Validation of Electronic Medical Database in Patients with Atrial Fibrillation in Community Hospitals

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Background: *The electronic medical database (EMD) has been increasingly used for clinical research as it reflects a real-world practice with large and heterogeneous samples. However, few studies have reported on the validity of EMD from community hospitals for research purposes.*
Objective: *To assess the validity of EMD based on data from patients with atrial fibrillation (AF) receiving care from community hospitals in Phitsanulok Province, Thailand.*
Material and Method: *The validity of EMD was determined using hand-written out-patient medical records (OPMRs) as a criterion standard. One hundred ninety three records of patient with ICD-10 of AF (I48) were retrieved from the EMD of two community hospitals between August 2007 and July 2008. For each patient, data of a randomly selected visit from the EMD was matched to data of the same visit from OPMRs, abstracted by a standardized data collection form. The EMD was cross-validated with OPMRs based on patient's diagnosis of AF, co-morbidities (risk factors for stroke) and bleeding events. All data were tabulated in a 2 x 2 format to calculate sensitivity, specificity and the Cohen's Kappa.*
Results: *Out of 193 AF patients retrieved from the EMD, 169 (87.56%) were documented as having a diagnosis of AF in OPMRs. The EMD data on risk factors for stroke showed moderate to high sensitivity (range: 66.67-100%) and high specificity (range: 98.77-100%). The agreement between the two databases was considered good to very good (calculated kappa range: 0.7942-0.9681). The specificity based on major bleeding was 100%l; however, sensitivity and the Cohen's Kappa could not be determined as the major bleeding diagnosis was found in neither the EMD nor the OPMRs.*
Conclusion: *The EMD of AF patients from community hospitals in Phitsanulok was valid and in good agreement with the OPMRs. The EMD from community hospitals appeared suitable for health research in patients with AF.*

Keywords: *Atrial fibrillation, Electronic medical database, Validity*

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The use of electronic medical database (EMD) for clinical research has been increasing nowadays. Some of the advantages in conducting a large database study include its reflection of a real-world practice, the heterogeneity, and large numbers of subjects[1]. Dean et al have reported that as many as 126 researches in the United States were conducted using electronic medical records for health outcome research between 2000 and 2007[2]. In Thailand, the EMD has been used in drug use research[3,4] and health economics as examples[5-10].

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Although providing several advantages as aforementioned, the EMD has its own limitations. For example, a discrepancy resulted from miscoding or incomplete coding of medication and diseases may lead to a false conclusion of study findings[1]. Therefore, it is suggested that the EMD must be validated prior to its use for health research[11].

As a part of a study to investigate quality of care for patients with atrial fibrillation (AF) in community hospitals in Phitsanulok, the validity of EMD in these hospitals is of great concern. To the best of the authors' knowledge, validity of EMD in community hospitals in Thailand has never been reported. Thus, the present study aimed to determine the validity of EMD in community hospitals in Phitsanulok by assessing accuracy of ICD-10 coding against the outpatient medical records (OPMRs) among patients with AF.

Material and Method

Setting

At the time of the present study, eight community hospitals served patients in the rural areas of Phitsanulok Province. Since the authors' intention was to validate the EMD against the hand-written OPMRs, only those hospitals that were still charting patient visits with hand-written OPMRs were considered eligible in the present study. The hand-written OPMRs were set as a criterion standard, given that physicians' own documentation of primary and secondary diagnosis for each patient visit was considered the most accurate source of information. Out of four community hospitals with hand-written OPMRs, two 30-bed community hospitals were randomly selected. Both hospitals served patients in the rural areas approximately 20-kilometers away from the city. The EMD comprised information on patient demographics, ICD-10 codes of primary and secondary diagnosis, received medications and other laboratory and diagnostic procedures. ICD-10 coding and other data were routinely entered into EMD based on OPMRs by trained medical statistics staffs or other trained personnel at each hospital.

The present study was approved by the Institutional Review Board of Human Research Committee at Naresuan University (53 01 02 0005). Data retrieval was also approved by the directors of both community hospitals prior to data collection.

Data collection

To obtain a list of patients with AF from EMD, the ICD-10 code of I48 were used to retrieve AF patients having outpatient visits between August 1, 2007 and July 31, 2008. For each patient, data on co-morbidities, including risk factors for stroke and bleeding events, were also retrieved by ICD-10 codes between August 1, 2006 and July 31 2009. The list of risk factors for stroke among patients with AF was taken from the 2006 guidelines of the American College of Cardiology/ American Heart Association and the European Society of Cardiology[12]. The co-morbidities were categorized as high risk factors (previous ischemic stroke or transient ischemic attack, embolism, mitral stenosis and the presence of prosthetic heart valves), moderate risk factors (diabetes, hypertension and heart failure) and weaker risk factors (coronary artery disease and thyrotoxicosis) according to the guidelines.

