

Pacemaker implantation in small hospitals: complication rates comparable to larger centres

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Aims

Some countries have a demography that makes it necessary to maintain relatively small pacemaker centres. We wanted to assess the quality of pacemaker surgery in two such hospitals.

Methods and results

Through patient records we gathered information on ~535 consecutive primary pacemaker implantations in two small pacemaker centres with 30 and 80 annual operations, respectively. All patients were followed for 3 years. All complications documented in the patient records were registered. Furthermore, we performed a non-systematic literature search comparing our data with reports from major centres published over the last 10 years. We found 72 complications in 64 (12.0%) of the patients, the most common being bleeding, lead failure, and pneumothorax. If minor bleedings without any consequences for the patients are excluded, the number of complications was 46 in 40 patients (7.5%). We had to reoperate on 5.2% of the patients. There was no statistically significant difference in complication rates between the two hospitals. Education candidates generated statistically significant more complications than experienced doctors (13.7 vs. 7.1%, $P < 0.05$).

Conclusion

There are no generally accepted norms of complication rates in pacemaker surgery. However, we found no indications that our centres have a rate of complications that is unacceptably high.

Keywords

Pacemaker • Complications • Rural hospitals

Introduction

In 2009, Scandinavian hospitals performed 11 608 primary pacemaker implants.¹ Although the equipment is constantly being improved, there are still a significant number of patients experiencing complications after surgery. Although some countries have come quite far in establishing national quality indices, there is still a lack of robust international quality data that can be used as the basis for the evaluation of own activity. The main reason is that study design and definitions differ significantly from report to report. High-quality, prospective studies are rare, and those available tend to have a design making them little applicable for the evaluation of an ordinary, unselected pacemaker practice.

Norwegian hospitals implanted 2333 pacemakers in 2009,¹ 489 new implants per million inhabitants. We have 25 pacemaker centres, each centre performed on average 93 new implants in 2009, ranging from ~30 to 300.

The present study was performed to evaluate the quality of pacemaker surgery in two smaller pacemaker centres in Northern Norway. Our region has a scattered population and our hospitals are relatively small. For the population, proximity to treatment is a quality factor, but the loss of technical quality is a potential negative result of decentralization.

We have retrospectively studied 535 consecutive primary pacemaker implantations in one small- and one medium-sized pacemaker centre and registered complications discovered within the first 3 years after initial surgery. Our

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findings are compared with results from a selection of international studies.

Methods

The project was approved by the Norwegian Social Science Data Services. Data were collected manually from patient records. This means that all complications judged by healthcare professionals to be clinically significant were registered.

Hospitals

Sandnessjøen hospital is the smallest pacemaker centre in Northern Norway, serving a population of 70 000 and performing an annual average of 28 primary pacemaker implantations in the study period. This is, however, not an accurate picture as the number of implantations varied widely from year to year, depending on the availability of staff. The hospital has 60 beds and two cardiologists. Nordland hospital in Bodø is a 5 h drive further north and is the nearest larger hospital. The air ambulance service is well established, but it has serious limitations because of difficult weather conditions.

Nordland hospital in Bodø serves a population of 170 000 and performed between 80 and 90 primary pacemaker operations annually in the study period. The hospital has 250 beds and six cardiologists.

All operations were done by a cardiologist or trainees under supervision. The proportion of operations performed by trainees was comparable in the two hospitals. The operations were done in standard operating rooms. All patients received a single pre-operative dose of dicloxacillin.

The patients had their first follow-up after 3–4 months, thereafter annually. Most patients were followed at the implanting centre, except for a few patients who moved to another region during the follow-up period. For these last patients, complete hospital records were obtained to reveal any complications registered locally.

Study period

In order to achieve the same number of cases from the two hospitals, the period of registration was longer in Sandnessjøen than in Bodø. In Sandnessjøen, we evaluated patient records from a 10-year period from 1 January 1997 to 31 December 2006. All patients were followed up for 3 years, and the final review of the medical records was done in the spring of 2010. In Bodø, we examined the results of a 3-year period in the middle of this decade—from 1 September 2000 to 31 August 2003. Patients from Bodø were also followed up for 3 years.

