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Using time-limited trials to improve surgical care for frail older adults

Mark D. Neuman, MD, MSc^{1,2}, Steven Allen, MD³, Margaret L. Schwarze, MD, MPP^{4,5}, and Joshua Uy, MD⁶

¹Department of Anesthesiology and Critical Care, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

²Leonard Davis Institute of Health Economics, Philadelphia, PA

³Department of Surgery, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

⁴Division of Vascular Surgery, Department of Surgery, University of Wisconsin–Madison

⁵Department of Medical History and Bioethics, University of Wisconsin–Madison

⁶Department of Medicine, Division of Geriatric Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia

Abstract

An 85-year-old male nursing home resident who is frail but enjoys his current quality of life is admitted with an acute high-grade small bowel obstruction potentially due to adhesions from prior abdominal surgery. The patient has significant tenderness on abdominal exam with involuntary guarding and signs of pneumatosis on the CT scan that are concerning for bowel ischemia. After discussing potential options for management, including surgical intervention and palliative care, the patient and his family express a desire to proceed with surgery because there is a small chance that he could return to his preoperative quality of life. The surgeon believes that his problem is potentially reversible but worries that the patient is at high risk for complications, which could lead to a prolonged ICU stay and subsequent death. How should the possibility of surgical complications be introduced? What plans, if any, should be made at this point for how to deal with complications if one or more occur?

Older adults with progressive geriatric conditions present difficult challenges in regards to surgical decision-making. For younger individuals and healthy older adults, decisions about how to treat an acute small bowel obstruction may be relatively straightforward; in these cases, surgery typically occurs as an isolated intervention intended to solve a discrete problem. Yet for older adults with cognitive impairment, advanced frailty, or severe comorbidity, deciding how to treat the same surgical problem may be far more complicated.

Corresponding author address: Mark D. Neuman, MD, M.Sc. Department of Anesthesiology and Critical Care Perelman School of Medicine at the University of Pennsylvania 1119 Blockley Hall 423 Guardian Drive Philadelphia, PA 19104 Office: (215) 746-7468 Fax: (215) 349-5341 neumann@mail.med.upenn.edu.

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Beyond the initial operation, postoperative care following major surgical procedures frequently involves additional interventions, such as feeding tube placement, intubation, or re-operation as needed to support recovery and treat complications. In these contexts, major operations for surgical diseases may come to appear to individuals with prognosis-limiting, nonsurgical illnesses not as isolated interventions, but as part of an end of life characterized by one invasive procedure after another.

Typically, when patients agree to proceed with surgery, surgeons assume that patients are committed to aggressive treatments in general, including treatment of all the postoperative issues that come up.¹ This perspective stems from a strong sense of personal responsibility for the life of the patient. However, this all-or-none mindset may not allow for older patients with pre-existing comorbidity and/or frailty a chance to return to their preoperative state and avoid subsequent burdensome treatments if they have a complicated postoperative course or when their goals are no longer achievable. For frail older patients with acute, potentially reversible surgical problems it is important to reconcile the patient's overall goals of care with wishes that patients may have to avoid escalating medical interventions near the end of life.

In contexts like these, the perspectives of geriatrics and palliative care can help surgeons, patients, and family members to communicate more effectively with each other. The concept of a “time-limited trial” represents a widely accepted approach to making decisions about invasive treatments—such as prolonged mechanical ventilation, tube feeding, or dialysis—in cases where the likely outcomes of such treatments are uncertain. As described by Timothy Quill and Robert Holloway, time-limited trials begin with a meeting between the care team, the patient, and the patient's family, if appropriate, to: (1) define the patient's acute problem and the patient's overall prognosis; (2) clarify the patient's goals and priorities; (3) identify objective markers for improvement or deterioration; (4) suggest a time frame, ranging from a few days to a month or more, for re-evaluation of the patients' status; and (5) define potential actions to take at the end of the trial or during the trial if complications arise.²

