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Development and pilot testing of a decision aid for surrogates of patients with prolonged mechanical ventilation

Christopher E. Cox, MD, MPH[1], **Carmen L. Lewis, MD MPH**[2], **Laura C. Hanson, MD MPH**[3], **Catherine L. Hough, MD MSc**[4], **Jeremy M. Kahn, MD MSc**[5], **Douglas B. White, MD MSc**[5,6], **Mi-Kyung Song, RN PhD**[7], **James A. Tulsky, MD**[8,9], and **Shannon S. Carson, MD**[10]

Carmen L. Lewis: carmen_lewis@med.unc.edu; Laura C. Hanson: lhanson@med.unc.edu; Catherine L. Hough: cterrlee@u.washington.edu; Jeremy M. Kahn: kahnjm@upmc.edu; Douglas B. White: whitedb@upmc.edu; Mi-Kyung Song: songm@email.unc.edu; James A. Tulsky: jtulsky@duke.edu; Shannon S. Carson: scarson@med.unc.edu

[1]Department of Medicine, Division of Pulmonary and Critical Care Medicine, Duke, University, Durham, NC

[2]Department of Medicine, Division of General Internal Medicine and Clinical Epidemiology, University of North Carolina, Chapel Hill, NC

[3]Department of Medicine, Division of Geriatric Medicine, Palliative Care Program, University of North Carolina, Chapel Hill, NC

[4]Department of Medicine, Division of Pulmonary and Critical Care; University of Washington, Seattle, WA

[5]Department of Critical Care, University of Pittsburgh, Pittsburgh, PA

[6]Program on Ethics and Decision Making in Critical Illness, University of Pittsburgh, Pittsburgh, PA

[7]School of Nursing, University of North Carolina, Chapel Hill, NC

[8]Department of Medicine, Center for Palliative Care, Duke University, Durham, NC

[9]Center for Health Services Research in Primary Care, VA Medical Center, Durham, NC

[10]Department of Medicine, Division of Pulmonary and Critical Care Medicine, University of North Carolina, Chapel Hill, NC

Abstract

Objective—Shared decision making is inadequate in intensive care units (ICUs). Decision aids can improve decision making quality, though their role in an ICU setting is unclear. We aimed to develop and pilot test a decision aid for shared decision makers of patients undergoing prolonged mechanical ventilation.

Setting—ICUs at three medical centers.

Subjects—53 surrogate decision makers and 58 physicians.

Design and interventions—We developed the decision aid using defined methodological guidelines. After an iterative revision process, formative cognitive testing was performed among surrogate-physician dyads. Next, we compared the decision aid to usual care control in a prospective, before/after design study.

Corresponding author& reprint requests: Christopher Cox; Duke University, Division of Pulmonary & Critical Care Medicine; Box 102043; Durham, NC 27710. christopher.cox@duke.edu; tel: (919) 681-7232; fax: (919) 681-8359.

Measurements and main results—Primary outcomes were physician-surrogate discordance for expected patient survival, comprehension of relevant medical information, and the quality of communication. Compared to control, the intervention group had lower surrogate-physician discordance (7 [10] vs 43 [21]), greater comprehension (11.4 [0.7] vs 6.1 [3.7]), and improved quality of communication (8.7 [1.3] vs 8.4 [1.3]) (all $p<0.05$) post-intervention. Hospital costs were lower in the intervention group ($110,609 vs $178,618; $p=0.044$); mortality did not differ by group (38% vs 50%, $p=0.95$). 94% of surrogates and 100% of physicians reported that the decision aid was useful in decision making.

Conclusion—We developed a prolonged mechanical ventilation decision aid that is feasible, acceptable, and associated with both improved decision making quality and less resource utilization. Further evaluation using a randomized controlled trial design is needed to evaluate the decision aid's effect on long-term patient and surrogate outcomes.

