Architecture of the Japan Ischemic Heart Disease Multimodal Prospective Data Acquisition for Precision Treatment (J-IMPACT) System

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Summary
The utilization of electronic medical records and multimodal medical data is an ideal approach to build a real-time and precision registry type study with a smaller effort and cost, which may fill a gap between evidence-based medicine and the real-world clinical practice. The Japan Ischemic heart disease Multimodal Prospective data Acquisition for PreCision Treatment (J-IMPACT) project aimed to build an clinical data registry system that electronically collects not only medical records, but also multimodal data, including coronary angiography and percutaneous coronary intervention (PCI) report, in standardized data formats for clinical studies.

The J-IMPACT system comprises the standardized structured medical information exchange (SS-MIX), coronary angiography and intervention reporting system (CAIRS), and multi-purpose clinical data repository system (MCDRS) interconnected within the institutional network. In order to prove the concept, we acquired multimodal medical data of 6 consecutive cases that underwent PCI through the J-IMPACT system in a single center. Data items regarding patient background, laboratory data, medications, and PCI/cardiac catheterization report were correctly acquired through the J-IMPACT system, and the accuracy of the multimodal data of the categories was 100% in all 6 cases.

The application of J-IMPACT system to clinical studies not only fills the gaps between randomized clinical trials and real-world medicine, but may also provide real-time big data that reinforces precision treatment for each patient.

Key words: Electronic medical records, Electronic data capture, Clinical registry, Percutaneous coronary intervention

Current concept of evidence-based medicine (EBM) is primarily dependent on the results from randomized controlled trials (RCTs). From a scientific standpoint, randomization is the best way to exclude measured and unmeasured confounders to compare the efficacies of treatment methods being tested; therefore, well-designed RCTs with adequate statistical power are conferred as the gold standard of EBM. However, RCT also holds limitations; RCTs are performed in a specific population with predetermined inclusion and exclusion criteria, which limits us to extrapolate the RCT results to daily practice on patients that might be excluded from the RCT concerned. Rigid inclusion and exclusion criteria may cause a slowed enrollment of subjects, which makes the result obsolete at the time of study completion. This issue is critical, especially in a rapidly evolving area such...
as percutaneous coronary intervention (PCI), where the therapeutic devices are continuously developing. Another limitation is the large amount of resources required to perform RCTs, including the costs of extra patient visits, data collection, and capture of study outcomes, which often demand funds from industry, or make the study too small to detect the differences in important outcomes (e.g. myocardial infarction or death) by the study treatments. Consequently, composite outcomes that comprise important outcomes and less important outcomes (e.g. surrogate outcomes or biomarkers) have been frequently adopted in recent RCTs. Less important components of composite outcomes tend to show higher event rates and larger treatment effects, which may obscure the meanings of the trials.

Registry type study based on the real-world clinical practice may complement the problems of RCT mentioned above. For examples, recent registry studies analyzed the clinical significance of coronary stent fracture, a rare adverse event after PCI, or the association between post-procedural coronary flow in primary PCI and the prognosis of acute myocardial infarction, for which RCTs are not applicable. On the other hand, registry may serve as a platform for patient recruitment to RCTs, as screening candidates from a registry greatly facilitates patient recruitment (i.e. registry-based RCT). To maximize the benefits of a registry study, it is ideal to record every clinical event at the time of occurrence into a form of electronic database for later analysis. However, such data collection is both time-consuming and costly, and these factors have prohibited its widespread adoption at the time of writing. Recently, developments in information technology (IT) have lowered the cost of its use and enabled its application in the field of medicine, leading to a widespread use of hospital information systems (HIS), including digital medical records, for daily practice in Japan, especially in larger hospitals. However, current HIS are usually intended for general clinical use and are not suitable to extract digital medical records for clinical research, including registry type study. Particularly, medical images, movies, and procedure reports are usually securely stored in specialized data storage separate from HIS. This situation prompted us to develop an electrical digital data capture system to acquire medical records and multimodal data, thus enabling us to build a registry database system.

