Commentary

Clinical trial of a weaning protocol

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Abstract

Krishnan and colleagues have conducted a prospective clinical trial of a weaning strategy previously demonstrated to enhance clinical outcomes of mechanically ventilated patients. They draw conclusions quite different from those drawn in an accompanying editorial. Krishnan and colleagues compared the outcomes of patients supported with mechanical ventilation for at least 24 hours. The outcome of those patients weaned from mechanical ventilation was compared with the outcome of those patients who received usual care. Although usual care was not defined, it was delivered in an unusual environment that included many systems improvement elements previously demonstrated to improve clinical outcomes. The investigators worked in a closed intensive care unit that employed large numbers of physicians (six residents, two postdoctoral fellows, and two attending physicians for a 14-bed unit), and used a structured standard checklist to make patient review during rounds more systematic. These features might reduce the difference in outcome between the protocol group and other patients in their unit. In addition, the experimental design allowed convergence of the method of care of protocol group patients with the method of care of other patients. Their results are compatible with either no effect of the protocol or with an inability to demonstrate the effect of the protocol because of the systems improvement elements in operation in their intensive care unit.

Keywords decision support, intensive care, protocol, research, safety

Krishnan and colleagues recently performed a prospective clinical trial of a protocol-based strategy to discontinue mechanical ventilation for intensive care unit patients requiring more than 24 hours of mechanical ventilation [1]. An accompanying editorial raised issues that I believe should also be addressed [2]. Krishnan and colleagues found no difference between their protocol weaning group and their usual care group, and they concluded that "protocol-directed weaning may be unnecessary in a closed intensive care unit with generous physician staffing and structured rounds" [1]. The journal editor, Tobin, concluded in his editorial that "an intelligent physician who customizes knowledge generated by a previous research protocol to the particulars of each patient is expected to outperform the inflexible application of that protocol" [2]. These are different perspectives and interpretations of the same work.

A common ethical framework for medicine includes the principle of nonmaleficence (avoiding harm) [3]. Patient safety has assumed a central role in research, and patient welfare takes precedence over other considerations [4,5]. In clinical practice, error rates are unacceptably high [6], and the difference between recommended medical interventions and those delivered to patients is unacceptably large [7]. The principle of nonmaleficence is therefore not adequately followed. This highlights the need for compelling research results from well-designed clinical studies and for the tools to implement the results in clinical practice.

One avenue of investigation, development, and progress has been the application of systems improvement [8] to medical practice. A central feature of the systems improvement approach is the application of standardized methods to our interactions with patients. These have taken many forms and include decision-support tools such as guidelines, recommendations, clinical paths, checklists, reminders, and protocols. Some protocols possess adequate detail to standardize decisions in circumstances in which clinicians would ordinarily make different decisions when they are given the same clinical scenario and patient data [9]. Most protocols do not contain this level of detail and, therefore, like guidelines and other decision-support tools, require clinicians

to provide the individual and variable judgments necessary to generate responses. Unfortunately, variation in delivered care is associated with unfavorable outcomes [10].

I believe Tobin was astute when he said "… the question is not what went wrong with protocolized weaning but what was right with usual care". Krishnan and colleagues allude to their control group as 'usual care', but they performed their study in an *unusual* environment that included many systems improvement elements previously demonstrated to improve clinical outcomes. They worked in a closed intensive care unit, employed large numbers of physicians (six residents, two postdoctoral fellows, and two attending physicians for a 14-bed unit), and used a structured standard checklist to make patient review during rounds more systematic. These features might reduce the difference in outcomes between the protocol group and other patients in their unit.

In addition, the experimental design allowed convergence of the method of care of the protocol group patients with the method of care of other patients for several reasons. First, they used a protocol already in use in one of their training hospitals (Johns Hopkins Bayview Medical Center) but not in use at the hospital at which they conducted their study (Johns Hopkins Hospital). Fellows and residents might have been influenced by direct exposure to the protocol or by exposure to colleagues at the other hospital, and all trainees, I expect, were exposed to common teaching. Second, the protocol was introduced at the Johns Hopkins Hospital to all staff members, including nurses and respiratory therapists, during a 2-month training period. This must have altered the perceptions of these staff members about clinical care imperatives and rules. Third, physicians caring for protocol group patients could use strategies other than protocol weaning strategies, and physicians caring for usual group patients could employ protocol procedures such as a frequency/tidal volume eligibility test if they wished. Fourth, as in the protocol group, nurses and respiratory therapists could interrupt a physician-ordered spontaneous breathing trial for a usual care group patient, if they wished. These four observations increase the chance of carryover of principles and approaches from the protocol group to the usual care group and move the protocol group and usual care group methods towards each other.

