

Research Article

Influence of implantation access on complication rates in pacemaker implantation: An analysis of quality insurance data

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Abstract

Purpose: According to older reports for implantation of pacemakers the access via vena cephalica (VC) is associated with less complications than the access via vena subclavia (VS), but the VS is still preferred. Valid data on head-to head comparisons between access via VC and VS regarding serious complications are missing. The aim of the analysis was to analyze potential associations between type of implantation access and complication rates on a representative dataset.

Methods: The dataset of the German Federal Council containing all procedures in Germany in 2013 was analyzed. The analysis included hospitalized 75,575 patients with primary pacemaker implantation. The statistical evaluation of the data set was based on a multivariate analysis.

Results: Overall, the rate of implantations via VS was two times higher than via VC (64% vs. 36%). There was significantly higher risk of overall complications (3.0% vs. 2.6%), i.e. surgical complications (1.0% vs. 0.5%), asystole (0.2% vs. 0.1%) and pneumothorax (0.7% vs. 0.1%) at the VS access; the VC access had a greater risk of dislocated atrial leads (0.8% vs. 0.6%).

Conclusion: Our analysis of a large-scale database shows that the overall rate of complications is low in primary pacemaker implantation.

Considering the rate of implantations via subclavian vein being twice as high as via cephalic vein, the clinical implications should be considered when choosing the access route and cephalic vein access should be preferred.

More Information

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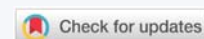
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Keywords: Pacemaker; Complication; Implantation access; Subclavian vein; Cephalic vein



Introduction

The implantation access either via vena cephalica (VC) or vena subclavia (VS) is the usual procedure in pacemaker implantation [1]. Each procedure has advantages and disadvantages such as success rate, procedure time incl. radiation exposure and complication rate.

In Germany, more implantations are performed via VS than via VC [2]. Reasons are the reported higher success rate, the shorter operation and fluoroscopy times, lower blood loss and the simple puncture of the vein [3-7]. Additionally, the access via VS is associated with a higher rate of pneumothorax [6,7].

Although access via VC is associated with less complications

and therefore represents an overall more gentle method for implantation of pacemakers [8], the VS is still preferred.

Valid data on head-to-head comparisons between access via VC and VS regarding serious complications is not available. Therefore, we analyzed potential associations between the type of implantation access and complication rates in a real world data set with 75,575 cases.

Methods

Dataset

The retrospective analysis is based on the 2013 dataset of the German Federal Council, held by the AQUA Institute (Göttingen, Germany) [9] containing information about all

inpatient primary pacemaker implantations performed in Germany during the registration year and consists data of 75,575 patients. The population could be recorded completely and therefore the specification of confidence intervals was not necessary.

Study population

A study population was recruited which included only patients who were implanted either exclusively via VS or exclusively via VC. Patients who used either both or a different implant access were excluded from further analysis. Consequently, the study population contains 69,957 patients (Table 1).

Statistical analysis

First, both groups of the study population (VC, VS) were analyzed and compared by using descriptive statistical methods. Categorical variables were recorded by absolute and relative data. Ratio-level data was described by using absolute and relative values, averages, standard deviations and range.

Subsequently, a multivariate analysis (FBSA = finest balancing score algorithm [10]) was applied to adjust the risk in order to exclude the influence of possible independent variables on the complication rates as far as possible. In a first step two cohorts of patients treated via VC or VS access were compared for all relevant variables by descriptive statistics. Secondly all patient-clusters with exactly the same risk-/condition-vector were identified based on the following variables: age, sex, ASA classification (ASA 1 – ASA 5), leading symptom, indication for implantation, etiology, ejection fraction (EF), estimated need of stimulation. All possible 1:1 exact matchings were included in these clusters and the complication rates for all possible exact matchings of both

cohorts, which converge to the result of the weighting for the identified clusters, were compared.

A χ^2 -test was applied to compare the complication rates of both groups for statistically significant differences. A p -value < 0.05 was considered as statistically significant.

Complications

The number of patients with at least one complication occurring at the time of discharge from hospital was recorded. The complications that appeared in this patient group were subsequently analyzed and described in more detail.

Table 2 shows a summary of the precisely recorded complications.

