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ORIGINAL ARTICLE

Validation of the national Danish ablation database: a retrospective, registry-based validation study

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ABSTRACT

*Aim.*To validate the National Danish Ablation Database (NDAD) by investigating to what extent data in NDAD correspond to medical records.

Type of study. Non-blinded, registry-based, retrospective, validation study. *Material and methods*. A sample of patients who underwent ablation for atrial fibrillation in Denmark between 1 January 2016 and 31 December 2016 were included. By utilizing medical records as gold standard, positive predictive (PPV) and negative predictive values (NPV) for NDAD were assessed and presented as five main categories: arrhythmia characteristics, demographics, cardiac history, complications, and medication. PPV's and NPV's exceeding 90% were considered as high agreement. *Results*. 597 patients (71.0% males) were included in the study. Median age was 63.1 (IQR: 54.9–68.4) years. The median PPV and NPV estimates across all variables were respectively 90.4% (95% CI: 68%–95.2%) (PPV) and 99.4% (95% CI: 98.4%–99.8%) (NPV) at baseline, and 91.7% (95% CI: 67.4%–95.4%) (PPV) and 99.3% (98.2%–99.3%) (NPV) at follow-up. *Conclusion*. The data registered in NDAD agrees to a great extent with the patients' medical records, suggesting NDAD is a database with high validity. As a result of low complication rate, the PPV- and NPV-estimates among complication variables were prone to somewhat greater uncertainty compared to the rest.

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Introduction

There have been major advancements in the treatment of cardiovascular disease for the last decades; however, cardiovascular disease still is one of the leading causes of morbidity and mortality in the world [1, 2]. There is a continuous need for research to find better prevention- and treatment techniques, but also to ensure the quality of the used techniques. National clinical quality registries can be used to monitor the quality of performed medical procedures and the results hereof. A limitation with various clinical databases is that these are typically not validated, and it is hard to do so as they often cannot be connected to other databases or medical records.

The use of administrative Danish databases is one of the key elements in conducting high qualitative research in Denmark. The registries are deterministically linked using the civil personal registration number, which is unique for each Danish citizen with an address in Denmark, making it possible for example to connect a medical procedure with an outcome. In Denmark, there are nationwide registries covering all health service contacts (both in the private and the public health care) and are in general regarded as of high quality [3–6]. In 2008–2009, the Danish arrhythmia working group initiated the National Danish Ablation Database (NDAD) as a nationwide registry, containing data of all performed percutaneous ablation procedures for tachyarrhythmias in Denmark. The database has been used as data source for previously published studies [7, 8], but has so far not yet been validated. In this non-blinded, registry-based, retrospective, validation study, we sought to evaluate and validate the data submitted to NDAD, and to examine the positive and negative prediction values (PPV's and NPV's) of clinical variables and procedure related complications among patients treated with percutaneous ablation for atrial fibrillation (AF).

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Supplemental data for this article can be accessed online at https://doi.org/10.1080/14017431.2022.2099009.

Material and methods

Civil registration number and the national Danish ablation database

Since 1968, all Danish citizens with an address in Denmark have had a civil registration number (CPR-number) [9, 10]. The CPR-number is unique to each Danish citizen and is connected to a range of databases. As a result, the registered data in the medical records can be compared to the corresponding data in a database, and therefore making validation of that particular database possible. NDAD has collected data of all performed percutaneous ablation procedures for cardiac arrhythmias in Denmark since 2012, and has been accepted as a national, clinical, quality database since February 2012. The data is prospectively collected and contains both ablation, demographic and medication data of patients undergoing percutaneous ablation for supraventricular and ventricular arrhythmias [11]. The main purpose of NDAD is to monitor the clinical quality of the performed ablations and ablation-related complications in Denmark, but also contains demographic data of the patients undergoing the procedures. All data input in the database are performed by either the ablation physicians, nurses or technicians in connection with the ablation procedure and during follow-up visits. In Denmark, there are seven cardiac ablation centres: (six public and one private), which all put their data into NDAD [11, 12].

