Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation

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CERTIFICATE OF APPROVAL

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Precis

I believe that there is an increasing role for public health research in clinical cardiac electrophysiology. It is my hope that this thesis will make a contribution to that end. I would like to thank those who supported this work, including the members of my thesis committee and my wife Lilia.

Abstract

Objectives: Atrial fibrillation is the most common sustained arrhythmia seen clinically today and is a major cause of morbidity, including stroke.[1] It is an arrhythmia, which frequently responds poorly, if at all, to medical therapy. Radiofrequency ablation of the atrioventricular node with permanent pacing of the right ventricle is an alternative to medications and results in control of the ventricular rate. While this procedure offers an attractive alternative to chronic medical therapy, there is little published evidence about the relative timing of pacemaker implantation and ablation procedures that would guide clinicians. Our hypothesis was that the combined approach of simultaneous pacemaker implantation and atrioventricular node (AVN) ablation, versus delaying the procedures, carries an increased risk due to early complications (within one month).

Methods: We included in the database one hundred and thirteen (113) patients from OHSU (USA) and eighty (80) patients from Sheba Medical Center (Israel) who underwent AVN ablation and pacemaker implant from 1990 through December, 2002 for an atrial arrhythmia (most commonly atrial fibrillation). We performed retrospective analysis of short-term (one month or less) complications and univariate group comparisons using t-test for continuous variables and chi-square for categorical variables. We performed a multivariate logistic regression analysis blending both continuous and categorical variables.

Results: Of the 193 patients, 73 were in the Early group (defined as having AVN ablation performed 1 to 7 days following pacemaker implantation) and 120 were in the

Late group (defined as having AVN ablation performed 8 or more days after pacemaker implant). Patients in the Early group were more likely to have a complication within thirty days of either procedure than patients in the Late group (15% vs 6.7%; p=.06) (OR=2.48, 95% CI 0.95-6.49). However, there was not a significant difference between the groups with respect to the total number of complications, the type of complications or number of days to complication. Using binary logistic regression, we found two variables to be predictive of early complication: female gender (OR=3.4, 95% CI 1.1-10.9) and year of ablation (OR=.81, 95% CI .70-.95).

Conclusions: Early pacemaker implant and AVN ablation (ablation performed within 7 days of pacemaker implant) are associated with a higher risk of short-term complication than separating the procedures by at least eight days.

Introduction

Atrial fibrillation (AF), with an estimated prevalence in the United States of 0.1 - 0.4 % of the population, is the most common arrhythmia (after premature ventricular contractions) and is a leading cause of morbidity. Worldwide, AF is commonly associated with rheumatic heart disease. However, it can also occur in the presence of other cardiac disorders or alone (so-called lone AF). The incidence of non-rheumatic AF increases with age, from 0.5% of the population between the ages of 50 and 59 to an estimated 9% in those older than 70.[2 3 4] While it is more prevalent in patients over age 50, it affects adults in all decades of life. There are three clinical forms of AF, paroxysmal (episodic and self-limited, not requiring medical intervention for cardioversion), persistent (episodic requiring medical intervention for cardioversion) and chronic (sustained for long periods of time or without cessation).

While AF can be well tolerated, it is frequently associated with clinical symptoms (e.g. fatigue, chest discomfort, shortness of breath) especially when patients develop a rapid ventricular rate. In addition to clinical symptoms, AF is associated with increased risk of stroke. Stroke in the setting of AF increases in frequency with age and certain well-defined risk factors, including reduced left ventricular function, hypertension, history of cerebrovascular accident (CVA) and female older than 65.[5] The risk of stroke varies with age from 0.5%/year in patients younger than 60 with AF and an absence of other preexisting conditions to >10%/year in the elderly.[6]

In an effort to reduce mortality and morbidity, and to improve quality of life, current AF therapy is aimed primarily at controlling heart rate response to AF and preventing stroke. Therapeutic options are also available to keep patients out of AF (and

in normal sinus rhythm), though recent evidence suggests that there is no mortality benefit to this. The AFFIRM trial of > 4000 patients found no significant difference in mortality rates but higher rates of hospitalization and adverse drug reactions in patients who were maintained on medications to control their rhythm vs. controlling their heart rate.[7] Another trial of 522 patients with persistent AF found that both the rate control and rhythm control groups had similar end points of death from cardiovascular causes, heart failure, thromboembolic complications, bleeding, need for implantation of a pacemaker, and severe adverse effects of drugs.[8]

For patients in whom AF rate control is the goal, medications have historically been used as the mainstay of therapy. In spite of the many pharmacologic options available for rate control, some AF patients are resistant to therapy and continue to have significant symptoms. Other patients are unable or unwilling to take medications. For these patients, non-pharmacologic options, both surgical (e.g. maze procedure) and non-surgical interventions (e.g. pulmonary vein isolation, AVN ablation and implantation of a permanent pacemaker), have been developed, though with greater degrees of patient risk to patients than medications. The Maze procedure requires an open-chest approach and results in significant scarring of the atria, with only limited success. AVN ablation and pacemaker implantation, on the other hand, is a less-invasive, non-surgical option with low morbidity, short recovery time and high rates of long-term symptom control. While the latter does not reduce the risk of stroke, it can provide patients with a controlled ventricular rate and significantly reduce symptoms.

The Ablate and Pace Trial prospectively assessed the effects of AVN ablation and pacemaker implant on health-related quality of life, survival, exercise capacity and ventricular function in 156 patients with symptomatic atrial fibrillation. Using a health status questionnaire, the investigators found a significant improvement in quality of life scores for all 8 subscales of the questionnaire and there was a statistically significant improvement in cardiac function.[9] Other studies have reported similar results.[10 11] Similarly, a comparison of AVN ablation and pacemaker implant vs. medication therapy in drug-resistant paroxysmal AF found ablation and pacemaker treatment were superior to drug therapy in controlling symptoms and improving quality of life.[12]

As with any invasive intervention, both AVN ablation and implantation of a permanent pacemaker are associated with short-term (less than one month) risks. Risks are related to both procedures. To date, there are no published data on the relative benefit to the patient of performing these procedures together versus separating them by at least a week. Given the relatively high prevalence of AF, the increasing need for therapeutic options for AF in an aging population, and the significant morbidity associated with untreated AF, improving the safety of this approach is an important public health issue.

Materials and Methods

Study Design: This was a cross-sectional study of all consecutive patients who were referred to OHSU (Portland, Oregon) and Sheba Medical Center (Tel Aviv, Israel) for AVN ablation. This study was approved by the Institutional Review Board of Oregon Health and Science University.

