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Development of a minimum data set for cardiac electrophysiology study ablation

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Abstract:

BACKGROUND: At present, there is no established national minimum data set (MDS) for electrophysiology study (EPS) ablation, which has led to a lack of standardization and variable assessment criteria in this context.

OBJECTIVE: The objective of this paper was to develop a MDS of EPS ablation as means of establishing an information management system or clinical registry in this field.

METHODS: In this cross-sectional and descriptive study, national and international cardiovascular scientific literature were studied to establish an initial set of data elements. In order to its validity, the population study composed of 15 cardiac electrophysiologists who asked to review the proposed data elements and score them in order of importance using a five-point Likert scale. The items scored as important or highly important by at least 60% of the experts (average score of 3 and higher) were included in the final list of MDS.

RESULTS: An MDS of cardiac EPS ablation was created with nine data classes, including administrative data, past medical history, sign and symptoms, physical examinations, laboratory tests, presenting status of heart conduction system, catheter ablation, postprocedure complications, and discharge outcomes. For each category, required variables data and possible respondents were determined.

CONCLUSIONS: Consensus was reached on a set of core data elements to standardize data collection for cardiac EPS ablation in order to achieve quality improvement and effectiveness indicators for the management of care process and health outcomes.

Keywords:

Cardiac electrophysiology study, catheter ablation, minimum dataset

Introduction

The electrical conduction system in the heart is very complex, and disease can occur in many locations within this unidirectional electrical circuit.[1] Clinical cardiac electrophysiology (EP) began in the late 1960s is used for the diagnosis and management of cardiac arrhythmias and conduction disorders.[2] Some of arrhythmias including postinfarct arrhythmia are instantly fatal if other arrhythmias are not instantly fatal but lead to important complications such as strokes.[3] Substantial advances in the treatment of arrhythmias as well as technological enhancements have allowed EP studies (EPSs) to be considered as an important subspecialty in cardiology. Currently, catheter ablation is the first or second line of treatment for the various cardiac arrhythmias.[4,5] This procedure has remarkably high success rate and can quietly increase patient's quality of life.[6]

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There is a major effort nationally and internationally to collect data that about patients undergoing high-risk, high-cost, and high-volume procedures such as cardiac interventions.[7]

It is most essential that health-care data can be collected in a uniform manner from a scientific perspective. Data collection is the most important part of health information management and clinical research systems; thus, development of a minimum data set (MDS) to collect data in a standard and integrated manner at the national level has made the use of it inevitable.[8,9]

An MDS is a coherent set of data elements accepted for mandatory collection and reporting at a national level.[10] MDS also can be considered as a basis for clinical registries and plays a pivotal role as primary step required in health care, to implement an effective and operative information system.[11] For these reasons, each variable and its associated response categories have been determined to promote the collection and reporting of comparable minimal data. In addition, a standardized format has been specified to enable the compilation of data from multiple investigators and locations.[12,13]

In order to accomplish quality enhancement, continuity care, and optimum care in the case of cardiac EPS ablation intervention, a MDS is suggested as a standard tool that can guide homogeneous data collection. To best of our knowledge, no research has been undertaken so far in order to identify MDS for cardiac EPS ablation in Iran, which it makes national and international benchmarking challenges. Therefore, the objective of this paper was to develop an MDS for cardiac EPS ablation as a means of establishing an information management system or clinical registry that could accelerate collection of reliable and detailed data from patients who have been undertaken to this cardiac invasive intervention. The specific goal of proposed MDS is to establish a consistent, interoperable, and national framework as a basis for both clinical care and research information systems.

