A Decision Support System for the Treatment of Patients with Ventricular Assist Device Support

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Summary
Background: Heart failure (HF) is affecting millions of people every year and it 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 transplant remains the gold standard treatment for end-stage HF when no contraindications exist. Traditionally, implanted Ventricular Assist Devices (VADs) have been employed in order to provide circulatory support to patients who cannot survive the waiting time to transplantation, reducing the workload imposed on the heart. In many cases that process could recover its contractility performance.

Objectives: The SensorART platform focuses on the management and remote treatment of patients suffering from HF. It provides an interoperable, extendable and VAD-independent solution, which incorporates various hardware and software components in a holistic approach, in order to improve the quality of the patients’ treatment and the workflow of the specialists. This paper focuses on the description and analysis of Specialist’s Decision Support System (SDSS), an innovative component of the SensorART platform.

Methods: The SDSS is a Web-based tool that assists specialists on designing the therapy plan for their patients before and after VAD implantation, analyzing patients’ data, extracting new knowledge, and making informative decisions.

Results: SDSS offers support to medical and VAD experts through the different phases of VAD therapy, incorporating several tools covering all related fields; Statistics, Association Rules, Monitoring, Treatment, Weaning, Speed and Suction Detection.

Conclusions: SDSS and its modules have been tested in a number of patients and the results are encouraging.

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1. Introduction
Heart failure (HF) can be defined as an abnormality of cardiac structure or function leading to failure of the heart to deliver oxygen at a rate commensurate with the requirements of the metabolizing tissues, despite normal filling pressures (or only at the expense of increased filling pressures) [1]. Common causes of heart failure include myocardial infarction and other forms of ischemic heart disease, hypertension, valvular heart disease and cardiomyopathy. It is a common, costly, disabling and potentially deadly condition. In developed countries, around 2% of adults suffer from heart failure, but in those over the age of 65, this rate reaches up to 6–10% [2]. For these reasons, together with the difficulty of having a sufficient number of heart donors, it is recognized that the de-
vice-based therapeutic approaches assume an increasing and important role in the treatment of HF patients, not only as bridge to transplant, but also as destination therapy. Additionally, in recent years, there is important evidence that patients assisted by Ventricular Assist Devices (VADs) can potentially recover the natural heart functions. VAD is a mechanical pump used to support heart function and blood flow in people who have weakened hearts. In this framework, the SensorART platform focuses on the management and remote treatment of patients suffering from heart failure by offering an interoperable, extendable and VAD-independent (i.e. working with different VAD types/brands) solution, which incorporates hardware and software components in a holistic approach, in order to improve the quality of the patients’ treatment and the workflow of the specialists [3]. In addition, SensorART enables specialists to better understand the patient-device interactions, and get an insight into new knowledge. The decision support component of the SensorART platform is the Specialist’s Decision Support System (SDSS) [4].

The SensorART platform in general and SDSS in particular comes to fill-in the gap of data analysis and related decision support in a rather new medical field where although an abundance of data is created, there is no systematic way to store, access and analyse it. Even more, in such patient data, hidden knowledge usually resides; still there are neither available tools to mine such data, nor related databases. Even statistical analysis and hypotheses testing are not supported by specialised tools and researchers have to create manually input files from medical records. Also, there are no systems capable of simultaneous monitoring and analysis of patient measurements. Such a tool could serve as a prognostic/alerting tool in everyday patient management and could significantly improve patient treatment by early identifying patient risk. Patient risk is currently estimated by generalised scoring systems which do not consider individual patient profiles. The VAD performance, customisable throughout pump speed selection, is mainly set empirically following a trial-error procedure without the support of intelligent process that uses the patient profile to elaborate the suggested speed.

In this framework, as all medical DSSs that use electronic clinical data and provide patient-specific information to clinicians with the aim of reducing medical errors [5], the proposed SDSS offers support towards three main directions: i) Analysis of patient data, hypothesis testing and extraction of hidden associations among patient variables. ii) Support on treatment decisions by providing estimation of adverse events risk and identification of patients that could be considered as candidates for weaning from VAD, and iii) Support on optimal setting of VAD speed based on patient profiles and estimated cardiac output obtained through a specially built VAD-circulatory system simulator [3]. Suction detection is also employed towards this direction. In order to create and integrate our SDSS into the clinical practice, the proposed SDSS should act pro-active and produce reminders, warnings, ask questions, analyse trends based on the data of the electronic record and on up-to-date medical knowledge while trained by the outcome of their decisions [6]. The proposed SDSS provides a holistic approach by supporting medical decisions and actions in the whole patient life-cycle. Before VAD implantation, using the SDSS the specialist is able to design the therapy plan by assessing patient status and the risk of adverse events associated to the implantation. This plan could even include the decision whether to implant a VAD or not. After the implantation, the specialist can use the SDSS to get a suggestion on the optimal VAD speed, can monitor patient and VAD parameters and assess the probability for an adverse event the following day. Eventually, the specialist can assess improvements in patient status that could denote adequate cardiac recovery, which in turn could lead to weaning from the VAD. Specialist’s research is also supported though hypotheses testing on a specially designed repository built with heterogeneous data coming from multiple sources (laboratories, implantable and wearable sensors).

In this paper we present the functionalities of the SDSS and its sub-components and we demonstrate their application on real patient data. The authors have presented an initial SDSS design in [3]; the current paper describes in detail the final implementation, including evaluation results on real patient datasets. The paper is organized as follows: In Section 2 an extended state of the art of related DSSs and methodologies in the field of VADs is presented. In Section 3 tools and components of the SDSS are presented in detail, while, in Section 4, the obtained results on a real patient dataset are provided. Finally, extensions and concluding remarks on the application of SDSS tools are discussed in Section 5.

2. Related Work

Current clinical practice related to treatment support of left VAD (LVAD) patients is characterized by none to limited application of information technology and intelligent decision support systems. In the literature only research works that support individual aspects of the problem have been referred.

