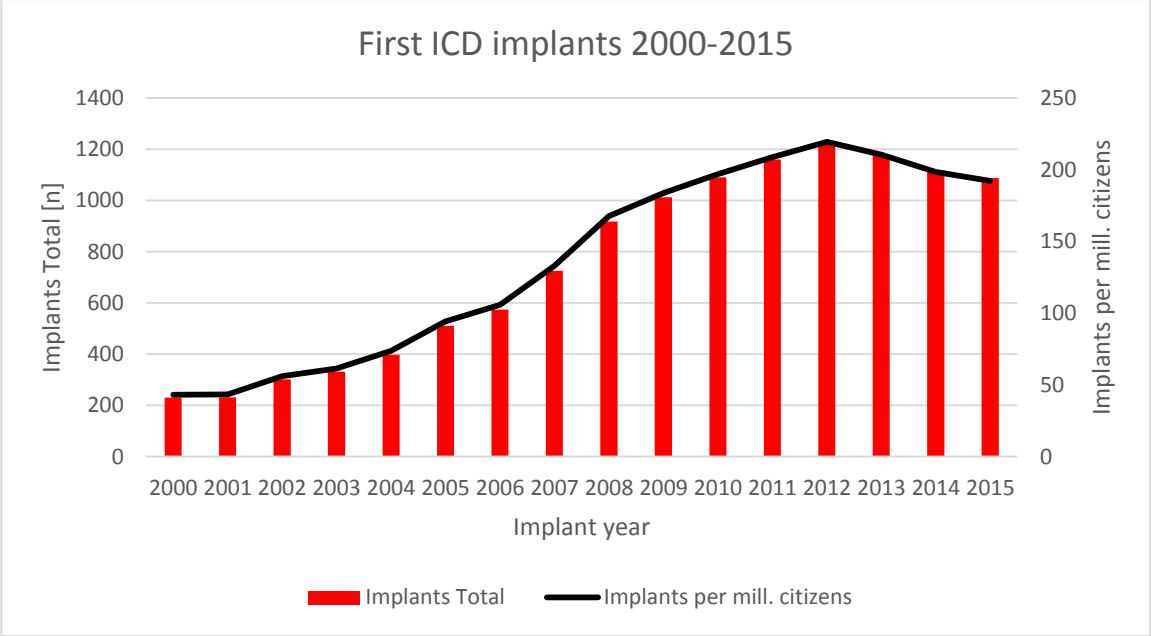

Figure 4.2 Number of first ICDs implants in Denmark 2000-2015 and number of ICDs per million citizens

4.1.3 First ICD implants 2015 per per million citizens per Region

	Procedure	Actual Device					
	First Implant			First Implant Total	Region	Citizens (1. January 2016)	First ICD implants per mill. citizens
Institution	ICD-VVI	ICD-DDD	CRT-D				
Gentofte	102	20	21	143	The Capital Region of Denmark and Region Zealand	2616673	189.6
Roskilde	64	36		100			
Rigshospitalet	156	34	63	253			
Odense	176	11	70	257	The Region of Southern Denmark	1211770	212.1
Ålborg	61	26	11	98	The North Denmark Region	585499	167.4
Aarhus	135	51	51	237	Central Denmark Region	1293309	183.3
Grand Total	694	178	216	1088		5707251	190.6

Table 4.3 Number of first ICDs implants in 2015 and number of ICDs per million citizens i different regions in Denmark

4.2 Pacing mode in first implants

4.2.1 Pacemakers 2000-2015

	Procedure																
	First Implant																First Implant Total
Actual Device	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	
PM-AAI	248	225	230	270	288	279	238	167	128	97	56	19	6	7	13	9	2280
PM-VVI	534	597	564	675	692	757	811	750	821	739	719	722	832	855	906	978	11952
PM-VDD	74	63	50	28	36	52	49	41	35	44	20	5	1	1			499
PM-DDD	1459	1507	1563	1545	1519	1620	1691	1708	1913	2067	2394	2459	2637	2649	2699	2805	32235
CRT-P	31	57	70	87	117	175	143	114	109	133	139	181	188	221	243	250	2258
Grand Total	2346	2449	2477	2605	2652	2883	2932	2780	3006	3080	3328	3386	3664	3733	3861	4042	49224