To assess the accuracy of EMD, the coding diagnosis from EMD from a randomly selected visit of each patient was cross-checked with the diagnosis made at the same visit in the hand-written OPMRs. Data in the OPMRs were abstracted with a standardized data collection form solely by one investigator (Chotchaisuwatana S). Data abstracted include diagnosis of AF, risk factors of strokes and any bleeding events.

Statistical analysis

To determine the validity and agreement between the EMD and OPMRs, the ICD-10 codes from EMD (Table 1) and abstracted data from OPMRs were used to construct a 2 x 2 table[13]. The sensitivity and specificity of the EMD with 95% confidence interval (95% CI) were calculated using the formula shown in Fig. 1. The agreement of the EMD and OPMRs based on the co-morbidities and bleeding events were calculated using Cohen's kappa (adjusted for chance agreement) with standard error (SE). The Cohen's kappa values of 0-0.2, 0.21-0.4, 0.41-0.6, 0.61-0.8 and 0.81-1.0 indicate poor, fair, moderate, substantial and almost perfect agreement, respectively[14]. All analyses were performed with Stata 10.0 software.

Results

Initially, 200 patients with AF (I48) of both community hospitals were identified from the EMD between August 1, 2007 and July 31, 2008. However, the OPMRs were missing for seven patients (1 patient from one hospital and 6 patients from the other), thus, the number of patients with a diagnosis of AF (I48) in EMD with available OPMRs for further analysis was reduced to 193 patients. The reasons for missing of these OPMRs were not known.

Among 193 patients documented as having AF in the EMD, 24 of them were not diagnosed with AF

OPMRs

EMD: Presence of risk factors	Yes	No	Total
Yes	A	B	A+B
No	C	D	C+D
Total	A+C	B+D	A+B+C+D

Sensitivity = (A/A+C) * 100
Specificity = (D/B+D) * 100

OPMRs = out-patient medical records; EMD = electronic medical database

Fig. 1 The 2 x 2 table used to calculate sensitivity and specificity

Table 1. ICD-10 codes of risk factors of stroke in AF patients and bleeding events

	ICD-10 codes
Risk factors of stroke in AF patient	
Ischemic stroke, Transient ischemic stroke (TIA)	I63.x-I66.x, I69.4 and G 45.9
Pulmonary embolism	I26.x
Deep vein thrombosis	I80.1, I80.2, I80.3, I80.8 and I80.9
Mitral stenosis	I05.0
Hypertension	I10.x-I13.x and I15.x
Diabetes mellitus	E10.x-E14.x
Impaired LV systolic function and/or Heart failure	I50.x, I11.0, I13.0 and I13.2
Coronary artery disease	I20.x-I25.x
Thyrotoxicosis	E05.x
Major bleeding	
Intracranial hemorrhage	I60-I62
Retroperitoneal bleeding	K66.1 and S36.8
Intraocular bleeding	H11.3, H31.3, H35.6, H43.1, H45.0
Other bleeding	
Gastrointestinal hemorrhage	K25-K28 subdivision 0.0, 0.2, 0.4, 0.6 and K62.5, K92.0, K92.1, K92.2
Spontaneous ecchymoses	R23.3
Hemorrhage from respiratory passages	R04.x

by their physicians in the OPMRs during the time of the present study. Thus, only 169 patients were truly identified as having AF according to the OPMRs. The likely reasons for the miscoding of these EMD include five records miscoding chronic obstructive pulmonary disease with acute exacerbation (COPD with AE) as AF, four records miscoding aortic regurgitation (AR) as AF, and three records miscoding allergic rhinitis (AR) as AF. In addition, 12 records were miscoded for unknown reasons. The miscoding was identified in 6.32% (6 out of 95 records) from one hospital and in 18.37% (18 out of 98 records) from the other hospital. Taken together, diagnoses of AF by the EMD were in accord with the OPMRs in the majority of patients (87.56%).