Keywords

decision aid; decision making; respiration; artificial; critical illness; prolonged mechanical ventilation

Introduction

Patients with prolonged mechanical ventilation experience high mortality and morbidity, poor quality of life, and require extended caregiving assistance from families and friends.[1, 2] Because the care of these patients is expensive and their number increasing annually,[3] prolonged mechanical ventilation is also an extraordinary financial burden for the health system.[1]

The decision about whether or not to continue life sustaining therapy in prolonged mechanical ventilation ideally would be guided by shared decision making—a collaborative communication process that aims to reach consensus about the treatment that is most consistent with patient values.[4] Although the use of shared decision making is endorsed by many major critical care professional societies, its implementation in the intensive care unit (ICU) is incomplete and infrequent.[5, 6] Deficiencies in shared decision making include inadequate provision of medical information such as treatment choices and prognosis, failure to elicit either understanding of patients' preferences or surrogates preferred decisional role, and generally poor communication quality.[7-12] Together, these deficiencies can reduce the quality, timeliness, and patient-centeredness of decision making.[13, 14]

Decision aids could be an effective way to address the problems surrounding decision making regarding patients undergoing prolonged mechanical ventilation. In general, decision aids improve the quality of decision making, increase comprehension and decisional participation, lead to more realistic expectations, improve the likelihood of solidifying a decision that aligns preferences and choice, and reduce the use of high cost procedures of unclear benefit.[15, 16] Their importance is underscored by their explicit promotion in the 2010 Affordable Care Act.[17] However, decision aids have not been tested extensively in an ICU setting. The objective of this study was to develop a decision aid for surrogate decision makers of patients with prolonged mechanical ventilation, and to pilot test its feasibility, acceptability, and effect on decision making quality and resource utilization.

Materials and Methods

Study design and participants

In this study, we sequentially developed a decision aid, performed formative cognitive testing among decision aid recipients, and compared the decision aid to usual care control using a prospective before (control)/after (decision aid) design (Figure 1).

Study staff screened general surgical and trauma, neurological, cardiac, and medical ICUs daily. Consecutive subjects were eligible if they were the person ≥18 years of age self-identified as being most involved in medical decision making for each patient mechanically ventilated for ≥10 days, a common definition for prolonged mechanical ventilation.[1] We excluded surrogates of patients with a tracheotomy placed for either emergency indications or for an ear, nose, or throat-related diagnosis; pre-admission tracheotomy; admission for severe burns; expected survival <72 hours, or age <18. We also excluded surrogates who were not conversational in English. Surrogates received $25 for participation in this study. We enrolled the primary ICU attending physician at the time of patient eligibility. All study procedures took place at Duke University, Durham Regional Hospital, and the University of North Carolina between April 2009 - July 2010 (Figure 1).

Development of the decision aid

Decision aid content derivation—We aimed to develop a decision aid that promoted the process of individualized shared decision making about whether to provide prolonged life support to a critically ill loved one.[4] Domain and quality criteria specified by International Patient Decision Aids Standards Collaboration guidelines guided decision aid development.[18] We defined the main decision about prolonged mechanical ventilation provision as a goal-based prioritization of patient-centered appropriate levels of treatment. The decision was presented as a continuum of options ranging from maximizing life prolongation to maximizing comfort; an intermediary area included a choice to aim for survival but avoid prolonged life support (Figure 2).[19] We developed a list of key topics relevant to decision making from the input of experts in related topic areas(decision making, communication, geriatrics, palliative care, critical care outcomes, clinical medicine, and ethics), the medical literature, and informal interviews with physicians and nurses. Decision aid content was designed to address four main domains of shared decision making: providing medical information relevant to critical illness, eliciting surrogates' understanding of patient values and surrogates' role preferences, and guiding deliberation (Figure 3). It included information on treatments and procedures, as well as individualized probabilistic information on likely mortality, functional independence, and ultimate disposition derived from validated models of one-year survival and population-based prospective prolonged mechanical ventilation studies.[1, 2] The decision aid was designed to elicit both the surrogate's understanding of the patient's life support preferences and their preferred decision making role trough questions embedded within it.[20] The decision aid also aimed to guide deliberative decision making by prompting the surrogate to consider likely patient outcomes, the pros and cons of each option, what direction they are leaning in the decision, and what additional questions remained. Short explanatory stories were included to improve clarity. One investigator (CEC) compiled this information into an initial self-administered, printed version that was 10 pages in length, written at a 6th grade reading level, and made generous use of simple diagrams to illustrate key points as recommended by experts in decision making.[21] The decision was revised slightly after incorporating the feedback on clarity and completeness from fifteen physicians and ten surrogates as well as from the group of experts.