Table 4.4 Number of first pacemaker implants and pacing modes in Denmark 2000-2015

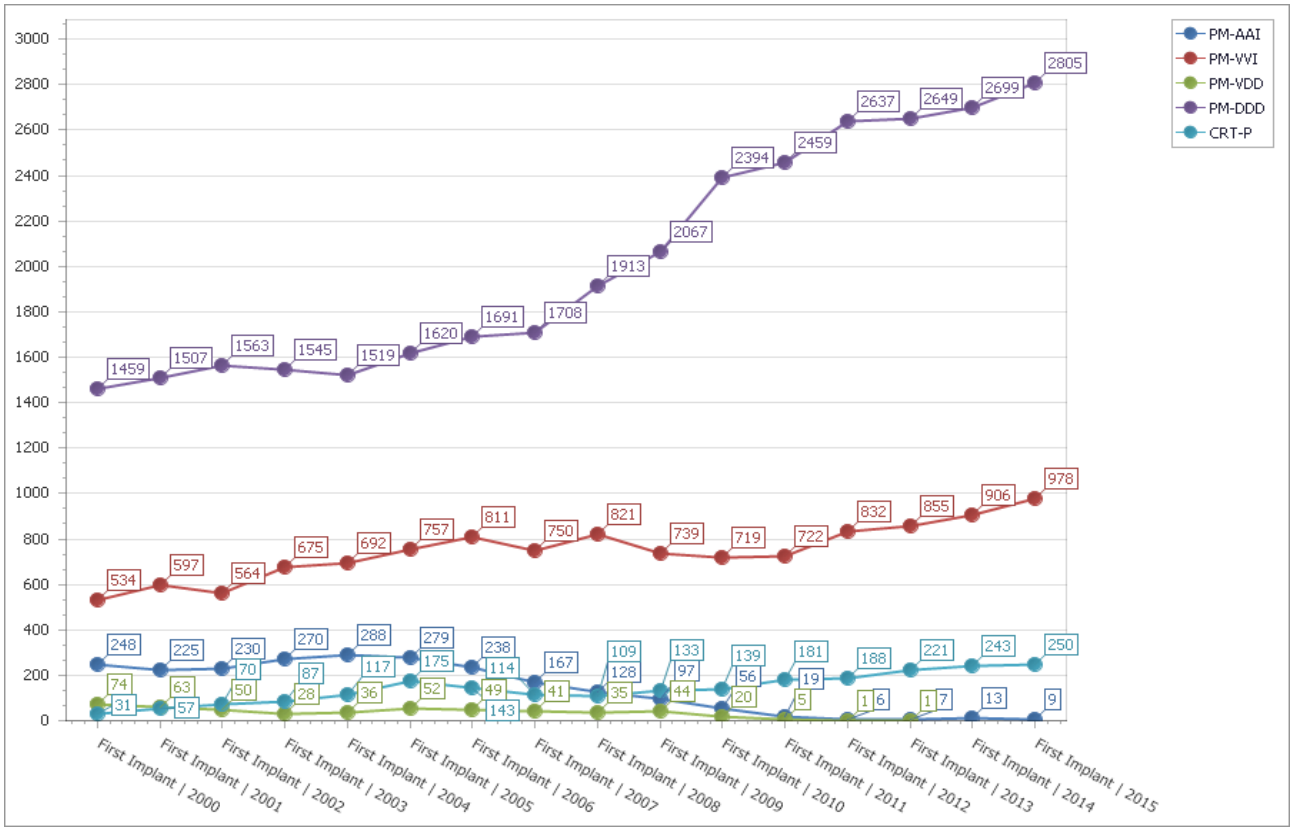

Figure 4.3 Number of first pacemaker implants and pacing modes in Denmark 2000-2015

