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Developing a Hybrid Decision Support Model for Optimal Ventricular Assist Device Weaning

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Abstract

Background—Despite the small but promising body of evidence for cardiac recovery in patients that have received ventricular assist device (VAD) support, the criteria for identifying and selecting candidates who might be weaned from VAD support have not been established.

Methods—A clinical decision support system (CDSS) was developed based on a Bayesian Belief Network that combined expert knowledge with multivariate analysis. Expert knowledge was derived from interviews of 11 members of the Artificial Heart Program at the University of Pittsburgh Medical Center. This was supplemented by retrospective clinical data from all VAD patients considered for weaning between 1996 and 2004 (n=19). Artificial Neural Networks and Natural Language Processing (NLP) were employed to mine these data and extract 28 most sensitive variables.

Results—Three decision support models were compared. The model, exclusively based on expert-derived knowledge, was the least accurate and most conservative. It under-estimated the incidence of heart recovery: incorrectly identifying 4 of the successfully weaned patients as transplant candidates. The model derived exclusively from clinical data performed better but mis-identified two patients: one who was successfully weaned, and one who ultimately needed a cardiac transplant. An expert-data hybrid model performed best, with 94.74% accuracy and 75.37% ~ 99.07% confidence interval, misidentifying only one patient who was weaned from support.

Conclusions—A CDSS may both facilitate and improve the identification of VAD patients who are candidates for cardiac recovery, and may benefit from device removal. It could be potentially used to translate success of active centers to those less established and thereby expand utilization of VAD therapy.

Keywords

Cardiac recovery; Circulatory assist device; Bayesian modeling; Transplant

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1. Introduction

The use of ventricular assist devices (VADs) for treatment of end-stage heart failure has steadily increased over the past 20 years [1, 2]. For a growing number of patients with advanced or refractory cardiac disease, VAD therapy has demonstrated the potential to extend life, improve the quality of remaining life [3-6], and even lead to cardiac recovery [7-8]. Following the first report of VAD weaning in 1995 [9], numerous centers have demonstrated the prospect of cardiac recovery for a subset of VAD patients, including University of Pittsburgh Medical Center (UPMC), Texas Heart Institute, Berlin Heart Center, Columbia Presbyterian, Toronto General Hospital, and others. Nevertheless, the incidence of VAD weaning remains relatively low compared to the volume of patients treated with VAD therapy [1, 10-13].

Although studies of myocardial function of VAD patients suggest that chronic unloading of the native heart can lead to “reverse” remodeling [5, 14-16], the underlying cellular, biochemical, and biomechanical mechanisms remain uncertain and are in fact topics of active research. It is therefore not surprising that different sets of criteria have been employed for attempting to wean patients from VAD support [4, 17-20]. Lack of a definitive marker in turn limits the confidence to screen patients for recovery, and may be partly responsible for the scarcity of VAD weaning.

The decision to wean a patient from VAD support is further complicated by the distributed expertise involved in post-operative management. It also entails competitive objectives (e.g. survival rate, quality of life, patient preference), and alternative treatment strategies. This complexity confounds efforts to articulate a definitive *algorithm* for identifying and facilitating cardiac recovery. Consequently, it also hinders the translation of the success of experienced centers to those less established.

The complexity and uncertainty of this decision process makes it an excellent candidate for a clinical decision support system (CDSS). Motivated by success of such systems in numerous fields of medicine [21-27], this study was undertaken to develop a CDSS specifically customized to the management of VAD patients, with particular emphasis on ventricular recovery. The clinical experience at UPMC with 19 VAD patients that were considered for weaning (between 1996 and 2004) [28-30] was used as the basis for evaluation of this model.

2. Material and Methods

Two primary sources of procedural knowledge were collected for the current study: retrospective statistical analysis of patient data and expert knowledge. These are described briefly below.