Based on data from 169 patients with AF in the EMD, the prevalence of risk factors for ischemic strokes and bleeding events are shown in Table 2. The most common risk factor for ischemic stroke from the EMD was hypertension (33.73%). Other less common risk factors include diabetes mellitus (10.06%) and impaired left ventricular systolic function or heart failure (9.47%). Embolism (pulmonary embolism, deep vein thrombosis) and major bleeding were not found during the study period. From Table 2, only the prevalence of thyrotoxicosis was found to be higher by the EMD (false positive), while the prevalence of some risk factors appears lower (false negative).

The sensitivity, specificity and Cohen's kappa of the EMD using OPMRs as standard were calculated for risk factors of ischemic stroke among patients with AF (Table 3). Overall, specificity was in the range of 98.77-100%. The sensitivity was in the range of 66.67-100.00%. The sensitivity was found the lowest for mitral stenosis (66.67%) and highest for thyrotoxicosis (100%). The Cohen's kappa indicating agreement between the two databases was in the range of 0.7942-0.9681.

The specificity of EMD for major bleeding was 100%; however, the sensitivity and Cohen's kappa could not be determined since the occurrence of major bleeding was not found in either the EMD or OPMRs.

Discussion and Conclusion

The results of the present study revealed that other diagnoses had been erroneously coded as AF in the EMD. The majority of errors occur as a result of miscoding, for example allergic rhinitis written as AR in OPMRs was coded as AF. The miscoding was possibly due to several reasons, for example difficult-to-read handwriting in the OPMRs, non-medical personnel performing the coding without knowledge of patient conditions, and limited amount of time for the coding process. Whether the discordance was repeated in every visit for those patients was not investigated

Table 2. Prevalence of risk factors of stroke and bleeding events based on data from OPMRs versus EMD

	Number of patients (%) (Total patients = 169)		
	OPMRs	EMD	Present in both databases
Risk factors of stroke			
Ischemic stroke, TIA	8 (4.73)	8 (4.73)	7 (4.14)
Pulmonary embolism	0	0	0
Deep vein thrombosis	0	0	0
Mitral stenosis	6 (3.55)	4 (2.37)	4 (2.37)
Hypertension	60 (35.50)	57 (33.73)	57 (33.73)
Diabetes mellitus	18 (10.65)	17 (10.06)	17 (10.06)
Impaired LV systolic function and/or heart failure	19 (11.24)	16 (9.47)	16 (9.47)
Coronary artery disease	14 (8.24)	11 (6.51)	11 (6.51)
Thyrotoxicosis	6 (3.55)	8 (4.73)	6 (3.55)
Major bleeding			
Intracranial hemorrhage	0	0	0
Retroperitoneal bleeding	0	0	0
Intraocular bleeding	0	0	0
Other bleeding			
Gastrointestinal hemorrhage	2 (1.18)	2 (1.18)	2 (1.18)
Spontaneous ecchymoses	0	0	0
Hemorrhage from respiratory passages	2 (1.18)	2 (1.18)	2 (1.18)

Table 3. Agreement and validity of risk factors of ischemic stroke in EMD with OPMRs as standard

Risk factors of ischemic stroke	Cohen's kappa (SE)	Sensitivity (95% CI)	Specificity (95% CI)
Ischemic stroke, TIA	0.8688 (0.0769)	87.50 (82.51-92.49)	99.38 (98.19-100.00)
Pulmonary embolism	-	-	100.00 (100.00-100.00)
Deep vein thrombosis	-	-	100.00 (100.00-100.00)
Mitral stenosis	0.7942 (0.0753)	66.67 (59.56-73.77)	100.00 (100.00-100.00)
Hypertension	0.9608 (0.0769)	95.00 (91.71-98.29)	100.00 (100.00-100.00)
Diabetes mellitus	0.9681 (0.0769)	94.44 (90.99-97.90)	100.00 (100.00-100.00)
Impaired LV systolic function and/or heart failure	0.9045 (0.0766)	84.21 (78.71-89.71)	100.00 (100.00-100.00)
Coronary artery disease	0.8706 (0.0763)	78.57 (72.39-84.76)	100.00 (100.00-100.00)
Thyrotoxicosis	0.8511 (0.0763)	100.00 (100.00-100.00)	98.77 (97.10-100.00)

SE = standard error; 95% CI = 95% confidence interval

further. However, it is very likely that the miscoding will occur in other visits as well since the authors observed repeatedly the same reasons for miscoding in the present study. Therefore, improvement through the coding process may contribute significantly to increase validity of the EMD. The hospital directors had been informed of the potential miscoding process and suggested that these discrepancies would be minimized through physician's direct entry of diagnosis.