Data collection

Patients who had undergone percutaneous ablation for AF between the 1 January 2016 and 31 December 2016, in six of the ablation centres in Denmark were selected for the analysis. One ablation centre was not included, as only three patients underwent percutaneous ablation for AF in that centre in 2016 [13]. The patients were selected in chronological order in which they had their ablation performed at each centre, with a maximum of ten patients included per centre per month in order to spread the selected patients among the different centres and dates, thus reducing selection bias. If patients had several ablations performed during the period, only the first ablation procedure was used.

Variables selected for comparison were the demographic data, medication, and procedure complications at the time of the procedure and at follow-up. By utilizing the CPR-number, demographic data as well as procedure data were collected by free-text search from the patients' electronic medical records. The demographic and medical data consisted of sex, age, ablation centre, date of ablation, previous cardiac and other medical history, CHA_2DS_2-VASc-score and -characteristics, medication prior to and one-year post-ablation, type of AF, AF associated symptoms and presence of pacemaker or implantable cardioverter-defibrillator. In order to simplify the reporting of the results for this article, the previous medical history category was further split up into an arrhythmia-, a cardiac history and a CHA_2DS_2-VASc category, even though this partition does not exist in NDAD.

The medication data at the date of the procedure and at follow-up was obtained by screening the patients' medical records combined with free-text search of both the generic and brand names of the medication drugs. In addition, in one of the regions, the Shared Medical Card (Faelles Medicinkort, FMK) [14] was available, and was used instead of the medical records. The data of the remaining demographic and complication variables were obtained by free-text search in the medical records, but also by including registered diagnosis codes according to the International Statistical Classification of Diseases and Related Health Problems (ICD-10) [15]. In the Capital Region of Denmark, an additional medication module (Medicinmodulet, The Medication Module), was used.

Complications were divided into two main categories: procedure-related complications and long-term complications. Procedure related complications consisted of atrial ventricular conduction block (AV-block), cardiac tamponade, embolism, perioperative mortality, nervous phrenicus paresis, pneumothorax, haematoma, and other undefined complication, whereas long-term complications consisted of deep vein thrombosis, oesophageal fistula, infection, pulmonary vein stenosis and the occurrence of either transient cerebral ischaemia (TIA) or ischaemic stroke. As a consequence of low complication rate, composite complication categories where synthesized, in which the complications were put into one of three main categories: no complication, mild/moderate complications and severe complications. Mild and moderate complications consists of: AV-block, haematoma and undefined complication (procedural complications), deep vein thrombosis and infection (late-term complications). The corresponding severe complications consisted of cardiac tamponade, embolism, death, nervous phrenicus paresis and pneumothorax whereas the severe late-term complications consisted of oesophageal fistula, pulmonary vein stenosis and pneumothorax. As the severe complications of percutaneous ablation were known and registered, it was decided the undefined complications consisted of either mild or moderate complications, hence were put into the mild/moderate complication category.

If an investigated variable did not have any registrations in NDAD nor did it occur in the medical records, it was interpreted as a 'No'-registration - that is no medication, no complications, no medical history nor any demography variables were present for that particular patient.

The data was collected by one of the authors (S.B.C) during 2018 to 2019. Medical records were used as gold standard. The investigator who performed the data collection did not have access to the cardiac image modalities from prior interventions; however, the procedures performed were described in the medical records.

Statistical analysis

Continuous variables are presented in medians and interquartile ranges (IQR), and categorical variables are presented as absolute numbers and percentages. For simplicity and future applicability of the results, the PPV's and NPV's were arranged into six main groups: arrhythmia, cardiac history, demography (CHA_2DS_2VASc-characteristics), medication, procedure complications (containing both procedural and long-term complications) and relapse. Comparisons between

the registered events in medical records and NDAD were investigated by McNemar's test with continuity correction. In order to validate the registered entries in the database, positive (PPV) and negative predictive values (NPV) with 95% binomial confidence intervals (CI) were obtained through the Wilson method. The PPV- and NPV-estimates were obtained by 2×2 tables comprising the proportion of correctly registered binary clinical variables. The true positive and true negative results represent how reliable a registration (PPV), or the absence of it (NPV), in the database is. Values above 90% were interpreted as high reliability.