Definition of complications

Both in the collection of our data and in our literature review, we have used the following definitions of complications, partly built on Pakarinen *et al.*² and Ellenbogen *et al.*³ The definitions are aligned to make the results more comparable to other publications.

Reoperation

Any situation in which it was necessary to do more than one surgical intervention to make the pacing system work, or to correct an unacceptable discomfort for the patient. Chest tubes for pneumothorax are not included.

Bleeding

Any swelling of the pocket with clinical suspicion of haematoma. Any external bleeding that required special attention from the medical staff.

Lead failure

Development of high pacing thresholds or sensing problems resulting in the need to programme the device to a different pacing mode or the need for reoperation.³ Thus, the term lead failure does not necessarily imply fracture or errors in production.

Pneumothorax

Absence of lung markings over the lung field ipsilateral to the pacemaker pocket assessed from the pre-discharge x-ray.² All such findings are included, regardless of the need of a chest tube.

Heart perforation: Procedure-related pericardial effusion or pericardial pain requiring prolonged post-operative surveillance or lead repositioning.²

Cardiac tamponade

Pericardial effusion causing haemodynamic compromise and requiring drainage.²

Device infection

Superficial wound infection or device system infection, defined as pocket infection or fever, associated with positive blood cultures without an infectious focus elsewhere.² We also include any perforation or near perforation even if there is no sign of infection.

Statistics

Differences in complication rates were analysed by means of GraphPad Prism 5.0 for Windows. Level of significance was calculated using the Fisher Irwin's test when the number of events was small and χ^2 test when the number was large. A two-tailed *P* value <0.05 was considered statistically significant.

Literature review

We have made a non-systematic literature search through PubMed for the years 1998–2010. We found 14 studies that more or less accurately render rates of adverse episodes in pacemaker surgery. The material includes both multi-centre and single-centre studies.

In some of the studies complication rates or the number of leads is specified as shares.^{4–8} In such situations it has been necessary to convert to absolute numbers for comparison. The results of our literature review are summarized in *Table 1*.

Results

During the study period, Sandnessjøen hospital had a total of 282 primary implantations, an average of 28 patients annually, while Bodø had 253 primary implantations and an annual average of 84 operations. Eight hundred and ninety-four leads were implanted. Sixteen (3.0%) of the operations were made with venous access through the cephalic vein, the others had subclavian venous access. Data for implant duration and fluoroscopy times were not available.

Patient characteristics are summarized in *Table 2*.

All patients were followed for 3 years, or until death. No patients were lost from follow-up, and data have also been collected if the patient moved or was transferred for follow-up elsewhere. There were no statistically significant differences in complication rates or frequency of reoperations between the two hospitals (*Table 3*).

No patients died during surgery. Twelve patients died during the first 30 days after implantation. One patient died from sudden