2.1 Data-derived Knowledge

In accordance with HIPAA (Health Insurance Portability and Accountability Act of 1996), de-identified patient data were obtained from the UPMC VAD registry via an honest broker. The study protocol was approved by Institutional Review Board at University of Pittsburgh. Patients included those supported by either left ventricular assist device (LVAD) or bi-ventricular assist device (BiVAD) who were originally identified as bridge-to-transplant but later considered for recovery between 1996 and 2004 (n=19). All patients were supported with the Thoratec (Pleasanton, CA, US) pneumatic paracorporeal systems except one who received the Thoratec implantable VAD. Of the 19 patients that were considered for weaning, 10 were eventually weaned and 9 received a cardiac transplant. Table 1 provides details of this cohort of patients.

A total of 250 numerical variables from 7 categories were analyzed using commercially available Artificial Neural Network (ANN) software (Clementine 7.0, SPSS, Chicago, IL) to identify the most predictive variables and their associated thresholds. The variables were decimated using the *prune* algorithm to eliminate those that were weakly correlated with weaning. To avoid overtraining, only 50% of the data sets were analyzed at a time [31]. Additional analysis was performed on the written shift notes recorded by the clinical staff responsible for routine monitoring and maintenance of these patients. Language patterns within the textual data contained therein were identified by Natural Language Processing (NLP) using the software program Concordance 3.2 (Watt, R.J.C., Dundee, UK) [32]. The word patterns were tabulated in order of frequency and context and compared between weaned and transplanted patients.

2.2 Knowledge Acquisition from Expert Panel

Knowledge derived from retrospective experience was elicited through a series of structured interviews and questionnaires of eleven members of the multi-disciplinary Artificial Heart Program at UPMC, including: surgery, clinical bioengineering, nursing, and psychiatry. The interview was conducted individually and in small groups to derive a binary decision flowchart for selecting VAD weaning candidates. The flowchart was reviewed and revised in a second interview. The individual flowcharts were combined into final version and were presented to the full panel for approval. Figure 1 depicts the resulting decision flowchart, comprised of a 5-tier health status screening followed by a 3-tier evaluation (8 variables) of cardiac recovery. It defines an optimal weaning candidate as a non-ischemic patient who has been supported by the VAD greater than 4 weeks, with normal cardiac rhythm, positive nutritional status, and normal end-organ function. Indices of cardiac recovery, gathered through echocardiographic (ECHO) measurements[29], were considered optimal if the patient was able to maintain an ejection fraction (EF) > 40%, ventricular power (PWR) > 4 (mW/cm^4), and positive change in stroke area (SA) with temporary suspension of VAD support. Patients who passed this initial screening were referred for right heart catheterization (RH CATH). The hemodynamics required to pass this secondary screening includes pulmonary capillary wedge pressure (PCWP) < 20 mmHg, cardiac index (CI) > 2.2 $l/min/m^2$, and heart rate (HR) < 100 bpm. Satisfactory results of RH CATH allow patients to undergo treadmill ergometry according to a modified Naughton protocol. Patients capable of achieving peak oxygen consumption (VO_2) > 15 (mg/kg/min) while maintaining a respiratory exchange ratio (RER) > 1.0 at maximal exercise he/she will be referred to cardiac surgery for removal of the VAD.

Due to the binary nature of the final decision flowchart, weaning is only recommended if all variables are in their positive state; while in reality, experts may consider less than ideal situations (having a combination of variables in their positive and negative states). Therefore, experts were asked to take part in two 12-item questionnaires in which they were presented hypothetical case reports in which each of the indices of health and cardiac status were toggled and asked to express their confidence of successful weaning under those conditions. These questionnaires were completed in two separate sessions. To ensure consistency, questions were repeated in reverse order. If the probabilities did not directly compliment each other, the experts were asked to reevaluate their estimates. A final 8×6 matrix of probabilities was derived from averaging the confidence estimates elicited from all experts.