The Japan Ischemic heart disease Multimodal Prospective data Acquisition for preCision Treatment (J-IMPACT) project aimed to build a HIS-based system that electronically collected not only medical records, but also multimodal data, including coronary angiography report and the PCI report, in standardized data formats for clinical studies. The development of the J-IMPACT system became possible based on several preceding projects focused on electrical medical data capturing, namely standardized structured medical information exchange (SS-MIX), coronary angiography and intervention reporting system (CAIRS), and multi-purpose clinical data repository system (MCDRS). At the time of writing, none of other systems function as J-IMPACT system. Here we report a proof-of-concept study of multimodal data acquisition through J-IMPACT system in the Kyushu University Hospital.

Methods

This study has been planned in accordance with the World Medical Association Declaration of Helsinki and was reviewed and approved by the institutional review board of the Kyushu University Hospital, Fukuoka, Japan (Institutional study number 28-49).

SS-MIX2: SS-MIX was developed by the Ministry of Health, Labour, and Welfare (MHLW) of the Japanese government in 2006, as a part of MHLW electronic medical examinations information exchange project that aimed to establish an environment in which medical information is exchanged in a standardized manner among patients, medical institutions, other related facilities. Current SS-MIX2 standards were established in 2012, and the updated standards and guidelines for the implementation of SS-MIX2 are published in the Japan Association for Medical Informatics website (written in Japanese). SS-MIX2 standard storage obtains most medical records, such as patient information, diagnoses, prescription records, and laboratory data, and is standardized to comply with the international organization for standardization (ISO) IS 27931, for HIS regardless of their developers. SS-MIX2 extended storage obtains virtually any additional electronic data regarding medical activity and procedures as text, audio, image, vector graphic, movie, medical waveform, including structured records of cardiac catheterization/PCI, electrocardiography (ECG), and ultrasound cardiology (UCG). SS-MIX2 has been a de facto standard for the standardization of medical records for data exchange and backup in Japan; i.e. one of the solutions for business continuation during accidents of HIS. In 2015, 844 hospitals in Japan installed SS-MIX2 storage system, according to the SS-MIX consortium website.

CAIRS-DB: CAIRS, which stands for Coronary Angiography and Intervention Reporting System, is a specialized reporting system for cardiac catheterization and PCI that is intended to standardize medical data for a research application. CAIRS collects several key data regarding coronary angiography (CAG) and PCI, including: 1) primary reason for procedure and related clinical data, 2) diseased coronary segments and percent stenosis, 3) data related to PCI procedures such as devices used (e.g. catheter, guidewires, balloons, and stents), balloon inflation time and pressure, and 4) Data regarding follow-up of PCI, including revascularization of the target lesions. CAIRS locally stores the above data into a structured query language database, named CAIRS-DB, which is installed within the picture archiving and communication system (PACS) network of the institution (Figure 1).

MCDRS: MCDRS is a hypertext markup language (HTML), server-client system for clinical data registry. Investigators can develop an electronic case report form (CRF) on a MCDRS server set-up within the local HIS network or in a remote institution over the internet. Upon a data capture query using a patient identification code and the date of an index event in the MCDRS web page, the MCDRS web application acquires patient data includ-
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Figure 1. Architectures of J-IMPACT System. The HIS as an electronic medical record system and CAIRS-DB in the PACS network were connected to SS-MIX2 as a data storage system through the firewalls. MCDRS as a data registration system acquires above data through SS-MIX2 gateway upon query from the MCDRS client. HIS indicates hospital information system; CRF, case report form; MIC, medical information center; PACS, picture archiving and communication system; SS-MIX2, standardized structured medical information exchange 2; MCDRS, multi-purpose clinical data repository system; CAIRS-DB, coronary angiography and intervention reporting system database. and FW, firewall.

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ing his/her name for confirmation and laboratory data from the SS-MIX2 storage electronically through the SS-MIX2 gateway system, and automatically fills the electronic CRF displayed in the MCDRS client. For instance, MCDRS obtains data of multiple laboratory examinations within a prespecified period before or after the date and time of the index event. A researcher will be prompted to select a series of laboratory data to fill the CRFs in the MCDRS client for the registration to the MCDRS server. Finally, the acquired data except patient identification code and patient name will be sent online and registered into the MCDRS server, with a new identification code given by the investigator for each clinical study (Figure 1). The latest information available in the MCDRS can be procured from the website9) (written in Japanese).

