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Development of a Hybrid Decision Support Model for Optimal Ventricular Assist Device Weaning

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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 a VAD have not been established.**

Methods. **A clinical decision support system was developed based on a Bayesian Belief Network that combined expert knowledge with multivariate statistical 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 the 19 VAD patients considered for weaning between 1996 and 2004. Artificial Neural Networks and Natural Language Processing were used to mine these data and extract 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 underestimated 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 misidentified 2 patients: 1 weaned successfully, and 1 that needed a cardiac transplant ultimately. An expert-data hybrid model performed best, with 94.74% accuracy and 75.37% to 99.07% confidence interval, misidentifying only 1 patient weaned from support.**

Conclusions. **A clinical decision support system may facilitate and improve the identification of VAD patients who are candidates for cardiac recovery and may benefit from VAD removal. It could be potentially used to translate success of active centers to those less established and thereby expand use of VAD therapy.**

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The use of ventricular assist devices (VADs) for treatment of end-stage heart failure has steadily increased during 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]. After the first report of VAD weaning in 1995 [9], numerous centers have demonstrated the possibility of cardiac recovery for a subset of VAD patients, including the 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 with 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 topics of active research. It is therefore not surprising that different sets of criteria have been used 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 postoperative management. It also entails competitive objectives, such as 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 centers that are less established.

The complexity and uncertainty of this decision process makes it an excellent candidate for a clinical decision support system. Motivated by the success of such systems in numerous fields of medicine [21–27], we undertook this study to develop a clinical decision support system specifically customized to the management of VAD patients, with particular emphasis on ventricular

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Abbreviations and Acronyms

ANN	= artificial neural network
APsys	= systolic arterial pressure
AST	= aspartate amino transferase
BBN	= Bayesian belief network
BiVAD	= biventricular assist device
BUN	= blood urea nitrogen
CI	= cardiac index
CREAT	= creatinine clearance
DCM	= dilated cardiomyopathy
ECHO	= echocardiography
EF	= ejection fraction
FAC	= fractional area change
FU	= follow-up
HR	= heart rate
HTx	= heart transplantation
LDH	= lactate dehydrogenase
LV	= left ventricle
LVAD	= left ventricular assist device
LVEF	= left ventricular ejection fraction
MG	= magnesium
METs	= metabolic equivalents
MPAP	= mean pulmonary artery pressure
NLP	= natural language processing
PCWP	= pulmonary capillary wedge pressure
PVR	= pulmonary vascular resistance
PWR	= ventricular power
RER	= respiratory exchange ratio
RET	= reticulocyte count
SA	= stroke area
TPG	= transpulmonary gradient
WU	= wood units
VAD	= ventricular assist device
VO_2%	= peak oxygen consumption

recovery. The clinical experience at UPMC with 19 VAD patients who were considered for weaning between 1996 and 2004 [28, 29] was used as the basis for evaluation of this model.

Material and Methods

The protocol for this study was approved by Institutional Review Board at University of Pittsburgh. Two primary sources of procedural knowledge were collected for the current study: retrospective statistical analysis of patient data and expert knowledge.

Data-Derived Knowledge

In accordance with the Health Insurance Portability and Accountability Act of 1996, de-identified patient data were obtained from the UPMC VAD registry through an honest broker. The study included 19 patients who were supported by a left ventricular assist device (LVAD) or a biventricular assist device (BiVAD) and originally identified as bridge-to-transplant but later considered for recovery between 1996 and 2004. Thoratec (Pleasanton, CA) pneumatic paracorporeal systems were used to support 18 patients and the Thoratec implantable VAD was used in 1. Of the 19 patients who were considered for weaning, 10 were eventually weaned and 9 received a cardiac transplant. Patient details are provided in Table 1.

A total of 250 numeric variables from 6 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. Additional analysis was performed on the written shift notes recorded by the clinical staff responsible for routine monitoring of these patients. Language patterns within the textual data contained in the shift notes were identified by natural language processing (NLP) using the software program Concordance 3.2 (R. J. C. Watt, Dundee, UK). Word patterns were tabulated in order of frequency and context and compared between weaned and transplanted patients.

Expert Knowledge

Knowledge derived from retrospective experience was elicited through a series of structured interviews and questionnaires of 11 members of the multidisciplinary Artificial Heart Program at UPMC, including surgery, clinical bioengineering, nursing, and psychiatry. The interviews were 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 a final version and presented to the full panel for approval. The resulting decision flowchart consisted of a five-tier health status screening, followed by a three-tier evaluation of cardiac recovery (Fig 1).