2.3 Decision Modeling

The variables extracted from data mining and expert interviews were modeled using a Bayesian belief network (BBN) using a custom-written software, GeNIe 2.0, developed at the Decision Support Laboratory at University of Pittsburgh [33]. The decision structure was represented graphically by depicting causal influences with arrows from parent variables (nodes) to children (nodes) [24]. By applying a probability distribution to each node, the joint probability is expressed as:

$$P(X_1, X_2, \ldots, X_n) = \prod_{i=1}^{n} P(X_i | parents(X_i)) \quad (2-1)$$

where $P(X_i \mid parents(X_i))$ represents the conditional probability of variable X_i, given the occurrence of the parents of this variable.

For each variable, mutually exclusive and cumulatively exhausted states were defined. Figure 2 shows an example of two of the nodes of the present model, illustrating the relationship between *primary device* and *outcome* (transplanted/weaned), and demonstrating their states, prior and conditional probabilities. Assuming all nodes were conditionally independent, all relevant variables identified by data mining were combined in a naïve BBN each having a direct relationship with outcome prediction. Three such BBN's were developed: (1) a *Data-driven Model*, comprised of 33 variables, (2) an *Expert Model* comprised of 15 variables, and (3) a *Hybrid Model* comprised of the combined set of 48 variables. The models were evaluated for each of the 19 patients in the study group by introducing the subset of available variables at the time of transplant or weaning to calculate the probability of weaning. These probability results were converted into a binary decision (*wean* or *transplant*) based on a threshold of 50%.

3. Results

The decision structure of the BBN models is shown in Figure 3. The variables (nodes) associated with the expert and data-driven models are separated by the dashed outline. The full set of nodes comprises the hybrid model.

3.1 Data-Driven Model

Data mining of the 250 numerical variables from 6 categories (demographics, complications, laboratory tests, exercise tests, RH CATH, and echocardiographic tests) using ANN yielded 28 variables that were most closely correlated with outcome, representing an 89% reduction in the data set. (See Table 2a-f.) In terms of *Demographics*, the ANN analysis identifies an *ideal* candidate for weaning as one who was supported by an LVAD rather than a BiVAD, implanted for < 100 days, < 38 years old, Caucasian, female, and non-ischemic (Table 2a). As noted in the analysis of the *Complications* variables (Table 2b), an ideal candidate for weaning is one with no history of renal complications or reoperation, and free from tamponade or other complications associated with bleeding. In terms of *Laboratory Tests* (Table 2c), the ANN analysis associated a greater chance of weaning with patients who had normal values for aspartate amino transferase (AST), creatinine clearance (CREAT), blood urea nitrogen (BUN), reticulocyte count (RET), magnesium (MG) and lactate dehydrogenase (LD). Based on the *Exercise* test (Table 2d), optimal candidates include those who are able to exercise for >= 5 minutes, with peak oxygen consumption > 45% (VO2%), metabolic equivalents > 4 (METS), and can perform at greater than 80% of maximum predicted heart rate (HR% target). Optimal *RH Catheterization* variables (Table 2e) include pulmonary capillary wedge pressure (PCWP) < 24 mmHg, pulmonary vascular resistance (PVR) < 1.1, mean pulmonary artery pressure (MPAP) < 25 mmHg, and a transpulmonary gradient (TPG) < 10 mmHg. Finally, the optimal *Echocardiographic* measurements associated with successful weaning (Table 2f) include ventricular power (PWR) > 4 mW/cm^4, a positive increase in stroke area (SA), stable systolic arterial pressure (ApSys), and stable fractional area change (FAC).

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This set of data with 28 elements was augmented with the frequency of keywords identified by NLP analysis within free text of the shift notes of the clinical engineers. These were clustered according to five contextual categories: (1) VAD malfunction, (2) socialization, (3) ambulation, (4) positive descriptor, and (5) nutrition. (See **Error! Reference source not found**. Table 3) When compared to transplanted patients, weaned patients were associated with fewer reports of VAD malfunction, better nutritional status, greater activity level, greater prevalence of positive descriptors, and received more visits from families and friends, as shown in Figure 4.