Table 1 Our data compared with other studies published during the last 10 years

	Haug et al.	Pakarinen (2010) ²	Wiegand et al. ^{9a}	Kiviniemi (1999) ⁴	Tobin (2000) ¹⁰	Villalba et al. ^{11b}	van Eck et al. ^{6h}	Møller et al. ⁵	Wiegand (2003) ^{7c}	Ellenbogen et al. ^{3d}	Klug et al. ¹²	Eberhardt et al. ^{13b}	Link et al. ^{14c,f}	Nery et al. ⁸	Nowak et al. ^{15g}	
Number of patients	535	567	3164	446	1332	2108	1198	5593	1214	2010	6319	1884	407	2417	17826	
Lead dysfunction	<i>n</i> 26	<i>n</i> 21	na	32	32	56	32	268	24	61	na ^e	56	9	na	411	
	No. of leads	894	865	na	547	2264	3078	2053	8993	1614	4020	171	2787	814	na	28760
	%	2.9	2.4		5.9	1.4	1.8	1.6	4.8	1.5		1.5	2.0	1.1		1.4
Pneumothorax	<i>n</i> 15	<i>n</i> 11	na	5	20	2	24	54	7	32	na	11	8	na	95	
	%	2.8	1.9		1.1	1.5	0.1	2.0	1.0	0.6		1.6	2.0		0.5	
Infection	<i>n</i> 4	<i>n</i> 11	9	12	na	4	6	15	4	4	91	na	2	24	20	
	%	0.7	1.9	0.3	2.7	0.2	0.5	0.3	0.3	0.2	1.4		0.5	1.0	0.1	
Bleeding	<i>n</i> 28	<i>n</i> 18	155	5	na	12	23	21	6	na	328	11	na	na	128	
	%	5.2	3.2	4.9	1.1	0.6	1.9	0.4	0.5		5.2	0.6			0.7	
Reop.	<i>n</i> 28	<i>n</i> 52	na	50	na	20	na	340	51	93	175	85	18	na	na	
	%	5.2	9.2		11.2	0.9		6.1	4.2	4.6	2.8	4.5	4.4			
Type of study	Ret	Ret	Ret	Ret	Pro	Ret	Pro	Reg	Ret	Pro	Pro	Ret	Pro	Ret	Reg	
Observ.	36	3	3	27	0	51	0	na	63	33	12	64	18	na	0	
Subcl. access	97	10	53	70	>95	15	90	47	51	na	na	58	73	na	44.5	
Lost (%)	0.0	0.0	0.0	7.3	0.0	na	0.0	1.0	0.0	0.0	14.5	0.0	na	na	0.0	

For lead dysfunction, the number of registered errors and total number of leads are listed. Percentage is calculated in relation to the total number of leads. For the rest, the proportion is calculated in relation to the number of patients. At the bottom of the table we have listed the length of the observation period (in months) for each study. Observation period equal to 0 indicates that only complications during the initial admission are included. Proportion of patients with venous access made through the subclavian vein (Subcl. access) is specified in percentage. Lost in the observation period specifies the percentage of the originally included patients that disappeared during the observation period.

Ret, retrospective; Pro, prospective; Reg, registry study; Reop, re-operation; Observ, observation period; na, not available; Subcl, subclavian venous access.

^aRetrospective study with a special focus on perioperative bleeding.

^bRetrospective study designed to evaluate a pacemaker-implantation done as day-surgery.

^cIncludes only complications that caused reoperation.

^dPatients included in MOST study, designed for the evaluation of mode selections in patients with sinus node disease.

^eNot possible to calculate due to inconsistent data in the article.

^fPatients included in PASE study, designed to evaluate mode selection in elderly.

^gRegistry study designed to study gender differences in complication frequency.

^hExcerpt from FOLLOWPACE study, prospective, designed to assess the cost-effectiveness of routine follow-up visits in patients with pacemaker.

Table 2 Patient characteristics, indication for pacemaker, choice of pacing mode and venous access to the heart

Total number		n	%
		535	
Age	0–40	6	1.1
	41–60	45	8.4
	61–80	281	52.5
	81–90	176	32.9
	>90	27	5.0
Female		237	44.3
Indication	Atrioventricular block	206	38.5
	Sick sinus syndrome	228	42.6
	Atrial fibrillation/flutter and bradycardia	77	14.4
	Tachycardia	4	0.7
	Other	20	3.7
Mode	DDD	359	67.1
	AAI	80	15.0
	VVI	96	17.9
Venous access	Subclavian	519	97.0
	Cephalic	16	3.0

Table 3 Assessment of complications and reoperations in the two hospitals

	Bodø		Sandnessjøen		P
	No	%	No	%	
Number of patients	253		282		
Lead dysfunction	11	4.3	15	5.3	0.69
Bleeding	1	0.4	0	0.0	0.47
Pneumothorax	10	4.0	5	1.8	0.9
Infection	3	1.2	1	0.4	0.35
Total number	25	9.9	21	7.4	0.36
Re-operations	12	4.7	16	5.7	0.70

Minor bleedings without any consequence to the patients are not included.

circulatory collapse the day after surgery. The patient was under permanent monitoring as he died, and no arrhythmia was observed. Autopsy did not reveal any exact cause of death. Eleven patients died after discharge from hospital, one from cerebral infarction, one from heart failure, two from malignant arrhythmia, three from myocardial infarction, and three from infections not related to pacemaker implantation. One patient died during cancer surgery.

