33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

An intelligent Decision Support System for the treatment of patients receiving Ventricular Assist Device (VAD) support

Evaggelos C. Karvounis, *Member, IEEE,* Nikolaos S. Katertsidis, Themis P. Exarchos, *Member, IEEE* and Dimitrios I. Fotiadis, *Senior Member, IEEE*

***Abstract*—The scope of this paper is to present the Specialist's Decision Support System (SDSS), part of the overall Decision Support Framework that is developed under the SensorART platform. The SensorART platform focuses on the management and remote treatment of patients suffering from end-stage heart failure. The SDSS assists specialists on designing the best treatment plan for their patients before and after VAD implantation, analyzing patients' data, extracting new knowledge, and making informative decisions. It creates a hallmark in the field, supporting medical and VAD experts through the different phases of VAD therapy.**

I. INTRODUCTION

Heart failure (HF) is affecting millions of people in the Western Countries every year, and is characterized by impaired ventricular performance, exercise intolerance, and shortened life expectancy. Despite significant advancements in drug therapy, mortality of the disease remains excessively high, as heart transplantation is the only accepted method to treat severe cases. Unfortunately, heart transplantation is limited by the number of donor organs, and therefore VAD support is nowadays considered an alternative for many cases of end-stage heart failure [1].

Traditionally, VADs have been employed in order to provide circulatory support to patients who cannot survive the waiting time to transplantation. However, two other roles have recently involved: "bridge to recovery" and "destination therapy". In these, the VAD reduces the workload imposed on the heart, which then can recover its contractility power.

The SensorART platform focuses on the management and remote treatment of patients suffering from heart failure. It provides an interoperable, extendable and VAD-independent solution, which incorporates different hardware and software components in a holistic approach, in order to improve the quality of the patients' treatment and the workflow of the specialists (Fig. 1). The SensorART platform consists of:

- Sensor Module: It is used to monitor both the VAD's and the patient's status through a set of implantable and wearable sensors (flow, pressures, thoracic impedance, ECG etc.).
- Signal Acquisition Module: A software component, which collects all signals coming from the sensors and present them, in a formal and easy-to-access way, to the patients. This component is deployed in a small portable device, such as a PDA.
- Hardware Controller: A hardware unit, on which the auto-regulation algorithm of the VAD is deployed. This unit, which communicates wirelessly with the VAD, is responsible to auto-adjust the provided blood flow of the VAD to the patient's heart according to signals from the Sensor Module. Moreover, this unit monitors the energy consumption, as well as the VAD functionality, generating the appropriate crucial and vital alert messages.
- Remote Control Framework: A software module, which is deployed in the specialists' personal computer and PDA. This module provides the capability of real-time remote-monitoring and controlling of the patient's and VAD's status.
- Decision Support Framework: It assists the specialists on deciding the best treatment strategy for a specific patient. It includes a VAD-heart simulation component, which gives to the specialists the possibility of modeling the behavior of a patient before and after VAD implantation, as well as a Decision Support System providing data analysis and projection tools.

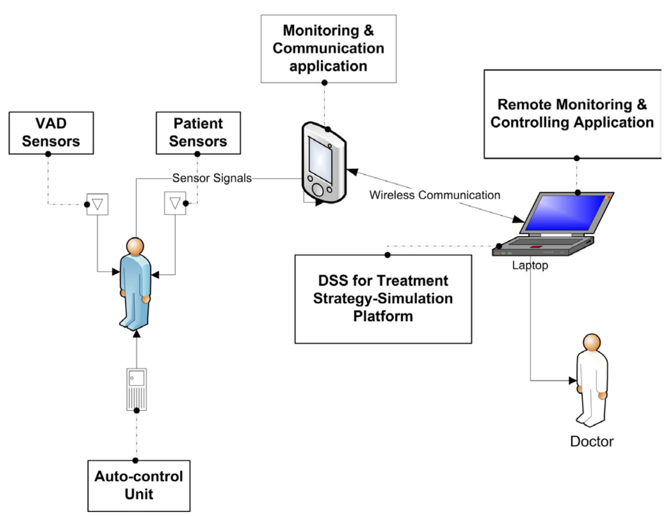

Fig. 1. Overall SensorART platform.