The predictions by this data-driven model summarized in Table 4a, mis-identified 2 of the 19 patients: classifying one patient that was successfully weaned as a transplant candidate, and one who was transplanted which the model identified as a candidate for weaning.

3.2 Expert Model

The predictive accuracy of the expert model is presented in Table 4b. This model was less accurate than the data model: identifying 6 of the 10 patients that were successfully weaned from VAD support; while the other 4 weaned patients were incorrectly identified as transplant candidates.

3.3 Hybrid Model

The hybrid model inherited the structure and numerical parameters from the previous two models. This model performed the best: producing only one incorrect prediction: recommending that a patient who had been weaned should have received a cardiac transplant. (See Table 4c.) This model has a prediction accuracy of 94.74% with 95% confidence interval between 75.37% and 99.07%. It is worthy of note that this patient eventually required a cardiac transplant within one year of weaning from VAD support.

4. Comments

The decision to wean a patient from VAD support entails processing complex, uncertain, and incomplete data which are dynamically evolving. In lieu of a definitive set of quantitative criteria, the decisions ultimately rely on the expert intuition and experience of the clinician. Consequently, those centers with greater patient volume are at an advantage compared to those treating only a few VAD patients per year. The introduction of clinical decision support system (CDSS) provides the potential to translate valuable expert knowledge to standardize, personalize and optimize VAD weaning therapy based on multi-factorial criteria. This may ultimately lead to a greater proportion of patients who are considered for weaning, which may in turn increase the proportion of patients initially referred for VAD insertion.

The translation of expert knowledge is not necessarily straightforward. In the present study, the counter-intuitive inaccuracy of the expert model suggests that the experts are not fully able to articulate the algorithm(s) by which they themselves formulate their treatment strategy. The data-driven model was also imperfect. It is also counter-intuitive that the combination of two imperfect models would yield an improved model. This may suggest that incorporation of expert knowledge serves to partially offset the effects of the small sample size of the data-driven model.

Conversely, the results of this study may be interpreted as suggesting that an otherwise imperfect model of the expert's decision process may be improved by the addition of quantitative, statistical data. Accordingly, the variables that were excluded from the expert model (Figure 1), yet shown to be statistically relevant can be subdivided into two sets: those which are consistent with clinical expectations and those which are either counter-intuitive or for which there is no clinical benchmark. The former variables, such as such as: *duration of implantation, gender, age, race,* etc. can be readily introduced into the expert model – with the approval of the expert – to correct for omissions that were "overlooked" when originally interrogating the expert(s). The counter-intuitive variables would be more appropriate for inclusion in the Bayesian component of the hybrid model.

A limitation of this study is the apparent bias introduced by the exclusive use of a single-center experience. The decision model would clearly benefit from enlarging the data set to include multiple centers and enlarging the expert knowledge base beyond the 11 polled in this study. Implementing this system across multiple medical centers will provide an opportunity to combine expert understanding of causal and/or synergistic relationships between parameters, which may improve the topology of the Bayesian network, compared to the naïve structure of the present model. On the other hand, it might be advisable to limit the data to the most experienced and/or successful centers, so as to translate their success to less experienced centers.

An additional bias was introduced by the pre-selection of the 19 patients used for this study. Although the prediction accuracy of the hybrid CDSS reported herein was very good (94.74%), the associated 95% confidence interval was relatively wide (75.37% ~ 99.07%). To achieve 94% lower bound of the confidence interval would require 1500 patients according to statistical power analysis. By virtue of the retrospective treatment of these data, it was not advantageous to include the 172 VAD patients that were *not* considered for weaning (between 1996-2004 at UPMC) since there is no way to discriminate retrospectively between patients that *could* have been entered into the weaning protocol. Likewise there is no way of knowing if the historic clinical decisions of the 19 patients are necessary *correct* or optimal decisions. Accordingly, an ongoing prospective study is currently being conducted wherein every consenting patient who receives a VAD is enrolled. By also evaluating long-term outcomes and adverse events, this ongoing study is hoped to provide a more informative and accurate decision support model.