Methods

An applied descriptive, cross-sectional study was conducted in 2018. To design this dataset, a combination of literature review and expert consensus approach was used. At first, a team of working party was presented to contribute the required skill. The research team comprised two specialists in cardiology and three experts in health information management. This gave the team the ability to develop an understanding of the research goals. An extensive literature review was undertaken in EPS-related data collection frameworks to identify potential data elements to be included in the MDS. To achieve this, at the first, a preliminary list of potential variables was extracted from international registries and other publication documents in this field;[14-19] moreover, medical records and cardiovascular forms were reviewed. Then, content validity of the questionnaire was evaluated using the comments from experts in the field of health information management and cardiology. To ensure the reliability of the questionnaire, it was completed by five of the aforementioned experts; they were requested to complete the questionnaire for the second time after 1 week. Spearman's rank correlation coefficient was used to evaluate the reliability of the questionnaire, which showed a coefficient of 85%. The completed questionnaires were analyzed using SPSS software (version 19.0, SPSS Inc., Chicago, Illinois, USA) and descriptive statistical techniques.

To determine the MDS of EPS ablation, the final data elements were chosen by 15 cardiologists with at least 3 years of work experience in medical centers performing cardiac invasive EP interventions. The experts participating in the study were asked to review the initial draft of variables to score the items according to the importance perceived by them based on a five-point Likert scale. In this scale, a score of 1 naturally represented the "lowest level of importance" and a score of 5 represented the "highest level of importance." Only the data elements with average score of 3 and higher were allowed into the MDS. Moreover, where asked from experts if intended to change, delete, or add a variable for a specific purpose, they should write an acceptable reason.

Results

We managed to collect 15 filled questionnaires out of 15 that had been distributed (100%). The mean age of respondents was 43 years, their average work experience was 7 years, and about 28% of them were female.

The cardiac EPS ablation-MDS was divided into four categories; a first section is administrative data, that is, included patient demographic and current episode of hospitalizations. The second section is clinical EP laboratory visit that is included past medical history, sign and symptoms, physical examinations, laboratory tests, and presenting status of heart conduction system [Table 1]. The third section is data elements related to catheter ablation procedure session [Table 2]. The fourth section is postprocedure evaluation that includes postprocedure complications [Table 3], discharge outcomes [Table 4].

Patient demographics

There was consensus to include name, last name, father's name, gender, date of birth, place of birth, marital status, education level, national number, home address, and phone number.

Table 1: Presenting status of heart conduction system

Data class	Selected data elements
Sinus node function	Normal sinus rhythm
	Sinus arrhythmia
	Wandering atrial pacemaker
	Sinus bradycardia
	Sinoatrial exit block
	Mobitz I
	Mobitz II
	Sinus arrest
	Sinus node dysfunction
	Sick sinus syndrome
	Sinus node dysfunction following cardiac surgery
	Ectopic atrial rhythm
AV conduction	Normal AV conduction
	Short PR interval
	Second-degree AV block
	PR prolongation (first-degree AV block)
	Advanced or high-degree AV block
	Third-degree AV block (complete heart block)
	AV conduction abnormality following cardiac surgery (transient or permanent)
	Congenital complete heart block
	Isorhythmic dissociation
	Paroxysmal AV block
	Preexcitation (delta wave)
Intraventricular conduction	Normal
	Left anterior fascicular block
	Left posterior fascicular block
	LBBB
	RBBB
	Incomplete RBBB
	IVCD, nonspecific
	Intraventricular conduction abnormality following cardiac surgery (transient or permanent)
SVT	Normal
	SVT
	Recurrent
	Persistent
	Paroxysmal
	Incessant
	APC
	AT
	Focal
	Multifocal
	AF
	Initial episode
	Paroxysmal
	Persistent
	Permanent
	Macro re-entrant AT
	CTI-dependent AF
	Non-CTI-dependent AF
	Macro–re-entrant AT related to previous cardiac surgery
	ST
	Inappropriate ST
	Persistent
	Intermittent/paroxysmal
	POTS
	AV node re-entry
	Slow-fast
	Fast-slow
	Slow-slow
	Junctional tachycardia
	Congenital JET
	Postoperative junctional tachycardia
	Focal junctional tachycardia
	Nonparoxysmal junctional tachycardia PJRT
	AV re-entrant tachycardia (concealed bypass tract)
	WPW syndrome
VT	Normal
	Sustained
	No sustained
	Narrow complex VT
	VT, monomorphic
	VT, polymorphic
	Catecholaminergic
	PVC
	Ventricular couplet
	Accelerated idioventricular rhythm
	VT storm
	Adenosine-sensitive VT
	Verapamil-sensitive VT
	Ventricular arrhythmias associated with long QT syndrome (Torsades de pointes)
	Congenital
	Acquired
	Bundle branch re-entrant tachycardia
	Outflow tract VT
	Right ventricular
	Left ventricular