In addition, overall median PPV and NPV for the six main categories are also provided, along with an interquartile range (IQR). As a result of low complication rates, some predicted values did not produce meaningful confidence intervals; thus, composite complication endpoints (defined as overall procedural and late complications) were considered for the PPV and NPV-values. In order to obtain PPV's and NPV's from the continuous variables (i.e. CHA_2DS_2VASc score and EHRA-class at baseline and follow-up), dichotomous dummy variables were created for the medical record and NDAD entries to reflect the absence (0) or presence (1) of the values for that particular patient, and then analysed in 2×2 tables as the rest of the dichotomous variables. An example of the dichotomization process can be seen in Table 1 in Appendix.

The PPV's and NPV's of each main group are displayed as tables and graphically as forest plots, whereas the individual PPV's and NPV's are presented in Appendix. The statistical analyses were performed in R (version 4.1.3, Windows 10) and RStudio (version 1.4.1103, The R Foundation, Vienna, Austria) with attached packages [16–20].

Ethical considerations

The collection of data was approved by the North Denmark Region and Danish Data Protection Agency (ID-number: 2017-238). According to Danish law, no consent is needed from participants when using registry data. Data from NDAD were acquired after approval from the Steering Committee of NDAD. In order to comply with GDPR data regulation laws, the data were collected into a REDCap (Research Electronic Data Capture) database hosted on servers at Aalborg University Hospital. [21, 22]

NDAD is financed through unrestricted grants from the medical industry (*Johnson & Johnson*, *Medtronic* and *Abbot*). The registry is controlled by members representing each ablation centre in Denmark.

Results

In 2016, 1979 patients underwent percutaneous ablation for AF in Denmark, of which 597 (30.2%) were selected for this study.

The median age was 63.1 (IQR: 54.9 days–68.4 days) years and 424 (71.0%) of the patients were males. Further demography characteristics are presented in Table 1. The patients were equally distributed among the six participating ablation centres.

Table 1. Population characteristics.

Variables	Medical record, (%)	NDAD, (%)	P-value[a]
Total	597	597	1.00
Ablation centre			1.00
Aalborg	91 (15.2)	91 (15.2)	
Aarhus	96 (16.1)	96 (16.1)	
Gentofte	103 (17.3)	103 (17.3)	
Odense	108 (18.1)	108 (18.1)	
Rigshospitalet	96 (16.1)	96 (16.1)	
Varde	103 (17.3)	103 (17.3)	
CHA_2DS_2VASc characteristics			
Congestive heart failure	108 (18.1)	68 (11.4)	<.05
Hypertension	251 (42.0)	215 (36.0)	<.05
Age 75+	29 (4.9)	29 (4.9)	1.00
Diabetes	34 (5.7)	28 (4.7)	.21
Ischaemic stroke/TCI	52 (8.7)	41 (6.9)	<.05
Peripheral artery disease	45 (7.5)	27 (4.5)	<.05
Age 65-74	214 (35.8)	214 (35.8)	1.00
Female sex	168 (28.1)	168 (28.1)	1.00
CHA_2DS_2VASc-score			
0	147 (24.6)	156 (26.1)	.22
1	156 (26.1)	179 (30.0)	<.05
2	154 (25.8)	148 (24.8)	.58
3	81 (13.6)	84 (14.1)	.79
4	43 (7.2)	23 (3.9)	<.05
5	15 (2.5)	5 (0.8)	<.05
6	1 (0.2)	2 (0.3)	1.00
Prior cardiac history			
Ischaemic heart disease	58 (9.7)	48 (8.0)	<.05
Dilated CM	31 (5.2)	19 (3.2)	<.05
Hypertrophic CM	11 (1.8)	11 (1.8)	1.00
Arrhythmogenic RV	0 (0.0)	0 (0.0)	1.00
Congenital heart disease	1 (0.2)	0 (0.0)	1.00
Mitral stenosis	1 (0.2)	1 (0.2)	1.00
Mitral regurgitation	10 (1.7)	18 (3.0)	.099
Aortic stenosis	5 (0.8)	2 (0.3)	.25
Aortic regurgitation	4 (0.7)	6 (1.0)	.48
No prior cardiac disease	470 (78.7)	496 (83.1)	<.05
Prior cardiac interventions			
PCI	44 (7.4)	40 (6.7)	.39
CABG	11 (1.8)	13 (2.2)	.48
Aortic valve surgery	6 (1.0)	6 (1.0)	1.00
Mitral valve surgery	5 (0.8)	5 (0.8)	1.00
Congenital surgery	1 (0.2)	1 (0.2)	1.00
AF ablation	64 (10.7)	60 (10.1)	.45
Ablation, other	84 (14.1)	73 (12.2)	<.05
No prior cardiac interventions	379 (63.5)	404 (67.7)	<.05
Arrhythmia characteristics			
Paroxysmal AF	379 (63.5)	378 (63.3)	1.00
Persistent AF	183 (30.7)	154 (25.8)	<.05
Below two years,	40 (6.7)	44 (7.4)	.62
Above two years	5 (0.8)	6 (1.0)	1.00
Dyspnea	441 (73.9)	469 (78.6)	<.05
Syncope	11 (1.8)	10 (1.7)	1.00
Dizziness	120 (20.1)	73 (12.2)	<.05
Palpitations	428 (71.7)	488 (81.7)	<.05
Pacemaker	1 (0.2)	1 (0.2)	1.00
No pacemaker	0 (NaN)	1 (0.2)	1.00
Baseline medication			
Beta blockers	389 (65.2)	400 (67.0)	.17
Calcium antagonists	37 (6.2)	37 (6.2)	1.00
Digoxin	52 (8.7)	52 (8.7)	1.00
Class 1 C antiarrhythmics	73 (12.2)	72 (12.1)	1.00
Sotalol	1 (0.2)	3 (0.5)	.48
Dronedarone	3 (0.5)	6 (1.0)	.25
Amiodarone	108 (18.1)	108 (18.1)	1.00
VKA	510 (85.4)	501 (83.9)	.27
Thrombin inhibitors	12 (2.0)	44 (7.4)	<.05
Factor Xa inhibitors	48 (8.0)	21 (3.5)	<.05
Complications			
Death	0 (0.0)	0 (0.0)	1.00
Cardiac tamponade	2 (0.3)	4 (0.7)	.48
Haematoma	3 (0.5)	1 (0.2)	.48
Atrioventricular block	0 (0.0)	0 (0.0)	1.00
Embolus	1 (0.2)	0 (0.0)	1.00
Pneumothorax	0 (0.0)	0 (0.0)	1.00

