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In Touch But Out of Time: Aggressive Hospital Discharge and Readmissions After Transcatheter Aortic Valve Replacement

Neal S. Kleiman, MD

The first trial of transcatheter aortic valve replacement (TAVR) demonstrated the utility of the procedure in infirm patients who were judged to have too high an operative risk to undergo open aortic valve replacement.[1] Since then, the rate of growth for valve technology as well as its clinical application have been astounding. In contrast to this initial application at the highest end of the risk spectrum, TAVR has proven successful in groups of patients with progressively decreasing acuity and is now undergoing evaluation in 2 large-scale trials of patients judged to be at low risk for open surgical aortic valve replacement. Keeping pace with these changes poses a major challenge when it comes to applying clinical outcome data to patients currently undergoing the procedure. One of the recent areas of focus has been simplifying the procedure and the entire hospital stay, with adoption of a "minimalist" approach[2] which involves use of conscious sedation rather than general anesthesia, nearly universal use of the femoral rather than a transapical or transthoracic approach, and earlier ambulation, more-aggressive movement toward shorter hospital stays, and direct to home discharge rather than transfer to skilled nursing or rehabilitation facilities.

Various measures have been used to assess the utility of these approaches. Whereas mortality is probably the outcome of choice (after all, aortic stenosis is a fatal disease), hospital readmission has become a popular surrogate. In addition to its utility as a surrogate—readmission rates are tracked and reported meticulously—this outcome has important financial implications for hospitals that deliver cardiac care. In 2012, under the Affordable Care Act, the Center for Medicare Services began a program entitled the Hospital Readmissions Reduction Program. For patients with several common diagnoses, including myocardial infarction, heart failure, and coronary artery bypass, Diagnosis Related Group payments are reduced up to 3% for hospitals whose rates of rehospitalization within 30 days are excessive.[3] Although TAVR is not currently included in this list, the high cost and increasing number of TAVR procedures (≈24 808 in 2015[4]) make it a potential target. Virtually all clinicians agree that reducing readmission rates is a laudable goal for reasons that are clinical as well as financial.

Data from Europe as well as the Nationwide Readmission Database and the Transcatheter Valve Therapies are all concordant in that they indicate that, as of 2015, 15% to 17% of patients who underwent TAVR required hospital readmission within 30 days[5–7] and 50% were readmitted within a year.[6,7] The majority of readmissions are reported to occur for noncardiac illness[5,6] and <1% are for valve-related issues.[4] Predictably, patient frailty and comorbidities, access site, procedural complications,[5–7] and hospital TAVR experience[8] are the most powerful predictors of hospital readmission. In addition to these factors, data from the Nationwide Readmission Database indicate that discharge to a skilled nursing facility contributed 16% to the risk of readmission.[5] This disposition occurs commonly in the population that, up to now, has undergone TAVR[7], and is potentially modifiable. Discharge directly to home, as opposed to a skilled nursing facility, has several potential advantages, largely stemming from its mandating early ambulation, earlier return to independence with resumption of normal activities, and reduced risk of hospital-acquired illness. In addition, under the Post-Acute Transfer (PACT), which reduces Diagnosis Related Group payment to hospitals for many patients discharged to a skilled nursing facility, there is financial motivation as well.[9] In the current issue of *JAHA*, Dodson et al utilize the Transcatheter Valve Therapies database in order to provide a more-detailed report on the relationship between discharge to an SNF versus aggressive direct discharge to home and the likelihood of readmission within 30 days.[10] Because the study evaluated hospital practice rather than individual patient characteristics, the analysis was performed at the hospital rather than the patient level. Hospitals were

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

From the Houston Methodist DeBakey Heart and Vascular Center, Houston, TX.

Correspondence to: Neal S. Kleiman, MD, Houston Methodist DeBakey Heart and Vascular Center, 6565 Fannin, MS F-1035, Houston, TX 77030. E-mail: nkleiman@houstonmethodist.org

J Am Heart Assoc. 2017;6:e007086. DOI: 10.1161/JAHA.117.007086.

stratified into quartiles dependent on the proportion of patients discharged directly to home rather than to extended care facilities during the period between November 2011 and March 2015. The distribution was somewhat skewed toward an aggressive policy, with some hospitals in the lowest quartile discharging 59% of patients directly to home, whereas among those in the highest quartile the range of direct to home discharge was 82% to 100%. Not surprisingly, hospitals in the highest quartile performed TAVR on patients with a slightly lower mean Society of Thoracic Surgeons predicted risk of mortality, were somewhat less likely to use general anesthesia and nonfemoral access, and had shorter intensive care unit stays. Nonetheless, after adjustment for these small differences between quartiles, there were no differences among quartiles in the rates of hospital readmission. An important finding resulting from this modeling was that 15.5% of the discharge disposition was a result of the hospital propensity for direct to home discharge whereas 84.5% of the variation was attributed to clinical factors. In other words, within the patient population studied—that undergoing commercial TAVR within the United States during this period—comorbidities and procedural complications far outweighed the efforts of practitioners to discharge patients home, at least as far as the risk of readmission was concerned. This study bears similarity to a recent report by Sud et al, who examined the relationship between duration of hospital stay (another potentially modifiable factor that might be expected to affect rehospitalization) and the likelihood of readmission within 30 days. Patients in that study underwent TAVR in Ontario between 2007 and 2014; the median length of stay was 6 days and 19% of hospital stays were <4 days. A patient-level analysis revealed no relationship between length of stay and the 30-day likelihood of readmission.[11]

