EVINCI Study: Management, Integration and Communication of Clinical and Imaging Data

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Abstract

The EVINCI European study (Evaluation of INtegrated Cardiac Imaging for the Detection, Characterization and Monitoring of Ischemic Heart Disease – number 222915) aims to evaluate the impact of a combined non-invasive anatomo-functional cardiac imaging strategy on the detection and management of ischemic heart disease (700 scheduled patients among 17 centers and 9 Countries). To reach this purpose for each patient we collected clinical, biohumoral, functional and anatomical imaging data. The large and complex amount of data required a dedicated technological work package for managing, integrating and reporting them in order to support medical decision and communication. We focused on the development of a system oriented to save and handle information, store raw images and to provide tools for imaging integration, multimodal reporting and educational purposes.

1. Introduction

Cardiovascular disease is the major cause of death across Europe and a major cause of morbidity and loss of quality of life. Indeed, the mortality due to cardiovascular diseases has progressively increased up to the last 20 years, while the mortality flattened tending to decline. Moreover, with the diffusion of new risk factors (i.e. physical inactivity, diabetes mellitus and obesity), the prevalence of ischemic heart disease (IHD) is actually increasing [1][2].

The purpose of the EVINCI study is the assessment of new strategies based on combined "anatomo-functional" non-invasive cardiac imaging and risk profiles assessed from clinical data and biomarkers for the early detection and characterization of IHD.

To reach this purpose, 695 patients with suspected IHD (intermediate pre-test probability) have been enrolled in several European centers, undergoing clinical and biohumoral characterization, including novel circulating markers of cardiovascular risk. Each enrolled patient underwent functional non-invasive stress imaging, chosen among positron emission tomography (PET), single photon emission tomography (SPECT), magnetic resonance imaging (MRI), ultrasound (US), and coronary anatomy assessment using computed tomography angiography (CTA) and invasive coronary angiography (ICA). European Core Labs were involved for blinded analysis of biohumoral and imaging data.

A relevant part of the EVINCI-study has been dedicated to the technological development (Figure 1) for collecting and managing clinical, biohumoral and imaging data, providing also new tools for imaging integration and for communication.

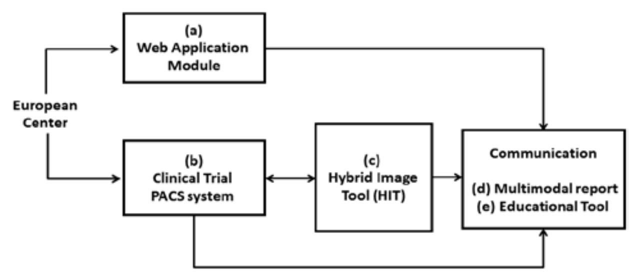

Figure 1. Schema of technological development.

The purpose of this paper is to give an overview of the different modules composing the technological module of EVINCI-study.

2. Dedicated web-application

A dedicated web site (Figure 1.a), based on open source software BMF (Bio Medical Framework) [3] and connected to a Central Server (CS) has been developed to allow centers to automatically enroll patients, receive an identification (ID) code for each enrolled patient and enter anonymised relevant data obtained throughout the study. Such information have been stored in a central database (DB). The same web site allowed the Core Labs to enter results of their blinded analysis. The stored information has been processed to give statistical results.

The homepage of developed web site is shown in Figure 2. Different account profiles have been created in order to set rules to access and manage data.

Figure 2: Homepage of EVINCI web site

3. Clinical trial PACS system

In order to store and distribute medical images a Clinical Trial PACS system (Figure 1.b) based on open source software (dcm4chee) has been developed. The clinical trial system was included in a communication network (Figure 3) connecting all enrolling centers and Core Labs with coordinating center located in Pisa.

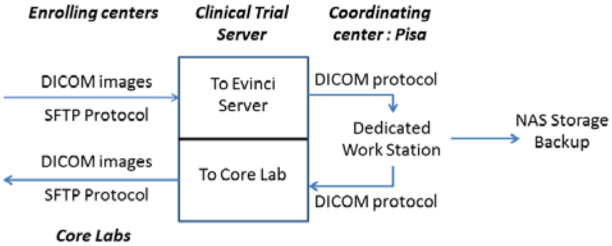

Figure 3. General schema of communication network.

The overall communication network is based on Openindiana Unix Operative system. The clinical trial server can receive DICOM images from enrolling centers via a DICOM store connection, and redistribute automatically the images to the Core Labs for blinded analysis. Every center received his own login and password in order to upload and download DICOM images using secure file transfer protocol facility (SFTP protocol). All images were also saved on an external repository (NAS) in order to reduce the risk of data loss on disk failure.

Additionally, all DICOM images sent to the coordinating center were stored in the GE AW 2.0-5.0 Server in order to allow each center to visualize the anonymized datasets. A VPN (Virtual Public Network) connection was used to guarantee the remote visualization of clinical cases stored in the server.

4. Hybrid image tool

The Hybrid Image Tool (HIT) development allows the integrated representation of anatomo-functional information derived from noninvasive multimodality cardiac imaging (Figure 1.c). In particular, the quantitative integration of coronary artery anatomy from CTA and regional functional information derived from PET and MRI have been considered. The schema of the developed method is shown in Figure 4.