Analysis of clinical studies often necessitates complex processes and multiple graphical representation of the results. An exploratory data analysis includes a variety of techniques, in order to discover hidden relationships, such as patterns or clusters in a dataset, identification of most important parameters, etc. Most professional software packages (IBM SPSS, Mathematica, SAS, etc.) are either only commercially available or hard to use, especially if one aims to generate or customize a huge number of similar graphical outputs. In addition, most statistics programs force users to import data from a database before they can use them, while in many cases there is no direct connection to the database.

Association rule mining has been applied in order to extract interesting relations between variables in medical databases. A Priori [7] is a well-known method using support-based pruning to systematically control the exponential growth of candidate itemsets. Doddli et al. [8] have investigated the application of association rules in medical data. Hu [9] utilized the association rules technique (using an Im-
proved A Priori algorithm) to conduct data mining on 285 cases of breast disease patients to create rules between tumor recurrence and other attributes such as age and tumor size. Srisraam et al. [10] used a Malaysian hospital dataset in order to decide on kidney dialysis treatment using association rules. Immanuela et al. [11] utilized an association rules technique on 477 patients in order to investigate the three most useful clinical findings for chronic diseases. Lee et al. [12] have proposed an association rule mining method on 1,247 young Korean adults to extract patterns related to acute myocardial infarction. Still, most commercial DSSs focus mainly on extracting statistical measurements from a given patient database and not on extracting new knowledge.

For VAD treated patients, several risk scores and assessment tools have been presented in the literature [13–30]. Some of them are mentioned here. The Heart Failure Survival Score (HFSS) [13] has been proposed for patient selection for LVAD support based on the estimation for expected survival during the next 1–3 years. It has been developed using statistical likelihood analysis. In the same context, the Seattle Heart Failure Model (SHFM) [14] and the Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure trial (REMATCH) [15] have been also employed. The Interagency Registry for Mechanically Assisted Circulatory Support registry (INTERMACS) [16] has been used for patient classification in risk groups, interval analysis [17] and timing of implant assessment [18]. Also, patient classification related to the risk of developing other diseases when undergoing LVAD implantation has been addressed with the Model for End-Stage Liver Disease (MELD) [19]. In addition, the RVF risk score (RVFRS) pre-operative tool [27] and the pre-operative RV stroke work index (RVSWI) [28] have also been presented in the literature. Still, most of the aforementioned studies are based on statistical analysis techniques only, while [25] and [30] employ data mining techniques.

Current clinical practice of LVAD patients seems to be lacking advanced visualization tools that can be used for monitoring day-to-day patient data. Such tools can prove to be significant assistants to patient monitoring, ideally linked to prognostic systems that can predict adverse events. The value of day-to-day data recorded in a patient diary is demonstrated in several studies presented in the literature, for both heart failure patients or for patients suffering from other chronic diseases and conditions. Kirchner et al. [32] proposed a heart failure patient monitoring system with implantable defibrillators. White et al. [33] performed diary data analysis for Heart Failure symptom recognition. Hayes et al. [34] included walking program diary data to study the effects of exercise training on the quality of life in LVAD patients.

As, in some cases, LVAD devices can lead to heart recovery – at least this being the vision for the future - a hard decision to be taken is patient weaning. A few models have been presented in the literature. Santelices et al. [35] proposed a model derived from retrospective medical experience, through a series of structured interviews and questionnaires of 11 members of the multidisciplinary Artificial Heart Pro- gram at the University of Pittsburgh medical center. Dandel et al. [36] analyzed data on cardiac morphology and function collected before VAD implantation, echocardiographic parameters recorded during “off-pump” trials, duration of HF before implantation, and stability of recovery before and early after VAD removal. To assess the predictability of post-weaning outcome without heart transplantation or other VAD implantation and to identify risk factors for post-weaning HF recurrence, the authors used the data collected before and during VAD support. Birks et al. [37] proposed a set of minimum criteria with the LVAD at 6000 rpm for 15 minutes for explantation. In the case of parameter improvement, the combination therapy was continued until the maximum improvement had been achieved in each patient. All above weaning models propose a set of simple crisp rules in order to identify weaning candidate patients and the final outcome of the related models is a yes/no suggestion without any quantification of the strength of this suggestion.

In the case of Pump Speed Selection, a few sensor-less methods for determining the pump speed were developed by using pump variables such as current, voltage and speed [38–40]. These methods were based on the observation that pressure across, and flow through, an LVAD can be inferred or estimated from the electrical current and frequency of the pump’s motor. Several other researchers have adopted a similar approach without the use of implantable sensors [41–43]. Control schemes to keep the average pressure across the pump (or between the aorta and the left ventricle) constant have also been developed [44–46]. These can provide a pump speed in the safe zone or optimal zone for a certain systemic vascular resistance. Other control approaches, such as using the heart rate as input have been reported [47]. Chen presented an improved method that incorporates the heart rate and the systemic vascular resistance (SVR), and responds to the physiological changes of the body instantaneously, based on the baroreflex and the built in cardiovascular regulation system [48]. McConalhy shows the constraints on cardiac output, left atrial pressure, and arterial pressure [49]. However, the proposed methodologies for pump speed selection present significant drawbacks like: they are reliable only in a relatively narrow range of pump variables, some methods do not take into account the change in SVR, etc.

Concerning detection of suction events in the available related signals (i.e. pump flow or pump current signals), several approaches have been proposed to evaluate it [50–53]. These approaches are based on the empirical observation of certain variables. Thus, some suction indices are based on time-domain features [54–57], frequency-domain features [55–57], and time-frequency-domain features [55–57]. Among them, there exist methods which extract features from the pump flow signal being one of very few signals that can be easily measured and use powerful pattern recognition algorithms to classify the signal into different pump states [57–61]. However, in the majority of the above described approaches, a large number of features are employed. Also, suction detection algorithms are used only in LVAD controllers [62].
3. Material and Methods

The SensorART platform continuously monitors and evaluates patient-device interactions and optimizes the heart unloading and support. In this direction, the proposed SDSS enhances the SensorART platform with advanced tools, thus enabling the realization of an “intelligent” VAD implementation. By facilitating such an approach, the SDSS aims at providing a better understanding of the patient condition and progress in order for the specialists to personalize and optimize the corresponding treatment support, determine the capacity of the natural heart to develop major or minor delivery according to the assisting time, identify risk factors and recovery mechanisms in order to recognize potential outcomes etc.