System installation: J-IMPACT system and its components, SS-MIX2, CAIRS, and MCDRS, are installed in the HIS network, PACS network, and the medical information center (MIC) network, respectively, and connected through firewalls in the Kyushu University Hospital network (Figure 1). The Kyushu University Hospital network is isolated from the internet according to the Kyushu University information security policy.

Proof-of-concept data acquisition: We performed a proof-of-concept study to electronically acquire multimodal data of 6 consecutive cases since who underwent PCI in January 2014, through the J-IMPACT system. In this proof-of-concept study, selected data items were implemented in the electronic CRF in the MCDRS server, regarding patient background, laboratory data, prescriptions, cardiac catheterization and PCI (Supplemental Table). One data manager and one medical doctor visually investigated the integrity of MCDRS-collected data with original medical records in the HIS and the CAIRS.

Results

In the Kyushu University Hospital, HIS and the components of J-IMPACT system, SS-MIX2, CAIRS-DB, and MCDRS were installed in each network segment and interconnected through firewalls in the institution’s local network (Figure 1). Structural data in the electronic medical records, such as prescription records and laboratory data in daily practice were regularly forwarded to the SS-MIX2 standard storage mainly for the purpose of data backup. PCI/cardiac catheterization report data in the CAIRS-DB were regularly forwarded to the SS-MIX2 extended storage.

We studied 6 consecutive patients who underwent PCI in January 2014 in the Kyushu University Hospital for this proof-of-concept data acquisition through J-IMPACT system. The clinical background of 6 patients is shown in the Table I. From a MCDRS client laptop computer, we accessed the MCDRS server with a web
Table I. Patient Characteristics

| Demographics | Total (n = 6) |
|--------------|-------------|
| Age (year [IQR]) | 64 [58, 72] |
| Gender (male, %) | 3, 50% |
| Risk factors | |
| Hypertension, % | 5, 83% |
| Diabetes mellitus, % | 3, 50% |
| Dyslipidemia, % | 6, 100% |
| Family history, % | 2, 33% |
| Smoking, % | 0, 0% |
| Past history of CAD, % | 2, 33% |
| Index PCI | |
| Indication | |
| STEMI, % | 2, 33% |
| NSTE-ACS, % | 1, 17% |
| Stable CAD, % | 3, 50% |
| Target vessel | |
| RCA, % | 2, 33% |
| LAD, % | 4, 67% |
| LCX, % | 0, 0% |

IQR indicates interquartile range; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; NSTE-ACS, non-ST-segment elevation acute coronary syndrome; CAD, coronary artery disease; RCA, right coronary artery; LAD, left anterior descending artery; and LCX, left circumflex artery.

browser. Case registration page prompted us to enter patient ID and the date of index PCI. Upon query from the MCDRS client, MCDRS immediately acquired patient data including background, laboratory data, prescriptions from the HIS, the PCI report from the CAIRS-DB, and displayed medical data in the CRFs (Figure 2). Regarding laboratory examinations, MCDRS obtains data of multiple laboratory examinations within 60 days before the date of index PCI. We selected a series of laboratory data that contains data most completely and filled the CRFs in the MCDRS client web browser.

We validated data acquired through the J-IMPACT system with original data sources in the HIS or the CAIRS reports system (Table II), and confirmed that all data category, including patient background, laboratory data, prescriptions, and PCI/cardiac catheterization report, were correctly acquired through the J-IMPACT system, and the accuracy of multimodal data of 4 categories was 100% in all 6 cases, proving the concept of electronic data capture of multimodal data.

Discussion

This report described for the first time an acquisition of multimodal medical data semi-automatically and electronically through MCDRS in combination with SS-MIX2 and CAIRS-DB that constitute the J-IMPACT system. Data items regarding patient background, laboratory data, PCI/cardiac catheterization, and prescriptions were promptly obtained through the J-IMPACT system and displayed in the MCDRS client for case registration (Figure 2). In this single center experiment, the simultaneous acquisition of multimodal data through an integrated system constituted a breakthrough in this field. To the best of the authors’ knowledge, none of the cardiac catheterization report systems or HIS systems in clinical use has attained this functionality.