For geriatricians and palliative care specialists, time-limited trials are powerful tools that help to facilitate value-based, goal-oriented medical decisions that make sense within the broader context of a patient's prognosis and their priorities for care. Time-limited trials explicitly recognize the possibility that an individual's prognosis and goals of care can change over time. By providing a mechanism by which treatment decisions can be re-evaluated in an iterative fashion using defined criteria for improvement or decline, time-limited trials offer patients near the end of life an alternative to all-or-none commitments to unfamiliar and potentially burdensome and painful interventions. Time-limited trials have been used across a range of clinical contexts—including treatment decisions for the critically ill,³ post-stroke care,⁴ and the management of end-stage renal disease⁵ and chronic lung disease⁶—to tailor difficult care decisions to individual priorities and to highlight important considerations that might otherwise be overlooked.

In the context of surgery, time-limited trials can help patients, families, and physicians make better decisions as to how surgical diseases should be treated, particularly in cases where immediate outcomes are difficult to predict, the burdens of treatment are significant, and the

risk of experiencing a complication is high.³ In these situations, surgeons can use a time-limited trial to place decisions about surgery and postoperative care in the context of the patient's larger prognosis and preferences for care,⁷ with subsequent reconsideration of these decisions over time. By building Quill and Holloway's five steps into their initial encounters with patients for whom surgery is being considered, surgeons can frame a major operation not as a discrete, isolated intervention, but as the beginning of an uncertain process that will require iterative re-evaluation (Table 1). As such, time-limited trials can offer patients the chance to have a good outcome—if surgery is effective and complications are avoided—but also allows them to change course if the burdens of treatment become too great or the likelihood of a positive long-term outcome is decreased by the occurrence of a complication. For patients near the end of life, time-limited trials can be paired with appropriate palliative care consultation to guide the management of distressing symptoms, assist the patient and family with goal setting, and prepare them for possible next steps in the event that treatments are not effective. In this way, time-limited trials can facilitate the effective use of palliative care to provide patients and surgeons with an additional layer of support during difficult cases.

By encouraging patients and surgeons to articulate and consider a range of potential positive and negative outcomes, time-limited trials can offer benefits for patients and surgeons that are both practical and emotional. For surgeons, this will require a major paradigm shift about the definition of surgical “success” through recognition that surgical “failure” occurs when overly burdensome, non-beneficial therapy is continued, even if the patient is still alive.^{8,9} This is especially important for older patients with life-limiting prognoses who often value quality over quantity of life and who may be more likely to forgo life-prolonging treatments that could result in functional or cognitive impairments. In these cases, time-limited trials can help provide a means of acknowledging the limitations of medicine upfront and avoiding the sense of personal failure that surgeons often experience when patients cannot be saved.

Such changes could be encouraged by promoting the collection and reporting of data on surgical quality-of-care for frail older adults that de-emphasizes comparisons based on 30-day mortality and instead rewards high-quality palliative care and patient engagement. A reporting system designed specifically for palliative surgery that measures how well surgical treatment represents purposeful care that is actually valued and desired by the patient and family could allow for variability in patient preferences and account for the change in individuals' priorities for care over time.¹⁰

In our practice, we have found time-limited trials to offer a useful, flexible approach to thinking through challenges inherent in surgical decision-making for older adults with limited prognoses. We have also found them to carry their own complexities; they require both a willingness to question traditional models of surgical decision-making and the collaboration of health professionals who may approach choices about surgery from markedly different perspectives.¹¹ Ultimately, addressing these challenges and working to integrate the perspectives of geriatrics and palliative care into surgical decision-making for older patients represent important steps towards improving surgical care for adults with limited prognoses. By bringing these two perspectives together, time limited trials hold

potential not only to help surgeons, patients, and families to make better decisions as to which interventions to pursue and which to forego; further still, they offer a practical means of making it clear that decisions about an individual's care, no matter the context, are not foregone conclusions but rather choices for informed patients and their families to make at every stage of life.