Figure 1 presents the role of the SDSS within the overall SensorART platform. The SDSS resides of the server side, accesses the SensorART repository where patient data are continuously stored, and communicates with the VAD Simulation Platform (in order to acquire customized simulation sessions). The SensorART repository itself is EUROMACS (www.euromacs.org) compliant so as to ensure interoperability; a special wrapper application ensures HL7 compatibility, as well. Data are generated on the client side either directly by the VAD itself, by implantable sensors and by wearable sensors (Continua alliance certified). An Autoregulation Unit used for VAD control and data collection, manages the data which, in turn, are sent through a portable device (e.g. a tablet) (running the Patients’ Monitoring Application) to the data repository. The SDSS and the Specialist’s Monitoring Application access this repository. They form a resourceful environment that provides valuable outcomes (patient condition/parameters, data analyses, risk factors, suggestions, estimations, etc.) to the specialists (i.e. clinicians, researchers, etc.). The SDSS offers support to medical and VAD experts through seven tools for Association Rules extraction, Statistics analysis, Treatment decision support, Monitoring, Weaning decision support, VAD Speed Selection and Suction Detection respectively.

The SDSS tools communicate with the following system parts: i) the SDSS User Interface that includes a set of pages/forms and controls allowing advanced interactivity with the users of the SDSS, ii) the VAD Simulation Platform providing a hybrid ventricular and circulatory model allowing specialists to simulate the behaviour of a patient’s circulatory system using different VAD types and functional parameters [63], iii) an R environment for statistical computing, and most important iv) the SensorART repository that provides storage and retrieval functionalities for all the data used in the SensorART platform and was developed to support the management of data that are used by the corresponding tools. The SensorART repository was designed and implemented with the following data entities: users, user groups, alerts and notifications, sensor measurements, VAD measurements, laboratory measurements, patient profiles etc. Various screenshots of the platform are presented in Figure 2.
while all seven SDSS tools are described in detail in the following paragraphs.

### 3.1 Association Rules Tool

Using the Association Rules Tool, the specialist can extract association rules, linking different patient variables based on patient data over a specific observation period. In particular, the Specialist can be assisted in analysis and research, by using data mining techniques in order to discover associations among different variables and discover new knowledge. Associations are in the form of Rules: IF (variable 1 > value 1) AND (variable 2 <= value 2) AND ... THEN (variable 3 > value 3) AND ... (variable n > value n).

By using this tool, various hypotheses on relationships among variables can be now examined (if confirmed) by existing data. The specialist can select the variables that will be included in the IF and the THEN parts, the patients that will be included and the time period (start and end date) of the analysis. Furthermore, he can filter the extracted rules by setting support and confidence thresholds. Rules together with their confidence and support values are presented to the specialist. Moreover, in order to acquire as much meaningful results as possible, a double filtering approach is followed by (i) ignoring features that have a high percentage of missing values in the database and (ii) ignoring records for which a high number of feature values is missing. The specialist can define the relevant thresholds.

The A Priori algorithm [7] was chosen as the rule mining algorithm, because of its robustness and ability to solve large problems using small computational power and time. The A Priori algorithm attempts to find subsets which are common to at least a minimum number of the itemsets, given an initial set of itemsets. The algorithm can find associations between different sets of data and the sets of rules (the algorithm’s outcome) implies how often items are contained in sets of data. It should be mentioned that, although several different approaches have been presented in the literature, A Priori remains the benchmark algorithm of the association rule mining field, while most of the other algorithms improve the computational time for mining the association rules from the dataset, still mainly producing the same set of rules [7]. The A Priori algorithm in general uses breadth-first search and a Hash tree structure to keep track of the candidate itemsets. Then, it generates these candidate itemsets of length N from the initial itemsets of length N – 1. Afterwards, the candidate itemsets which have an infrequent sub pattern are pruned. Finally, the ultimate candidate set contains all frequent-length itemsets. The problem of association rule mining is defined as:

Let \( I = \{i_1, i_2, ..., i_d\} \) be the set of all items in a dataset, and \( T = \{t_1, t_2, ..., t_y\} \) be the set of all transactions. Each transaction has a unique identifier and contains a set of items, called an itemset. An itemset with \( k \) items is called a \( k \)-itemset. An important property of an itemset is its support count, which refers to the number of transactions which contain this particular itemset. An association rule is a conditional implication among itemsets, of the form \( X \Rightarrow Y \) where \( X \) and \( Y \) are disjoint itemsets, i.e. \( X \cap Y = \emptyset \). The strength of the rule can be measured in terms of its support and confidence. The rule has support \( s \), if \( s \% \) of transactions include all the items in both \( X \) and \( Y \), and confidence \( c \) if \( c \% \) of transactions containing also contain \( Y \). Support is an important measure, because a rule that has very low support may occur simply by chance. Confidence, on the other hand, measures the reliability of the inference made by a rule. Hence, the data mining task for association rules can be broken into two steps. The first step consists of finding all frequent itemsets, i.e. itemsets that occur in the database with a certain user specified frequency, called minimum support. The second step consists of forming the rules among the frequent itemsets. Initially, the data and the assigned support and confidence values are read. Then, the data are preprocessed by a parsing tool, and the preprocessed data are used as input to the A Priori algorithm and exports the results to a file. The parsing tool operates as follows: taking into account the percentage of the non-missing values that the user has filled in, the algorithm counts the number of missing values per variable and if the sum of the missing values exceeds the desired user percentage, then the whole variable is not taken into account when the A Priori rule mining algorithm runs, producing results only for the variables that fulfill the user defined criteria.