We found 73 complications in 64 (12.0%) patients. There was no statistically significant difference in complication rate between patients below and above the age of 80 years.

The frequency of the various complications is summarized in Table 1.

We recorded bleeding in 28 patients. Only one patient needed transfusion. The rest mainly consisted of minor haematomas,

without any consequence for the patient. If these are not counted, the number of complications are 46 in 40 patients (7.5%).

Reoperations

In our material, 28 (5.2%) of patients required reoperation. Of these, 20 patients were reoperated for lead dislocation, and this was the most common reason for surgical revision. Reoperations themselves are not counted as complications, as the incident that leads to the reoperation already is counted.

Bleeding

Pocket bleeding was observed in 5.2% of the patients and was thus the most common complication. One patient needed blood transfusion after bleeding; otherwise there were no serious bleedings. No patients needed surgical revision for their haematomas, and as far as we can see from the patient records, there were no prolongations of hospitalization or other consequences from the bleedings. It is of interest to note that pocket haematoma was not recorded in any of the patients who subsequently developed infection.

Lead failure

No patient had failure of more than one lead. Lead failure occurred in 4.9% of our patients and was the second most frequent complication. We implanted a total of 894 leads and found dysfunction in 26 (2.9%). Of these, 20 patients were reoperated and six pacemakers were reprogrammed to a less optimal pacing mode. Twenty-five appeared during the first 30 days after surgery and one was discovered later.

Pneumothorax

Fifteen patients (2.8%) had pneumothorax. Of these, eight patients needed a chest tube. Venous access was via cephalic vein cutdown in 16 patients (3.0%). In the rest, venous access was done via subclavian vein puncture. All cephalic vein cutdowns were done in Sandnessjøen hospital.

Heart perforation and cardiac tamponade

We observed no patients with heart perforation or cardiac tamponade.

Device infection

Four (0.7%) patients had infections related to pacemaker surgery. In two patients the infection was discovered during the first 30 days after surgery, and both these developed systemic infections. The last two started later than 30 days after surgery and both were infections limited to the pocket.

Operator volume and experience

A total of eight doctors performed independent surgery during the study period. Table 4 displays complication frequency and need for reoperation in relation to operator volume. Three of the doctors were fully qualified cardiologists, while the other five were trainees in cardiology under supervision.

Education candidates operated 124 patients and generated 17 (13.7%) complications and 9 (7.3%) reoperations. The specialists performed 411 operations and generated 29 (7.1%) complications,

Table 4 Activity and complication rate per doctor

	Number of operations during study period	Approximate number of operations prior to study period	Years during study period	Average yearly number of operations	Number of complications	%	Number of reoperations	%
Doctor 1	228	70	10	22.8	11	4.8	10	4.4
Doctor 2	133	60	3	44.3	11	8.3	5	3.8
Doctor 3	58	150	3	19.3	7	12.1	4	6.9
Doctor 4	47	25	3	15.7	6	12.8	1	2.1
Doctor 5	45	0	2	22.5	6	13.3	5	11.1
Doctor 6	20	0	1	20.0	4	20.0	2	10.0
Doctor 7	8	0	1	8.0	0	0.0	0	0.0
Doctor 8	4	0	1	4.0	1	25.0	1	25.0

Doctors 1 to 3 were fully qualified cardiologists throughout the period, while four to eight were under training. The numbers do not give a complete picture of the activity because Doctors 1 to 3 also were responsible for supervising the trainees under their operations. In addition, some of them worked elsewhere in parts of the study period and thus had a higher activity than stated in the table. All the experienced doctors had a considerable volume prior to the study period. Minor haematomas without any consequence for the patient are not counted.

and 19 (4.6%) reoperations. The difference is statistically significant for complication rate ($P < 0.05$), but not for reoperations ($P = 0.26$).