(*continued*)

Table 1. Continued.

Variables	Medical record, (%)	NDAD, (%)	P-value[a]
Paresis of n. phrenicus	0 (0.0)	0 (0.0)	1.00
Other complications	5 (0.8)	2 (0.3)	.25
No complications	572 (95.8)	588 (98.5)	<.05
Recurrence			
No recurrence	309 (51.8)	420 (70.4)	<.05
Recurrence	137 (22.9)	121 (20.3)	.077
Paroxysmal recurrence	109 (18.3)	81 (13.6)	<.05
Persistent recurrence	20 (3.4)	16 (2.7)	.42
Atrial flutter recurrence	18 (3.0)	12 (2.0)	.21
Documented recurrence	102 (17.1)	88 (14.7)	.077
Recurrence symptoms	163 (27.3)	140 (23.5)	<.05
Complications at follow-up			
Death	0 (0.0)	0 (0.0)	1.00
Cardiac tamponade	2 (0.3)	1 (0.2)	1.00
Haematoma	5 (0.8)	0 (0.0)	.074
Atrioventricular block	1 (0.2)	0 (0.0)	1.00
Embolus	1 (0.2)	0 (0.0)	1.00
Pneumothorax	0 (0.0)	0 (0.0)	1.00
Paresis of n. phrenicus	1 (0.2)	1 (0.2)	1.00
Other complications	9 (1.5)	1 (0.2)	<.05
No complications	449 (75.2)	575 (96.3)	<.05
Late complications			
Infection	2 (0.3)	1 (0.2)	1.00
DVT	0 (0.0)	0 (0.0)	1.00
Pulmonary vein stenosis	1 (0.2)	1 (0.2)	1.00
Ischaemic stroke/TCI	1 (0.2)	0 (0.0)	1.00
Oesophageal fistula	1 (0.2)	0 (0.0)	1.00
Atrial flutter	9 (1.5)	7 (1.2)	.72
No late complications	455 (76.2)	567 (95.0)	<.05
Relapse within a year	149 (25.0)	130 (21.8)	<.05

NDAD: National Danish Ablation Database; TCI: transient ischaemic stroke; CM: cardiomyopathy; RV: right ventricle; PCI: percutaneous coronary intervention; CAGB: coronary artery graft bypass surgery; AF: atrial fibrillation; VKA: vitamin K antagonists.
[a]Derived from McNemar's test.