Cognitive testing—Trained research staff used a validated, semi-structured, theory-based cognitive testing methodology to determine if the decision aid was clear and understandable, contained acceptable information, and was useful in prolonged mechanical ventilation decision making.[22] A study staff member reviewed each page of the decision aid with surrogates, asking them with open-ended questions about their general interpretation of the page's meaning as well as its importance and value to them. Physicians were interviewed in person on the day of the surrogate interview to obtain their estimate of one-year patient survival and to rate their acceptability of the decision aid.

Evaluation of the decision aid versus usual care control

Overview—Surrogates and physicians completed identical study questionnaires in person on the day of enrollment but before the intervention, as well as within two days after a family-physician meeting. Intervention surrogates reviewed the decision aid after enrollment and were briefly instructed in its use by study staff; surrogates kept the decision aid throughout the study period. Control surrogates received no additional information. Participants in both groups were scheduled to attend an ICU physician-family meeting within two days of enrollment, generally coinciding with two weeks post-intubation. The study protocol did not specify the content of this unstructured meeting, requesting only that physicians ask intervention surrogates if they had any questions about the decision aid content.

Data collection and outcomes measures—We collected data from in-person interviews as well as from patients' medical charts including admitting diagnoses, sociodemographics, Charlson comorbidity scores,[23] limitations in activities of daily living,[24, 25] acute physiology scores (APACHE II),[26] quality of life (EuroQOL 5-Dimension Scale),[27] symptoms of anxiety and depression (Hospital Anxiety and Depression Scale),[28] mechanical ventilation duration and outcome, and hospital and ICU lengths of stay.

The primary outcomes were physician-surrogate discordance for expected one year patient survival, quality of communication with physicians, and medical comprehension. The validated physician-surrogate discordance score was calculated as the absolute difference between physicians' and surrogates' prognostic estimates for one year patient survival on a 0-100% scale.[8, 29] Discordance scores can range from 0 (maximal concordance) to 100 (maximal discordance). Physician-surrogate communication was characterized using the Quality of Communication (QOC) scale, a validated 17-item (mean score range 0 [worst] - 10 [best]) instrument.[30] Surrogates' understanding of diagnosis, prognosis, and treatments was assessed using a 12-item (score range 0 [poor comprehension] to 12 [excellent comprehension]) adapted version of the medical comprehension scale (MCS).[7] Satisfactory comprehension for each item was defined as either correct identification of each relevant factor or prognostic estimate within +/-25% of physicians' estimates. The decisional conflict scale (DCS), a 16-item instrument (lower scores reflecting more uncertainty) was used to evaluate decisional uncertainty.[31] We assessed the feasibility of adoption of the decision aid using enrollment rates and measured acceptability by query of subjects about whether the decision aid was an acceptable way to approach the prolonged mechanical ventilation decision (agree/disagree). Secondary outcomes were measured using single-item, Likert scale (strongly agree, agree, uncertain, disagree, strongly disagree)measures of surrogates' trust of ICU physicians, conflict with physicians, and whether physicians discussed patients' expected one-year survival and functional status. Total hospital costs were gathered from administrative databases.