4.2.2 ICDs 2000-2015

	Procedure																
	First Implant																First Implant Total
Actual Device	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	
ICD-VVI	141	150	177	229	270	303	327	476	571	540	531	534	640	694	691	694	6968
ICD-DDD	77	75	99	73	88	117	143	128	191	247	297	295	257	211	185	178	2661
CRT-D	12	6	25	29	39	90	104	121	156	226	262	331	327	275	241	216	2460
Grand Total	230	231	301	331	397	510	574	725	918	1013	1090	1160	1224	1180	1117	1088	12089

Table 4.5 Number of first ICD implants and pacing modes in Denmark 2000-2015

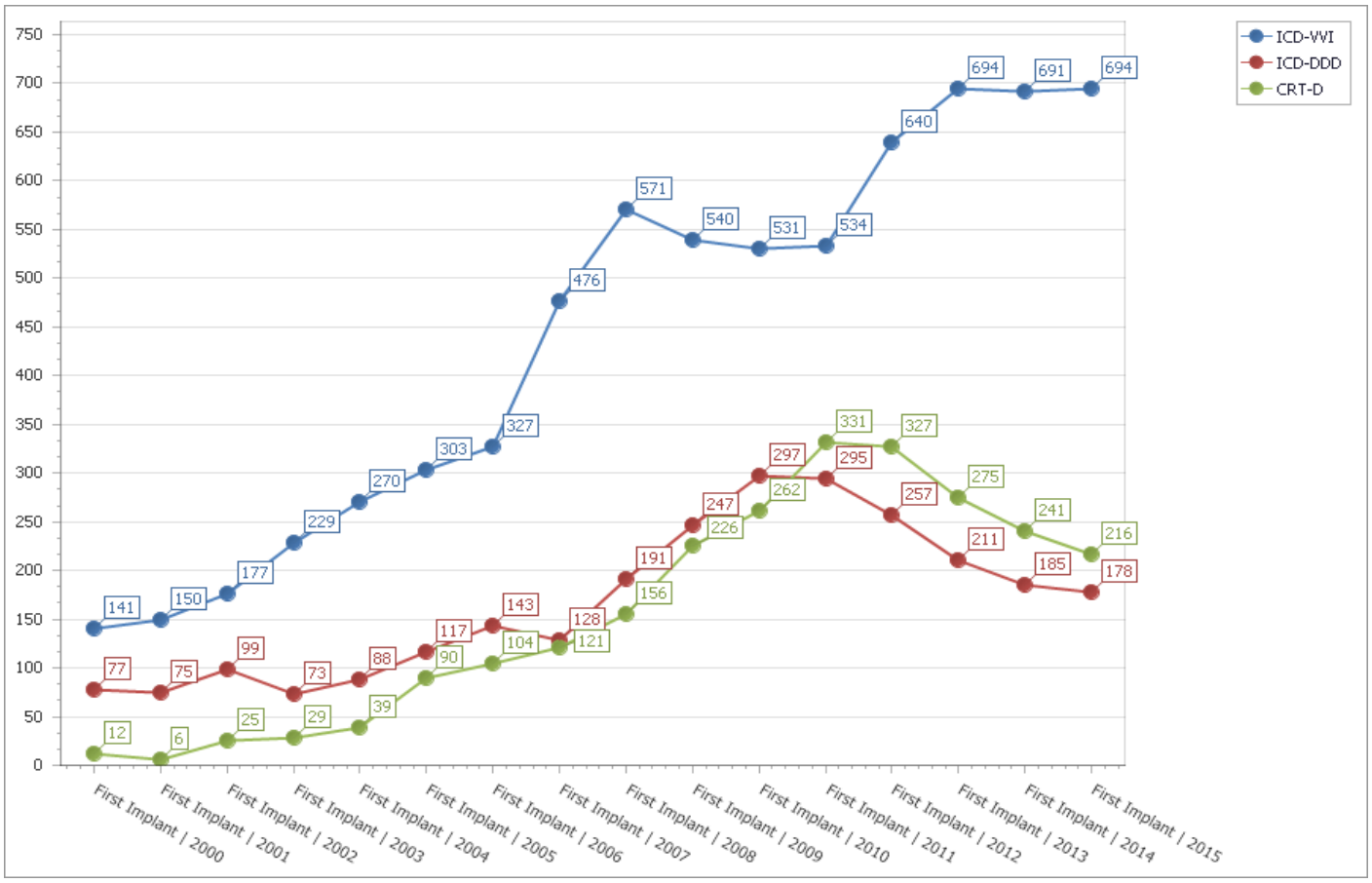

Figure 4.4 Number of first ICD implants and pacing modes in Denmark 2000-2015

5 Quality in device treatment 2015

5.1 Complications after all implants in 2015

5.1.1 Major complications (either major clinical impact or resulting in reoperation) per institution up to 120 days after implant

Complications within 120 days after implant procedure in 2015

Complication type	Institution													Total
Procedure related	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	
Cardiac perforation not req. pericardiocentesis		1	1			3	2	5				2	6	**20**
Cardiac perforation req. pericardiocentesis		1	1				1	2		1		6	1	**13**
Deep venous thrombosis		1	1		1	2	1	1						**7**
Haemothorax not req. drainage							1							**1**
Haemothorax req. drainage							1							**1**
Local pocket infection / Skin erosion			1	1		1		2			1	6	8	**20**
Pneumothorax not req. drainage			2		2			1				4	2	**11**
Pneumothorax req. drainage	1		3	1	2	1	3	6	2		2	6	1	**28**
Stroke or RIND or TIA					1			1	1		1	1		**5**
Systemic infection / endocarditis	3		3			3	8					3	5	**25**
Lead related														
Connector failure								1						**1**
Displacement	5	7	7	5	7	14	18	17	2	3	2	13	5	**105**
Extracardiac stimulation				1			1							**2**
Generator-lead interface problem			1											**1**
High defibrillation threshold							2							**2**