### 3.2 Statistics Tool

The multitude of data generated in the medical field requires the adoption of intelligent analysis techniques that allow specialists to summarize and present their knowledge, get insight into the data, test hypotheses, draw conclusions and directly interact with all the available information. Thus, the Statistics Tool provides specialists with instruments for: i) Analyzing and interpreting large patient data directly from the SensorART repository through powerful statistical techniques and Kaplan-Meier analysis, ii) Examining the results of previous therapeutic regimens and obtaining quantitative explanations of the observations through relevant statistical tests and iii) Generating efficient reports with intelligent data visualization. Using the tool the medical expert has multiple options, including the selection of population of interest, to work only with data from specific visits, to choose the variables of interest (e.g. heart related, sensor related, laboratory related) and the method of interest from a complete set of basic and advanced features covering both clinical and research needs of clinical partners (basic statistics-mean, variance, std, quantile, length, paired T-test, unpaired T-test, F-test, \( \chi^2 \) tests and Kaplan-Meier analysis).

The Statistics Tool is based on the R environment (http://www.r-project.org) for its back-end functionalities except for the Kaplan-Meier component. The latter allows specialists to perform survival analysis and generate a Kaplan-Meier plot. In clinical studies, the researchers are usually interested in the time until the patients in a study present a specific event or endpoint. In the context of SensorART, these were defined as death, cerebral bleeding, gastrointestinal bleeding, ischemic stroke, TIA (transient ischemic attack) and thromboembolic events. The Kaplan-Meier tool is based on a standard algorithm for determining, directly from the SensorART repositories, the fraction of patients living...
Figure 2  Screenshots from (a) Association Rules Tool, (b) Statistics Tool, (c) Treatment Support Tool and (d) Weaning Tool
up to the occurrence of a specific event. The starting time is always considered the time of VAD implantation and thus the start of treatment.

3.3 Treatment Support Tool

The Treatment Support Tool supports the specialists on the most suitable treatment plan according to the condition/phase of the patients (stabilized clinical state, normal phase in home conditions, worsening phase and/or reanimation phase). Its functionality includes the calculation of several acknowledged risk scores along with the prediction of alternative treatments outcome with respect to adverse events appearance. More specifically, the Treatment Support Tool provides two functionalities, calculation of known risk scores and treatment prediction based on risk for adverse event appearance.

In the first case, several known scores of survival are incorporated into the tool to allow rapid decisions and to foresee possible complications after VAD implant. All risk scores are calculated for similar and partially overlapped – but not identical – objectives including prediction of: i) Expected survival/the risk of death on medical therapy, ii) Expected survival/the risk of death after LVAD implantation and iii) Probability of specific complications (e.g. right ventricular failure) after LVAD implantation. Unfortunately, some risk factors for death without operation are also associated with worse postoperative survival and/or higher probability of complications, making difficult to define the risk/benefit profile for individual patients. In this context, four risk scores are included in the Treatment Support Tool:

- the Heart Failure Survival Score (HFSS), which provides an estimation of expected 1-year survival [13],
- the Seattle Heart Failure Model (SHFM), which provides an estimation of expected 1-, 2- and 3-year patient survival [14],
- the Model for End-Stage Liver Disease (MELD), which estimates risk for multi-system malfunctions and post-operative complications [19],
- the RVF risk score (RVFRS), which estimates risk for right ventricular failure [27].

Concerning risk prediction based on adverse events appearance, this modality assesses the risk of adverse events in the case of LVAD implantation. It has been developed by applying machine learning techniques in an annotated dataset. In model building, several widely known classification methodologies have been tested: Naïve Bayes classifier (NB), k-nearest neighbor (kNN), Decision trees (DT), Random forests (RF), Multilayer perceptron (MLP) neural networks and Support Vector Machines (SVMs), using commonly used parameters, proposed in the literature:

- NB classifier was implemented by modeling numeric values using normal distributions.
- kNN was implemented with \( k = 3 \) and based on the Euclidean distance.
- DT were implemented using the C4.5 algorithm, using the pessimistic error rate based method (sub-tree replacement) for pruning, with confidence factor 0.25 and 2 as minimum instances in a leaf.
- MLP architecture was implemented with 1 hidden layer, 0.3 learning rate and 500 maximum number of epochs.
- RFs were based on 10 decision trees.
- SVM was implemented with polynomial kernel.

Based on the obtained results (presented in Section 4) and the fact that the medical experts preferred a mechanism that can offer interpretability of the classification outcome, the DT have been finally selected.

3.4 Monitoring Tool

The Monitoring Tool offers monitoring of day-to-day LVAD and patient parameters and their association with the appearance of specific adverse events. The monitoring parameters used are: Pump flow, Pump speed, Pump index, Pump power, Temperature, Systolic blood pressure, Diastolic blood pressure, Pulses, Weight, INR and Anticoagulant treatment. Those parameters can come directly from the patient or, in the future implementation of the Sensor-ART platform, can be automatically obtained through a set of implantable and other sensors. In addition, several adverse events are also recorded including bleeding, arrhythmia, heart failure, thromboembolism (major), thromboembolism (minor) and pump thrombosis.

The patterns that were used to develop the prognostic model were extracted from the dataset. Again, NB classifier, kNN, DT, RF and MLP classifiers were tested, while DT have been finally selected based on the obtained results (Section 4) and the fact that the medical experts preferred the idea of a transparent decision mechanism against a black-box approach (such as e.g. in the case of MLPs).

3.5 Weaning Tool

The Weaning Tool can be used to identify the most appropriate candidates for weaning from the VAD support. As already mentioned in Section 2, all proposed approaches reported in the literature for supporting optimal ventricular assist device weaning make use only of strict rules. In our proposed tool, a Fuzzy Knowledge Subsystem is incorporated in order mainly to be more flexible on the decision boundaries and closer to the human logic compared to classical binary (crisp) logic. More specifically, the Weaning tool enables specialists to create and modify expert rules for weaning, in the form of comprehensive and personalized IF-THEN rules. The tool combines expert knowledge with fuzzy 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. The tool is based on the crisp engine and the fuzzy knowledge subsystem [64], in order to create initial knowledge-based models and then transform them into fuzzy models. All patient data, such as patient information (e.g. demographics, medical history, medication), VAD parameters, sensor measurements, laboratory measurements and clinical evaluations, are used as inputs into the fuzzy models, in order to provide the status of each patient (candidate for weaning or not).
Concerning the Fuzzy Knowledge Subsystem, being the most innovative part of the Weaning tool, the main idea is to produce a fuzzy model for a specific domain of application based on initial knowledge for this area provided by domain experts. This knowledge is formatted in a set of initial crisp rules, i.e. a collection of “IF...THEN...” rules. More specifically, each crisp classification rule \( r_i^{\text{cr}}(x, \theta_i^{\text{cr}}) \) is expressed as:

\[
d_i^{\text{cr}} = g_{[\text{cr}]}^{\text{op}_j} \left( a_j, \theta_i^{\text{cr}} \right) \land \ldots \land g_{[\text{cr}]}^{\text{op}_j} \left( a_j, \theta_i^{\text{cr}} \right) = 1, \quad a_j = \theta_i^{\text{cr}}, \quad \text{else, } \quad 0,
\]

where \( g_{[\text{cr}]}^{\text{op}_j} \) is the crisp membership function, with \( \text{op}_j = \{=, \neq, <, >, \leq, \geq \} \) and defined as can be seen in ▶Figure 3.

The symbol “\( \land \)” denotes the binary AND operator. All crisp rules from the medical rule set that have as consequent the same class are combined in a single class rule, defined as:

\[
M^{\text{cr}} \left( x, \Theta^{\text{cr}} \right) = \Phi^{\text{cr}} \left( R_1^{\text{cr}}, R_2^{\text{cr}}, \ldots, R_N^{\text{cr}} \right),
\]

where \( M^{\text{cr}} \) is the crisp model, \( \Theta^{\text{cr}} \) is the threshold vector containing all thresholds used in the model, \( \Phi^{\text{cr}} \) is a decision function and \( N \) is the number of classes in the problem, and thus the number of class rules \( R^i \).

The crisp model \( M^{\text{cr}} \) can be transformed into an equivalent fuzzy model \( M^{f} \) as follows: The crisp membership function \( g^{\text{cr}} \) is replaced by a fuzzy one \( g^{f} \). The binary AND and OR operators are replaced by \( T_{\text{norm}} \) and \( S_{\text{norm}} \) functions, respectively. The decision function \( \Phi^{\text{cr}} \) is replaced by a defuzzification function \( \Phi^{f} \).

Based on these changes, the fuzzy model is defined as:

\[
M^{f} \left( x, \Theta^{f} \right) = \Phi^{f} \left( R_1^{f}, R_2^{f}, \ldots, R_N^{f} \right),
\]

where, \( \Theta^{f} \) is the parameter vector containing all parameters used in the fuzzy model and \( R^i \) is the fuzzy class rules, defined as:
where \( r_i \) is the fuzzy rule defined as:

\[
\begin{align*}
R_i^f(x, \theta_i^f) &= T_{\text{norm}}(r_1^f(x, \theta_1^f), \ldots, r_n^f(x, \theta_n^f)), \\
S_{\text{norm}}(g_1^f(a_1, \theta_1^f), \ldots, g_n^f(a_n, \theta_n^f)).
\end{align*}
\]

The obtained fuzzy model \( M^f \) is optimized with respect to \( \Theta^f \) parameters. For this purpose an objective function must be defined using a training dataset (such as the square error function), and then minimized with respect to a \( \Theta^f \) using a local or global optimization technique. Local optimization techniques start from an initial point and result to the respective local minimum while global optimization techniques attempt to find at least one local minima (which are potentially global) of the objective function inside a bounded set. The described methodology for fuzzy expert systems creation is based on the fuzzyfication of an initial (crisp) medical rule set. Thus, the final fuzzy expert system is the initial rule set with more “flexible” boundaries and optimized based on a training set.

The methodology can be applied to any given rule set. In the framework of the Weaning Tool, the crisp and fuzzy rule engines have been developed for two relevant models in the literature i.e. the Dandel et al. [36] set of rules and Birks et al. [37] flow chart. Although, the original versions of the models include only crisp rules, fuzzy models have also been developed since the definition and parameter set of the fuzzy model allows it to be extremely more flexible and thus being able to cope with the complexity of the respective medical decision.

### 3.6 Speed Selection Tool

Setting the pump speed of the VAD is an important parameter in order to achieve the optimal cardiac output, and ensure the patient’s quality of life. In a critical care setting, the desired operating point of the VAD may be determined by a specialist or technical personnel and adjusted to provide more or less cardiac output depending on the status of the patient. However, when the patient leaves the critical care setting, a clinician is no longer readily available and the device must provide adequate cardiac output to sustain the patient’s level of activity without clinical supervision. In addition, as the patient recovers and regains his strength, a change in the VAD speed might be required.

Cardiac output can be increased by increasing the pump speed. However, two important constraints should be taken into account regarding the pump speed. First, if the speed is too low, blood may regurgitate from the aorta to the left ventricle through the pump (backflow). Second, if the pump speed is too high, the pump will attempt to draw more blood from the ventricle than is available, resulting in the suction phenomenon. A solution to maximize cardiac output while operating the pump at a safe speed is to operate the pump at a speed just below suction. The drawback to this solution is that a pump speed that does not cause suction may still have adverse effects on other physiological parameters.

In this framework, the proposed Speed Selection Tool has been developed enabling the specialists to analyze simulation sessions from the VAD Simulation platform, investigate the potential effect on important hemodynamic variables (such as cardiac output and arterial pressure) and determine a pump speed that provides adequate cardiac output for the patient to maintain his current level of activity. In this framework, we designed a flowchart (Figure 4a) for the speed selection process currently followed after the operation. The Left Atrial Pressure (LAP) check is substitute for echo examination, which is used to check if the aortic valve is opening correctly.

As shown above in the flowchart, the automated identification of VAD pump speed depends on the automated detection of suction events in the pump flow signal. In this framework, a tool has been developed (Suction Detection Tool), connected with the Simulation Platform, in order to provide to the specialists a powerful assistant in their attempt to analyze data from simulation sessions, identify different pump states and possible issues regarding to the suction phenomenon. The process is shown graphically in Figure 4b. The Suction Detection Tool processes simulation sessions from the Simulation Platform, allowing specialists to simulate the be-
haviour of a patient's circulatory system, using different VAD types and functional parameters in order to be supported to the speed decision.