Acknowledgments

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Abbreviation List

Term	Abbreviation
Artificial neural network	ANN
Systolic Arterial Pressure	ApSys
Aspartate Amino Transferase	AST
Bayesian Belief Network	BBN
Bi-ventricular assist device	BiVAD
Blood Urea Nitrogen	BUN
Clinical decision support system	CDSS
Cardiac Index	CI
Creatinine Clearance	CREAT
Echocardiography	ECHO

Term	Abbreviation
Ejection Fraction	EF
Fractional Area Change	FAC
Heart Rate	HR
Dehydrogenase	LD
Left ventricular assist device	LVAD
Magnesium	MG
Mean Pulmonary Artery Pressure	MPAP
Natural language processing	NLP
Pulmonary Capillary Wedge Pressure	PCWP
Pulmonary Vascular Resistance	PVR
Ventricular Power	PWR
Respiratory Exchange Ratio	RER
Reticulocyte Count	RET
Right Heart Catheterization	RH CATH
Stroke Area	SA
Transpulmonary Gradient	TPG
University of Pittsburgh Medical Center	UPMC
Ventricular assist device	VAD
Peak Oxygen Consumption	VO_2

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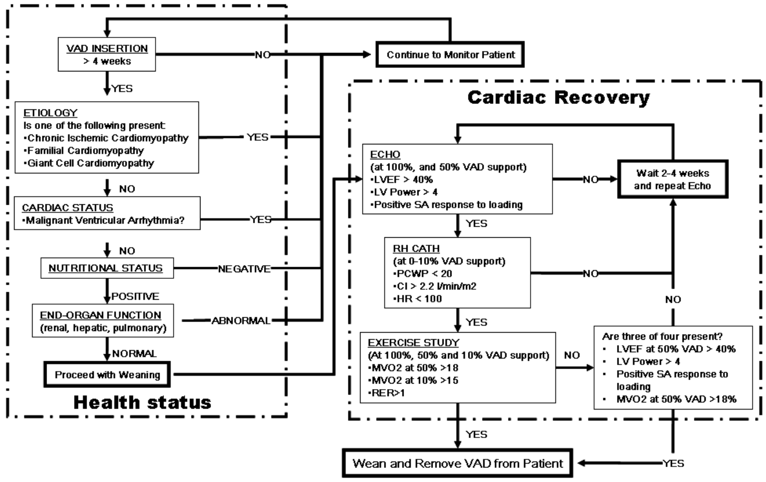

Figure 1.

Flowchart of the knowledge derived model for assessment of patients' readiness for weaning, based on expert interviews. (ECHO: echocardiogram weaning study, LV: left ventricle, EF: ejection fraction, SA: stroke area, RH CATH: right heart catheterization, PCWP: pulmonary capillary wedge pressure, CI: cardiac index, HR: heart rate, MVO2: Peak oxygen consumption, RER: respiratory exchange ratio)

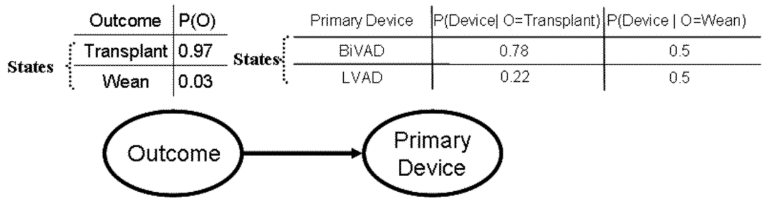

Figure 2.

Simple example of relationship between variables “Primary Device” and “Outcome” illustrating nodes, states and probabilities.