Patients: We included in the database one hundred and thirteen (113) patients from OHSU and eighty (80) patients from Sheba Medical Center (Israel) who underwent AVN ablation and pacemaker implant (or who had an existing pacemaker at the time of ablation) from 1990 through December, 2002. AVN ablation was performed on one hundred and fifteen (115) patients at OHSU, but two were lost to follow-up. Most (though not all) patients had AF which was not well controlled by medical therapy and AVN ablation was performed for symptom control. All patients either had an existing permanent pacemaker in place when considered for AVN ablation or had one implanted as part of their planned ablation.

We defined complications as those which could result in prolonged hospitalization, the need for an additional procedure or increased mortality. Complications were grouped as follows: lead/device (device failure, lead failure, lead threshold rise, need for lead repositioning, cardiac wall perforation due to lead manipulation), lung (pneumothorax), pericardial effusion, infection at the site of the pacemaker implant, ventricular tachycardia or fibrillation, and sudden cardiac death.

Statistical Analysis: We performed statistical analysis to evaluate associations between the occurrence of complications and patient characteristics using SPSS 11.5 software package (SPSS Inc., 2002). We performed retrospective analysis of short-term (one month or less) complications. We performed univariate group comparisons using t-test for continuous variables and chi-square for categorical variables. We performed a multivariate logistic regression analysis blending both continuous and categorical

variables. We presented continuous variables as mean (SD) and categorical variables as proportions with 95% CIs.

Results

Patient Characteristics:

The mean (SD) age of the cohort was 66.3 (12.7) years and 55.4% were female. The mean age at time of ablation increased from 1990 (53.3) to 2002 (68.7) (Table 15, Graph10).

By medical center: Patients at the two medical centers were similar in age, gender, distribution of patients in Early vs Late groups and number of days to complication (Table 2). With respect to comorbidities (defined in Table 14), the proportion of patients with DM, CM, HTN, AF, PAF, PSVT/WPW and SSS were found to be significantly different between the centers, though the number of patients with each diagnosis relative to the entire study population was limited (Table 4).

By therapy group: The two groups (Early vs Late) were similar in age, gender and number of days to complication (Table 1). With respect to comorbidities, only the proportion of patients with CAD was statistically significant (Table 3).

Study Findings:

Patient distribution: From 1990 to 2002, the number of patients undergoing AVN ablation increased. This was true in both centers, though the first reported procedures

were performed at Sheba in 1994 and data were available only through 2001 (Table 5). During this period, the number and proportion of Late group patients increased (Graph 1, Table10). This was true in both centers (Graph 2 and 3).

Complications: From 1990 to 2002 the number of complications varied (Graph 4), but the percentage of patients with complications decreased (Table 10). The Early and Late groups were different with respect to the percentage of patients who had a complication (15% vs 6.7% respectively; p=.06; Table 7). There was not a significant difference between the groups with respect to the total number of complications, the type of complications or mean number of days to complication (Table 7). The two centers were similar with respect to the number of patients who had a complication and the total number of complications. The mean number of days to complications was greater at Sheba (1.31 vs 0.25; p=.03; Table 8).

Risk factors: Table 9 shows univariate analysis using binary logistic regression. Two independent variables were identified as risk factors: gender and year of ablation. The odds ratios for year of ablation and gender are .81 and 3.4 respectively. This suggests that female patients are 3.4 times more likely to have a complication than male patients and the risk of complication decreased over the years of the study.

Analysis by Gender: Overall, females were older than males in this study population (mean age in years, 67.9 v 64.4; p=.06; Graph 5). Males and females appeared to be evenly distributed between medical centers (Table 2, Graph 6) and groups (Table 1,

Graph 7). In comparing genders, the only baseline variable which was significantly different was a history of heart valve repair or replacement. No other baseline differences were found. Of the 19 patients with complications,15 (79%) were female (Table 11). The gender distribution in the Early group (72.7% female) and Late group (87.5% female) were similar (Graph 9). Of the 11 OHSU patients with complications, 11 (100%) were female; of the 8 Sheba patients with complications, 4 (50%) were female (Table 12, Graph 8). With respect to type of complication, the only significant difference between female and male was the number of lung complications (0 vs 6, p=.026; Table 13).

Analysis at one day: Analysis of the database defining the Early group as having both procedures on the same day and the Late group as having them one or more days apart revealed similar results as the initial analysis (Table 17 & 18). The only significant difference between the groups was the number of patients experiencing a complication.

Discussion

AF is the most common clinically significant cardiac rhythm disturbance in the world today and is associated with significant mortality and morbidity. Because the incidence increases with age, it has become a major public health issue as populations worldwide age. In spite of advances in therapy over the last 50 years, treatment of AF has proven to be problematic. There is still no reliable or cost-effective prevention and each mode of therapy has limited success and associated risks of complication.

Today, current treatment of AF is aimed primarily at alleviating symptoms and reducing the risk of morbidity, primarily from stroke. Medical therapy of AF can be expensive, must be individualized to the patient and is frequently inadequate to control symptoms. While other therapeutic options are available, they are also not without drawbacks. Interventional approaches include the surgical Maze procedure and catheter-based electrical isolation of the pulmonary veins from the left atrium. The Maze procedure is highly invasive, involving an open-chest approach and scarring of the atria (by making a number of incisions that disrupt the AF re-entrant circuits), and has had limited success. Pulmonary vein isolation has the potential to be highly successful in selected patients, but the technique is still being refined and, consequently, it has limited availability.

A non-surgical therapeutic option for patients in whom medical therapy has failed involves pacemaker implantation followed by AVN ablation. These two procedures together are relatively safe and offer an attractive alternative to either chronic medical therapy or an interventional approach. One critical question about this option involves selecting the optimal delay between implant and ablation. To date, no published data exists to guide clinicians. We designed this retrospective study to address this question.

In this study we utilized the existing databases of two comparable large regional university medical centers which have been performing AVN ablations since the early 1990s. We divided patients among those who had had AVN ablation within one week of pacemaker implant, vs those whose procedures were separated by eight or more days. We found the baseline characteristics of patients at both centers and between both groups to be similar. While we found some differences with respect to comorbidities, the

unexpectedly low numbers of cases raises concern about underreporting. In addition, we did not find these differences in comorbidities to be particularly clinically relevant.