AV=Atrioventricular, LBBB=Left bundle branch block, RBBB=Right bundle branch block, IVCD=Intraventricular conduction delay, VT=Ventricular tachycardia, SVT=Supra-VT, APC=Atrial premature complex, AT=Atrial tachycardia, AF=Atrial fibrillation, ST=Sinus tachycardia, POTS=Postural orthostatic tachycardia syndrome, CTI=Cavotricuspid isthmus, JET=Junctional ectopic tachycardia, PJRT=Permanent form of junctional tachycardia, WPW=Wolff–Parkinson–White, PVC=Premature ventricular complexes

Current episode of hospitalization

There was consensus to include care facility name, physician name, admission date, reason for admission, insurance payers, and medical record number.

Past medical history

The first section of the clinical EP laboratory visit category is related to past medical history which was classified into four subsections of cardiovascular disease history, noncardiovascular disease history, family history of cardiovascular diseases, and prior history of cardiovascular procedures.

Table 2: Heart catheter ablation procedure session

Data class	Selected data elements
General procedure information	Date of procedure
	Duration of procedure
	Indication of catheter ablation
	Symptoms
	Desire for drug-free lifestyle
	Stroke prophylaxis
	Sudden death prophylaxis
	Frequent ICD discharges
	Diagnostics and therapeutic instrument
	CARTO system use
	EnSite system use
	Irrigation catheter use
	Sedation type
	Minimal sedation
	Moderate sedation
	Deep sedation
	General anesthesia
	Ablation type
	PVI
	Surgical ablation
	Ablation of the AV node
	Ablation for SVTs
	Ablation for VT
	Catheter placement
	Right atrium
	Right ventricle
	Left atrium
	Left ventricle
	CS
	Other cardiac veins
	His bundle position
	Pericardium
	PV
	Vena cava
	Pulmonary artery
	Other (specify)
	Source of energy
	Nonirrigated radiofrequency
	Radiofrequency with closed irrigation
	Radiofrequency with open irrigation
	Ultrasound ablation
	Microwave ablation
	Laser balloon (endoscopic ablation system)
	Cryothermal ablation
	Duty-cycled radiofrequency energy
	Other ablation technique
	Number of energy
	Applications
	Total time of energy
	Applications
	If ablation was not attempted indicate reason
	Ablation was performed
	Not indicated
	Target not identified
	Tachycardia not inducible
	Target high risk
	Target not reached
	Other
	PVI assessed with circumferential vein catheter
If current ablation strategy is "PVI"	Number of veins present
	One, two, three, four, five, six
	Number of veins targeted
	One, two, three, four, five, six
	Number of veins isolated
	One, two, three, four, five, six
	Attempt to isolate the PV
	LSPV
	LIPV
	RSPV
	RIPV
	Isolation confirmation
	Entrance block
	Exist block
	Bidirectional block
	Adjunctive ablation lesions
	Adjunctive ablation location
	SVC
	Coronary sinus
	Ligament/vein of Marshall
	CTI
	Atypical atrial flutter lines
	Other