Discussion

Northern Norway has, due to long distances and difficult transport conditions, found it appropriate to retain a decentralized hospital structure. This means that the number of certain medical procedures will be lower than what is recommended in guidelines and what is usually performed in countries with a more concentrated population. It is possible that a low volume may result in lower surgical quality. Such a loss of treatment quality may be acceptable if the alternative centralization increases transport time to the extent that this itself becomes a quality-reducing factor. Nevertheless, it is important that the technical quality is controlled so that measures can be taken if complication rates become unacceptably high.

To obtain a sufficient number of operations for comparison from the smallest hospital, we had to go as far back as 1997. Since then, there has been a huge development of pacing equipment and technique. This makes interpretation of the data difficult, but many of the studies we are comparing us with have collected data in the same period, and the conclusions should therefore be durable.

Complications in device-surgery still are a relatively common problem. In 1999, Kiviniemi *et al.*⁴ reported complications in 13.2% of such patients and it seems that this number has not changed substantially over the past decade. We found 12.0% and Pakarinen *et al.*² found 12.2%.

We have compared our data with figures from the international literature. The literature contains no standardized norms of acceptable complication frequency in device-surgery. The problem with such comparisons is, therefore, that the presumptions behind the numbers in the studies can be very different.

The data referred to in our study were not collected with the aim of reporting complications, and the number of operations is fairly small. The populations included in the studies we are comparing us with may vary, and the sampling methods may diverge. Thus, statistical analysis on differences in complication rates between various studies will in general not be appropriate.

Literature review

Our study is retrospective, and like most other similar works, we have identified—through the hospital archive—all patients that have received a pacemaker during the time period in question. We have then extracted the relevant information from their hospital records.

Prospective, dedicated studies are probably the trials best suited to give a correct picture of the quality and frequency of complications. Such studies are rare. The prospective studies we have found are all designed for a different purpose than to evaluate complications in an unselected ordinary pacemaker practice. Thus, patients, operators, or other conditions are selected in a way that may affect the results.

The quality of registry studies depends on data reported from the pacemaker centres. Møller *et al.*⁵ included 8.5% of the patients in their registry study in an audit and found that 16.0% of complications were not reported to the registry. On the other hand, van Eck *et al.*⁶ found no such deviations in a similar audit of 6.2% of the patients in their prospective study. There is still a possibility that this is a consistent phenomenon, both in registry studies and in prospective multicentre studies.

Retrospective studies based on patient records will always be unselected. High data quality still depends on the accuracy of the patient records, and complications not documented in the record represent a potential source of error. In addition, the lack of pre-defined data sampling, and the fact that our data are rather old, also makes the interpretation difficult. On the other hand, our patient population has been very stable, and we

have been able to follow every single patient for 3 years. We are therefore confident that the outline of our complications is fairly complete.

Complications in our data

Our study includes only primary pacemaker implantations. Other studies include both new implantations and secondary operations, such as upgrade procedures and generator replacements, which are known to be associated with a slightly higher frequency of pacemaker-related infections. Some studies also include implantations of implantable cardioverter defibrillators and cardiac resynchronization devices, procedures which also lead to more complications. Our rate of complications should, therefore, be expected to be lower than studies containing more complex procedures, i.e. that by Pakarinen *et al.*²

Our complication rate does not appear to be unacceptably high. Pakarinen *et al.*² have higher frequency of reoperations compared to our data, while Møller *et al.*⁵ found fewer patients with pneumothorax. We used subclavian venous access in 97.0% of the operations, which is the highest percentage of all the studies we have reviewed. This probably explains the difference in the incidence of pneumothorax. Rates of lead failure and infections are the same in our material as in these studies.

In the Nordland hospital, all patients were operated on with venous access via subclavian puncture. In Sandnessjøen hospital selected patients (e.g. patients suffering from emphysema and patients using anticoagulation) were operated on with venous access via cephalic vein cutdown. This may explain the observation that Sandnessjøen has a somewhat lower rate of pneumothorax (though not statistically significant) than Nordland hospital.