The complication rates before and after risk adjustment were recorded. After risk adjustment, the influence of the independent variables (age, sex, ASA classification, leading symptom, indication for implantation, etiology, ejection fraction (LVEF), estimated need of stimulation) can be largely excluded and the observed differences can be attributed to the implantation approach.

Results

Characteristics of matched patient pairs

Out of the total cohort of 69,957 patients 19,643 pairs with identical profile of all factors could be identified. The profile of all 1:1 matching pairs is summarized in table 3. The characteristic values marked in bold were recorded most frequently.

Complications: primary endpoint

The overall complication rates were 3.0% in the total

Table 1: Characteristics of total and study population.

	Total population	Study population		
		Total	VC	VS
number of patients (n)	75,575	69,957	25,217 (36%)	44,740 (64%)
mean age	76.18 years	76.3 years	76.67 years	76.18 years
women (n)	34,252 (45.3%)	31,695 (45.3%)	11,081 (43.9%)	20,614 (46.1%)
men (n)	41,323 (54.5%)	38,262 (54.7%)	14,136 (56.1%)	24,126 (53.9%)

Table 2: Complete list of complications within the dataset.

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Intraoperative or perioperative complications	Arrhythmias	Asystole
	Complications requiring intervention	Ventricular fibrillation
		Pneumothorax
		Haemothorax
		Pericardial effusion
		Pocket hematoma
Postoperative complications	Lead dysfunction	Atrial lead
		Ventricular lead
	Lead dislocation	Atrial lead
		ventricular lead
	Wound infection	CDC 1
		CDC 2
		CDC 3
Other complications requiring intervention	Not specified in dataset	

population and 2.9% in the study population (VC 2.6%, VS 3.0%).

The complications most frequently recorded in the total population - listed in descending frequency - were lead dislocation (1.4%), pneumothorax (0.5%), lead dysfunction (0.4%), asystole (0.2%), pericardial effusion (0.2%), pocket hematoma (0.2%), unspecified (0.2%), ventricular fibrillation (0.1%), haemothorax (0.04%), wound infection (0.03%). Rate of in-hospital mortality was 1.4% in both groups.

Table 4 shows the complications recorded for which a statistically significant difference was determined between the two implant approaches (VC, VS) before risk adjustment.

Table 5 shows the complications recorded for which a

statistically significant difference was determined between the two implant approaches (VC, VS) after risk adjustment in matched cohorts.

Of all patients in the total population who faced at least one complication, 49.1% were male and 50.9% were female. In the study population, 49.2% were male and 50.8% were female. Overall, woman had a higher risk of complications in all subgroups, as shown in table 6.

Selection of pacemaker type: secondary endpoint

In total, two-chamber systems were most frequently implanted, the DDD system accounting for the largest proportion. CRT systems accounted for the smallest proportion of all implanted systems. The exact proportions of

Table 3: Profile of all 1:1 matching pairs.

Number of patient pairs	19,943			
Mean age	77.07 years			
ASA classification	ASA 1: 6.3%	ASA 2: 45.0%	ASA 3: 46.9%	ASA 4: 1.7%
Leading symptoms	Dizziness: 51.9%	Singular cardiac syncope: 10.3%		Recurring syncope: 28.7%
Pacemaker indication	AV- II: 11.6%	AV-Block III: 26.3%	Sick sinus syndrome: 39.8%	Bradycardia in atrial fibrillation: 20.0%
Etiology of rhythm isturbances	unknown: 90.3%			
Ejection fraction (LVEF)	≤ 35%: 0.4%	> 35 – 50%: 9.1%	> 50%: 79.9%	unknown: 10.5%
Estimated need of stimulation	permanent (> 90%): 20.9%	frequent (5% – 90%): 70.2%		rare (< 5%): 8.9%

Table 4: Statistically significant different complications before risk adjustment.

	Total population (n) = 75,575	Study population (n)= 69,957		p - value*
		VC (n) = 25,217	VS (n) = 44,740	
Incidence of at least one complication	3.0%	2.6%	3.0%	0.002
Lead dislocation	1.4%	1.5%	1.3%	0.017
- atrial lead	0.7%	0.8%	0.6%	0.013
Pneumothorax	0.5%	0.1%	0.7%	< 0.001
Asystole	0.2%	0.1%	0.2%	0.037
Haemothorax	0.04%	0.02%	0.01%	0.035
Wound infection	0.03%	0.01%	0.04%	0.038

*p - value ≤ 0.05 was considered significant.