Finally, the usual care group was not specified and no decision-making rules were articulated. One therefore cannot be assured that usual care was associated with a consistent method, even in their highly structured environment with systems improvement elements in place. It is probable that the usual care group received care that varied both because of variability between staff members and because of temporal changes during the conduct of the clinical trial. I expect that temporal changes during the trial would probably move the care of usual care group patients and that of the protocol group patients closer together.

In any case, Krishnan and colleagues recognize these limitations and draw an appropriate and conservative conclusion that protocols may not be necessary if other systems improvement elements are in place [1]. Their conclusion seems consistent with the study data and with previous publications. An alternate conclusion is also supported. The suspected convergence of care in protocol and usual care groups may have reduced the signal size and necessitated the study of many more than the planned number of patients. Tobin, on the other hand, extrapolates their results inappropriately in my view, and concludes that physicians using physiologic principles will do a better job by themselves than when following protocols [2]. This conclusion is neither supported by the data of Krishnan and colleagues nor by the large body of literature concerning error in medicine [6], concerning low compliance of clinicians with recommended treatments [7], concerning variation in practice [10], and concerning comparisons of outcomes with and without protocols [9,11–18].

Competing interests

None declared.

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References

1. Krishnan JA, Moore D, Robeson C, Rand CS, Fessler HE: **A prospective, controlled trial of a protocol-based strategy to discontinue mechanical ventilation.** *Am J Respir Crit Care Med* 2004, **169:**673-678.
2. Tobin MJ: **Of principles and protocols and weaning.** *Am J Respir Crit Care Med* 2004, **169:**661-662.
3. Beauchamp T, Childress J: *Principles of Biomedical Ethics*, 3rd edition. New York: Oxford University Press; 1989.
4. Tobin MJ: **The role of a journal in a scientific controversy.** *Am J Respir Crit Care Med* 2003, **168:**511-515.
5. Miller FG, Silverman HJ: **The ethical relevance of the standard of care in the design of clinical trials.** *Am J Respir Crit Care Med* 2004, **169:**562-564.
6. Kohn L, Corrigan J, Donaldson M (Eds): *To Err is Human – Building a Safer Health System*. Washington, DC: National Academy Press; 1999.
7. Committee on Quality of Health Care in America (Ed): *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
8. Deming W: *Quality, Productivity, and Competitive Position*. Cambridge, MA: Massachusetts Institute of Technology, Center for Advanced engineering Study; 1982.
9. Morris A: **Treatment algorithms and protocolized care.** *Curr Opin Crit Care* 2003, **9:**236-240.
10. Wennberg JE: **Unwarranted variations in healthcare delivery: implications for academic medical centres.** *Br Med J* 2002, **325:**961-964.
11. McDonald CJ: **Protocol-based computer reminders, the quality of care and the non-perfectability of man.** *N Engl J Med* 1976, **295:**1351-1355.
12. Tierney W, McDonald C, Hui S, Martin D: **Computer predictions of abnormal test results – effects on outpatient testing.** *JAMA* 1988, **259:**1194-1198.
13. Evans RS, Pestotnik SL, Burke JP, Gardner RM, Larsen RA, Classen DC: **Reducing the duration of prophylactic antibiotics use through computer monitoring of surgical patients.** *Ann Pharmacother* 1990, **24:**351-354.

14. Grimshaw J, Russell I: **Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations.** *Lancet* 1993, **342:**1317-1322.
15. Johnston M, Langton K, Haynes B, Mathieu A: **Effects of computer-based clinical decision support systems on clinician performance and patient outcome.** *Ann Intern Med* 1994, **120:** 135-142.
16. Pestotnik S, Classen D, Evans R, Burke J: **Implementing antibiotic practice guidelines through computer-assisted decision support: clinical and financial outcomes.** *Ann Int Med* 1996, **124:**884-890.
17. Hunt D, Haynes R, Hanna S, Smith K: **Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review.** *JAMA* 1998, **280:**1339-1346.
18. Morris A: **Algorithm-based decision making.** In *Principles and Practice of Intensive Care Monitoring*. Edited by Tobin M. New York: McGraw-Hill; 1998:1355-1381.