The most significant finding of the study is that patients in the Early group have a higher risk of experiencing a procedure-related complication than patients in the Late group. The risk is of a complication from either procedure. We also found that, over time, the percentage of patients in the Early group declined while the percentage in the Late group increased (at both centers) and this trend paralleled a downward trend in the percentage of patients with complication. A secondary analysis defining the Early group as having both procedures on the same day (rather than up to seven days apart) showed similar results with a lower p value. This indicates that there is a difference between groups in terms of likelihood of a complication and this difference extends up to seven days between procedures. Delaying the pacemaker implantation greater than seven days is not associated with a statistically significant reduction in risk of complication.

A close analysis of patient characteristics found no factors which appeared to account for the findings of higher risk in the Early group. In particular, patient age does not appear to be a factor influencing the likelihood of a complication. In fact, the mean age of the population actually increased during the same period that the proportion of patients with complications declined. The only two independent variables which we could identify as risk factors for complication were year of ablation and gender. The risk of a complication appears to be inversely related to when the ablation was done within this 13 year period. That is understandable, given that fewer patients in the Late group had complications and the ratio of Late vs Early group patients increased with time.

While we found that female gender is predictive of increased risk in logistic regression modeling, there are no other factors associated with female gender which appear to account for this. The females in this study were older than the males, but age itself does not appear to be associated with risk of complication. Also, there is no reason clinically why being female should predispose to increased risk. Given the relatively small number of patients with complications (19 out of 193) and the fact that 79% of patients with complications were female (including all OHSU patients), it is difficult to reliably conclude that being female is a true risk factor. If there is some common element associated with those female patients who had complications, it is not apparent from the available data.

Study Limitations: While the results of this study provide compelling evidence that delaying AVN ablation after pacemaker implant by at least one week reduces risk of complication, the design of the study has limitations. As with any procedures, operator and institutional experience change with time and this could affect the rate of complications. Greater experience often results in an improvement in technique and reduction in complications. Also, because this was a retrospective analysis using printed records, we were limited in our ability to verify some patient information. Only a prospective study design would allow us to control for a potential lack of data. Also, the small number of patients with complications in the entire group (19 of 193) limited our ability to perform subgroup analysis. Finally, the most clinically relevant information about complications may not be the type of complication, but whether the complication is major or minor. The distinction between major and minor complication was not

established prior to the start of this study and, given the limitations of data availability in this retrospective analysis, would be difficult to determine with certainty at this point.

Summary and Conclusions

In summary, we found that, on retrospective analysis of an existing database, early pacemaker implant and AVN ablation (ablation performed within 7 days of pacemaker implant) are associated with a higher risk of complication than separating the procedures by at least 7 days (OR=2.48, 95% CI 0.95-6.49). Increasing age does not appear to be a factor influencing the likelihood of a complication. In fact, the only independent variables which we could identify as risk factors for complication were year of ablation and gender. The risk of a complication appears to be inversely related to when the ablation was done within the 13-year period of this study, which could be explained by improving operator skill with time. While we found that female gender is predictive of increased risk in logistic regression modeling, there is no reason clinically why being female should predispose to increased risk and this finding is likely an artifact of the small number of patients with complications. Overall these findings suggest that separating the procedures by at least one, and ideally seven, days may lower the risk of patient complication.

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Table 1:
Demographics and Characteristics of Patients by Study Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall	Early Group* N (%)	Late Group** N (%)	p-value
Total number of patients	193	73 (37.8)	120 (62.2)	
M/F	86/107	36/37	50/70	.30
Mean age at ablation in years (SD)	66.3 (12.7)	64.5 (13.3)	67.4 (12.3)	.12
Mean days to complication from either procedure (SD)	.69 (3.4)	.59 (2.4)	.75 (3.9)	.75

*Patients for whom pacemaker and ablation procedures were done within one week
**Patients for whom pacemaker and ablation procedures were separated by greater than one week

Table 2:
Demographics and Characteristics of Patients by Center, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall	OHSU	Sheba	p-value
Total number of patients	193	113 (58.5)	80 (41.5)	
M/F	86/107	49/64	37/43	.69
Mean age at ablation in years (SD)	66.3 (12.7)	64.5 (14.3)	67.4 (10.1)	.12
Patients in Early Group* – N (%)	73 (37.8)	37 (32.7)	36 (45)	.08
Patients in Late Group* – N (%)	120 (62.2)	76 (67.3)	44 (55)	.08

Table 3:
Comorbidities at Time of Ablation of Patients by Study Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Early Group* (N=73) N (%)	Late Group** (N=120) N (%)	p-value
DM	3 (4.1)	10 (8.3)	.26
CRI	2 (2.7)	6 (5.0)	.45
Valve repair/replacement	5 (6.8)	7 (5.8)	.78
HOCM	2 (2.7)	5 (4.2)	.61
CHF	8 (11.0)	19 (15.8)	.35
CM	17 (23.3)	21 (17.5)	.33
HTN	8 (11.0)	23 (19.2)	.13
PAT	2 (2.7)	3 (2.5)	.92
Afltr	0	3 (2.5)	.17
AF	37 (50.7)	54 (45)	.44
PAF	4 (5.5)	17 (14.2)	.06
ST	2 (2.7)	0	.07
PSVT/WPW	10 (13.7)	19 (15.8)	.69
CAF	14 (19.2)	13 (10.8)	.11
CAD	10 (13.7)	33 (27.5)	.03
SSS	4 (5.5)	5 (4.2)	.68

*Patients for whom pacemaker and ablation procedures were done within one week
**Patients for whom pacemaker and ablation procedures were separated by greater than one week

Table 4:
Comorbidities at Time of Ablation of Patients by Center, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003*

	OHSU (N=113) N (%)	Sheba (N=90) N (%)	p-value
DM	13 (11.5)	0	.00
CRI	7 (6.2)	1 (1.3)	.09
Valve repair/replacement	5 (4.4)	7 (8.8)	.22
HOCM	3 (2.7)	4 (5.0)	.39
CHF	19 (16.8)	8 (10)	.18
CM	13 (11.5)	25 (31.3)	.01
HTN	30 (26.5)	1 (1.3)	.00
PAT	5 (4.4)	0 (0)	.06
Afltr	3 (2.7)	0 (0)	.14
AF	32 ((28.3)	59 (73.8)	.00
PAF	21 (18.6)	0 (0)	.00
ST	1 (0.9)	1 (1.3)	.80
PSVT/WPW	8 (7.1)	21 (26.3)	.00
CAF	11 (9.7)	16 (20)	.11
CAD	30 (26.5)	13 (16.3)	.09
SSS	9 (8.0)	0 (0)	.01