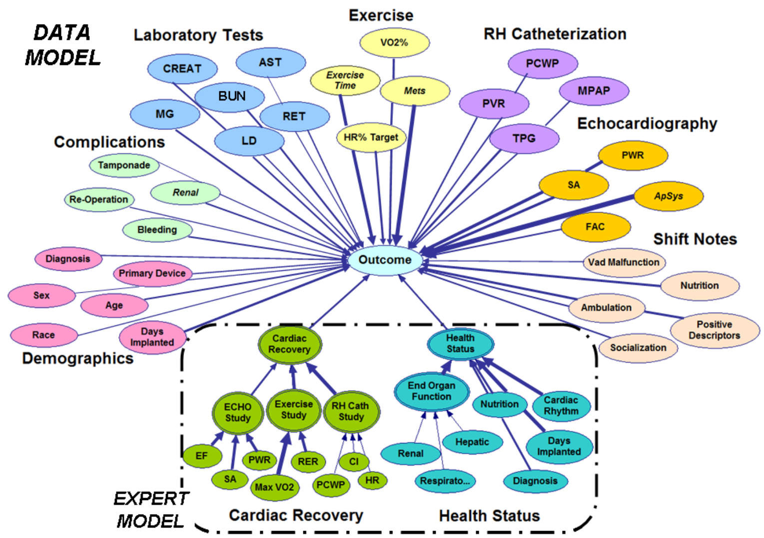

Figure 3.
Hybrid BBN model combining expert and data models.

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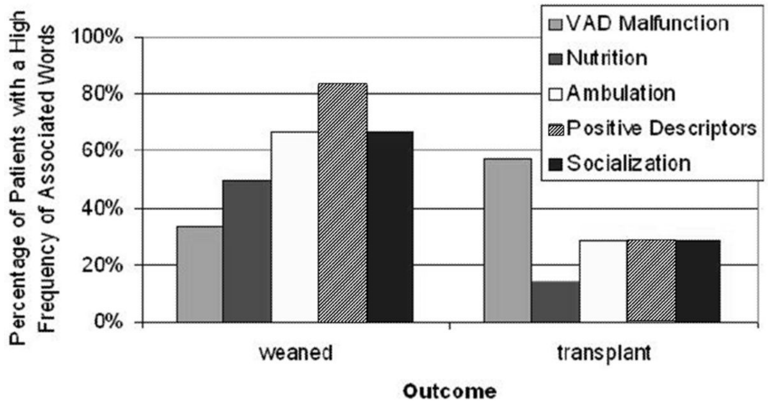

Figure 4.
Results of natural language processing (NLP) of shift notes.

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Table 1

Summary of patients' outcome, device configuration, one-year post-explant status and available data categories

Patient ID	Outcome	Device Configuration	1-year Post-Explant Follow-Up	Demographics	Complications	Laboratory	Right Heart Cath	Echocardiography	Exercise	Shift Notes
1560	Transplanted	Bi-VAD	Alive	√	√	√	√	√	√	
4075	Transplanted	Bi-VAD	Alive	√	√	√	√	√	√	
7869	Transplanted	Bi-VAD	Alive	√	√	√	√	√		√
8411	Transplanted	Bi-VAD	Alive	√	√	√	√	√		√
8883	Transplanted	Bi-VAD	Alive	√	√	√		√		√
8118	Transplanted	Bi-VAD	*Died*	√	√	√	√	√		√
9284	Transplanted	Bi-VAD	*Died*	√	√	√	√	√	√	√
8682	Transplanted	LVAD	Alive	√	√	√		√		√
8794	Transplanted	LVAD	*Died*	√	√	√		√		√
2297	Weaned	BiVAD	Alive	√	√	√	√	√		
8854	Weaned	BiVAD	Alive	√	√	√		√	√	√
9061	Weaned	BiVAD	Alive	√	√	√	√	√		√
9714	Weaned	BiVAD	Alive	√	√	√	√	√	√	√
1838	Weaned	BiVAD	*Transplanted, Alive*	√	√	√	√	√		
3496	Weaned	LVAD	Alive	√	√	√	√	√	√	
7747	Weaned	LVAD	Alive	√	√	√	√	√	√	√
7822	Weaned	LVAD	Alive	√	√	√	√	√	√	√
9264	Weaned	LVAD	Alive	√	√	√	√	√	√	√
4823	Weaned	LVAD	*Transplanted, Died*	√	√	√	√	√	√	