Table 5: Statistically significant different complications after risk adjustment in matched cohorts.

	VC	VS	p - value*
Number of patients (n)	19,643	19,643	
Incidence of at least one complication	2.6%	3.0%	0.018
Surgical complications ^a	0.5%	1.0%	0.005
Asystole	0.1%	0.2%	0.047
Pneumothorax	0.1%	0.7%	< 0.001
Dislocated atrial lead	0.8%	0.6%	0.027
Intra-hospital mortality	1.4%	1.4%	0.691

*p - value ≤ 0.05 was considered significant.

^acontains complication with need for intervention: pneumothorax, haemothorax, pericardial effusion, pocket hematoma.

Table 6: General and gender-specific complication rates.

	[n]	Patients with at least one complication	Complication risk depending on gender	
			female	male
total population	75,575	3.0%	3.3%	2.7%
study population	69,957	2.9%	3.2%	2.6%
VC	25,217 (36%)	2.6%	2.9%	2.4%
VS	44,740 (64%)	3.0%	3.4%	2.7%

Comparison VC and VS male: p = 0.094*

Comparison VC and VS female: p = 0.011*

*p - value ≤ 0.05 was considered significant

the different systems were: VVI 21.1%, AAI 0.2%, DDD 76.2%, VDD 0.6%, CRT with atrial lead 1.6%, CRT without atrial lead 0.14%, other 0.17%.

All systems, with the exception of the VDD system, were implanted via the VS in more than 50% of the cases. The exact distribution is shown in table 7.

Intervention and fluoroscopy time: secondary endpoint

The mean cutting-suture time was numerically 0.7 minutes longer after implantation via the VS than via the VC (VS 53.46 min – VC 52.76 min).

The mean fluoroscopy time was numerically 0.67 minutes longer after implantation via the VS than via the VC (VS 4.82 min – VC 4.15 min).

Mortality: secondary endpoint

As data collection took place at the time of discharge from the hospital, only the intra-hospital mortality rate could be determined.

During the observation period 1.4% of the patients of the total population died in the hospital. 48% of them were female and 52% were male. Altogether 1.5% of all female and 1.3% of all male patients died. Hence the mortality rate of female patients was higher.

In the study population, the mortality rate in both groups was 1.4%. A statistically significant difference did not exist ($p = 0.691$). The mortality rates of both sexes also showed no statistically significant differences in regards to the implant access method (p (male) = 0.445, p (female) = 0.153).

Discussion

The study is based on a completely recorded population in Germany of the year 2013. The data is characterized by high quality and completeness [11]. Therefore, despite some limitations, valid results can be assumed.

Implantation access

Within the observed patient cohort, a total of 92.6% of all implantations were performed either via VS or via VC. The proportion of implantations via VS was almost twice as high as the proportion of implantations via VC (64% vs. 36%).

The results are consistent with those of several other

smaller studies in which VS was preferred [3,4,8,12]. Regarding the generally higher implantation rate via VS access, the annual report of the German pacemaker and defibrillator register even speaks of a “trend towards the wrong right” [13].

It is noteworthy that the number of implantations via VS has decreased slightly since 2015 and that the access via VC is used more frequently [2].

Complication risk

The overall complication risk of 3.0% is lower than expected from previous studies [8,12,14–17]. We found a significantly higher risk of any complication after using the VS approach (3.0% vs. VC 2.6%) which confirms results of previous smaller studies [8,18,19].

Furthermore, we found that after risk adjustment, VS access is associated with a significant higher risk for asystole and pneumothorax. The higher risk for the development of pneumothorax after subclavian puncture is sufficiently known and is described in many studies without further investigation of possible reasons [5–7,20]. Within the study population, 90% of the observed pneumothoraces occurred after subclavian puncture. The difference was statistically highly significant ($p < 0.001$). Regarding the risk of asystole, there are no studies available which investigated the influence of implantation access. Only one study could be found which indicates the risk of asystole after pacemaker implantation [16]. However, this study does not establish a correlation between risk of asystole and implantation access.