3.7 Suction Detection Tool

Initially, an interconnected upload mechanism allows the submission of simulation sessions from the VAD Simulation Platform. The dataset requested is composed of cardiac and circulatory variables and other parameters important to obtain the specific object's (patient or animal) patho-physiological condition. The operator, adjusting the circulatory model parameters is able to obtain the desired hemodynamic status. Some of the data transmitted from SDSS to VHSP are: patient's weight, cardiac output, mean central venous pressure, duration of simulation etc, selected according to clinical partner's suggestions. Next, the simulated pump flow signal is returned back to SDSS, together with the following traces: Left Atrial Pressure, Left Ventricular pressure, Aortic Pressure, VAD Flow, heart rate, Total Cardiac Output and pump speed in RPM.

A new suction detector algorithm has been developed based on the detection of the sudden decreases in signal's baseline. The methodology is based on online estimation of a Gaussian Mixture Model (GMM) with two mixtures corresponding to non-suction & suction classes. More specifically, the proposed methodology is consisted of three steps: i) signal windowing, ii) GMM based classification and iii) GMM parameter adaptation. In our GMM model the only time varying parameter that was selected is the mean of the non-suction mixture [64]. Reducing degrees of freedom in the model ensures higher reliability.

4. Datasets and Results

In order to evaluate each proposed tool, related datasets were used. In the case of Treatment Support Tool and especially of the risk of adverse events prediction, sample data from 49 patients have been used. The variables recorded are mentioned in Table 1.

The re-hospitalizations for all patients for the first year and follow-up data have been used to determine the occurrence of adverse events: among 49 patients treated with VADs; 35 had no relevant adverse events; 3 had bleeding episodes and 11 died. The dataset have been obtained from the Heart Failure and Transplantation Division, "A. De Gasperis" Cardiothoracic & Vascular Department, Niguarda Ca’ Granda Hospital, Milan, Italy. Although being very common, infections of the entry site of the driveline were not considered as relevant adverse events, and thus were excluded from the study. The dataset included several missing values thus replacement of missing values has been applied using the 3-Nearest Neighbors technique. As the number of the prototypes per category is unbalanced, resampling from the normal distribution of the minority class procedure has been employed, i.e. a normal distribution was calculated for each feature, and then, N random values were included from the study. The dataset included several missing values thus replacement of missing values has been applied using the 3-Nearest Neighbors technique.

<table>
<thead>
<tr>
<th>(a)</th>
<th>Initial dataset (D1)</th>
<th>(b)</th>
<th>Initial dataset with replaced missing values (D2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sens (%)</td>
<td>PPV (%)</td>
<td>Acc (%)</td>
</tr>
<tr>
<td>NB</td>
<td>37.66</td>
<td>36.89</td>
<td>67.35</td>
</tr>
<tr>
<td>kNN</td>
<td>32.9</td>
<td>43.15</td>
<td>57.14</td>
</tr>
<tr>
<td>DT</td>
<td>35.58</td>
<td>35.14</td>
<td>67.35</td>
</tr>
<tr>
<td>RF</td>
<td>30.48</td>
<td>23.19</td>
<td>65.31</td>
</tr>
<tr>
<td>MLP</td>
<td>32.9</td>
<td>31.5</td>
<td>57.14</td>
</tr>
<tr>
<td>SVM</td>
<td>44.85</td>
<td>46.46</td>
<td>69.39</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(c)</th>
<th>Resampled dataset (D3)</th>
<th>(d)</th>
<th>Resampled dataset with replaced missing values (D4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sens (%)</td>
<td>PPV (%)</td>
<td>Acc (%)</td>
</tr>
<tr>
<td>NB</td>
<td>85.85</td>
<td>86.19</td>
<td>85.71</td>
</tr>
<tr>
<td>kNN</td>
<td>69.59</td>
<td>69.24</td>
<td>67.35</td>
</tr>
<tr>
<td>DT</td>
<td>79.65</td>
<td>79.41</td>
<td>79.59</td>
</tr>
<tr>
<td>RF</td>
<td>84.91</td>
<td>87.34</td>
<td>85.71</td>
</tr>
<tr>
<td>MLP</td>
<td>80.12</td>
<td>80.12</td>
<td>79.59</td>
</tr>
<tr>
<td>SVM</td>
<td>87.6</td>
<td>88.35</td>
<td>87.76</td>
</tr>
</tbody>
</table>
In order to develop the prognostic procedure that assesses the risk of an adverse event appearance in the next day (Monitoring Tool), based on the recorded data for the last three days, data from six patients were included. The dataset have been obtained from the Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium. The patterns that were used to develop the prognostic model were extracted from this dataset. In order to extract a pattern, four consecutive days should exist in the recording and in this case the data from the three days are used as features and the event from the fourth day as the annotation. Thus, the dataset is formulated as: $D = \{X, T\}$ where $X$ being a $33 \times N$ matrix with each row being one data pattern of the dataset with 33 features (i.e. the 11 variables for three consecutive days), and $T$ being the annotation of the respective pattern. Using this procedure, a dataset with 1026 patterns has been created, including patterns covering three classes, being normal (1022), ventricular tachycardia (3) and heart failure (1). Initially, since the number of the patterns per category is unbalanced, the same resampling procedure (resampling from the normal distribution of the minority class) was applied to create a balanced dataset.

The classification methodologies that were employed include NB classifier, kNN, C4.5, RF and MLP neural networks, using the parameters already mentioned previously. Evaluation was performed using: i) the 10-fold stratified cross validation method and ii) the initial dataset (before the resampling) and the respective confusion matrices were obtained, while metrics such as classification accuracy and sensitivity/positive predictive value per class are calculated. The obtained results are shown in Table 3.

In the framework of the Weaning Tool and the optimization of the fuzzy model, data from 11 patients are used, collected from the 3rd Cardiology Department, School of Medicine of the University of Athens in Greece from 2004 to 2009. Almost 70 parameters are recorded. Four (4) of the patients were successfully weaned from VAD. Recordings were made in three main patient conditions, i) on pump, ii) off pump for 5 mins, and iii) off pump for 15 min. The set of rules presented by Birks et al. [37] were used as input to the above described methodology and the results are presented using the above described dataset.