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REFERENCES

- Schwarze ML, Bradley CT, Brasel KJ. Surgical “buy-in”: the contractual relationship between surgeons and patients that influences decisions regarding life-supporting therapy. *Crit Care Med*. 2010; 38:843–848. [PubMed: 20048678]
- Quill TE, Holloway R. Time-limited trials near the end of life. *JAMA*. 2011; 306:1483–4. [PubMed: 21972312]
- Schenker Y, Tiver GA, Hong SY, et al. Discussion of treatment trials in intensive care. *J Crit Care*. 2013; 28:862–869. [PubMed: 23768446]
- Creutzfeldt CJ, Holloway RG. Treatment decisions after severe stroke: uncertainty and biases. *Stroke*. 2012; 43:3405–3408. [PubMed: 23150658]
- Rinehart A. Beyond the futility argument: the fair process approach and time-limited trials for managing dialysis conflict. *Clin J Am Soc Nephrol*. 2013; 8:2000–2006. [PubMed: 23868900]
- Fried TR, Vaz Fragoso CA, Rabow MW. Caring for the older person with chronic obstructive pulmonary disease. *JAMA*. 2012; 308:1254–1263. [PubMed: 23011715]
- Oresanya LB, Lyons WL, Finlayson E. Preoperative Assessment of the Older Patient: A Narrative Review. *JAMA*. 2014; 311:2110–2120. [PubMed: 24867014]
- Raiten JM, Neuman MD. “If I had only known”—on choice and uncertainty in the ICU. *N Engl J Med*. 2012; 367:1779–1781. [PubMed: 23134380]
- Olson TJ, Schwarze ML. Failure-to-pursue rescue: truly a failure? *Ann Surg*. Dec 26.2013 Epub ahead of print.
- Schwarze ML, Brasel KJ, Mosenthal AC. Beyond 30-day mortality: aligning surgical quality with outcomes that patients value. *JAMA Surg*. Jun 4.2014 Epub ahead of print.
- Glance LG, Osler TM, Neuman MD. Redesigning surgical decision making for high-risk patients. *N Engl J Med*. 2014; 370:1379–1381. [PubMed: 24716679]

Table 1

Application of the time-limited trial model to a family discussion regarding care for a frail 85-year-old man with a high-grade small bowel obstruction.

Communication goal	What we would say
1. Define acute problem and overall prognosis; define options for treatment of the acute problem. Characterize potential benefits and risks of treatment options.	<p>You have a bowel obstruction and we need to discuss the best way to care for you.</p> <p>We have a choice between operating on your bowels or focusing primarily on your comfort.</p> <p>We can operate on your bowel obstruction and you might be able to get back to your life at the nursing home where you could live for several months or maybe even a year or two.</p> <p>Based on your age and because you are quite frail, there is a high potential for complications. For example, the bowel could leak after surgery, or you could develop an abdominal infection; if one of these complications occurs, you would need to go back to the operating room for another surgery or need invasive treatments in ICU.</p> <p>If your wishes are to avoid surgery, we can focus our efforts on helping you be comfortable and allow nature to take its course.</p>
2. Clarify expectations for surgery and recovery; reconcile goals and treatment options.	<p>From your perspective, what is the best outcome that we could have for you in this situation?</p> <p>What do you think about that outcome?</p>
3. Identify objective markers for improvement or deterioration with the selected course of treatment.	<p>If you decide to go ahead with surgery, we are going to be following your recovery closely to look for signs that you are getting better.</p> <p>If you are able to eat, breathe comfortably and have less pain after surgery that will indicate to us that you are getting better.</p>
4. Identify a time at which the initial treatment choice can be re-evaluated.	<p>If you are still unable to eat one week after surgery, or if you are struggling to breathe and are very uncomfortable we should sit down and talk about all our options at that point.</p>
5. Define potential actions during the trial and ask for initial preferences regarding subsequent treatments.	<p>If you were to develop a leak or get an abdominal infection after surgery, you could become much sicker very quickly and a second surgery would be needed.</p> <p>How would you feel about having more surgery or needing a breathing tube or other treatments in the ICU?</p>