The flowchart defines an optimal weaning candidate as a nonischemic patient who has been supported by the VAD for more than 4 weeks, with normal cardiac rhythm, positive nutritional status, and normal end-organ function. Indices of cardiac recovery, gathered through echocardiographic measurements [29], are considered optimal if the patient is able to maintain an ejection fraction exceeding 40%, ventricular power exceeding 4 (mW/cm^4), and positive change in stroke area with temporary suspension of VAD support. Patients who pass this initial screening are referred for right heart catheterization.

The hemodynamics required to pass the secondary screening include pulmonary capillary wedge pressure less than 20 mm Hg, cardiac index exceeding 2.2 $L/min/m^2$, and heart rate less than 100 beats/min. Satisfactory results of right heart catheterization allow patients to undergo treadmill ergometry according to a modified Naughton protocol. Patients capable of achieving peak oxygen consumption exceeding 15 mg/kg/min, while maintaining a respiratory exchange ratio that exceeds 1.0 at maximal exercise, are referred to cardiac surgery for removal of the VAD.

Owing to the binary nature of the final decision flow-

Table 1. Summary of Patients' Outcome, Device Configuration, 1-year After Explant Status, and Available Data Categories

Patient ID	Outcome	Device	FU After Explant (1 yr)	Demographics	Complications	Laboratory	RHC	Echo	Exercise	Shift Notes
1560	HTx	BiVAD	Alive	✓	✓	✓	✓	✓	✓	. . .
4075	HTx	BiVAD	Alive	✓	✓	✓	✓	✓	✓	. . .
7869	HTx	BiVAD	Alive	✓	✓	✓	✓	✓	. . .	✓
8411	HTx	BiVAD	Alive	✓	✓	✓	✓	✓	. . .	✓
8883	HTx	BiVAD	Alive	✓	✓	✓	. . .	✓	. . .	✓
8118	HTx	BiVAD	Died	✓	✓	✓	✓	✓	. . .	✓
9284	HTx	BiVAD	Died	✓	✓	✓	✓	✓	✓	✓
8682	HTx	LVAD	Alive	✓	✓	✓	. . .	✓	. . .	✓
8794	HTx	LVAD	Died	✓	✓	✓	. . .	✓	. . .	✓
2297	Weaned	BiVAD	Alive	✓	✓	✓	✓	✓	. . .	. . .
8854	Weaned	BiVAD	Alive	✓	✓	✓	. . .	✓	✓	✓
9061	Weaned	BiVAD	Alive	✓	✓	✓	✓	✓	. . .	✓
9714	Weaned	BiVAD	Alive	✓	✓	✓	✓	✓	✓	✓
1838	Weaned	BiVAD	Htx, alive	✓	✓	✓	✓	✓	. . .	. . .
3496	Weaned	LVAD	Alive	✓	✓	✓	✓	✓	✓	. . .
7747	Weaned	LVAD	Alive	✓	✓	✓	✓	✓	✓	✓
7822	Weaned	LVAD	Alive	✓	✓	✓	✓	✓	✓	✓
9264	Weaned	LVAD	Alive	✓	✓	✓	✓	✓	✓	✓
4823	Weaned	LVAD	HTx, died	✓	✓	✓	✓	✓	✓	

BiVAD = biventricular assist device; FU = follow-up; HTx = heart transplantation; LVAD = left ventricular assist device; RHC = right heart catheterization.

chart, weaning is only recommended if all variables are in their positive state; whereas in reality, experts may consider less than ideal situations, such as patients who have a combination of variables in their positive and negative states. The experts were therefore 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 of the experts.

Decision Modeling

The relationships between variables extracted from data mining and expert interviews were modeled using a