The widespread application of VAD therapy has increased research in the field, and as a result a few DSS have been proposed over the past years. These mainly target in:

Manuscript received April 13, 2011. This study was supported in part by FP7-ICT- 2009 SensorART project ('A remote controlled Sensorized ARTificial heart enabling patients empowerment and new therapy approaches', FP7-248763).
E.C. Karvounis, N.S. Katertsidis, T.P. Exarchos and D.I. Fotiadis are with the Biomedical Research Institute-FORTH, GR 45110, Ioannina, Greece (e-mail: ekarvuni@cc.uoi.gr, nkaterts@cc.uoi.gr, exarchos@cc.uoi.gr, fotiadis@cs.uoi.gr).

identification of a suction detector for rotary blood pumps; determination of an optimal VAD pump speed; and identification and selection of VAD patients, which can be weaned from the VAD.

Regarding the first case, suction is an event that occurs when a rotary pump tries to draw more blood than is available. Suction may cause ventricular collapse to occur, which can cause chest pain and cardiac tissue damage. In literature, several approaches have been proposed to solve the suction detection problem. These approaches are based on empirical observation of certain variables. Thus, some suction indices are based on time domain characteristics and the spectral energy content of signals, such as pump flow and pump current [3]. Instead of using just one indicator, a combination of indices can also be employed [4].

Considering the pump speed selection problem, a few sensorsless methods for determining the optimal pump speed were developed by using pump variables such as current, voltage and speed [5]. Several other researchers have adopted a similar approach without the use of implantable sensors [6,7].

For a growing number of patients with heart failure, VAD therapy has demonstrated the potential to extend life, and even lead to cardiac recovery [8]. However, the incidence of VAD weaning remains relatively low compared with the volume of patients treated with VAD therapy. In addition, the underlying cellular, biochemical, and biomechanical mechanisms remain uncertain and thus, different sets of criteria have been proposed for attempting to wean patients from VAD support [9]. These differences may arise from different types of heart failure, different medical treatments during mechanical unloading, differences in devices used for ventricular support etc. So far, only one clinical DSS has been reported in the literature for supporting ventricular assist device weaning [10].

The scope of this paper is to present in detail the architecture and functional specifications of the SDSS, based on the initial research results and user requirements analysis. In the context of the SensorART platform, the SDSS plays an important role, providing valuable information and support the specialists with regard to the treatment strategy for their patients.

II. Materials and Methods

A. Specialist's Decision Support System Design

As depicted in the high-level architecture of SensorART, the SDSS is an essential component of the platform, part of the overall Decision Support Framework. It assists the specialists to:

- Select the most appropriate candidates for VAD weaning.
- Decide on the best treatment strategy in terms of medication.
- Analyze patients' data and extract new knowledge.
- Identify different pump states and possible issues related to the suction phenomenon.
- Draw conclusions about the most appropriate pump speed settings.

The SDSS combines both medical knowledge and data-driven techniques [11], and its design is based on acknowledged standards and principles that ensure the avoidance of either technical or business barriers.

B. SDSS Overall Architecture

In the following figure (Fig. 2), the architecture of the SDSS is presented in detail.