High impedance													1	**1**
High pacing threshold	1	1	2				3	3				1	3	**14**
Insulation failure										1			2	**3**
Lead dislodgement without intervention			1	1			3		4			1		**10**
Sensing / pacing failure				2		1								**3**
Twiddler's syndrome	1													**1**
Undersensing		1		1				2				2	1	**7**
														281

Table 5.1 Major procedure- and lead related complications within 120 days after all implant procedures in 2015

5.1.2 Major complications (either major clinical impact or resulting in reoperation) per procedure type up to 120 days after implant

Complications within 120 days after implant procedure in 2015

Complication type	Procedure			Total
Procedure related	**First implant**	**Replacement**	**Up-Downgrade**	
Cardiac perforation not req. pericardiocentesis	7		1	**8**
Cardiac perforation req. pericardiocentesis	5		0	**5**
Deep venous thrombosis	5		2	**7**
Haemothorax not req. drainage	1			**1**
Haemothorax req. drainage	1			**1**
Local pocket infection / Skin erosion	10	8	2	**20**
Perforation not req. pericardiocentesis	10		2	**12**
Perforation req. pericardiocentesis	8			**8**
Pneumothorax not req. drainage	11			**11**
Pneumothorax req. drainage	26		2	**28**
Stroke or RIND or TIA	5			**5**
Systemic infection / endocarditis	13	7	5	**25**
Lead related				
Connector failure	1			**1**
Displacement	90	7	8	**105**
Extracardiac stimulation	1		1	**2**
Generator-lead interface problem	1			**1**
High defibrillation threshold	1	1		**2**
High impedance	1			**1**
High pacing threshold	10	1	3	**14**
Insulation failure	3			**3**
Lead dislodgement without intervention	9		1	**10**
Sensing / pacing failure	2	1		**3**
Twiddler's syndrome	1			**1**
Undersensing	6		1	**7**
Total	228	25	28	**281**
Percent of all procedures	4.4	1.7	6.6	

Table 5.2 Major procedure- and lead related complications within 120 days after different procedures in 2015