Statistical analyses—The sample size was chosen to represent what we felt to be a reasonable sample (roughly 15%) of ICU patients at our institutions who receive prolonged

mechanical ventilation, with group division chosen to achieve a 1:1.5 control to intervention ratio. Categorical data are presented using number (percentage) and continuous data as means (standard deviations) or medians (interquartile ranges [IQR]). For the prospective evaluation of the decision aid to control, we used analysis of covariance tests to compare post-intervention differences in the primary outcomes within subjects between control and decision aid groups after verifying normality assumptions with Shapiro-Wilk tests, incorporating baseline questionnaire scores in regression equations.[32] For secondary outcomes, we compared study groups using Fisher's exact tests for categorical variables and either Kruskal-Wallis tests or *t*-tests for continuous variables. Because cost data were skewed, we used generalized linear models with a gamma distribution and a logarithmic link function to compare total hospital costs by study group.[33, 34] We used Stata, version 11 (College Station, TX) for all analyses and considered a $p < 0.05$ to be significant. Institutional Review Boards at all study sites approved the study procedures. Portions of these data have been presented previously in abstract form.[35]

Results

Cognitive testing

16 surrogate decision makers and corresponding patients' 16 primary ICU attending physicians participated in formative cognitive testing of the decision aid. Surrogates were diverse in age (range 44-70), gender (55% female), and ethnicity (27% non-white). All reported that the decision aid was useful in understanding prognosis and treatment options, as well as motivating them to engage in discussions with the medical team about treatment options including palliative care; none reported associated psychological distress. All physicians reported that the decision aid was acceptable and complementary to family meetings. Prior to viewing the decision aid, only 2 (12%) surrogates could correctly estimate patients' one year survival within 25% of the physician's estimate, whereas afterward, all 16 (100%) could do so correctly. Further, before viewing the decision aid no surrogates could articulate any specific goals of treatment other than “survival,” yet afterward all 16 (100%) accurately described the 3 goals of treatment presented. Minor revisions based on participant critiques were subsequently incorporated in the final decision aid (Online Supplement).

Evaluation of the decision aid versus usual care control

Baseline characteristics and hospital course—In the prospective evaluation, a total of 10 surrogate decision makers received usual care and 17 received the decision aid; three surrogates refused participation. Surrogates were younger and mostly female. Most surrogates reported symptoms of either depression (85%) or anxiety (70%) on the day of enrollment. There were no statistically significant between-group differences in sociodemographic characteristics or psychological distress (Table 1). Patients were generally elderly, male, and possessed a number of chronic medical comorbidities; few, however had baseline dependencies in activities of daily living. There were no clinically important between-group differences in pre-enrollment length of stay. Attending physicians were from both medical (74%) and surgical (26%) services; no physicians refused participation.

Outcomes—Compared to control, decision aid recipients had lower post-intervention physician-surrogate discordance scores for expected one year patient survival (7 [10] vs 43 [21], $p=0.001$), improved quality of communication scores (8.7 [1.3] vs 8.4 [1.3]; $p=0.03$), higher medical comprehension scores (11.4 [0.7] vs 6.1 [3.7], $p=0.001$), and lower decisional conflict scale scores (0.2 [0.4] vs 0.9 [0.9], $p=0.004$) (Figure 3). Decision aid recipients also had lower physician-surrogate discordance for one-year functional independence (7 [6] vs 38 [32], $p=0.011$).

Secondary outcomes are shown in Table 2. Compared to control, decision aid surrogates reported more frequent discussions with physicians about expected long-term patient survival and functional status (both p=0.013). A trend toward improved physician trust and physician conflict was observed in the intervention group, though this was not statistically significant. Three (30%) control patients and 10 (59%) intervention patients had a change in advance directive status during the study (p=0.15). Total hospital costs were lower in the decision aid group ($110,609 vs $178,618; p=0.044), a finding possibly explained by lower costs for ICU room (p=0.098), respiratory therapy (p=0.086), and pharmacy (0.002). Decision aid group patients had numerically fewer ventilator days, ICU days, and hospital days, though these differences were not statistically significant. There were no clinically important group differences in discharge disposition or hospital mortality.

Intervention feasibility was demonstrated by the high enrollment rate of eligible subjects (90%), the fact that all family meetings were held within 2 days of enrollment (70% within 24 hours), and our observation that all subjects were able to review the decision aid within an hour with no more than fifteen minutes of staff support. Support for the acceptability of the intervention was demonstrated by the report of 16 (94%) surrogates that the decision aid was useful in the decision making process; one surrogate felt unprepared to receive the information contained in the decision aid. All physicians reported that the decision aid was useful and that its discussion in a family meeting setting was acceptable.