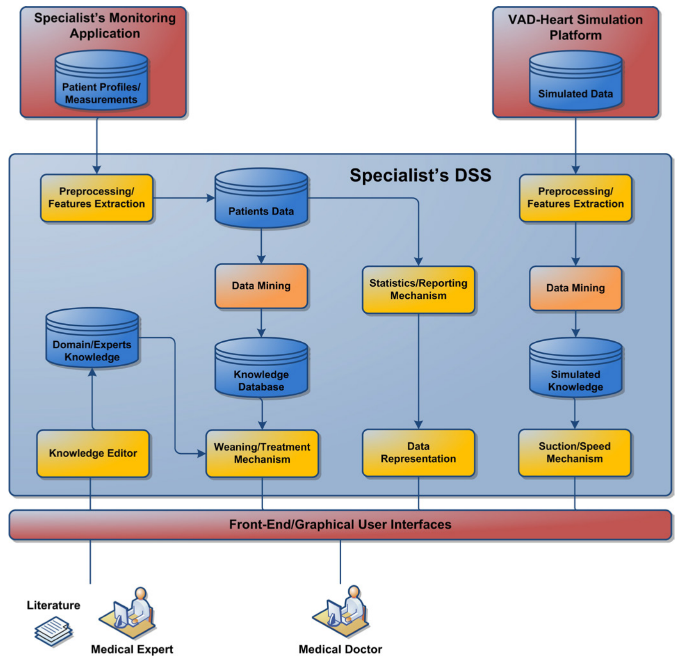

Fig. 2. Architecture of the SDSS.

The SDSS is a Web-based application providing multiple functionalities to the specialists. It creates a hallmark in the field, supporting medical and VAD experts through the different phases of VAD therapy. Rather than addressing a single issue, the SensorART SDSS enables specialists with advanced techniques [11], in order to effectively assess and exploit data from two categories:

Real patient data from the Specialist's Monitoring Application, through two different modules:

Weaning and Treatment Module: This module combines expert knowledge with multivariate statistical analysis, in order to support the specialists on the weaning decision (i.e. the selection of patients with adequate cardiac recovery that may be removed from the VAD therapy), and on the most suitable treatment plan in terms of medication, according to the condition/phase of the patients (stabilized clinical state, normal phase in home conditions, worsening phase and/or reacutisation phase).

Emphasis is given on advanced methodologies that ensure:

- Robustness and reliability.
- Extended spatial and temporal coverage.
- Increased confidence.
- Reduced ambiguity and uncertainty.

- Robustness against interference.
- Improved resolution.

Multiple classification techniques are evaluated for the analysis and processing of data. A classification technique or classifier is a systemic approach to building classification models from an input data set and many schemes have been used in clinical decision making and disease management problems. Each classification technique employs a learning algorithm to identify a model that best fits the relationship between the attribute set and the class label of the input data. A key objective of the learning algorithm is to build models with good generalization capability. The classification techniques employed include artificial neural networks (ANN) [12], Bayesian inference techniques [13], the Shafer and Dempster method [14], Support Vector Machines [15], etc. The module handles patients' data coming from the Specialist's Monitoring Application, as well as knowledge data coming from medical and VAD experts. These data are processed and analysed in order to provide support for the treatment (in terms of medication) and situation of each patient (candidate for weaning).

The Weaning and Treatment Module includes the components described below:

- *Preprocessing/Features Extraction:* It is used to preprocess all data received from the SensorART platform. These include patients' profiles, VAD measurements, lab measurements, medications, history of events etc. After the appropriate transformations, all data are stored for further retrieval and analysis. In addition, specific features are extracted for ease and effective process in other components.

- *Patients Data Repository:* It is the main repository of the SDSS. Within it, all data of the monitored patients are collected and stored, after their preprocessing from the Preprocessing/Features Extraction component. The Patients Data repository is connected with the Data Mining component and the Statistics/Reporting Mechanism.

- *Data Mining:* It is one of the intelligent components of the SDSS. The Data Mining component is used to analyze all data coming from the SensorART platform, and provides the extracted knowledge to the Weaning/Treatment Mechanism, as well as, the medical and VAD experts. The Data Mining component uses data from the SensorART platform, and provides the resulted knowledge to the Knowledge Database.

- *Knowledge Database:* This repository contains the knowledge that is generated from the Data Mining component, after the analysis of the acquired patients' data.

- *Domain/Experts Knowledge:* This repository includes all the knowledge coming from the medical experts, and the literature related to treatment and patient selection for VAD weaning.