The on-pump data and the off pump for 5 mins data were used for optimization. These included 10 patterns for weaning and 22 patterns for non-weaning. The training dataset is formulated as: $D_{max} = \{X, T\}$ where $X$ being an $6 \times 32$ matrix with each row being one data pattern of the dataset (i.e. $X_i = x$, with $i = 1, ..., 32$ ), and $T$ being an $2 \times 32$ matrix with each row being the annotation of the respective pattern (i.e. $T^i = t$ with $t = 1, ..., 32$). A target vector for a specific data pattern $(t)$ is defined as:

$$t = \begin{cases} [1,0] & y_1(\text{wean and remove VAD from patient}) \\ [0,1] & y_2(\text{no wean}) \end{cases}$$

(8)

The optimization function is based on the sum of square errors function:

$$L_{\text{norm} \cdot \Theta}(x, \Theta') = \sum_{i=1}^{32} M^i(X^i, \Theta') - T^i(9)$$

A local optimization technique has been used. As mentioned above, by setting: $\theta_{i, a}' = \theta_i'; \theta_{i, d}' = 1$ it is: $M(x, \Theta') \rightarrow$
Finally, concerning the Suction Detection Tool, two different datasets, provided by the Institute of Biocybernetics and Biomedical Engineering of Polish Academy of Sciences (IBBE-PAS) and annotated by medical experts, are used in order to test our methodology:

1. 10 pump flow signals with suction events approximately 46 minutes in total duration are collected from the VAD Simulation Platform which enables the specialists to simulate the behaviour of a patient’s circulatory system with connected a real assist device (e.g. nonpulsatile blood pump) [64].

2. 26 pump flow signals approximately 20 hours are produced from a numerical simulator, simulating different medical cases with predefined pathologies. A large number of medical realistic cases with patient pathologies were defined and determined by medical doctors [64].

The confusion matrices, sensitivities, specificities and the total accuracy are given in Table 6 and Table 7 for the two datasets, respectively.

5. Discussion

In recent years, the use of VADs for the treatment of end stage heart failure has steadily increased. This widespread application has increased research in the field, however, based on the literature review, decision support systems concerning VAD patients have not been proposed over the past years; only research works that support individually aspects of the problem have been presented. In this context, the SDSS is innovative, supporting medical and VAD experts through the different phases of VAD therapy. This paper focuses on the presentation of the SDSS, the main decision support component of the Sensor-ART system. SDSS assists specialists on designing the best treatment plan for their patients before and after VAD implantation, analysing patients’ data, testing hypotheses, extracting new knowledge and making informative decisions.

The proposed SDSS Tools have been integrated in a unified environment, covering all the specialist’s requirements and providing a unique selection of features. More specifically, all Tools are web-based, accessible through an intuitive graphical interface allowing secured access to available data. In addition, different types of data and detailed reports are provided to the medical experts from the majority of the Tools. More important, the proposed system doesn’t address just a single issue but assists the specialists on remote monitoring and VAD control and receive information on patient status. It enables the design of the most proper treatment plan for every patient before and after VAD implantation and enables the analysis of patients’ data for the extraction of new knowledge and making informative decisions. Finally, the SDSS enables the potential to translate valuable expert knowledge into standardized, personalized and optimized VAD therapy.

Summarizing, the proposed system presents several advantages:

<table>
<thead>
<tr>
<th>Initial fuzzy model $\Theta_f^{initial}$</th>
<th>$\Theta_f'_{max}$</th>
<th>Optimized fuzzy model $\Theta_f''$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annotation</td>
<td>Regression</td>
<td>Annotation</td>
</tr>
<tr>
<td>wean</td>
<td>no wean</td>
<td>wean</td>
</tr>
<tr>
<td>fuzzy model</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>no wean</td>
<td>6</td>
<td>22</td>
</tr>
</tbody>
</table>

Table 5: Weaning Tool Classification Results for Sensitivity (Sens), Positive Predictive Value (PPV) and Accuracy (Acc), for the Initial ($\Theta_f^{initial}$) and the Optimized ($\Theta_f''$) Fuzzy Models

<table>
<thead>
<tr>
<th>$\Theta_f^{initial}$</th>
<th>$\Theta_f''$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Square error</td>
<td>10.87</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td>40</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>100</td>
</tr>
<tr>
<td>Classification accuracy (%)</td>
<td>81.25</td>
</tr>
</tbody>
</table>

Table 6: Weaning Tool Confusion Matrices for the Initial ($\Theta_f^{initial}$) and the Optimized ($\Theta_f''$) Fuzzy Models

<table>
<thead>
<tr>
<th>DATASET I</th>
<th>GMM No Suction</th>
<th>GMM Suction</th>
<th>DATASET II</th>
<th>GMM No Suction</th>
<th>GMM Suction</th>
</tr>
</thead>
<tbody>
<tr>
<td>No-Suction</td>
<td>1904</td>
<td>71</td>
<td>63547</td>
<td>1568</td>
<td></td>
</tr>
<tr>
<td>Suction</td>
<td>117</td>
<td>510</td>
<td>3480</td>
<td>4555</td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>0.96</td>
<td>0.81</td>
<td>0.98</td>
<td>0.57</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>0.94</td>
<td>0.88</td>
<td>0.95</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>Accuracy</td>
<td>0.93</td>
<td>0.93</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• It includes tools covering all aspects of VAD patients’ management, thus providing an overall VAD patient management system and decision support mechanism and not just a problem-specific technique.
• It follows a holistic approach, including all models presented in the literature along with user-defined models, thus providing a “mixture-of-experts” approach.
• It provides an automated and easy-to-use platform that can be operated using either data from the database or by data-input forms.