The overall median PPV between the medical records and the NDAD was 92.2% (IQR: 79.5%–100%). The highest PPV-estimate was seen in the CHA_2DS_2VASc-category, in which "Age 65–74" had an estimated PPV of 100% (95% CI: 98.2%–100%). In contrast, the lowest PPV-estimate was found in the complication category at baseline, in which Mild/moderate procedural complications had a PPV-estimate of 23.5% (95 CI%: 9.6%–47.3%).

The corresponding median NPV was 99.3% (IQR: 95%–99.8%). High NPV-estimates were found in several categories (CHA_2DS_2-VASc, cardiac history, arrhythmia, medication and complications), in which both arrhythmogenic right ventricle, congenital heart disease, aortic valve stenosis, former aortic valve replacement, former mitral valve surgery, former congenital surgery, the use of Sotalol or Dronedarone at follow-up, mild and moderate procedural complications, severe late complications as well as the presence of pacemaker had an estimated NPV of 100% (95%: 99.4%–100%), whereas the lowest estimates was found in the complication category, in which No late complications had an estimated NPV of 45.5% (95% CI: 16.3%–61.2%). The estimated PPV's and NPV's for all included variables are visualized as forest plots in Figures 1–8 in Appendix.

The median PPV and NPV estimates across all variables were respectively 90.4% (95% CI: 68%–95.2%) (PPV) and 99.4% (95% CI: 98.4%–99.8%) (NPV) at baseline, and 91.7% (95% CI: 67.4%–95.4%) (PPV) and 99.3% (98.2%–99.3%) (NPV) at follow-up. The individual PPV's and NPV's for each main category are presented in Table 2. A total of 19 (3.18%) the patients did not have any registrations in the complication category (neither at baseline nor late-term complications); hence, they were transferred to the 'No'-complication-category. In all, there were registered 16 (2.68%) complications in the medical records, and nine (1.51%) in NDAD. All registered complications in the medical records and NDAD can be seen in Table 3. All PPV- as well as NPV-tables and plots are presented in Appendix.

Table 2. PPV- and NPV-estimates among the six main categories.

Main category	PPV-estimate	PPV 95% CI	NPV-estimate	NPV 95% CI
Arrhythmia	0.89	0.74–0.92	0.99	0.98–1.00
Cardiac history	0.97	0.57–0.98	1.00	0.99–1.00
CHA2DS2-VASc	0.78	0.73–0.83	0.99	0.98–1.00
Complication	0.48	0.19–0.84	1.00	0.99–1.00
Medication, baseline	0.94	0.81–0.96	0.98	0.97–0.99
Medication, follow-up	0.92	0.74–0.96	0.99	0.98–1.00
Relapse	0.82	0.77–0.86	0.75	0.71–0.79

PPV: positive predictive value; NPV: negative predictive value; CI: confidence interval.

There were some significant differences in the input of data between the two sources: the presence of dilated cardiomyopathy, congestive heart failure, hypertension, vascular disease as well as the use of factor Xa inhibitors or thrombin inhibitors (Table 1), beta blockers, DOAC or vitamin K antagonists at one year follow-up. In the majority of the variables, there was a general over-representation of registrations in the medical records than in NDAD.

Discussion

Registry data of ablation for AF have various appliances, both in scientific research but also as a monitoring tool. The use of administrative databases in studies are widespread, and the registered data in these databases are often seen of as high quality, even though there have not been many validation studies on these data sources. To our knowledge, this is the first study that validates an ablation database. Furthermore, our study also authenticates the results from prior studies within similar subjects conducted in Denmark [7, 8]. Our study proves that NDAD is a database in which data to a large extent corresponds to what can be found in patients' medical records and NDAD is therefore suitable as a tool for future studies. Even though there were some discrepancies, the overall PPV's and NPV's were high, and corresponds to a large extent to what was found in a similar Danish registry study performed by Kristensen *et al* [4]. As presented in Figures 1–5 in Appendix and Table 2, the NDAD suffer from lower PPV than NPV, especially among the medical drug variables. This may be due to the restricted access to the medication data in 5 of the 6 ablation centres in the study. Our study also confirms that the ablation procedures for AF performed at Danish ablation centres are conducted with a combination of high quality and safety, with expected complication rates between 0% and 0.8% for both severe procedural, post-procedural as well as long-term complications. These numbers are lower than described in previous studies, and this could be attributed to the ablation strategy in Denmark,