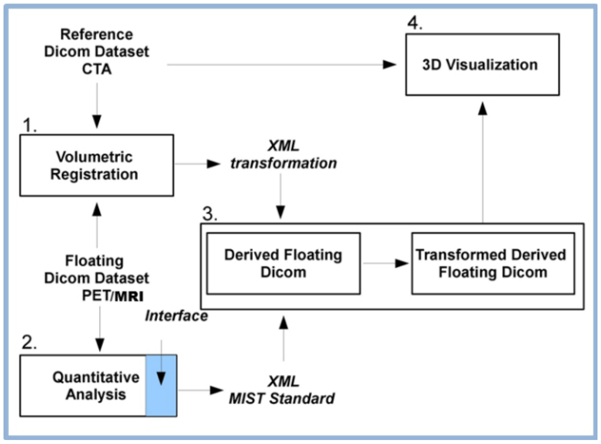

Figure 4. Schema of HIT.

The basic idea behind the HIT is to exploit image analysis tools yet available at the involved sites for clinical or pre-clinical research purposes and to develop interfaces, based on the standard eXtensible Markup Language (XML) protocol [4], for the communication of different modules.

In particular, the developed method can be described considering four main modules: 1) the volumetric registration tool for spatial matching of reference (anatomical) and floating (functional) datasets producing the XML transformation file containing the parameters of transformation; 2) the quantitative analysis of functional datasets based on validated software normally used in the clinical routine able to produce the XML MIST (Multimodal Image Storage and Transfer) file containing geometrical and quantitative information; 3) the generator of the derived functional datasets; 4) the 3D visualization tool of integrated anatomical and quantitative functional information [5]. An example of 3D integration of coronary artery anatomy obtained using CTA imaging and quantitative information myocardial flow reserve obtained by analysis of PET images is shown in Figure 5.

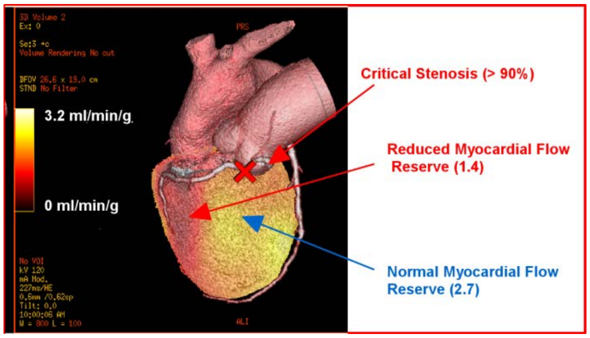

Figure 5. Example of 3D integrated representation of anatomo-functional information.

5. Multimodal report

Based on the information saved during the EVINCI study into the dedicated web application module and the clinical trial PACS system a new tool for multimodal reporting (MMR) has been created (Figure 1.d). Indeed, the main purpose of MMR was to organize, integrate and visualize all the available information (clinical, biological and cardiac imaging data) belonging to each patient. The MMR was designed to logically and hierarchically organize the patient data in a "picture" able to synthetically summarize the disease status underlining the key alterations in terms of "evidence", "causes" and "treatment". Such picture has been developed to be shared among different subjects (i.e. cardiologist, cardiac surgeon, family doctor and the patient himself), as support for decision making and follow-up. As shown in Figure 6, all the available information have been organized in several sections. The first one ("The Heart") provides the patient with the basic notions on circulation as well as with the explanation of the medical jargon used in the report. The following sections ("Description", "ECG", "LV Imaging", "CA Imaging") contain all the clinical and instrumental data of the patient giving a detailed clinical evaluation of cardiac disease, and the "Integration" section is able to provide a low and high resolution combined visualization. The last two sections ("Diagnosis" and "Decision") explain the diagnosis in terms of evidence and causes and describes the treatment suggested to the patient respectively.

6. Educational task

Starting from the MMR described above and using the information included on it, we developed a web-based educational tool (EduCAD) (Figure 1.e). EduCAD is directed to young cardiologists for training in the appropriate use of multimodal imaging technology in patient with suspected ischemic heart disease, promoting the culture of multimodal imaging for cardiac diseases assessment. The main proposal of educational task is to allow user to learn among different validated clinical cases, selected from EVINCI population, building up a diagnostic pathways on the basis of clinical evidence and appropriateness criteria for the use of noninvasive and invasive tests. The final user's conclusion and diagnostic imaging pathway is compared to the opinion of expert's specialists [6].

The web-based educational tool has been included into a dedicated website : www.escardio.org/educad

Figure 6. Example of the graphic user interface of the multimodal report.

Figure 7. Homepage of EduCAD website.

7. Conclusion

Early detection and non-invasive assessment of IHD is an important goal of clinical research, with the main purposes to improve quality of life and find new strategies for individual evaluation and treatment. This purpose entails the acquisition, analysis and management of a large amount of data that have to be compared and integrated in order to reach a valid diagnosis and medical conclusion. The technological package of EVINCI study gave us the possibility to implement valid methods to save data analysis, to store raw data images, and to combine and integrate all available information for reporting and education purposes. The acquired background could be the starting point for future applications and projects.

Acknowledgements

The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 222915 (EVINCI Study).

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