Discussion

In this pilot study among surrogate decision makers of patients with prolonged mechanical ventilation, we developed a decision aid that was feasibly administered, well accepted by surrogates and physicians, and associated with improved decision making quality. Compared to usual care control, the decision aid was associated with improved physician-surrogate concordance for long-term survival, quality of communication, and medical comprehension, as well as reduced decisional conflict. Given the trend toward lower length of stay in the intervention group, there is a suggestion that the decision aid may expedite the decision making process, thereby reducing resource utilization.

Problems with ICU decision making have been reported for decades. Medical information including prognosis is often not shared by physicians, is inaccurate, and is poorly understood by surrogates.[7-9, 12, 36-38] This is particularly true in prolonged mechanical ventilation, in which unrealistically optimistic prognostication among physicians and surrogates is common.[8] These communication deficiencies can impair comprehension, increase discordance and conflict, and can threaten the patient-centeredness of the decision itself.[8, 39]

This decision aid is one of the first ICU-based interventions to address specific deficiencies in informed decision making. It also has potential to improve the process of shared decision making, a model widely endorsed by consensus groups but uncommonly implemented in clinical practice.[5, 40] The decision aid explicitly promotes shared decision making by providing medical information, eliciting surrogate decision makers' understanding of patient preferences and their preferred decision role, and guiding deliberation.[6] In so doing, the decision aid aims to stimulate collaborative communication between physicians and surrogates, therefore addressing sources of potential conflict and distrust. The decision aid also represents a pragmatic approach that could be easily disseminated and inexpensively implemented in clinical practice. Additionally, it targets risk factors for greater length of stay by encouraging more timely “in the moment” decision making, improving physician time efficiency, and focusing on causes of surrogate-physician discordance and conflict.[2, 39, 41] By acting as an adjunct to the decision making process, the decision aid also addresses the time constraints of an ICU workforce gap that will continue to widen in the

future.[42] Further, the decision aid has the potential to improve long-term surrogate decision maker outcomes because it addresses risk factors for psychological distress including physician-surrogate discordance, poor communication and comprehension, multiprovider contradictions, inadequate medical information provision, and elicitation of preferred decisional roles.[7, 13, 43]

Our study has several limitations. First, the complexity and individuality of ICU decision making cannot be distilled completely into a decision aid that at best represents an adjunctive tool in the surrogate-physician dynamic. The decision aid is not a replacement for good quality communication and does not address all important end of life issues confronting providers such as communication skills training, fundamental values conflicts, prognostic uncertainty, and patients who lack surrogate decision makers. Second, it may be challenging to implement the decision aid in different populations and care locations. Specifically, the intervention does not address many of the diverse range of educational, linguistic, ethnic, cultural, and religious characteristics that may influence surrogates' decisions and may not address all outcomes of importance to decision makers.[44-46] Future versions of the decision aid could be written at an even lower reading level, translated into other languages, and adapted to include local sociocultural factors that weigh heavily in decision making. Third, because print-based decision aids have limited flexibility in adapting to different user information needs, we are currently evaluating a web-based format that could also allow widespread, inexpensive access to decision support.[47] Fourth, generalizations about the intervention's benefit are limited by the modest sample size, quasi-experimental design, and potential differences in case-mix and temporal trends. Group-based cost differences appear generally related to length of stay, though the notable signal associated with pharmacy costs may suggest a more specific focus on post-intervention simplification of management. More detailed study is required with long-term follow up to determine the decision aid reduces resource utilization, and if so, through what mechanisms. Because family meetings were not recorded, we are unable to assess how the decision aid may have affected the surrogate-physician interaction itself. A randomized controlled trial is needed to determine its efficacy.