*See table 14 for definitions of abbreviations

Table 5:
Number of Patients by Center, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	1990	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	Total
OHSU	3	9	7	3	6	1	3	11	26	24	20	113
Sheba	*	*	1	12	5	14	6	5	18	19	**	80
Total	3	9	8	15	11	15	9	16	44	43	20	193

*No procedures performed these years at this center
**No data available for this year at this center

Table 6: Percentage of All Patients in Each Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	1990	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Early Group (% of total)	100	77.8	62.5	73.3	45.5	80	33.3	25	13.6	27.9	25
Late Group (% of total)	0	22.2	37.5	26.7	54.5	20	66.7	75	86.4	72.1	75

Table 7:
Procedure-related Complications by Study Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall (N=193)	Early Group* (N=73) N (%)	Late Group** (N=120) N (%)	p-value
Mean days to complication from either procedure (SD)	.69 (3.4)	.59 (2.4)	.75 (3.9)	.75
Patients with complications N (%):	19 (9.8)	11 (15.1)	8 (6.7)	.06
Total number of complications:	35	20	15	.13
By type of complication: N (% of total)				
Lead/Device complication	20	10 (50)	10 (67)	.47
Lung complication	6	4 (20)	2 (13)	.14
Pericardial effusion	5	3 (15)	2 (13)	.30
Infection at site of pacemaker implant	2	1 (5)	1 (7)	.72
Ventricular Tachycardia or Fibrillation	1	1 (5)	0	.20
Sudden Cardiac Death	1	1 (5)	0	.20

*Patients for whom pacemaker and ablation procedures were done within one week
**Patients for whom pacemaker and ablation procedures were separated by greater than one week

Table 8:
Procedure-related Complications by Center, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall N=193	OHSU N=113	Sheba N=80	p-value
Mean days to complication from either procedure (SD)	0.69 (3.4)	0.25 (1.4)	1.31 (5.0)	.03
Patients with complications N (%):	19 (9.8)	11 (9.7)	8 (10)	.33
Total number of complications:	35	15	20	.95
Type of complication: N (% of total complications)				
Lead/Device complication	20 (57)	6 (40)	14 (70)	.10
Lung complication	6 (17)	6 (40)	0 (0)	.04
Pericardial effusion	5 (14)	1 (7)	4 (20)	.08
Infection at site of pacemaker implant	2 (6)	0 (0)	2 (10)	.09
Ventricular Tachycardia or Fibrillation	1 (3)	1 (7)	0 (0)	.40
Sudden Cardiac Death	1 (3)	1 (7)	0 (0)	.40

Table 9: Binary Logistic Regression Analysis, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Variable	**Coefficient**	**Standard Error**	**Two-sided p-value**	**Odds Ratio**	**95% Confidence Interval**	**Difference Associated with Odds Ratio**
Year of ablation	-.207	.078	.008	.813	.698-.947	Year of ablation
Gender	1.227	.593	.039	3.41	1.067-10.9	Female vs male

Table 10: Number of patients with complications by year, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Year of ablation	All patients with complications N (% of patients in that year)	Patients with complication, Early group N (% of patients in that year)	Patients with complication Late group N (% of patients in that year)	Total number of patients Early group	Total number of patients Late group
1990	0	0	0	3	0
1993	3 (33.3)	3 (42.9)	0	7	2
1994	3 (37.5)	2 (40.0)	1 (33.3)	5	3
1995	1 (6.7)	1 (9.1)	0	11	4
1996	3 (27.3)	3 (60.0)	0	5	6
1997	1 (6.7)	1 (8.3)	0	12	3
1998	1 (11.1)	0	1 (16.7)	3	6
1999	1 (6.3)	1 (25.0)	0	4	12
2000	2 (4.5)	0	2 (5.3)	6	38
2001	4 (9.3)	0	4 (12.9)	12	31
2002	0	0	0	5	15
Total	19 (9.8)	11 (15.1)	8 (6.7)	73	120

Table 11: Number of male vs female patients with complications among193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Total Number of patients	Patients with complication	% of all patients with complication	p-value	Calculated OR
Female N (%)	107 (55.4)	15 (14)	(79)	.03	
Male N (%)	86(44.6)	4 (4.7)	(21)		
Total	193	19	(100)		3.3
Early Group					
Female N (%)		8 (21.6)	(72.7)	.11	
Male N (%)		3 (8.3)	(27.3)		
Total		11			3.0
Late Group					
Female N (%)		7 (10)	(87.5)	.08	
Male N (%)		1 (2)	(12.5)		
		8			5.4

Table 12: Number of male vs female patients with complications by center, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall	OHSU	Sheba	p-value
Female N (%)	15 (79)	11	4	
Male N (%)	4 (21)	0	4	.01
Total	19			

Table 13: Number of male vs female patients with lung complications, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Lung complication	No lung complication	p-value
Female N	6	101	
Male N	0	86	.03
Total	6	187	

Table 14: Definition of terms, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

DM	Diabetes mellitus
CRI	Chronic renal insufficiency
HOCM	Hypertrophic obstructive cardiomyopathy
CHF	Congestive heart failure
CM	Cardiomyopathy
HTN	Hypertension
PAT	Paroxysmal atrial tachycardia
Aflltr	Atrial flutter
AF	Atrial fibrillation
PAF	Paroxysmal atrial fibrillation
ST	Sinus tachycardia
PSVT/WPW	Paroxysmal supraventricular tachycardia (including Wolff-Parkinson-White syndrome)
CAF	Chronic atrial fibrillation
CAD	Coronary artery disease
SSS	Sick sinus syndrome

Table 15: Mean age of patients at time of ablation by year, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Year of ablation	Mean age at ablation	N	Std. Deviation
1990	53.3333	3	23.45918
1993	64.6667	9	13.78405
1994	66.0000	8	12.55843
1995	61.0667	15	8.19814
1996	62.1818	11	12.25413
1997	67.9333	15	11.09354
1998	59.1111	9	17.91957
1999	68.7500	16	11.00606
2000	66.2500	44	12.47346
2001	69.6047	43	12.54352
2002	68.6500	20	13.27156
Total	**66.3316**	**193**	**12.75343**

Table 16: Odds Ratio of Risk of Complication, Early vs Late Groups, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Complication Yes	Complication No	OR	95% CI
Early Group	11	62	2.48	0.95-6.49
Late Group	8	112		