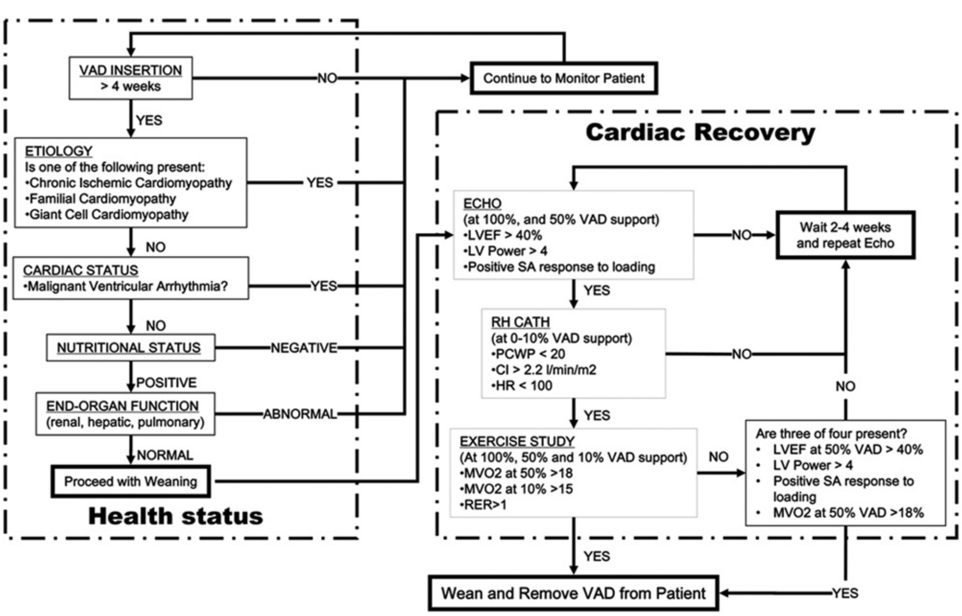

Fig 1. Flowchart shows the knowledge-derived model for assessment of a patient's readiness for weaning from left ventricular assist device (VAD) support, based on expert interviews. (CI = cardiac index; ECHO = echocardiogram weaning study; EF = ejection fraction; HR = heart rate; LV = left ventricle; MVO_2 = peak oxygen consumption; PCWP = pulmonary capillary wedge pressure; RER = respiratory exchange ratio; RH CATH = right heart catheterization; SA = stroke area.)

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Bayesian Belief Network (BBN) using a custom-written software, GeNIe 2.0, developed at the Decision Support Laboratory at the University of Pittsburgh [30]. 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:

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

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 BBNs were developed: (1) a data-driven model, consisting of 33 variables, (2) an expert model consisting of 15 variables, and (3) a hybrid model consisting 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%.

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.

Data-Driven Model

Data mining of the 250 numeric variables from 6 categories (demographics, complications, laboratory tests, exercise tests, right heart catheterization, and echocardiographic tests) using an ANN that yielded 28 variables that most closely correlated with outcome, representing an 89% reduction in the raw data (Table 2A–F).

Demographically, the ANN analysis identifies an ideal candidate for weaning as one who is supported by an LVAD rather than a BiVAD, implanted for less than 100 days, younger than 38 years old, white, female, and nonischemic (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 is free from tamponade or other complications associated with bleeding.

In terms of laboratory tests (Table 2C), the ANN analysis associates a greater chance of weaning with patients whose values for aspartate amino transferase, creatinine clearance, blood urea nitrogen, reticulocyte count, magnesium, and lactate dehydrogenase are within normal references ranges.

On the basis of the exercise test (Table 2D), optimal candidates include those who are able to exercise for 5 minutes or more, with peak oxygen consumption exceeding 45%, metabolic equivalents exceeding 4, and can perform at greater than 80% of the maximum predicted heart rate.

Optimal right heart catheterization variables (Table 2E) include pulmonary capillary wedge pressure of less than 24 mm Hg, pulmonary vascular resistance of less than 1.1 WU, mean pulmonary artery pressure of less than 25 mm Hg, and a transpulmonary gradient of less than 10 mmHg.

Finally, the optimal echocardiographic measurements associated with successful weaning (Table 2F) include ventricular power exceeding 4 mW/cm^4, a positive increase in stroke area, stable systolic arterial pressure, and stable fractional area change.

This set of data with 28 elements was augmented with the frequency of keywords identified by NLP within the free text of the shift notes of the clinical staff. These were clustered according to five contextual categories: (1) VAD malfunction, (2) socialization, (3) ambulation, (4) positive descriptors, and (5) nutrition (Table 3). When compared with the transplant recipients, 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 (Fig 4).

The predictions by this data-driven model, which are summarized in Table 4A, misidentified 2 of the 19 patients: classifying 1 patient who was successfully weaned as a transplant candidate and 1 who underwent transplantation as a candidate for weaning.