- *Knowledge Editor:* It provides the ability to create and maintain the expert knowledge (in the form of clinical rules), used in the alerting Weaning/Treatment Mechanism.

- *Weaning/Treatment Mechanism:* It is one of the core components of the SDSS. The Weaning/Treatment Mechanism provides reasoning for the treatment (in terms of medication) and situation of a patient (candidate for weaning), by mapping his data through the Domain/Experts Knowledge Database and the Knowledge Database.

Knowledge Discovery and Statistics Module: This module assists specialists in conducting profound analysis and research, originated from patient data and previous cases. An advanced methodology based on association rule learning [16] is employed, thus allowing the discovery of interesting relationships hidden in the large datasets that are created in SensorART for each patient individually, and for all patients treated by a specialist. Using this, the specialists are able to define various variables for which associations are searched within the recorded datasets through the use of easy and efficient interfaces, discover interesting interrelations and extract new knowledge from multiple and heterogeneous archived data that reflect everyday lifestyle and medical information, etc.

Main components of the module are:

- *Statistics/Reporting Mechanism:* It provides specialists with tools for analyzing collected patients' data, and discovering/reporting new knowledge. This may be specific for a patient under investigation or for a group of patients, who share common characteristics. The Statistics/Reporting Mechanism is connected with the Patients Data repository and the Data Representation component.

- *Data Representation Module:* It handles the presentation of the extracted knowledge from the patients' data (in terms of corresponding association rules). This may be presented in textual format, cross-tabulation tables, or graphically using 2D and 3D diagrams. The most suitable format is selected depending on user needs.

Simulated patient data from the VAD-Heart Simulation Platform, through:

Suction and Speed Optimization Module: The Suction and Speed Optimization Module provides to the specialists a powerful assistant in their attempt to effectively plan the treatment strategy for a patient. The module handles data from simulation sessions generated in the VAD-Heart Simulation Platform. These data are analysed in order to determine the pump status, and draw conclusions regarding the pump speed settings.

Two main components are included in the Module:

- *Preprocessing tool:* It is used to preprocess data received through the VAD-heart simulation component. These include measurements (pump flow, pump speed, aortic pressure, ventricular pressure etc.) related to simulation sessions that are configured and executed by medical and VAD experts. In addition, specific features are extracted for ease and effective process in other components.

- *Data Mining:* It is one of the intelligent components of the SDSS. The Data Mining component is used to analyse data coming from the VAD-heart simulation component, and provide the extracted knowledge to the Suction/Speed Mechanism.

- *Simulated Knowledge:* This repository contains the knowledge that is generated from the Data Mining component, after the analysis of the simulated data acquired from the VAD-heart simulation component.

- *Suction/Speed Mechanism:* The Suction/Speed Mechanism provides reasoning to the specialists in their attempt to identify different pump states and possible issues, as well as decide about the most appropriate pump speed settings.

Several features in the frequency and time domains are explored and employed, with the aim to capture the underlying nature of the corresponding physiological signals. Frequency-domain features are based on heuristic observations that the spectral energy content of the signals, changes when the patient is experiencing suction while time-domain features are based on a beat-to-beat analysis of signal patterns. The classification scheme is addressed by intelligent machine-learning techniques, such as Artificial Neural Networks, Support Vector Machines, or Random Forests. The output of the suction detector and other parameters are provided as inputs in a knowledge-based expert system designed to derive inferences about the optimal pump speed settings. The system proposes adjustments to pump speed according to the required cardiac output and pressure perfusion. It may be based on a fuzzy-logic inference system [17]. Such a system involves an input fuzzification, an inference engine and an output defuzzification procedure.

III. Conclusions

Table 1 provides a first insight of the SensorART SDSS features in relation to the most prominent works reported in the literature. In this context, the SDSS creates a hallmark in the field, supporting medical and VAD experts through the different phases of VAD therapy. Rather than addressing a single issue, the SDSS assists specialists on designing the best treatment plan for their patients before and after VAD implantation, analysing patients' data, extracting new knowledge, and making informative decisions. The introduction of the SDSS enables the potential to translate valuable expert knowledge into standardized, personalized, and optimized VAD therapy. As a future work, the SensorART SDSS will be further developed and validated, using data from multiple medical centers.