Table 17:
Demographics and Characteristics of Patients by Study Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall	Early Group* N (%)	Late Group** N (%)	p-value
Total number of patients	193	70 (36.3)	123 (63.7)	
M/F	86/107	35/35	51/72	.25
Mean age at ablation in years (SD)	66.3 (12.7)	64.3 (13.5)	67.5 (12.2)	.10
Mean days to complication from either procedure (SD)	.69 (3.4)	.61 (2.5)	.73 (3.9)	.82

*Patients for whom pacemaker and ablation procedures were done on the same day
**Patients for whom pacemaker and ablation procedures were separated by one or more days

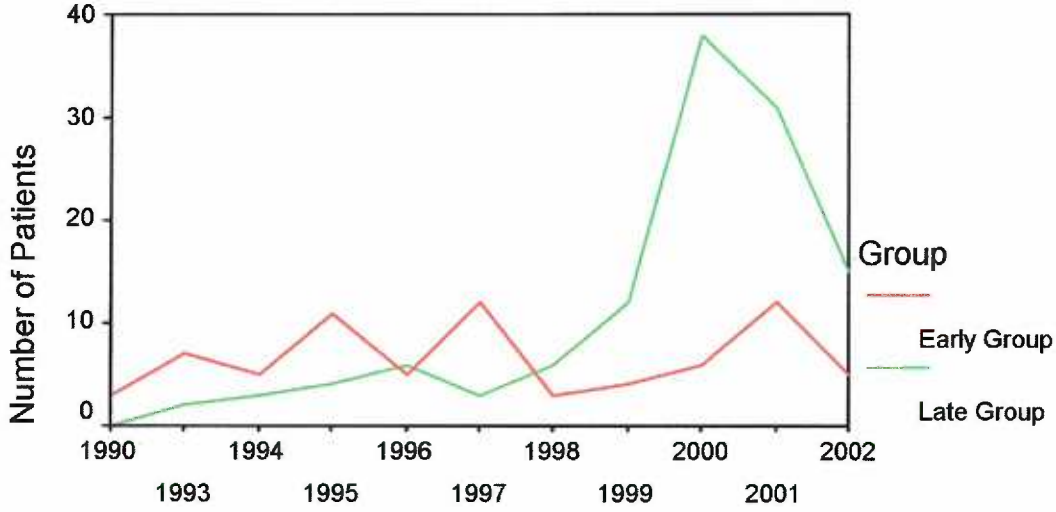
Table 18:
Procedure-related Complications by Study Group, 193 patients, Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

	Overall (N=193)	Early Group* (N=70) N (%)	Late Group** (N=123) N (%)	p-value
Mean days to complication from either procedure (SD)	.69 (3.4)	.61 (2.5)	.73 (3.9)	.82
Patients with complications N (%):	19 (9.8)	11 (15.7)	8 (6.5)	.04
Total number of complications:	35	20	15	.13
By type of complication: N (% of total)				
Lead/Device complication	20	10 (50)	10 (67)	.41
Lung complication	6	4 (20)	2 (13)	.12
Pericardial effusion	5	3 (15)	2 (13)	.27
Infection at site of pacemaker implant	2	1 (5)	1 (7)	.69
Ventricular Tachycardia or Fibrillation	1	1 (5)	0	.19
Sudden Cardiac Death	1	1 (5)	0	.19

*Patients for whom pacemaker and ablation procedures were done on the same day
**Patients for whom pacemaker and ablation procedures were separated by one or more days

Graph #1: Number of patients per group per year, all patients

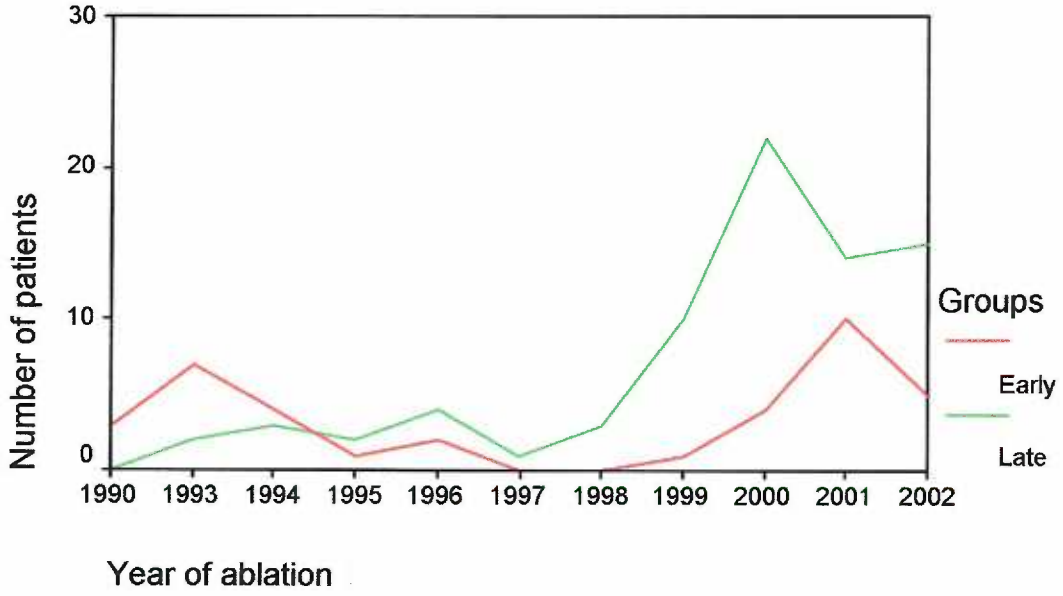
N = 193



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph #2: Number of patients per group per year, OHSU only

