Increased Mortality Following Telemonitoring in Frail Elderly Patients: Look Before You Leap!

Telemonitoring is often proposed as an efficient way to provide health care. The recent study by Takahashi et al[1] examining telemonitoring in vulnerable patients with mixed chronic diseases clearly reflects the need for meticulous scientific approaches to study these types of interventions. Telemonitoring aims at early detection and prompt action in the case of health deterioration. Although patients reported high satisfaction and a sense of safety,[2] telemonitoring failed to reduce hospital admissions and emergency department visits. Surprisingly, it resulted in a 4-fold increase in mortality risk (relative risk, 3.8; 95% CI, 1.3-11.0). This suggests that telemonitoring in frail elderly patients is hazardous, causing more harm than good. However, one can question the validity of this conclusion.

A well-considered interpretation of the observed increased risk of mortality among patients receiving telemonitoring requires crucial information on timing and causes of death, which is currently lacking. The combined end point analysis ignores the true time-related impact of the exposure on mortality and health care utilization. In addition, it would have been informative to compare between-group characteristics of fatal cases vs nonfatal cases and indications for hospital admissions and emergency department visits.

Despite randomization, it is not clear if both groups were comparable regarding their baseline mortality risk. An important constraint to obtain unbiased effect estimates in a randomized controlled trial (RCT) is that comparison groups are equivalent in terms of prognosis. It is well-established in statistical literature that hypothesis testing is inappropriate to evaluate differences in the distribution of baseline patient characteristics between treatment groups in RCTs.[3] Nevertheless, the authors decided, based on P values, that both groups were balanced and adjustment of potential confounders was not necessary. It needs to be emphasized that even nonsignificant ($P > .05$) imbalances of strong prognostic factors may still result in substantial bias and therefore requires adjustment.[4] For example, chronic obstructive pulmonary disease, diabetes mellitus, and congestive heart failure were not statistically imbalanced between the treatment groups and yet are important risk factors of mortality and hence potentially confounding the effects of telemonitoring.

These questions actually reflect the largest drawback of the study: the lack of substantial insight in the assumed relation between patient characteristics, intervention, and outcome. In intervention testing, the RCT is the final step, following a sequence of steps from initial preclinical research through phase 1 and phase 2 studies. The study by Takahashi et al[1] warrants careful consideration of the benefits of telehealth interventions. Moreover, it shows the need of careful development and testing of nonpharmaceutical interventions.[5]

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Telehealth Monitoring With Nurse Clinician Oversight

We would like to provide evidence from our own observations that contradict the conclusions in the article by Takahashi et al[1] and the accompanying Invited Commentary.[2] We performed a 3-year study using a model similar to the one described by Takahashi et al,[1] a comprehensive telehealth monitoring with nurse clinician oversight.[3] Our patients were also selected by a statistically derived "risk score" that used administrative data to inform the algorithm. Only those in the highest risk category were included in our study. Significant improvements in hospitalization rates and hospital charges were reported in our 1-year pilot findings, and these continued in subsequent years with added enrollees (unpublished data, 2012).

There are 3 major differences between our study and the study by Takahashi et al[1] that may explain why our results were so successful. First, our selection algorithm included functional status and state of nutrition as variables included in the risk score regression model. As Lynn[4] postulates in her 2005 special report, perhaps fragility, not frailty, is the better predictor of future hospitalization. Second, our patients were drawn from a not-for-profit chronic hemodialysis system, a population with end-stage renal disease and multiple comorbidities. These