Besides the advantages derived from the overall system, each individual tool of the SDSS is either innovative or presents advantages and novelties compared to other approaches proposed in the literature.
• The knowledge discovery tools (Association Rules Tool and Statistics Tool) allow the medical expert to extract new knowledge and data associations or analyze the data using statistical techniques. Such an analysis has neither presented as research in the literature (data mining on VAD data) nor publicly offered as an automated tool.
• In the same manner, currently there is no other research in the literature that monitors LVAD patients using day-to-day data and employs these data for automated prognosis of adverse events. Thus, the Monitoring Tool constitutes one of the innovations of the SDSS, providing valuable assistance to patient management.
• The Treatment Support Tool includes all medical scores presented in the literature along with alternative support with respect to adverse events appearance, based on patient pre-operation and post-operation data.
• Regarding VAD Weaning, the SDSS provides a holistic approach, including all related models presented in the literature allowing the addition of newer models that may be derived. In addition, all available models are automatically transformed into fuzzy sets, thus overcoming fundamental limitations of the crisp logic. The Weaning Tool provides a “mixture-of-experts” approach, allowing the medical user to assess if a patient is candidate for weaning using all available knowledge weaning models and thus leading to the most informative decision.
• The Speed Optimization and Suction Detection Tools are connected with a VAD-Heart simulator providing the ability to test several different hypotheses. More specifically, they provide to the medical users a powerful assistant in their attempt to effectively plan the treatment strategy for a patient. In this framework, medical users are able to load different simulation sessions from the VAD Simulation Platform: i) Analyzing data in terms of the suction problem, ii) investigating the potential effect on important hemodynamic variables and iii) determining a pump speed that maintains a safe physiological operating point while providing adequate cardiac output for the patient.

In order to evaluate our risk prediction tools (namely the Treatment Support Tool and the Monitoring Tool) a wide selection of classifiers following different approaches (probabilistic, neural, non-parametric, decision tree, ensemble) were tested. As each of the classification approaches can capture distinctive data characteristics, the wide testing of algorithms ensures that selected models are the ones best adapting to the problem. Furthermore, well-known cross-validation techniques were employed (leave-one-patient-out cross-validation and 10-fold-stratified cross-validation), thus ensuring the quality of the obtained results. Especially in the case of the leave-one-patient-out cross-validation technique the algorithms each time are validated with new, unseen data from a new patient, evaluating in this way the generalization ability of the classifier. In addition, existing treatment scores included in the system (namely the HFSS, SHFM, MELD, RVFRS) have been already validated in related studies [13, 14, 19, 27] respectively.

The validation of the proposed platform as a system is carried out separately for each component. In order to verify that the proposed modules meet user specifications and fulfill user intended purpose, we recorded the conclusion derived after a trial process. The medical users used personalized annotated data to test the reliability of the exported results. A specific questionnaire based on the System Usability Scale (SUS) methodology was used [65]. The validation process verified that all modules actually meet user needs, the majority of the functional specifications were correct in the first place while verification ensured that the product has been built according to the initial requirements and design specifications. An average SUS score of 72.5% was identified from medical experts. During the tests, fine-tuning and suggestions were mentioned by the users, contributing to the robustness of the modules. Validation of the obtained results (in terms of accuracy, etc.) has been carried out with initial patient sets provided by Niguarda Ca’ Granda Hospital, University Hospital Leuven and University of Athens, as de-

<table>
<thead>
<tr>
<th>Table 7</th>
<th>Classification Accuracy Results for Treatment Support, Monitoring, Weaning and Suction Detection Tools of the SDSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDSS component</td>
<td>Dataset</td>
</tr>
<tr>
<td>Treatment Support Tool</td>
<td>49 patients</td>
</tr>
<tr>
<td>Monitoring Tool</td>
<td>6 patients / 1026 patterns</td>
</tr>
<tr>
<td>Weaning Tool</td>
<td>11 patients / 32 patterns</td>
</tr>
<tr>
<td>Suction Detection Tool</td>
<td>36 simulated signals / approximately 23 hours</td>
</tr>
</tbody>
</table>
scribed in Section 4. Data-use agreements have been signed with respective bodies. Still, additional patient data/trials are needed to verify the accuracy of the tools. Currently the SDSS is populated with data from participating hospitals/centers. As the number of new VAD implanted patients per year is not very high and patients have to be monitored for a long period so as to include potential adverse events in the dataset, large scale trials with the collaboration of additional institutions are needed before the SDSS is put into everyday clinical practice.

The powerful and complete nature of the SDSS implies that specialized personnel of cardiovascular centers are expected to primarily utilize this system: i) Cardiac and vascular surgeons who are responsible for the implantation and weaning of the VAD devices. ii) Cardiologists and general clinicians who are responsible for the on-going care and management of the patients and require advanced expertise in order to make specific adjustments to the treatment plan, e.g. regulate drug therapy, titrate medical therapy to the functioning of the VAD device etc., (iii) Biologists and similar researchers interested in investigating and understanding the patient/VAD hemodynamic relationships during assistance.

Furthermore, the proposed system will be potentially used to transfer the success and deductions of the most experienced centers to those less established. In general, VAD therapy entails processing complex, uncertain and incomplete data which are dynamically evolving. As a consequence, the medical centers with a greater patient volume are at an advantage compared with those that treat only a few VAD patients per year. The introduction of the proposed SDSS has been proposed over the past years. In this context, the proposed SDSS creates a hallmark in the field, supporting medical and VAD experts through the different phases of VAD therapy. Seven complete tools have been developed and integrated in a unified environment, covering all the specialists' requirements and providing a unique selection of features. Using the SDSS management of VAD patients can be changed. Treatment decisions are supported by models and tools that can estimate patient risk (for death or adverse events). VAD speed selection currently done mainly with a trial-error process is optimized using simulations, therefore minimizing patient risk. Monitoring patient measurements and VAD parameters altogether is a major enhancement in current patient management and is further exploited for the early identification of potential adverse events. Research is also supported by tools that mine the specialized repository and extract knowledge to complement the knowledge already embedded to the system. As a result, the SDSS fulfills all the functional requirements proposed by the medical experts while assists specialists on designing the best treatment plan for their patients before and after VAD implantation, analysing patients' data, hypothesis testing, extracting new knowledge and making informative decisions.

Acknowledgements

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