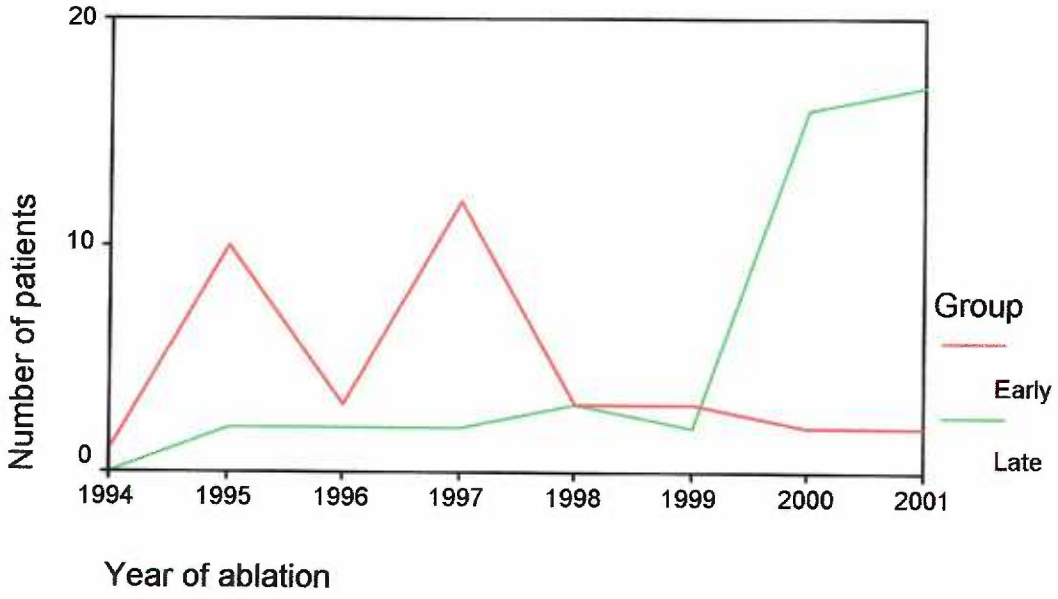
N = 113



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

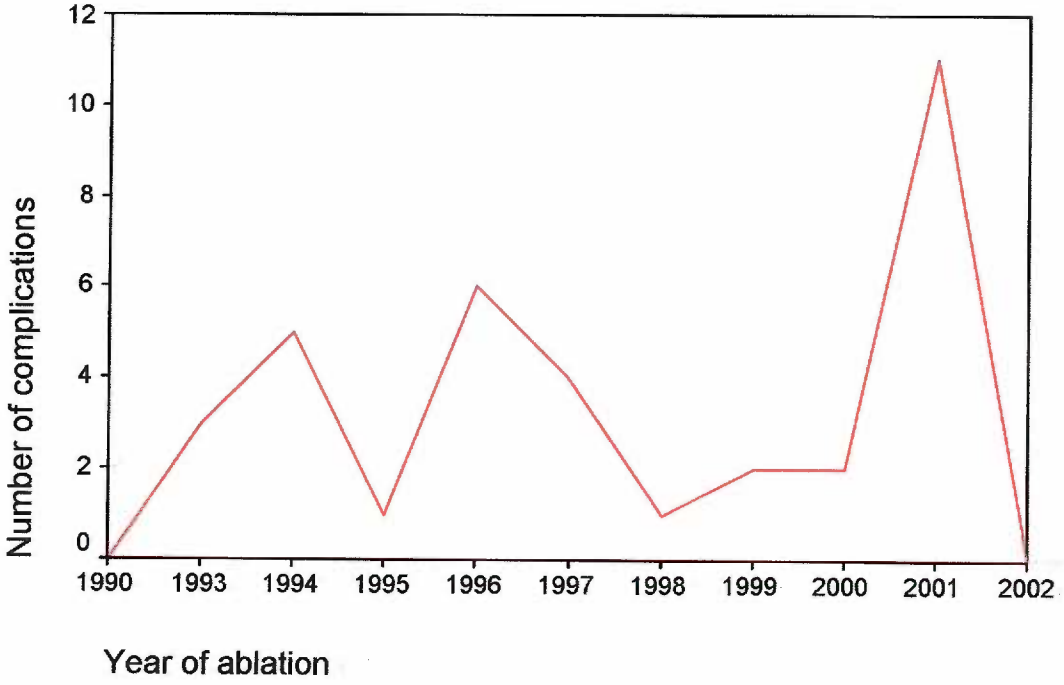
Chart #3: Number of patients per group per year, Sheba only

N = 80



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

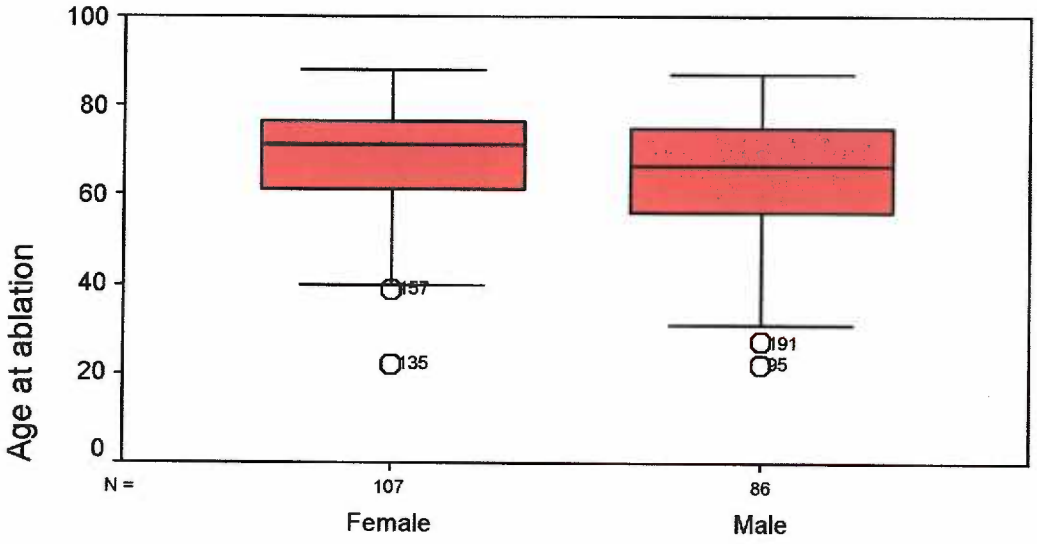
Graph #4: Number of complications per year



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph #5: Age at ablation by gender