As a result of the present study design, the specificity and sensitivity of coding for AF diagnosis in the EMD could not be determined. Identification of ICD-10 for AF (I48) from EMD was chosen as the method of data recruitment for comparison with OPMRs. Therefore, patients who had been diagnosed with AF in the OPMRs, but were not entered into the EMD for any reason, would have been missed in the present study. Nonetheless, this database is still useful for study on quality or pattern of care for AF patients as any subjects recruited into a study will mostly have the condition.

The measurement of the two databases agreement based on risk factors of ischemic stroke

revealed an almost perfect agreement (Cohen's kappa ranged from 0.7942 to 0.9681). However, the agreement and sensitivity could not be determined for some of the risk factors such as embolism [pulmonary embolism (PE), deep vein thrombosis (DVT)] and major bleeding. The major reason was attributed to these diagnoses not being found among samples during the study period. Since this study was conducted in community hospitals, patients who were receiving care at these two hospitals tended to have less severe illness. More complicated cases, such as those with PE/DVT and high bleeding risk, were usually taken care at hospitals with more specialized care and therefore were not found in the EMD of community hospitals.

The coding for co-morbidities in patients with AF, using OPMRs as standard, was found to be in moderate to high sensitivity. Coding of mitral stenosis was with the lowest sensitivity (66.67%) among others. The explanation for this finding includes miscoding of mitral stenosis (I05.0) as mitral valve insufficiency (I34.0), or endocarditis (I38). Other co-morbidities were found to have sensitivity higher than 78%. The specificity of coding for co-morbidities in EMD appeared to be higher than 95%. The high specificity was expected and in agreement with a previously reported study[15]. Wilchesky et al conducted a study on validation of diagnostic code within medical service claims, reporting that the specificity of coding for co-morbidities, collectively known as 18 Charlson comorbidity index, were higher than 95%. However, the sensitivities were varied from 0 to 70%. Schneeweiss[1] had suggested that in assessing accuracy of EMD, a lack of specificity of the measurement is worse than a lack of sensitivity in most circumstances.

To the best of the authors' knowledge, the present study was the first to investigate validity of the EMD in community hospitals in Thailand. Validity of the database in this setting is of great interest since a high proportion of care is provided in community hospitals and subject to scrutiny for quality improvement purposes. Evaluation on quality of care using EMD as a data source has been increasingly proposed as they reflect a real-life practice in such hospitals. In present study, database on patients with AF were chosen for validation since study on quality of care for this patient group is planned in the near future. The time for data sampling was extended over a period of three years (2006-2009), to be representative of the true quality of the EMD.

Some limitations in the present study merit discussion. One limitation concerned the number of community hospitals chosen for EMD validation. From eight community hospitals in Phitsanulok, only four hospitals were still using hand-written OPMRs during the time of the present study. This left us with only four hospitals to select from. Thus, limited numbers of samples may influence the generalizability of the results to all hospitals. However, the remaining four community hospitals, not recruited into the present study, have utilized physician's direct entry of diagnosis and medical orders. This led the authors to speculate that the accuracy of EMD among those hospitals may become even higher, thus incorporating EMD data from these four hospitals should not compromise the validity issue of database study in community hospitals in Phitsanulok.

It should be noted that OPMRs were set as a criterion standard in the present study. Since no confirmation of OPMRs accuracy had been conducted, the accuracy of the EMD was thus based on the physicians' documentation of their diagnosis in the OPMRs, undetermined to be definitely accurate. As a result, whether the EMD in community hospitals reflects accurately patient conditions remain unanswered by the present study.

In conclusion, the EMD of patients with AF possessed high validity and were in good agreement with the data from the OPMRs. Thus, the EMD from community hospitals appear suitable for health research in patients with AF.

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Potential conflicts of interest

None.

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ความถูกต้องของข้อมูลจากฐานข้อมูลอิเล็กทรอนิกส์ทางการแพทย์ในผู้ป่วยภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้วในโรงพยาบาลชุมชน

สมจิตร โชติชัยสุวัฒน, อรัมษ์ เจษฎาญานเมธา, ณธร ชัยญาคุณาพฤกษ์, เกตุจันทร์ จำปาไชยศรี