The only complication, which occurred significantly more frequently after puncture of the VC, was the dislocation of atrial leads. Previous publications have indicated that the fixation mechanism has a significant influence on the dislocation rates of leads [20,21]. No publication could be found that investigated the association between implantation access and atrial lead dislocations.

According to Link, et al. different complication rates of both access routes depend on patient characteristics [17]. We were able to exclude this influence as far as possible by using an exact matching of all documented variables.

Complications showing a significant difference between the two approaches before but not after risk adjustment are lead dislocations in general, haematothorax and wound infection. This implies that the independent variables age, sex, ASA classification, leading symptom, indication for implantation, etiology, ejection fraction (LVEF) and estimated need of stimulation have an assumingly significant influence in regards to the occurrence of these complications.

We found a significantly higher complication risk in women, regardless of implant access. The higher gender-specific risk has already been described in previous studies [14,22].

Table 7: Implantation accesses of the pacemaker systems.

System implanted	VC	VS
VVI	42%	58%
AAI	39%	61%
DDD	35%	65%
VDD	52%	48%
CRT with atrial lead	11%	89%
CRT without atrial lead	15%	85%
Other	33%	67%

Implanted pacemaker types depending on implantation approach

In previous studies it has been described that the VC is often only suitable for the implantation of single-chamber systems due to its small size [4,5]. In contrast to this in our analyzed population all systems could be successfully implanted via both accesses. All systems were implanted via the VS in over 50% of the cases, with exception of the VDD system, which was successfully implanted via the VC in 52% of the cases. The implantation of more than one lead is therefore technically possible.

Intervention and fluoroscopy time

We found shorter intervention and fluoroscopy times after implantation via VC than via VS. The mean cutting-suture time was 0.7 minutes shorter and the mean fluoroscopy time was 0.67 minutes shorter. We can thus agree with the publication by Eberhard, et al. which describes an extended intervention- and fluoroscopy time after subclavian puncture [23]. Other studies describe a longer implantation time with access via VC [4,5,24].

However, it should be noted that fluoroscopy and intervention time is influenced by several factors. For example, the choice of the implanted system has an influence on the duration of the intervention (the time required increases with the number of leads to be implanted [12,23,25]). The surgeon's experience also has a significant influence [12]. However, these factors could not be investigated within the framework of data analysis.

Mortality

The mortality rates reported in previous studies range between 0.1% and 1.3% and the determined intra-hospital mortality (1.4%) rate is comparable to previous studies [6,8,14,17]. We recorded intra-hospital mortality at time of discharge from the hospital. A follow-up was not possible due to the data acquisition. Furthermore, it was not possible to conclude the exact cause of death. The reason is that the discharge diagnosis was only death and not its exact cause. Thus, it can only be reported how many intra-hospital deaths occurred, but not exactly why the patients died.

There was no statistically significant correlation between implant access and mortality rate.

Limitations

The data collection only took place in inpatient area, outpatient implantations were not considered. Furthermore, only a limited number of patient characteristics were recorded. It is not possible to conclude on existing risk factors, lifestyle habits or other diseases. There is also no information available on the surgeon's level of experience and the exact cause of intra-hospital death. Because of pseudonymization, the data set also does not allow conclusions about the number of procedures within the hospital in which the implantation

took place and the volume/outcome relation. A follow-up after hospital discharge was also not possible based on the dataset, therefore no mean survival times or long-term complications could be determined.

A more recent and comparable German dataset was not available, but according to the German Heart Report the absolute implantation rates have not changed substantially since 2013 [26].

Conclusion

Our analysis of a large-scale database shows that in patients with primary pacemaker implantation the overall rate of complications is relatively low. But even after adjustment for available risk factors there are differences between the access routes: whereas VS access route is associated with statistically significant higher risk of overall complications, asystole and pneumothorax, the VC access has a greater risk of dislocated atrial lead.

In view of the two times higher rate of implantations via VS (64% vs. 36%) the clinical implications should be considered when choosing the access route and the VC access should be preferred. For some time, leadless pacing for single chamber stimulation is an alternative to conventional implantation via VC or VS. However, long term data are still lacking [27].

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