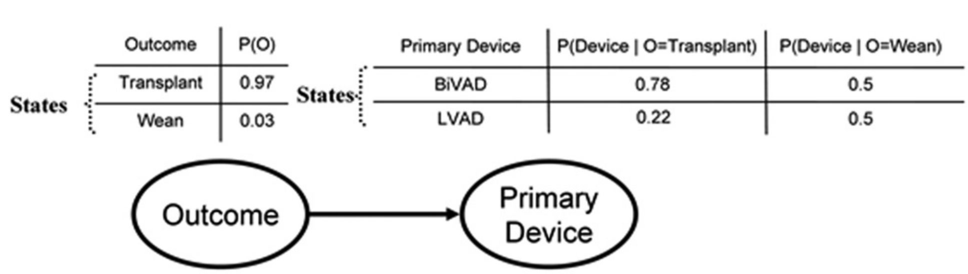

Fig 2. Simple example of the relationship between variables primary device (P[D]) and outcome (O) illustrating nodes, states, and probabilities. BiVAD = biventricular assist device; VAD = ventricular assist device)

Fig 3. Hybrid Bayesian belief network model combining expert and data models. (See the Abbreviations List for expansions of the abbreviations.)

Expert Model

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

Hybrid Model

The hybrid model inherited the structure and numeric variables from the previous two models. This model performed the best. It produced only one incorrect prediction, recommending that a patient who had been weaned should have received a cardiac transplant (Table 4C). This represented a prediction accuracy of 94% (95% confidence interval, 75% to 99%). It is worthy of note that the latter patient eventually required a cardiac transplant within 1 year of weaning from VAD support.

Comment

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 a greater patient volume are at an advantage compared with those that treat only a few VAD patients per year. The introduction of a clinical decision support system provides the potential to translate valuable expert knowledge to standardize, personalize, and optimize VAD weaning therapy based on multifactorial 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 counterintuitive 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 counterintuitive 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

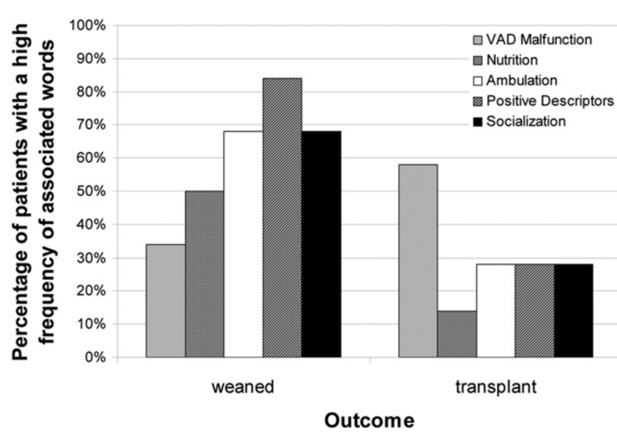

Fig 4. Results of natural language processing (NLP) of shift notes.

ADULT CARDIAC

Table 2. (A–F) Artificial Neural Network Analysis Results of 28 Independent Variables[a]

Node Name and State	Wean No.	Transplant No.
(A) Minimized Set of Patient Demographics Variables		
Primary device		
BiVAD	5	7
LVAD	5	2
Days implanted		
<100	8	2
>100	2	7
Age, y		
≤37	7	3
>37	3	6
Race		
White	9	7
Asian	1	0
Black	0	1
Arabic	0	1
Sex		
Female	7	5
Male	3	4
Diagnosis		
Dilated cardiomyopathy		
Postpartum	4	2
Myocarditis	3	0
Idiopathic	1	3
Ischemic	1	1
Heart disease		
Acute ischemic	1	2
Valvular	0	1
(B) Minimized Set of Complication Variables		
Bleeding		
No	6	2
Yes	4	7
Reoperation		
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		
Aspartate amino transferase		
0–250 U/L	6	4
>250 U/L	4	5
Creatinine		
0–1.9 mg/dL	7	2
>1.9 mg/dL	3	6
Blood urea nitrogen		
2.0–47.0 mg/dL	7	2
Out of range	3	7
Reticulocyte count		
3.2–10 × $10^6/\mu L$	5	3
Out of range	2	5
Magnesium		
1–2.6 mEq/L	7	2
Out of range	3	7
Lactate dehydrogenase		
167–1022 U/L	5	2
Out of range	5	6
(D) Minimized Set of Exercise Test Variables		
Exercise time		
≥5 min	7	1
<5 min	0	3
Peak O_2 consumption, %		
>45	6	1
<45	1	2
Metabolic equivalents		
>4 METs	6	0
<4 METs	1	3
Heart rate % target		
>80	6	1
<80	1	2
(E) Minimized Set of Right Heart Catheterization Variables		
PCWP		
<24 mm Hg	7	3
>24 mm Hg	2	4
Peripheral vascular resistance		
<1.1 WU	5	1
>1.1 WU	4	4
Mean pulmonary artery pressure		
<25 mm Hg	7	3
≥25 mm Hg	2	4
Transpulmonary gradient		
<10 mm Hg	7	2
≥10 mm Hg	1	4
(F) Minimized Set of Echocardiographic Variables		
Ventricular power		
>4	7	1
<4	1	7
Stroke area		
Increased >0.2 cm^2	5	0
Maintained	2	1
Decreased >0.2 cm^2	2	6
Systolic arterial pressure		
Change <40 mm Hg	5	0
Change >40 mm Hg	0	4
Fractional area change		
Change <10%	6	2
Change >10%	3	5