N = 193

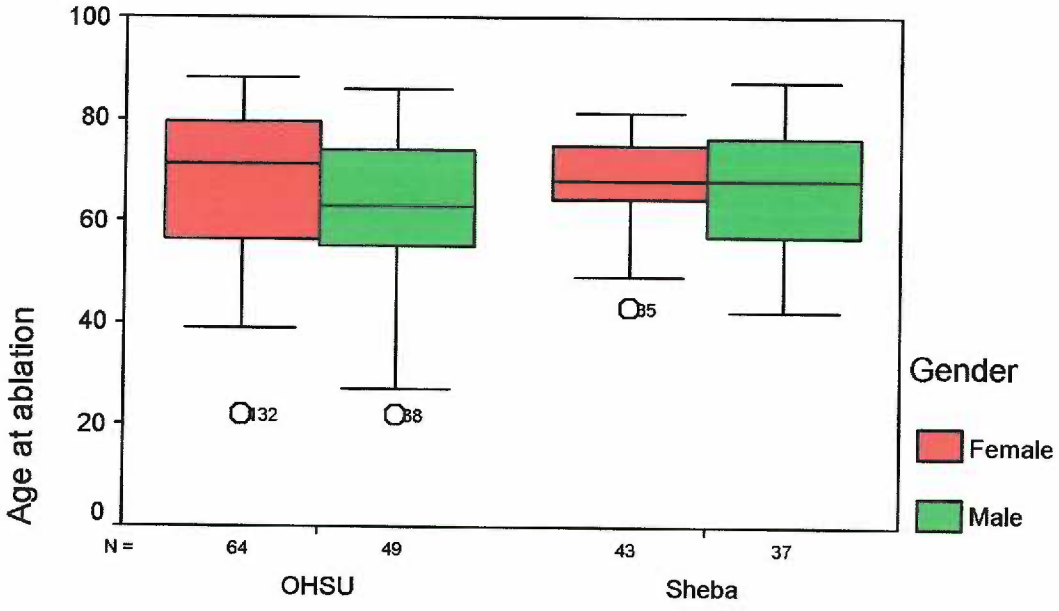


Gender. Mean age female = 67.9. Mean age males = 64.4.

(p = .06)

Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph 6: Age distribution for gender at each center (N = 193)

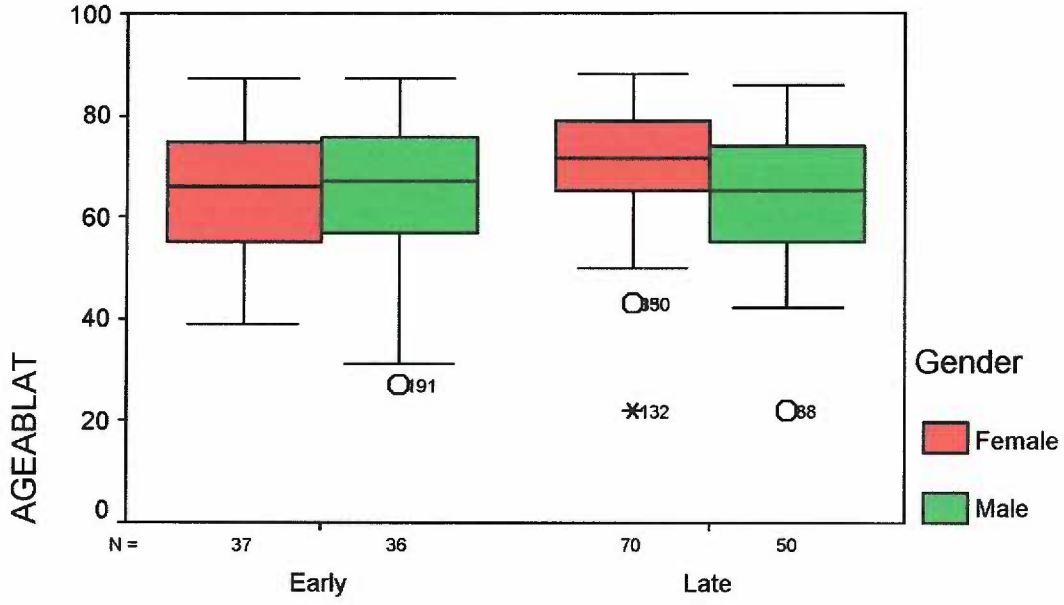


SOURCE

Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph 7: Age comparison of genders