Conclusion

We found that a novel decision aid for surrogate decision makers of patients with prolonged mechanical ventilation was feasible and acceptable, and may improve the quality of ICU decision making and reduce resource utilization. Additional research is needed to determine the decision aid's true effectiveness and its impact on long-term outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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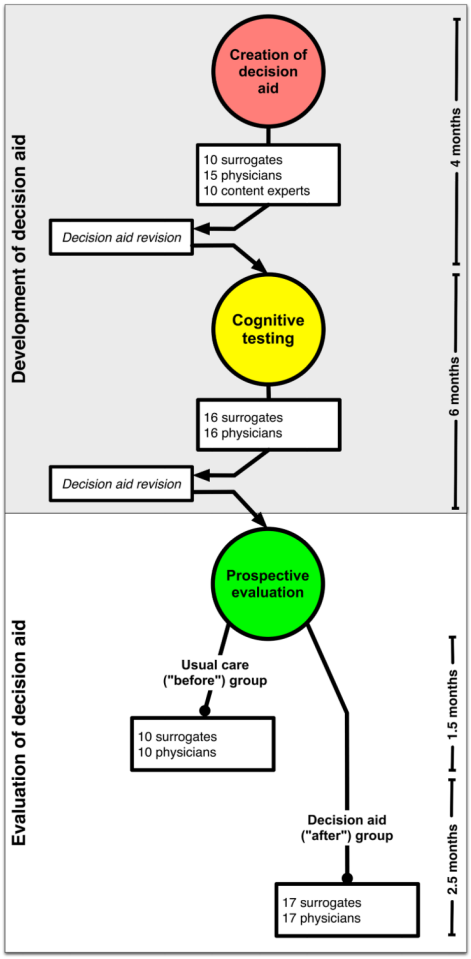

Figure 1. Study overview

This study consisted of the development and evaluation of the decision aid. The development stage consisted of the creation and the cognitive testing of the decision aid. The prospective evaluation compared usual care control (“before”) to the decision aid (“after”) in a pre-post intervention design. The duration of each study component is shown on the right side of the figure.

Figure 2.
Decision aid display of the clinical choice: goals of treatment.