Table 2

Artificial neural network (ANN) analysis results of 28 independent variables, organized by data category; corresponding states for each variable and patient numbers of two outcomes under different variable states

(a) Minimized set of patient Demographics variables

Node Name	State	Wean	Transplant
Primary Device	Bi-VAD	5	7
	LVAD	5	2
Days Implanted	<100	8	2
	>100	2	7
Age	<=37	7	3
	>37	3	6
Race	Caucasian	9	7
	Oriental	1	0
	Black	0	1
	Arabic	0	1
Sex	Female	7	5
	Male	3	4
Diagnosis	DM Postpartum	4	2
	DM Myocarditis	3	0
	DM Idiopathic	1	3
	DM Ischemic	1	1
	Acute Ischemic HD	1	2
	Valvular HD	0	1

(b) Minimized set of Complication variables

Node Name	State	Wean	Transplant
Bleeding	No	6	2
	Yes	4	7
Re-Operation	No	4	2
	Yes	6	7
Tamponade	No	9	7
	Yes	1	2
Renal	No	10	7
	Yes	0	2

(c) Minimized set of Laboratory Test variables

Node Name	State	Wean	Transplant

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(a) Minimized set of patient Demographics variables

Node Name	State	Wean	Transplant
AST	0-250	6	4
	>250	4	5
CREAT	0-1.9	7	2
	>1.9	3	6
BUN	2.0-47.0	7	2
	out of range	3	7
RET	3.2-10	5	3
	out of range	2	5
MG	1-2.6	7	2
	out of range	3	7
LD	167-1022	5	2
	out of range	5	6

(d) Minimized set of Exercise Test variables

Node Name	State	Wean	Transplant
Exercise Time	>= 5 mins	7	1
	< 5 mins	0	3
VO2%	> 45	6	1
	< 45	1	2
METS	> 4	6	0
	< 4	1	3
HR% Target	> 80	6	1
	< 80	1	2

(e) Minimized set of RH Catheterization variables

Node Name	State	Wean	Transplant
PCWP	< 24	7	3
	> 24	2	4
PVR	< 1.1	5	1
	> 1.1	4	4
MPAP	< 25	7	3
	>= 25	2	4
TPG	< 10	7	2
	>= 10	1	4

(a) Minimized set of patient Demographics variables

Node Name	**State**	**Wean**	**Transplant**

(f) Minimized set of Echocardiographic variables

Node Name	State	Wean	Transplant
PWR	> 4	7	1
	< 4	1	7
SA	increased > 0.2	5	0
	maintained	2	1
	decreased >0.2	2	6
ApSys	change < 40	5	0
	change > 40	0	4
FAC	change < 10	6	2
	change > 10	3	5

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Table 3
Word examples for five contextual categories in NPL processing

VAD malfunction	Socialization	Ambulation	Positive descriptor	Nutrition
alarm positive flash (poor filling)	visiting family friends	walked stairs bike, chair outside physical therapy	happy good improving talkative	eating cafeteria (good) appetite

Table 4

Predictions of each of three models compared to actual clinical strategies. Note, one "falsely" predicted transplant who was actually weaned from VAD ultimately received transplant at 1-year

(a) Model 1: Data-Derived Knowledge

		Actual	
		Wean	**Transplant**
Predicted	Wean	9	1
	Transplant	1	8
	Total:	10	9

(b) Model 2: Expert Derived Knowledge

		Actual	
		Wean	Transplant
Predicted	Wean	6	0
	Transplant	4	9
	Total:	10	9

(c) Model 3: Hybrid (Expert + Data)

		Actual	
		Wean	Transplant
Predicted	Wean	9	0
	Transplant	1*	9
	Total:	10	9

*required transplant at 1-year post-weaning