[a] Tables are organized by data category; corresponding states for each variable, and patient numbers of two outcomes under different variable states.

BiVAD = biventricular assist device; LVAD = left ventricular assist device; METs = metabolic equivalents; PCWP = pulmonary capillary wedge pressure; WU = wood units.

addition of quantitative, statistical data. Accordingly, the variables that were excluded from the expert model (Fig 1), yet found to be statistically relevant, can be subdivided into two sets: those that are consistent with clinical expectations and those that are either counterintuitive or for which there is no clinical benchmark. The former variables, such as duration of implantation, gender, age, and race, can be readily introduced into the expert model—with the approval of the expert—to correct for omissions that were overlooked when the expert was originally interrogated. The counterintuitive 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 who were polled in this study. Implementing this system across multiple medical centers will provide an opportunity to combine expert understanding of causal or synergistic relationships between variables, which may improve the topology of the Bayesian network, compared with the naïve structure of the present model. On the other hand, it might be advisable to limit the data to the most experienced or successful centers to translate their accumulated knowledge to less experienced centers.

An additional bias was introduced by the preselection of the 19 patients used for this study. Although the prediction accuracy of the hybrid clinical decision support system was very good (94%), the associated 95% confidence interval was relatively wide (75% to 99%). To improve the lower bound of the confidence interval to, say, 94% 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 and 2004 at UPMC because 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 were necessarily the 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 hopes to provide a more informative and accurate decision support model.

Table 3. Word Examples for Five Contextual Categories in Natural Language Processing

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

Table 4. (A–C) Predictions of Each of Three Models Compared With Actual Clinical Strategies[a]

Predicted	Actual Wean	Transplant
(A) Model 1: Data-Derived Knowledge		
Wean	9	1
Transplant	1	8
Total	10	9
(B) Model 2: Expert-Derived Knowledge		
Wean	6	0
Transplant	4	9
Total	10	9
(C) Model 3: Hybrid (Expert Plus Data)		
Wean	9	0
Transplant	1[b]	9
Total	10	9

[a] Note: one "falsely" predicted transplant who was actually weaned from ventricular assist device support ultimately received transplant at 1 year. [b] Required transplant at 1-year after weaning.

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INVITED COMMENTARY

As with many modern technological advancements, the application of ventricular assist device (VAD) care to a broad spectrum of patients can quickly result in out of control costs for healthcare delivery. Currently, VADs are used primarily as a method to safely prolong the waiting period for patients needing a cardiac transplant. However, with the recent Food and Drug Administration approval of a durable nonpulsatile, long-term VAD for patients who are not transplant candidates, it will become important to be able to identify patients that will benefit most from this therapy. Ideally, the existence of a predictive rule which can be widely applied and that will result in an accurate prediction of the outcome of therapy in any given individual would be extremely useful. Traditional risk-outcome prediction models (based primarily on logistic regression analyses) are dependent on having many patients and many events. In the case of VAD therapy, often there are only a small number of patients and events, even though there may be a great deal of information available on any given patient. Thus, newer methods of predicting outcomes become important in this population.

In the current report, Santelices and colleauges [1] use a hybrid decision support model (combining a data-dervied model with an expert consensus model) to arrive at a decision regarding the weanability of VAD support. They demonstrate that the hybrid model performed better than either the expert-derived model or the the data-derived model in identifiying patients who were successfully weaned from VAD therapy. The data used to derive the hybrid-model consists of information from the preoperative, perioperative, and postoperative periods.

Unfortunately, the use of such a rule may be limited because it cannot be used to determine the eligibility of a patient before the therapy is offered. However, if the prospective use of this rule results in avoiding heart

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