Although both studies are essentially negative, they should not be regarded as evidence that aggressive discharge policies should be abandoned. First, in the study of Dodson, the 15.5% contribution made by hospital practice may seem small, but viewed in the context of the fairly subtle differences in readmission rates reported in recent years, this proportion is still fairly substantial. In a comparison of readmission rates before and after adoption of the Hospital Readmissions Reduction Program, the risk-adjusted drop in readmissions was only 13.4%.[12] Under the Hospital Readmissions Reduction Program, comparison between hospitals that were versus those that were not penalized revealed that the relative differences in readmission rates for myocardial infarction and heart failure were also small—14.6% and 12%, respectively.[13] Thus, seemingly small differences in readmission rates are likely to have important financial important consequences for hospitals.

An even more-important caveat to keep in mind is that TAVR has become an extremely dynamic field; within the Transcatheter Valve Therapies registry, there has been steady evidence of a downward drift in patients' comorbidities over the past 4 years.[4,14] Viewed in this context, the study by Dodson et al may underestimate the current contribution of an aggressive discharge to home stance. Given that valves have become easier to implant and as the acuity of the patient population continues to decrease, the relative contributions of patient comorbidity and of procedural complications to the likelihood of readmission will decrease, whereas those of postprocedural ambulation and discharge to home may well increase. This trend is likely to accelerate as TAVR use expands. The Sapien S3 valve was approved for use in patients at intermediate risk (Society of Thoracic Surgeons predicted risk of mortality ≈3–15%) for open surgery in August 2016, and the CoreValve Evolut received such approval in July 2017. Trials in patients at even lower risk (Society of Thoracic Surgeons predicted risk of mortality <3) are underway now. In the current report, patient baseline characteristics predicting readmission included glomerular filtration rate <30 mL/min and nonfemoral access. The frequencies of these 2 factors were 5.4% and 32.8%, respectively.[10] By comparison, in the SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial of TAVR in patients at intermediate surgical risk, published earlier this year, only 2% of patients had creatinine levels >2 mg/dL and nonfemoral access was performed in 6.3% of patients.[15] Similarly, 12% of patients in the current study were on home oxygen as compared with 5% in the Sapien 3 observational study of patients at intermediate surgical risk.[16] It is possible, then, that the 15.5% contribution of a direct to home policy will increase in magnitude as TAVR finds more mainstream applications and the degree of illness in patients drifts downward. In this setting, adoption of a more "minimalist" approach,[2] and a "fast track" protocol, would make sense. Although such an approach would seem intuitive, there is still little evidence to support its use, and the migration of the procedure to a lower risk group of patients with a longer survival horizon, in whom low-frequency complications would be viewed as catastrophic, may still mandate more-intense observation. At least 1 study in the more-mature field of percutaneous coronary intervention has shown limited benefit from a similar approach.[17] A strong argument can therefore be made that investigations such as these will need to be revisited in the changing TAVR environment.

The timing of the studies by Dodson[10] and by Sud,[11] and our own study referencing the Nationwide Readmission Database,[8] all point to a major limitation in our current ability to assimilate clinical data, given that all 3 may already be outdated. This problem is particularly vexing in a field that has been as dynamic as TAVR. All 3 studies were published in 2017, although the most recent data they utilize were collected in early 2015. In contrast, the relatively blunt instrument (as far as data collection is concerned), The Federal Register, contains data through Fiscal Year 2016. Among the 23 117 TAVR claims

submitted last year, 57% were coded under Diagnosis Related Group 267 (major comorbidities not present); this group had an average length of stay of 3.5 days.[18] Obviously, the latter report lacks the granularity needed to make clinical plans, but the ability to generate and disseminate data so quickly illustrate that it is possible to move the field more rapidly than we are currently doing.

The need to maintain data that reflect the current state of the field is intense. The current report and others like it provide worthy goals that, although challenging, promise to increase the utility of registry data reporting. Whereas the processes of data collection, reporting, and quality control are time-consuming, and data analysis must be done carefully, the Center for Medicare Services database indicates that such data can be accrued and processed rapidly. Hopefully, this goal will soon be achieved through direct electronic transfer of data from the hospital electronic health record to registry databases. An important challenge is that the variety of data collected is broad and includes laboratory, imaging, procedural, and clinical data, some of which have previously been regarded as unconventional. For example, in the current report, Dodson et al noted that only 3 in out of 4 hospitals reporting data within Transcatheter Valve Therapies were able to provide frailty data on >80% of patients and 5-m walk data on >50%.[10] Rapid capture and processing of such information is going to be especially critical as we try to understand the changes in patient characteristics and the effects of changes in the way we manage patients during and after TAVR.

Disclosures

Kleiman is a member of the TransCatheter Valve Therapy Registry Research and Publication Committee. The views expressed represent his own perspective.

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Key Words: Editorials • Aortic Stenosis • Readmission • TAVR