The advantages of electronic data capture (EDC) in clinical studies over manual data collection are well recognized; even a simple EDC web server/client system can achieve (1) cleaner data collection with format and/or range assurance, (2) more efficient data collection without assessment or digitization of written data, (3) faster or real-time access to data, and (4) resulting in lower costs.10) Data integrity of an EDC is critically important for clinical trials, especially for regulatory purposes. The Food and Drug Administration of United States has issued a guidance for the industry (Part 11, electronic records) with regard to the use of electronic records and electronic signatures,11) and a guidance for Electronic Source Data in Clinical Investigations.12) The validation of computerized systems to ensure record integrity is also labeled as Good Automated Manufacturing Practice by the International Society for Pharmaceutical Engineering. These pieces of guidance have an intention to promote the need for capturing source data in electronic form, including data originating in health care systems, for the purpose of clinical research and drug evaluation.

The J-IMPACT system comprises the links between the MCDRS case registration server and the SS-MIX2 that stores data from HIS and CAIRS-DB (Figure 1). The J-IMPACT system enables a one-stop, semi-automatic acquisition of multimodal electronic data, which will readily be registered to MCDRS server on-the-fly, excluding a possibility of errors while manually inputting to conventional EDC systems. Current MCDRS acquires data from HIS or CAIRS at the moment of the editing of CRFs. In the event that original electric medical record data are updated, CRFs also need to be updated by the researchers by acquiring updated data through MCDRS or by manual editing. In addition, current MCDRS does not recognize any electronic signature associated with each data item from the HIS; however, obtained data in this study completely matched to the original data in the HIS and CAIRS, and proved the concept of electronic acquisition of multimodal clinical data in the J-IMPACT system.

Limitations and perspectives: The present study remains a proof-of-concept study in a single center with a limited number of subjects, which should be addressed as an important limitation of this study. In this study’s perspective, the J-IMPACT system can be extended to a nationwide standard data repository for multicenter studies. Indeed, the J-IMPACT system is also being implemented on different versions of HIS or cardiac catheterization/PCI report systems, including the Jichi Medical University hospital, the Jichi Medical University Saitama Medical Center, the Tohoku University Hospital, and the University of Tokyo Hospital (Table III). Indeed, multimodal data have been collected in the same standardized formats in each participating institute, and data consistency has been internally confirmed (data not shown).

However, there are several possible technical issues to be resolved to combine data from multiple centers,
Figure 2. Multimodal Data Acquisition through the J-IMPACT System. In the proof-of-concept study, clinical data of 3 cases, including prescriptions, laboratory data, and PCI report data, were acquired through MCDRS upon query from the MCDRS client. Data were validated in comparison with their original data. HIS indicates hospital information system; PACS, picture archiving and communication system; SS-MIX2, standardized structured medical information exchange 2; MCDRS, multi-purpose clinical data repository system; and PCI, percutaneous coronary intervention.

| Data items            | Original data source | Case 1 | Case 2 | Case 3 | Case 4 | Case 5 | Case 6 |
|-----------------------|----------------------|--------|--------|--------|--------|--------|--------|
| Patient background    | HIS                  | 6/6    | 6/6    | 6/6    | 6/6    | 6/6    | 6/6    |
| Laboratory data       | HIS                  | 27/27  | 33/33  | 36/36  | 30/30  | 29/29  | 33/33  |
| Prescription          | HIS                  | 1/1    | 9/9    | 4/4    | 13/13  | 12/12  | 7/7    |
| PCI/cardiac catheterization | CAIRS             | 68/68  | 64/64  | 69/69  | 61/61  | 69/69  | 61/61  |
| Total                 | -                    | 102/102| 112/112| 115/115| 114/114| 110/110| 101/101|

HIS indicates hospital information system; PCI, percutaneous coronary intervention; and CAIRS, coronary angiography and interventional reporting system.

Firstly, the methods of laboratory examinations are standardized in compliant to the Japan Laboratory Accreditation Cooperation (JLAC) version 10\(^{13}\) in all participating hospitals; however, the units including the use of exponential numbers for blood cell counts differ among participating hospitals (data not shown), which need conversions using the units recorded in the SS-MIX2 storage to assure interexchangeability. Secondly, there may be differences among cardiac catheterization/PCI report systems in response to the clinical demands and/or the preferences of the physicians in different hospitals. To maintain the consistency and interexchangeability of data from multicenter systems, CAIRS-DB data set should be held; however, in the event a research group aims to maintain only a minimum common data set, the application of SEAMAT, a Standard Export datA forMAT for the export and the exchange of medical data established by the Japanese Circulation Society IT/database council,\(^{14}\) is warranted. The data set collected in the cardiac catheterization/PCI report systems is primarily based on clinical demands, but should also meet potential research objectives while minimizing an extra work burden to the physicians.