5.2 Lead access

5.2.1 Ratio of cephalic vein cut-down to subclavian vein puncture in lead implants during first device implants

Lead access in first implants in 2015
Ratio of cephalic|subclavian vein

	Institution													Total
Lead type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
Atrial	3.57	3.65	2.77	2.27	1.54	2.34	0.42	2.66	1.49	1.36	2.72	1.1	1.32	**1.75**
Right ventricular pace	3.76	3.28	3.24	2.44	1.54	2.3	4.24	3.04	1.38	1.64	2.85	1.59	1.52	**2.33**
Right ventricular defibrillation			5.26			2.75	4.51	3.16				1.00	1.38	**2.49**
Left ventricular pacing			0.06			1.36	0.02					0.00	0.17	**0.31**
Total	**3.67**	**3.45**	**2.68**	**2.37**	**1.55**	**2.22**	**1.16**	**2.90**	**1.43**	**1.52**	**2.79**	**1.18**	**1.23**	**1.88**

Table 5.3 Ration of cephalic cut-down to subclavian vein puncture in lead access during first device implant

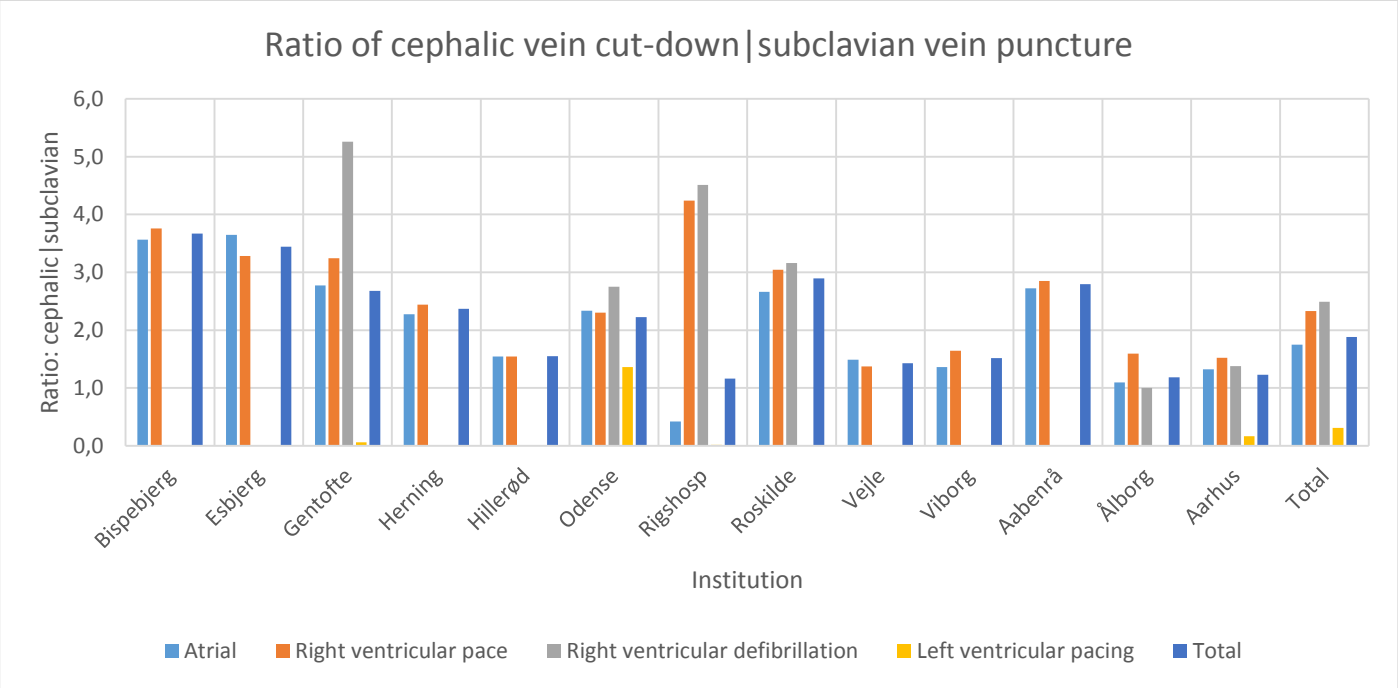

Figure 5.1 Ration of cephalic cut-down to subclavian vein puncture in lead access during first device implant