TABLE I
SDSS FEATURES IN RELATION TO OTHER WORKS

Features	Santelices et.al [10]	Karantonis et al [4]	McConahy [7]	SensorART SDSS
Data-driven Knowledge	X	X	X	X
Expert Knowledge	X			X
Real data	X	X	X (from calves)	X
Simulated data				X
Weaning	X			X
Medication Treatment				X
Statistics Analysis				X
Suction		X		X
Speed			X	X

References

[1] E. Birks, P.D. Tansley et al. "Left Ventricular Assist Device and Drug Therapy for the Reversal of HF," *New Eng. J. Med*, vol. 355 (18), pp. 1873-1884, 2006.

[2] SensorART: A remote controlled Sensorized Artificial heart enabling patients empowerment and new therapy approaches (Grant agreement no.: 248763). Available: http://www.sensorart.eu/

[3] J.R. Boston, J.F. Antaki and M.A. Simaan, "Hierarchical Control of Heart-Assist Devices," *IEEE Robotics & Automation Magazine*, vol. 10, pp. 54-64, 2003.

[4] D.M. Karantonis, D.G. Mason, R.F. Salamonsen, P.J. Ayre, S.L. Cloherty, and N.H. Lovell, "Classification of physiologically significant pumping states in an implantable rotary blood pump: patient trial results", *ASAIO J.*, vol. 53 (5), pp. 617-22, 2007.

[5] J.F. Antaki, S. Choi, J.R. Boston, K.C. Butler, D.C. Thomas, and D.V. Amin, "Speed control system for implanted blood pumps", US Patent 6,066,086: Nimbus Inc, 2000.

[6] S.H. Chen, "Baroreflex-Based Physiological Control of a Left Ventricular Assist Device", thesis, The School of Engineering, University of Pittsburgh, 2006.

[7] D.C. McConahy, "Application of multiobjective optimization to determining an optimal left ventricular assist device (LVAD) pump speed", thesis, The School of Engineering, University of Pittsburgh, 2007.

[8] A. Mano, T. Nakatani et al. "Which factors predict the recovery of natural heart function after insertion of a left ventricular assist system," *J Heart Lung Transplant*, vol. 27, pp. 869–874, 2008.

[9] Dandel M, Weng Y, et al, "HF reversal by ventricular unloading in patients with chronic cardiomyopathy: criteria for weaning from ventricular assist devices," *Eur Heart J.*, 2010.

[10] L.C. Santelices, Y. Wang, et al. "Development of a Hybrid Decision Support Model for Optimal Ventricular Assist Device Weaning," *Ann Thorac Surg*, vol.90, pp.713-720, 2010.

[11] M.C. Maria, J. Antonio et al., *Handbook of Research on Developments in e-Health and Telemedicine: Technological and Social Perspectives*, IGI Press, 2010.

[12] M.H. Hassoun, *Fundamentals of Artificial Neural Networks*, MIT Press, 2010.

[13] C. Howson, P. Urbach, *Scientific Reasoning: the Bayesian Approach (3rd ed.)*, Open Court Publishing Company, 2005.

[14] G.A. Shafer, "Perspectives on the Theory and Practice of Belief Functions," *International Journal of Approximate Reasoning*, vol. 4, pp. 323-362, 1990.

[15] C.M. Bishop, *Pattern Recognition and Machine Learning*, Springer, 2007.

[16] H. Jochen, G. Ulrich, and N. Gholamreza, "Algorithms for association rule mining-A general survey and comparison". *SIGKDD Explorations*, vol. 2(2), pp. 1-58, 2000.

[17] S. Farinwata, D. Filev and R. Langari. *Fuzzy control synthesis and analysis*, John Wiley & Sons, 2000.