Length of the observation period affects the number of complications, especially infections and lead failure. Ellenbogen *et al.*³ specified their complication rate at 30 days to be 4.8%, after 90 days 5.5%, and after 3 years 7.5%. Wiegand *et al.*⁷ found 54.9% of complications in-hospital, and 68.6% during the first 3 months after the operation. Nery *et al.*⁸ found infections up to 496 days after the operation; the average time to recognition of infections was 272 days after surgery.

Some studies specify lead failure as a percentage of the number of patients.^{2,10} Most studies, however, calculate the lead failure as a proportion of implanted leads. We have only included studies in our review in which it was possible to determine the number of implanted leads. Comparing the proportion of leads that failed in our study with the literature gives the impression that we have unusually high rates of lead failure. Some studies^{5,10} have counted lead failure only when the lead is revised. Our data, however, also include six patients who have not been reoperated but managed by, e.g., reprogramming of the device. If we exclude these patients from the comparison, our rate of lead failure differs less from other reports.

Duration of observation probably also affects rate of lead failure. Three of the five studies that have a lower frequency of lead failure than ours only include complications registered in-hospital. Such differences in the definition of complications are probably more important in explaining observed variations than real differences in the incidence of adverse events.

Ten studies contain details on haematomas and bleeding. The studies that only include bleeding demanding reoperation find an incidence just below 1%.^{4–7,11,13,15} Studies including all haematomas find an incidence around 5%.^{9,12} Our definition 'any swelling of the pocket with clinical suspicion of haematoma' is rather wide and gives a certain room for individual discretion. Removing minor bleedings from the material reduces our total complication rate to 7.1%.

The proportion of patients who needs more than one operation to make the pacing system function properly is a good and robust quality indicator. Both prospective and retrospective studies, and probably also registry studies, will capture such additional procedures. Some authors have taken the consequence of this and limited registration of complications to those that have caused additional surgery.^{7,13} If we adjust for differences in observation time, such an approach could be used as the norm for quality in device-surgery. The average percentage of reoperations in 10 studies (including ours) is 5.3%. However, the range is large and the results difficult to interpret because of variations in study design and observation period.

Eberhardt *et al.*¹³ find an increased complication rate among older patients. There was no such difference in our material, nor in the other studies we have reviewed.

Frequency of complications in relation to the operator's experience

Our study shows, in accordance with other studies, higher complication rates after operations performed by doctors with little experience compared with more experienced colleagues. At the same time, the experienced doctors have presumably operated on the most challenging patients, where one can assume that the risk of complications is higher. This means that the real difference in frequency of complications can be even greater.

Our doctors have nevertheless less experience than those in other studies. In the study of Pakarinen *et al.*² four cardiologists did 325 operations during 1 year, which on average provides over 80 operations per year, twice as many as our most active operators. All our experienced operators have had periods prior to the study period with higher activity. This observation may have several explanations, but the fact that our operators have an acceptable complication rate may indicate that intensive training over a period may compensate for less practice in periods of lower activity.

The observed difference in complication rate between trainees and fully educated personnel is not as large as reported in other studies.² However, supervision may represent an additional strain on a small and less experienced staff and thereby lead to a larger all over complication rate.

Conclusion

There are no generally accepted standards regarding registration of complications in device surgery. Therefore, it is difficult to find good benchmarks for quality. In addition, the number of patients in our study is too small to draw sturdy conclusions.

However, our way to organize the pacemaker service has brought arrhythmologic and electrophysiologic knowledge to an area with a scattered population and difficult transportation conditions. In this context we find our pacemaker service acceptable. The present study does not reveal any reasons to change practice.

Like other authors, we found a higher rate of complications in operations performed by trainees. Small pacemaker centres may be particularly exposed to this, and education should probably be relocated to larger hospitals. In addition, many of our complications are related to subclavian vein access. We will consider using cephalic cutdown to a greater extent.

Good control of complication rates is important. Some countries have established national pacemaker registries, while others are in the process. Such registries should be organized in a way that facilitates comparison of complication rates between individual pacemaker centres and between local and national or international data.

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