Advanced Healthcare

Development of Adrenal Venous Sampling (AVS) Support System for Primary Aldosteronism

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1. Introduction

Primary aldosteronism (PA), the most common type of secondary hypertension, accounts for about 10% of the estimated 40 million cases of hypertension in Japan and is said to be two to twelve times more likely to result in complications than essential hypertension.[1)] Primary aldosteronism occurs when one or both adrenal glands secrete excessive amounts of a certain hormone called aldosterone. Unlike essential hypertension, which accounts for 90% of cases and can have a wide variety of causes, primary aldosteronism is considered hypertension that can be completely cured by treating the adrenal glands.

Basically, adrenal venous sampling (AVS) is performed to identify the area inside the adrenal gland that is secreting too much aldosterone. AVS involves using an angiography system to insert a catheter up to the left and right adrenal veins, so that blood can be selectively sampled from the adrenal veins. Then the blood acquired from the adrenal veins is analyzed to diagnose primary aldosteronism, but that process involves the following two issues.

- **Speed of Adrenal Vein Blood Analysis**
  Typically, blood is acquired from the adrenal veins and then the hormones aldosterone and cortisol are quantitated by the immunoassay method (immunological measurement method). Such measurements are typically performed at an external testing laboratory, which can take several days before results are obtained and makes it difficult to determine analysis results on the same day as AVS examinations.

- **Hand-Written Records of Blood Acquisition Locations and Analytical Results**
  To precisely determine the area of excessive aldosterone secretion, blood must be acquired selectively from several locations in the left and right adrenal veins. That requires recording a combination of the acquisition positions in the blood vessel, the ID numbers of the blood collection tubes where each blood sample was placed, and the results of hormone analysis. Normally, hand-written anatomical information and numeric data are managed separately.

Tohoku University has been involved in that type of super-selective adrenal venous sampling for many years. Given that Shimadzu Corporation has extremely advanced technology for not only medical systems, but also analytical and measuring instruments, Tohoku University worked with Shimadzu to jointly develop new solutions for performing blood analysis more quickly and integrating images with medical records.

2. Description of Technology

The AVS support system (for research use) developed for integrating X-ray images and localized blood analysis results is shown in **Fig. 1**. The system comprises a Shimadzu liquid chromatograph mass spectrometer (LCMS) system, AVSsolution software, which is newly developed LCMS data analysis software that was optimized for AVS, and Sampling Viewer software, which creates records that integrate analytical results with DICOM images acquired with an angiography system. Because the AVSsolution software can provide reference values for analysis results within the same day of AVS examination, measurements can be performed quickly. Furthermore, recording reference images with the blood acquisition position indicated in X-ray images (DICOM images) using the Sampling Viewer software and creating AVS reports can help improve workflow efficiency. The use of digital technology can be expected to prevent human errors as well.

Fig.1 AVS Support System Developed for Integrating X-Ray Images with Localized Blood Analysis Results (for Research Use)

Next, an example of workflow using the AVS support system is shown in Fig. 2. First, X-ray images (DICOM images) acquired by the angiography system are sended into Sampling Viewer. Then the blood collection tube ID information is loaded and recorded at the corresponding position in the X-ray image where the blood was acquired. That provides a record of which collection tube contains the blood acquired from any particular position in the vein. Next, the blood collection tube is carried to the LCMS system, where the same collection tube ID information is loaded and the data is analyzed to determine the quantity of aldosterone and cortisol in the blood, as shown in Fig. 3. LCMS enables selective detection and rapid sample measurement based on mass information about target compounds.

The LCMS system and Sampling Viewer software communicate via the hospital's internal network, so that analysis results are automatically recorded in Sampling Viewer. Eventually, Sampling Viewer