Upon the resolution of these issues, different makes of HIS and cardiac catheterization/PCI report system may also be linked to the J-IMPACT system through the SS-MIX2 standard and CAIRS-DB, which may minimize the initial costs to implement the J-IMPACT system. In the future, standardized multicenter clinical data will be col-
Table III. Vendors of J-IMPACT Components

| Hospital Information System | Cardiac Catheterization/PCI Report |
|-----------------------------|-----------------------------------|
| SS-MIX2                     | CAIRS-DB                          |
| Kyushu University Hospital  | Fujitsu Ltd.                      |
| Tochigi Medical University  | Fujitsu Ltd.                      |
| Jichi Medical University    | FUJITSU Ltd.                      |
| Jichi Medical University    | TOSHIBA Medical Systems, Co.      |
| Saitama Medical Center      | TOSHIBA Medical Systems, Co.      |
| Tohoku University Hospital  | FUJITSU Ltd.                      |
| The University of Tokyo Hospital | TOSHIBA Medical Systems, Co.      |

In this study, we acquired data from cardiac catheterization/PCI report system that were generated outside of the HIS. In the area of cardiovascular medicine, multimodal data such as electrocardiography, ultrasound cardiology and cardiac scintigraphy are generated in daily practice. SEAMAT standards for modalities other than cardiac catheterization/PCI report systems are published on the official website of the Japanese Circulation Society\(^{14}\) for clinical examination device vendors and medical institutions. The data exported in the SEAMAT to the SS-MIX2 extended storage can be readily utilized through MCDRS (Figure 3), which may overcome differences of clinical examination devices to drive multicenter studies.

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Regarding the quality of prospective registry study, it is important to collect reliable patient outcome data. Medical records regarding cardiovascular events, such as cardiovascular death, ischemia-driven coronary revascularization, and stroke, are sometimes not diagnosed correctly or recorded precisely in daily practice. Although context-dependent computed analysis of electronic medical records is ideal to capture cardiovascular events comprehensively, one of the currently best solutions is an integration of CRF into HIS and J-IMPACT. The use of CRF can standardize the medical records of cardiovascular events, in conjunction with the global standards such as clinical data interchange standards consortium Operational

Figure 3. Future Perspectives of J-IMPACT System. The J-IMPACT system is intended to be used in multicenter studies, connecting to the central MCDRS server. Multimodal data including physiological examinations such as electrocardiography (ECG) or ultrasound cardiology (UCG) will be collected in the SEAMAT standard into SS-MIX-2 extended storage, to be registered in the MCDRS server. HIS indicates hospital information system; CRF, case report form; PACS, picture archiving and communication system; SS-MIX2, standardized structured medical information exchange 2; MCDRS, multi-purpose clinical data repository system; CAIRS-DB, coronary angiography and intervention reporting system database; SEAMAT, standard export data format; and FW, firewall.

lected through secure connections through virtual private network over the internet, to the central MCDRS server (Figure 3), which may offer faster data collection and lower total costs of registry studies.
Data Model (ODM)-XML standards. Cardiovascular event records collected through CRF templates will be stored in the SS-MIX2 extended storage and will readily be available for case registration through the MCDRS (Figure 3).

Conclusions

In conclusions, we reported a proof-of-concept study to acquire multimodal medical data electronically through the J-IMPACT system, which accomplished for the first time a simultaneous acquisition of multimodal clinical data in electronic forms in a single system, including patient background, laboratory data, prescriptions, and cardiac catheterization/PCI reports. On-going development of the J-IMPACT system may achieve a more comprehensive and multicenter data collection. The application of the J-IMPACT system to clinical studies not only fulfills the gaps between randomized clinical trials and real-world medicine, but may also provide real-time big data that reinforces precision treatment for each patient.

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Disclosures

Conflicts of interest: None.

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Supplemental Files

Supplemental Table
Please see supplemental file; https://doi.org/10.1536/ihj.18-113