Table 3. Number of registered complication events in the medical records compared to the National Danish Ablation Database (NDAD).

Complication	Medical record, n	NDAD, n	Absolute difference	Complication rate, % Medical record / NDAD
Procedure-related complications				
Atrioventricular block	0	0	0	0.00 / 0.00
Cardiac tamponade	2	4	−2	0.34 / 0.67
Death	0	0	0	0.00 / 0.00
Embolism	1	0	1	0.17 / 0.00
Haematoma	3	1	2	0.50 / 0.17
Paresis of. n. phrenicus	0	0	0	0.00 / 0.00
Pneumothorax	0	0	0	0.00 / 0.00
Unspecified complication	5	2	3	0.84 / 0.34
No complication	572	588	−16	95.81 / 98.49
Late complications				
Deep vein thrombosis	0	0	0	0.00 / 0.00
Infection	2	1	1	0.34 / 0.17
TCI/ischaemic stroke	1	0	1	0.17 / 0.00
Oesophageal fistula	1	0	1	0.17 / 0.00
Pulmonary vein stenosis	1	1	0	0.17 / 0.17
No complication	455	567	−112	76.21 / 94.97

NDAD: National Danish Ablation Database.

which is: few high-volume centres with few operators; this leading to highly qualified personnel conducting the procedures. Furthermore, our results suggest that the selection of patients for percutaneous ablation for AF is suitable. These findings are in line with prior studies in the field, which indicates that our study population to a great extent correspond to the general population that undergo ablation procedures for AF [23–25]. As a result of low complication rate among the patients in our study material, especially the PPV's produced great confidence intervals. Even though the complications were pooled into three main categories in order to produce more meaningful confidence intervals, the observed complications were still low, which could explain the uncertainty among these variables.

There may be multiple explanations for the discrepancies seen in Table 1 and Table 4. First, the data collection in the medical records were obtained by screening the patients' entire medical records, from birth to present day. The NDAD entries are carried out in a limited time period in a patient's life; thus, one may exclude variables which are not directly relevant to the performed procedure in NDAD which can be found years prior to the procedure in the medical records. Second, as there were some important discrepancies among the medication variables, one can presume that the patients have been given either beta blockers, DOAC or VKA prior (years) to the procedure but may have been shifted to other medication drugs closer to the procedure. Patients who underwent ablation for AF in Denmark before 2017 were required to either take either VKA or Dabigatran prior to their AF ablation procedure. If a patient received e.g. Xarelto the years prior, the medical records would record this as a match for the free-text search, whereas the NDAD would only register the VKA or Dabigatran treatment, thus leading to a discrepancy. The same may be true for some the discrepancies found among cardiac conditions and prior procedures in Table 1: some cardiac conditions, such as the dilated cardiomyopathy, have a history of being reversible when found early. Tachycardia induced dilated cardiomyopathy is a reversible form of cardiomyopathy [26, 27], and a patient who no longer suffers from the condition will still be a "match" in the free-text search process during the data collection process, whereas the NDAD would not register it as a relevant condition during the ablation procedure. In addition, the observed difference in reported relapse of AF after ablation may be attributed to the lack of a universal definition of relapse.

Table 4. Medication at follow-up.

Medication	Medical record, *n*	NDAD, *n*	*p* Value
Amiodarone	33 (5.5%)	19 (3.2%)	.071
Beta blockers	217 (36.3%)	269 (45.1%)	<.05
Calcium antagonists	20 (3.4%)	19 (3.2%)	1.00
Class 1 C antiarrhythmics	11 (1.8%)	14 (2.3%)	.25
Digoxin	11 (1.8%)	13 (2.2%)	.48
DOAC	73 (12.2%)	184 (30.8%)	<.05
Dronedarone	1 (0.2%)	1 (0.2%)	1.00
Sotalol	2 (0.3%)	2 (0.3%)	1.00
Vitamin K antagonists	194 (32.5%)	210 (35.2%)	<.05

NDAD: National Danish Ablation Database; DOAC: direct oral anticoagulants.