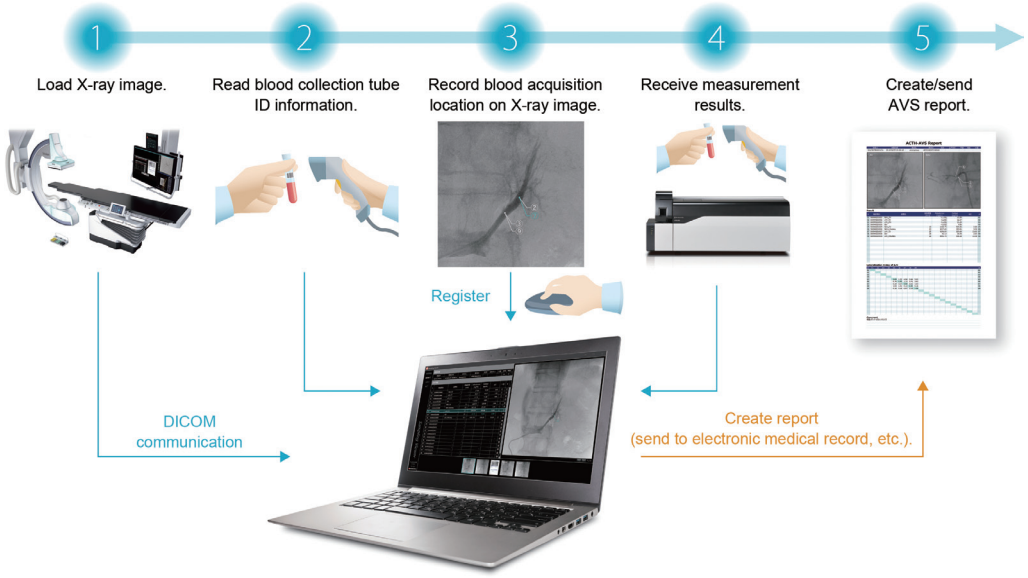
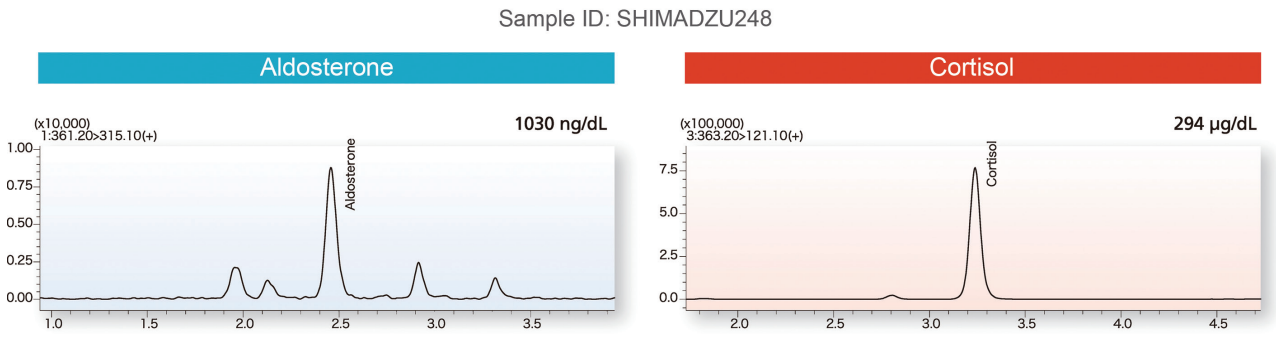


Fig.2 Example of AVS Support System Workflow



Data provided by: Tohoku University Graduate School of Medicine

Fig.3 Example of LCMS Aldosterone and Cortisol Analysis

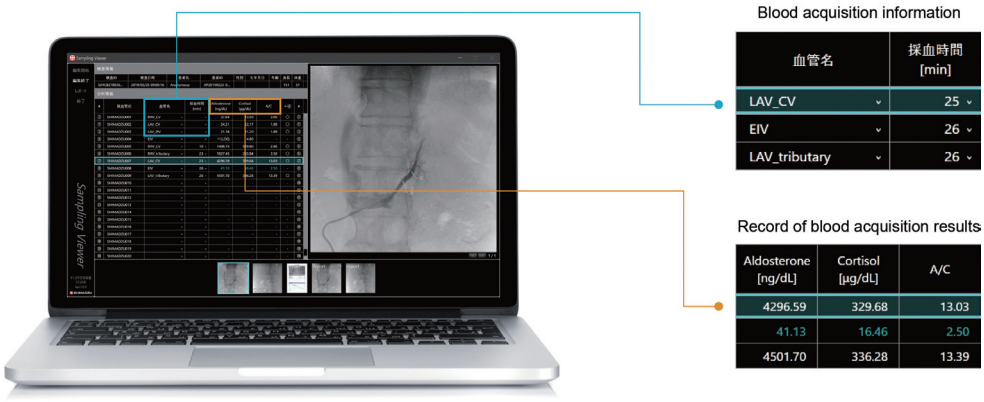


Fig.4 Example of Integrated Record from Sampling Viewer

creates an integrated record that includes the positions where blood was acquired, collection tube ID information, and analytical results, so that all the information can be confirmed in one location (Fig. 4).

3. Summary

The AVS support system described in this article was developed for the purpose of creating new solutions based on the integration of Shimadzu's core medical systems technologies with analytical and measuring instruments technologies. The project initially started when several Shimadzu engineers visited Dr. Kei Takase, a professor of Department of Diagnostic Radiology at the Tohoku University School of Medicine, in July 2015 to search for unmet needs in the healthcare field. That is when we learned about primary aldosteronism and carefully toured their workplace, which later led to the joint research project. To generate new concepts for healthcare equipment development, we need to continue fostering such close partnerships with healthcare facilities, rather than only with companies. Lastly, I would like to use this opportunity to sincerely thank Dr. Takase and others for allowing our engineers to keep visiting their workplace and for the many helpful suggestions they provided for this development project.

Reference:

1) Kei Takase, "IVR Technology for Curing Hypertension—Minimally Invasive Treatment for Primary Aldosteronism Using Adrenal Venous Sampling Technology—," Clinical Research, Innovation and Education Center, Tohoku University Hospital
https://www.crieto.hosp.tohoku.ac.jp/seedlist/seed01.html (referenced in May 10, 2019)

Note: The software and LCMS-8050 liquid chromatograph mass spectrometer described in this article have not been approved or certified as a medical product or medical device for in vitro diagnostic purposes under the Japanese Pharmaceutical and Medical Device Act. Therefore, they cannot be used for medical diagnostic purposes or associated procedures.