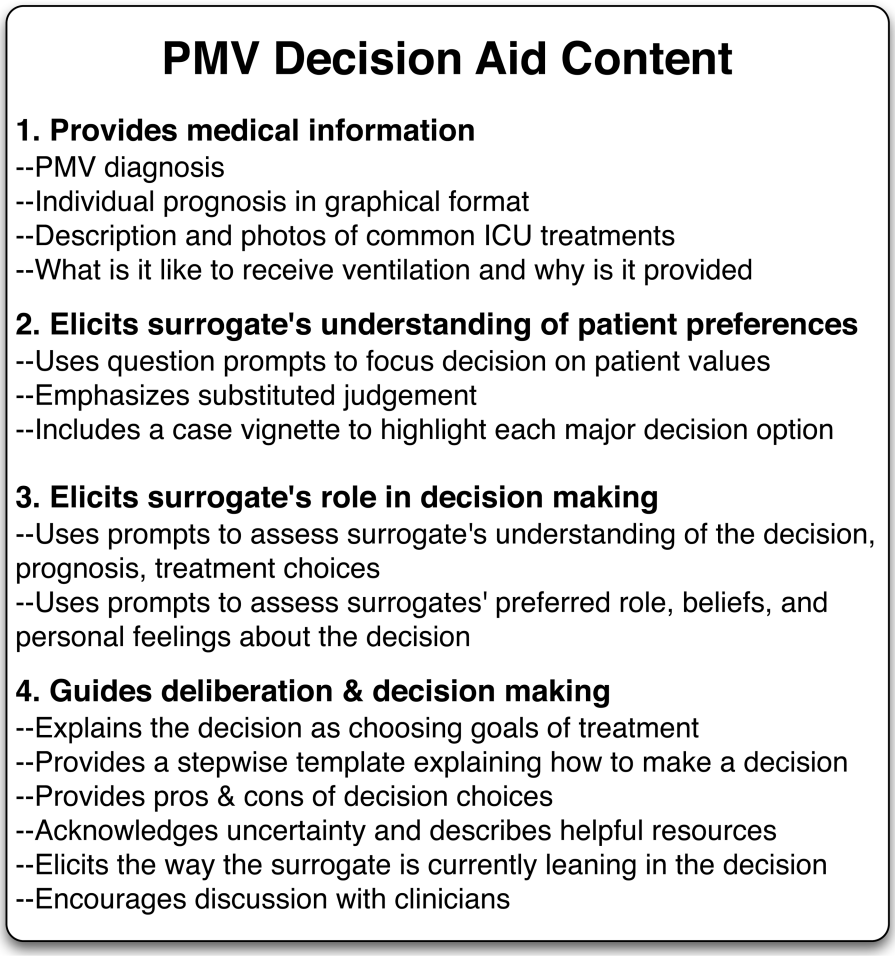

Figure 3.
Summary of decision aid content.

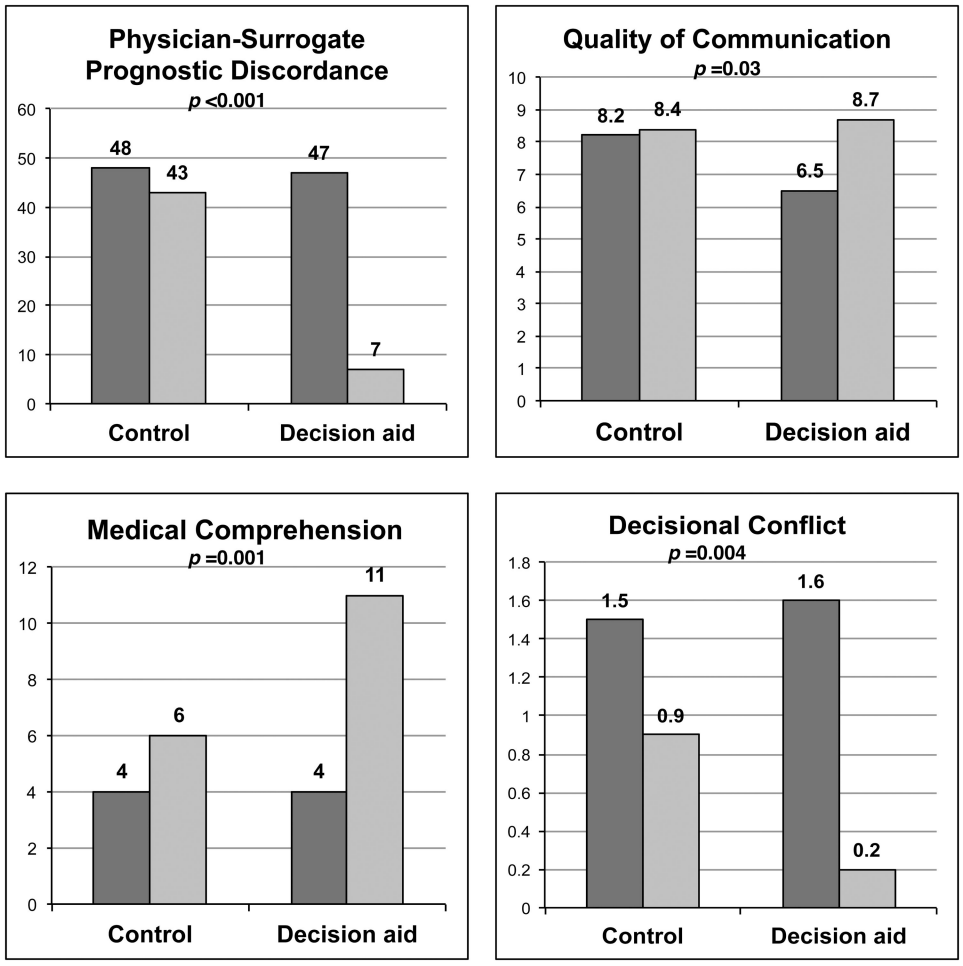

Figure 4. Primary outcomes of the prospective evaluation study

Primary study outcomes are compared between decision aid and usual care control groups. The dark and light bars represent pre- and post-intervention scores, with the corresponding mean values shown above each. P values are derived from analysis of covariance tests.