AV=Atrioventricular, VT=Ventricular tachycardia, SVTs=Supra-VTs, CS=Coronary sinus, PV=Pulmonary vein, PVI=PV isolation, LSPV=Left superior PV, LIPV=Left inferior PV, RSPV=Right superior PV, RIPV=Right inferior PV, SVC=Superior vena cava, CTI=Cavotricuspid isthmus, ICD=Implantable cardioverter-defibrillator

a. History of cardiovascular diseases that included heart failure, heart failure stage, hypertrophic cardiomyopathy, nonischemic dilated cardiomyopathy (DCM), idiopathic DCM, right ventricular cardiomyopathy, restrictive cardiomyopathy, pericarditis, peripheral vascular disease, stable angina, unstable angina, non-STEMI, STEMI, primary valvular heart disease, tetralogy of Fallot, ventricular sepal defect, common ventricle, Ebstein's anomaly, atrial septal defect, amyloidosis, Chagas disease, giant cell myocarditis, left ventricular aneurysm, left ventricular noncompaction syndrome, right ventricular dysplasia, and sarcoidosis
b. History of noncardiac diseases that included stroke, transient ischemic attack, chronic renal failure, currently on dialysis, chronic lung disease, diabetes mellitus, hyperthyroidism, hypothyroidism, cirrhosis disease, obstructive sleep apnea, patient life expectancy of ≥1 year by physician estimate, cancer, hyperlipidemia, hypertension, cigarette smoker, and opium addiction

Table 3: Postprocedure complications

Major complications	Minor complications
Cardiac arrest	Inappropriate shocks
Myocardial infarction	Bleeding
Transient ischemic attack	Pericardial effusion
Drug reaction	Vascular damage
Pericardial tamponade	Arteriovenous fistula
Stroke	Hematoma
Tricuspid valve injury	Hemothorax
VT	Air embolism
Ventricular fibrillation	Pneumothorax
Death	Infection
Cardiac perforation	Infection requiring antibiotics
Coronary venous dissection	PV injury
Urgent cardiac surgery	Sever PV stenosis
Deep venous thrombosis	Esophageal injury
Cardiac valve injury	
Conduction block	
Peripheral embolus	
Peripheral nerve injury	
Upper extremity edema	
Set screw problem	
Venous obstruction	
Valve injury	
Pulmonary embolism	
AV fistula	

AV=Atrioventricular, VT=Ventricular tachycardia, PV=Pulmonary vein

Table 4: Discharge information

Data items	Data items subcategories
Discharge date	
Discharge location	Discharged to home or self-care (routine discharge)
	Discharged/transferred to a nursing facility
	Discharged/transferred to a short-term general hospital for inpatient care
	Discharged/transferred to an IRF
	Hospice care
	Left against medical advice or discontinued care
Discharge status	Alive
	Expired
If deceased, death during the procedure	
If deceased, cause of death	
Date of follow up	
Discharge prescribed drugs	

IRF=Inpatient rehabilitation facility

c. Family history of cardiovascular diseases that included family history of arrhythmias, family history of recurrent syncope, specific familial arrhythmia syndromes, family history of sudden cardiac death, family history of ischemic heart disease, and familial history of cardiomyopathy
d. History of invasive cardiac interventions/surgery that included previous pacemaker (pacemaker type and pacemaker indication), previous Implantable cardioverter-defibrillator (ICD) implant (ICD type, ICD implant site, ICD implant date, and ICD indication), prior catheter ablation (number of ablation procedures, ablation target, and energy source), prior diagnostic coronary angiography, prior percutaneous coronary intervention, prior coronary artery bypass grafting, prior heart transplant, and prior valve surgery.

Sign and symptoms

This category was included of asymptomatic, fatigue, palpitations, dyspnea, chest pain, NYHA functional classification, presyncope, syncope, orthopnea, paroxysmal nocturnal dyspnea, and cardiac arrest/aborted sudden death.

Physical examinations

This category was included of heart rate, blood pressure, respiratory rate, height, weight, third heart sound (S3), fourth heart sound (S4), lung examination, and waist circumference.