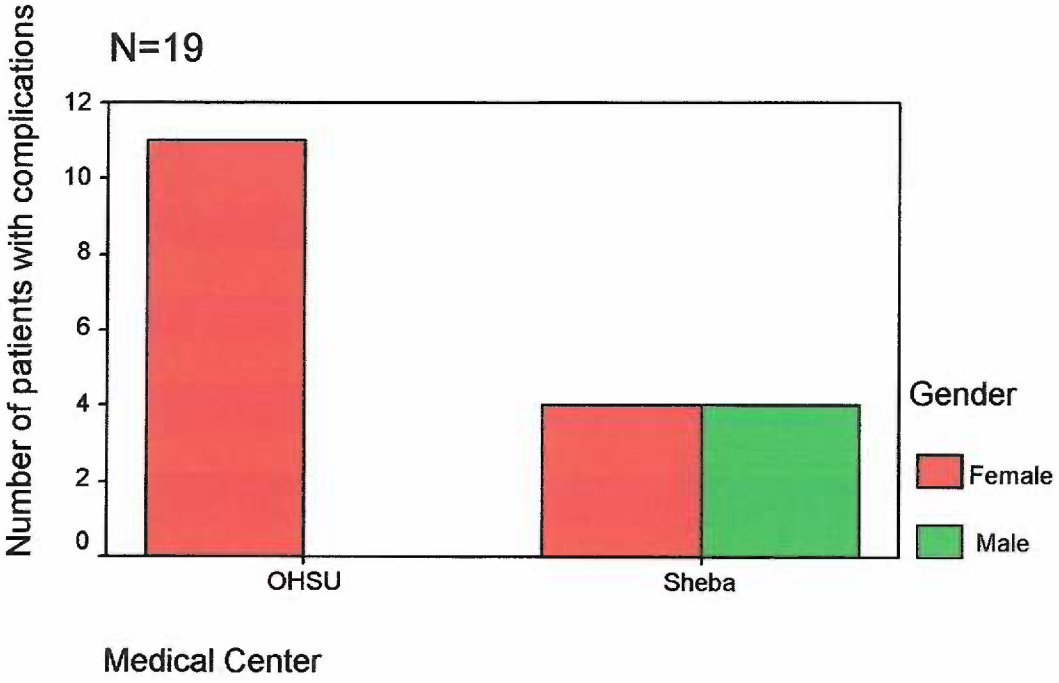
Early and Late groups



Early vs Late Groups

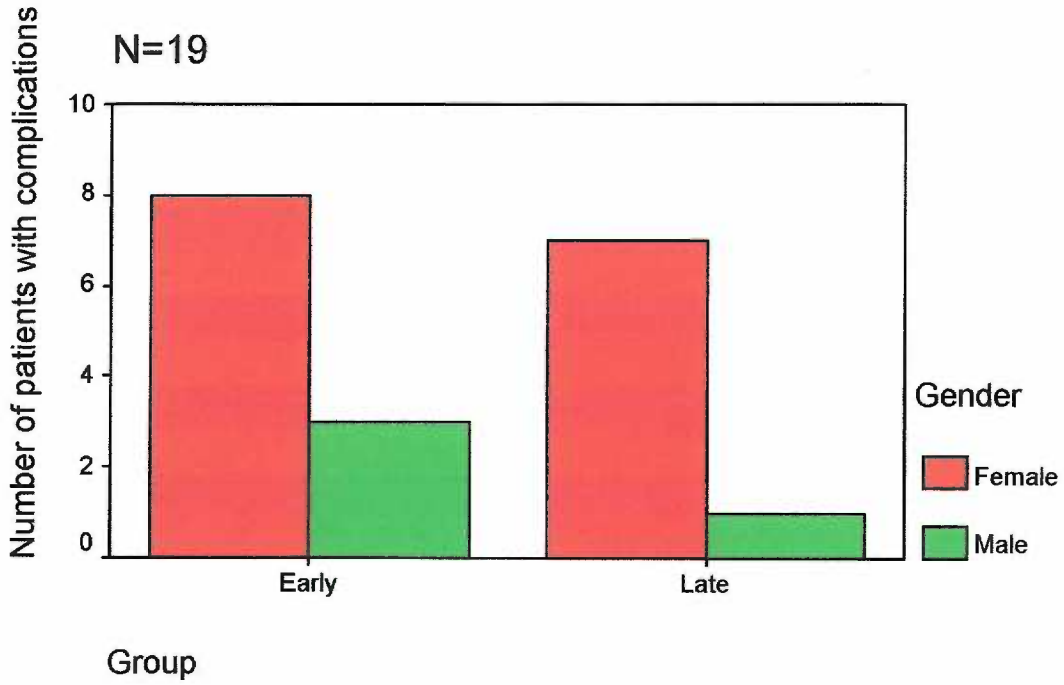
Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph 8: Gender distribution among patients with complications at each center



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

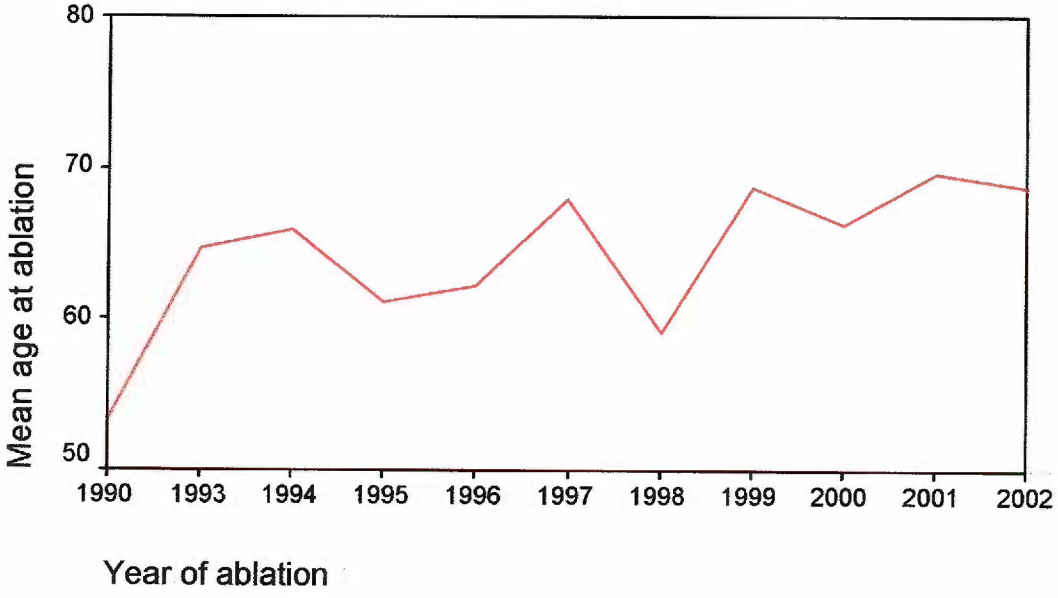
Graph 9: Gender distribution for patients with complications in each group



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph 10: Mean age of all patients by year of ablation

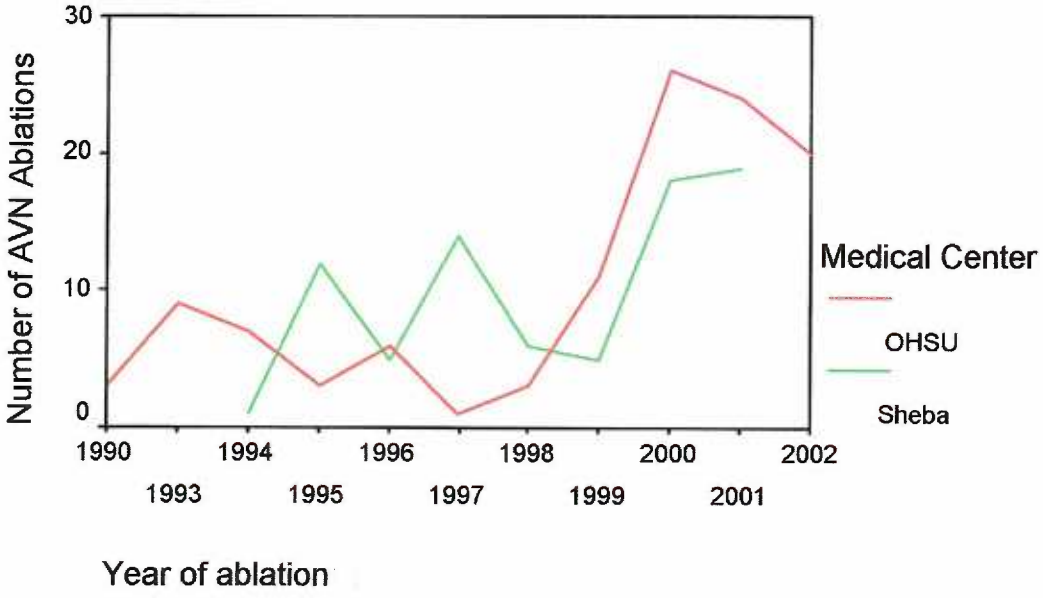
N=193



Optimal Timing for Atrioventricular Node Ablation after Pacemaker Implantation, 2003

Graph #11: Number of AVN ablations per year at each center

N=193



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