Table 1
Patient and surrogate characteristics in evaluation stage

Characteristic	Patients (*n*=27)	Surrogates (*n*=27)
Age	68 (55, 73)	55 (44, 70)
Female	11 (41%)	17 (63%)
Race & ethnicity *		
White	17 (63%)	16 (63%)
African-American	10 (37%)	10 (37%)
Place of residency before admission		
Home	24 (89%)	27 (100%)
Nursing facility	1 (4%)	
Rehabilitation facility	2 (7%)	
Employed, full- or part-time	9 (33%)	11 (40%)
Insurance status		
Private	8 (30%)	
Government (Medicare or Medicaid)	17 (63%)	
Self-pay	2 (7%)	
Chronic comorbidities †	4 (3, 5)	
Dependencies in activities of daily living ‡	1 (0, 11)	
Primary ICU admission diagnosis §		
Acute lung injury	9 (33%)	
Other respiratory failure	6 (22%)	
Septic shock	5 (19%)	
Neurological	3 (11%)	
Post-operative	2 (7%)	
Cardiac	2 (7%)	
APACHE II score, ICU day 1	29 (23, 35)	
Do not attempt resuscitation order, day of enrollment	0	
EuroQOL 5 Dimension index score, day of enrollment		0.84 (0.77, 0.84)
Hospital Anxiety and Depression Scale, day of enrollment		
Total score		22 (17, 29)
Depression subscale score >7		23 (85%)
Anxiety subscale score >7		16 (70%)

Results as number (%) or median (*interquartile range*).

* One patient and one surrogate reported ethnicity as Hispanic.

† Charlson comordity score.

‡ ADL and IADL score.

[§] *Other respiratory* includes pneumonia and chronic obstructive pulmonary disease exacerbations; *neurological* includes ischemic stroke and subarachnoid hemorrhage; *cardiac* includes myocardial infarction and out of hospital cardiac arrest. There were no statistically significant differences in characteristics listed in the table between patients and surrogates by study group.

Table 2
Secondary outcomes of prospective evaluation by study group

Characteristic	Study Group		*p*
	Control *n*=10	Decision Aid *n*=17	
Physician discussed long-term survival	3 (30%)	14 (88%)	0.013*
Physician discussed long-term functional status	3 (30%)	14 (88%)	0.013*
Increased trust in physicians	1 (10%)	7 (41%)	0.19*
Surrogate-physician conflict	3 (30%)	2 (12%)	0.33*
Surrogate change in preferences for goals of treatment	3 (30%)	10 (59%)	0.15*
Less aggressive	2	6	
More aggressive	1	4	
Mechanical ventilator days	34 (18, 49)	22 (14, 46)	0.25†
Mechanical ventilator outcome§			0.57*
Liberation	3 (30%)	3 (15%)	
Tracheotomy	5 (50%)	11 (50%)	
Withdrawal from ventilator	2 (20%)	6 (30%)	
ICU length of stay	48 (30)	28 (25)	0.08†
Hospital length of stay	57 (33)	37 (32)	0.14†
Hospital mortality	4 (50%)	7 (38%)	0.95*
Hospital costs	$178,618 ($115,154)	$110,609 ($89,356)	0.044‡
Disposition			0.29*
Home independent	0	0	
Home with paid care	1 (13%)	1 (6%)	
Long-term acute care facility	1 (13%)	7 (39%)	
Skilled nursing facility	1 (13%)	1 (6%)	
Rehabilitation facility	3 (38%)	1 (6%)	
Other hospital	0	1 (6%)	
Dead	4 (50%)	7 (39%)	

Values shown as number (*percent*), mean (*standard deviation*) or median (*interquartile range*). *p* based on

*Fisher's exact test,

†Kruskall-Wallis test, or

‡generalized linear model with gamma distribution and logarithmic linkage.

§Sum is >100% because of multiple outcomes observed.