Laboratory data

This category includes blood urea nitrogen, complete blood count, hemoglobin, platelet count, hemoglobin, hemoglobin A1c, hematocrit, white blood count, sodium, creatinine, potassium, fasting blood sugar, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, prothrombin time (PT), partial PT, and thyroid-stimulating hormone.

Since the main focus of this paper is to present a MDS of EPS ablation the tables classified these data elements.

Discussion

In the context of this study, we have demonstrated the need and feasibility for establishing EPS ablation MDS at national level that was achieved through experts' consensus following extensive discussions with a range of related expertise.

According to the results of this study, data elements were identified and subsequently categorized into the administrative, EPS laboratory visit, catheter ablation procedure, postprocedure complications, and discharge information sections. These sections including of data elements believed to be essential and sufficient for uniform reporting of EPS ablation intervention into health information system or clinical registry in this field. One of the incentives for developing an MDS is to promote health through providing high-quality information. Furthermore, the MDS could be used for

monitoring the patient's condition, health-care provider or system assessment, and comparison in national and international levels, as well as serving as an indicator of health care provided by different care settings.[8]

While the term MDS is commonly thought to describe an essential, uniform set of data elements should be collected across time and organizations. Svensson-Ranallo *et al*. suggest that MDS term is also widely used in health care to describe an ontology, an existing set of data elements used for a specific purpose, and a standardized protocol for collecting data.[20]

In a study by Bauer and Sieber (2007), it has been stated that the MDS could be the first step for moving toward data standardization of malnutrition and for the evaluation of the results of the conducted studies.[21] Mahmud *et al*. stated that minimum standard set of outcome measures for cataract surgery is important for meaningful comparison across contexts.[22] Davey *et al*. stated that MDS should be easily integrated into clinical practice and should not be mistaken for a clinical guideline and should not add workload to the clinicians.[23] Hawes *et al*. showed that an MDS provides considerable improvement in the accuracy and comprehensiveness of the information in residents' medical records, affects the comprehensiveness of the care plan, care quality, and life quality, and reduced the duration of hospitalization[24]

We hope that our MDS will enable and accelerate improvements in the outcomes of patients who undertaken to EPS ablation intervention, by providing consistent measurement of meaningful outcomes and allowing comparison between different care providers. Data interoperability between health information systems is an important goal that has focused by much research and received significant funding worldwide. While data collection in care settings should ideally enable data reuse for epidemiology, public health, or research, it is still difficult to reuse the data produced in care setting. Therefore, one aim of developed MDS in this study is that can be used as infrastructure for data interoperability between medical information systems in clinical and research domains related to EPS ablation.[25]

Conclusions

Due to the importance of EPS ablation as a first line in treatment of heart conduction system disorders, it is necessary to create the MDS for uniform reporting this procedure into clinical registry or electronic health record. Therefore, this study suggests comprehensive and uniform data elements in order to improve data efficiency and data quality in EPS ablation intervention. Consequently, comparability of the developed MDS from different analyses and researches will be possible in various levels. Using these data elements, it is possible to structure data collection and communication with health-care providers in a standard manner.

We acknowledge that this work does have limitations. The proposed MDS has not been widely consulted on and has been derived from consensus opinions of cardiologist physicians in Tehran heart center hospital. However, the working group has made these required data elements based on the best currently available appropriate evidence and a vast collective wealth of experience. Moreover, it is not possible to comprehensively collect all the data items which limit the practicality of the MDS; however, this will be outweighed by providing the most required data elements and possible subcategories. Nevertheless, the MDS developed in the current study could be updated by specialists in other heart central hospitals to develop cardiac EP registries or information systems in this field. Once completely accepted and applied, this MDS will be suitable in facilitating clinical research, registry reporting, administrative reporting and regulatory compliance, and all aspects of patient undertaken to EPS ablation procedure. Future studies on this subject are recommended to use Delphi studies in focus groups to develop other application-specific MDSs and information system capabilities for other domains of cardiovascular diseases.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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