Limitations of the study

Data collection

The study was based on variables and complications registered in the NDAD, and therefore limits the data and variables investigated to what is available in that particular database. There may be some rare, unknown complications in connection with percutaneous ablation that still are not known, and consequently are not registered. Furthermore, the follow-up period for patients who had undergone percutaneous ablation for AF in Denmark is one year, thus limits the detection of potential complications that may occur later. Some variables which have great clinical interest, e.g. rare but severe procedure-related and long-term complications, were not observed neither in the medical records nor in the database, which meant that no valid PPV's could be obtained. In order to investigate rare complications, a larger study population is needed.

In our study, the patients' medical records were used as gold standard. Even though medical records in general correspond well to reality, they are not perfect and also written in a clinical setting. As a consequence of limited time to

register data in clinical practice, an unknown degree of under-reporting can be suspected, both in the medical records but also in NDAD. If time is limited, one can expect only positive complications, findings or symptoms are registered, whereas variables that are uncertain or are time-consuming to investigate are left out. Due to privacy restrictions, the use of the FMK to collect medication data was restricted to patients in only one of the regions in Denmark [14]. Hence, the medication variables in NDAD were compared to medication data registered in two different data sources (medical records and FMK). As a consequence, the data collection from the remaining regions' medical records was executed by free text-search, thus introducing the risk of type-one errors such as typos in either the medical records or in the search strings; a mismatch here would result in under-reporting. Especially one group variable (medication at follow-up) had high discrepancy between the medical records and the database registrations. An alternative approach to utilizing medical records as gold standard could be to use other, already validated, Danish databases, thus improving the completeness and validity of data. There was only one person who was responsible for the data collection for this article and can obviously be a source of error. Even though the majority of the variables were binomial, there were still continuous variables which could be interpreted in various way leading to either under- or over-reporting. The registered severe complications in both the NDAD and medical records were double-validated by one of the other co-authors.

During our study period, the $CHADS_2$-score was superseded by the CHA_2DS_2-VASc-score in 2012, and therefore affect s the potential variable input of the patients included prior to this date. As our study only included one patient before 2012, the effect is expected to be minor. Lastly, the decision to pool the complications into three main complications reduces the applicability of the results, but was required in our study in order to produce meaningful estimates and associated confidence intervals. This is a "consequence" of highly skilled ablation cardiologists in Denmark, thus resulting in a low-risk, high-gain procedure.

Ablation in Denmark compared to other countries

Denmark is a country in the northern part of Europe and have a tax financed public health system. As illustrated in the 2017 EHRA White Book and as well as Raatikainen *et al.* [28, 29], the number of ablations performed per capita in Denmark are high, and only a few invasive cardiac centres are performing these. This is not a commonly seen in other countries [29]. Consequently, the validity and the expected rate of procedural and late complication in the present study may not compare to countries with a different health care or ablation set-up.

Missing validation aspects

Our study was restricted to only examine the agreement between the database and medical records, but did not investigate the intra- or interobserver variation of the two data sources. Even though the NDAD is designed to be as simple as possible when registering data, there will still be a slight variation between two persons submitting data, or for one observer on two different occasions, which will affect the validity of NDAD. The variation in the medical records are expected to be even larger. Also, as both medical doctors and technicians are responsible for submitting data, it may also influence the degree of completeness of the data submitted.

This study was performed on data regarding ablation for AF and the results cannot be transferred to other types of ablations. However, the amount of data which is inserted in NDAD for AF ablations is much more comprehensive compared to data input for simple ablations as for accessory pathways. We can therefor assume that also data regarding simple ablations in NDAD are valid.

Conclusion

The Danish Ablation Database is a reliable database that in great extent corresponds to the patient's journal records and it can be a useful tool in registry research in the future. In order to validate severe but rare complications in the database, a greater study population is needed.

Disclosure statement

No potential conflict of interest was reported by the authors

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