ภูมิหลัง: *ปัจจุบันมีการใช้ข้อมูลจากฐานข้อมูลอิเล็กทรอนิกส์เพื่อการวิจัยทางสุขภาพมากขึ้น เนื่องจากข้อมูลดังกล่าวสะท้อนการดูแลผู้ป่วยในภาวะความเป็นจริง อีกทั้งเป็นแหล่งข้อมูลที่มีตัวอย่างจำนวนมาก และมีความหลากหลาย อย่างไรก็ตามมีการศึกษาถึงความถูกต้องของข้อมูลจากฐานข้อมูลอิเล็กทรอนิกส์น้อยมาก โดยเฉพาะอย่างยิ่งฐานข้อมูลอิเล็กทรอนิกส์ในโรงพยาบาลชุมชน*

วัตถุประสงค์: *เพื่อประเมินความถูกต้องของข้อมูลจากฐานข้อมูลอิเล็กทรอนิกส์ ในผู้ป่วยที่มีภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้วที่รับการรักษาในโรงพยาบาลชุมชน จังหวัดพิษณุโลก*

วัสดุและวิธีการ: *ประเมินความถูกต้องของข้อมูลจากฐานข้อมูลอิเล็กทรอนิกส์ โดยเปรียบเทียบกับการบันทึกการวินิจฉัยในเวชระเบียนผู้ป่วยนอก ในผู้ป่วยที่ได้รับการวินิจฉัยเป็นภาวะหัวใจห้องบนเต้นผิดจังหวะ ชนิดสั่นพลิ้ว (ICD-10: I48) จากโรงพยาบาลชุมชน 2 แห่ง ในช่วงวันที่ 1 สิงหาคม พ.ศ. 2550 ถึง 31 กรกฎาคม พ.ศ. 2551 ผู้ป่วยแต่ละคนจะถูกสุ่มวันที่มาตรวจรักษาจากฐานข้อมูลอิเล็กทรอนิกส์ แล้วนำไปเปรียบเทียบกับข้อมูลจากข้อมูลในเวชระเบียน ผู้ป่วยนอกที่ได้จากการเก็บข้อมูลโดยใช้แบบเก็บข้อมูลที่สร้างขึ้น ความถูกต้องของฐานข้อมูลอิเล็กทรอนิกส์ ประเมินจากการลงรหัสวินิจฉัยภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้ว ภาวะโรคร่วมที่เป็นปัจจัยเสี่ยงของโรคหลอดเลือดสมองอุดกั้น และภาวะเลือดออกผิดปกติ จัดข้อมูลทั้งหมดลงในรูปแบบตาราง 2 x 2 เพื่อคำนวณค่าความไว (sensitivity), ความจำเพาะเจาะจง (specificity) และค่าความสอดคล้อง (Cohen's Kappa)*

ผลการศึกษา: *ผู้ป่วยภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้วจากฐานข้อมูลอิเล็กทรอนิกส์จำนวน 193 คน พบผู้ป่วย 169 คน (ร้อยละ 87.56) ถูกบันทึกเป็นภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้วจริงในเวชระเบียนผู้ป่วยนอก พบการลงรหัสโรคร่วมที่เป็นปัจจัยเสี่ยงของโรคหลอดเลือดสมองอุดกั้นจากฐานข้อมูลอิเล็กทรอนิกส์มีค่าความไว และความจำเพาะค่อนข้างสูง กล่าวคือ อยู่ในช่วง 66.67-100% และ 98.77-100% ตามลำดับ อีกทั้งมีค่าความสอดคล้องของการวินิจฉัยโรคร่วมที่เป็นปัจจัยเสี่ยงของโรคหลอดเลือดสมองอุดกั้นระหว่างฐานข้อมูลอิเล็กทรอนิกส์กับเวชระเบียนผู้ป่วยนอกอยู่ในระดับดีถึงดีมาก (kappa 0.7942-0.9681) ส่วนการลงรหัสภาวะเลือดออกผิดปกติ (major bleeding) มีความจำเพาะ 100% แต่อย่างไรก็ตามไม่สามารถหาค่าความไว และความสอดคล้องของการลงรหัสภาวะเลือดออกผิดปกติได้ เนื่องจากไม่พบอุบัติการณ์ของภาวะดังกล่าว*

สรุป: *ข้อมูลอิเล็กทรอนิกส์ทางการแพทย์ของผู้ป่วยภาวะหัวใจห้องบนเต้นผิดจังหวะชนิดสั่นพลิ้วในโรงพยาบาลชุมชนมีความถูกต้อง และความสอดคล้องกับข้อมูลในเวชระเบียนผู้ป่วยนอก และสามารถนำไปใช้ในงานวิจัยสุขภาพได้*