**Chapter 20: Cost Effectiveness Analyses in Transcatheter Aortic Valve Replacement**

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**Background: What is the cost of an aortic valve replacement?**

The standard measure in clinical practice used to determine the cost effectiveness of a given treatment is the incremental cost effectiveness ratio (ICER). ICER corresponds to the ratio between the incremental cost of one treatment compared with another and the incremental benefit (ICER = [cost of treatment 1 – cost of treatment 2] / [benefit of treatment 1 – benefit of treatment 2]). The health benefit is determined as added life years or quality adjusted life years (QALYs). In the United States, an ICER of less than $50,000 per QALY gained is typically considered cost effective. The value of $50,000 per QALY is arbitrarily based on the approximate ICER for hemodialysis.[1]

Both the PARTNER and the CoreValve pivotal trials collected cost data prospectively. During PARTNER 1, the Edwards Sapien balloon-expandable valve had a commercial price of $30,000. During the US CoreValve High Risk trial, the cost of the CoreValve device was $32,000. Given the fact that these transcatheter valves cost approximately three to five times as much as a surgical bioprosthetic aortic valve, there has been significant interest in analyses focused on the cost effectiveness of TAVR.

With respect to Cohort A of the PARTNER 1 trial evaluating TAVR versus SAVR in high risk patients, a standard bioprosthetic aortic valve was priced at $5,277 compared to $30,000 for the Edwards SAPIEN valve system. Separate analyses were conducted for transfemoral (TF) and transapical (TA) approaches. Costs of admission were based on hospital billing data and procedural costs were calculated based on item counts and unit prices. TF TAVR procedural costs were significantly higher than SAVR ($36,652 vs $14,475), but on average TAVR patients had a shorter mean length of stay in a critical care unit by more than 2 days (Table 1). At the 12-month point, costs were similar for the TF-TAVR and SAVR groups (mean difference $1,247) (Table 2). Based on bootstrap simulation, TF-TAVR was economically dominant in 55% of simulations, and economically attractive with an ICER of $50,000 per QALY gained in 70.9% of cases (Table 3). Of note, dominance in this binary bootstrap simulation reflects the situation where one intervention has a total cost less than the other intervention. Economically attractive refers to the situation where a procedure is considered "cost effective"; that is, the ICER falls below a set threshold value. In 86.6% of simulations TA-TAVR was economically more costly and had less QALYs than SAVR. As the authors note, the main driver of procedural costs was the cost of the valve itself.[2] From this analysis, the authors conclude that: (1) TAVR is favored in terms of quality of life outcomes and cost effectiveness, so long as access is transfemoral. These findings do not hold true for TA-TAVR which is associated with lower 12-month QALYs and increased overall costs as compared with SAVR. This study is limited primarily by the follow up period of 12 months. Echo surveillance is not routinely recommended following surgical implantation of bioprosthetic valves in the first decade. By contrast, surveillance seems to be much more frequent following TAVR due to concern for paravalvular leak, valve leaflet hypomobility, valve degeneration and patient prosthesis mismatch.[3] Therefore, the imaging follow up alone likely would contribute to higher lifelong costs for the transcatheter cohort.

Regarding the CoreValve US Pivotal trial in high risk patients, costs were calculated for TAVR and SAVR procedures and the associated admission using hospital billing and accounting data. The procedural costs were tabulated by multiplying counts of resources used by the appropriate prices based on index prices from two study centers. Index admission cost was higher for TAVR ($11,260 for the index admission; (Table 1) as was projected lifetime cost ($17,849; Table 2). However, TAVR reduced length of stay by 4.4 days on average. With respect to cost-effectiveness metrics, TAVR had a projected lifetime gain of 0.32 QALYs over SAVR. ICERs were $55,090 per QALY, and $52,897 when examining transfemoral access cases alone (Table 3). Based on sensitivity analysis the authors estimated a reduced cost of $1,650 at the index admission would lead to an ICER under $50,000 per QALY gained.[4] From this analysis, the authors conclude that: TAVR is a more expensive treatment option both in terms of index admission and lifetime costs. Despite modestly higher costs, TAVR is arguably cost-effective with an ICER just above $50k per QALY gained. To achieve an ICER of <$50k, the valve price would need to be reduced by $1,650. (2). This study's inherent limitation is that the lifetime cost estimates rely on projections of patient survival, which introduces uncertainty into the model.

During the 2017 TCT annual meeting, Cohen et al. reported on the cost-effectiveness of TAVR in intermediate risk patients. In this study, Medicare claims data was tracked for patients who underwent TAVR as part of PARTNER-2A (n=994) and Sapien 3 (n=1,077) trials compared with the SAVR arm of PARTNER-2A. With respect to PARTNER-2A, TAVR patients experienced a shorter length of stay (6.4 vs 10.9 days) and lower hospital admission costs ($61,433 vs $58,545). At 2-year follow up, total costs of SAVR were higher than those of TAVR (Sapien XT $107,716 vs SAVR $114,132; $P = 0.01$). Based on projected survival, patients would realize a gain of 0.18 QALYs. Of note, the investigators reported a decreased readmissions rate with TAVR which reduced follow up expenses (follow-up costs TAVR $26,861 vs SAVR $38,238).[5] The analysis was repeated for the Sapien 3 cohort and similar trends in cost savings were found for TAVR. While this study seems to have a more definite conclusion in terms of both cost savings and improved quality outcomes, the limitation in this case is that authors do not investigate cost to the hospital, rather they examine overall costs to the health care system. Therefore, while it may seem economically advantageous to offer TAVR in intermediate risk patients, it is not clear based on DRG reimbursement whether hospitals would benefit economically. In fact, the touted collateral studies/patient evaluated to recoup the loss/procedure by hospitals has not been reported and obviously varies widely at TAVR sites.

Review of index admission costs for both the TF and TA Sapien valve and SAVR in the PARTER 1 cohort A trial, TAVR/SAVR in CoreValve High Risk trial, and PARTNER Intermediate Risk trial are described in Table 1. Cost measures at the one-year point are listed in Table 2. QALY and ICER data is listed in Table 3.

**Modifying Procedural Cost**

*Balloon-expandable vs self-expandable valves*

Since publication of the CHOICE Trial in 2015, it has been widely reported that there is an increased risk of heart block and need for a permanent pacemaker with a self-expandable (SE) versus balloon-expandable valves. In the CHOICE Trial, 23.4% of patients who received a balloon-expandable

valve versus 38.0% who received a self-expandable valve required a new pacemaker.[6] In a 2016 German publication, the authors found that balloon-expandable valves were associated with shorter procedural times, the need for fewer personnel, and a lower frequency of arrhythmias necessitating a permanent pacemaker and consequently fewer days in the ICU. The group concluded TAVR performed with Sapien balloon-expandable technology cost 24% less than the self-expanding Medtronic CoreValve.[7]

*Experience, volumes, and outcomes*

Multivariable modeling using results from the PARTER 1 trial indicate that approximately 25% of the index admission cost is related to post-operative complications, such as a major vascular bleeds, stroke, and arrhythmias necessitating a pacemaker.[8] Reducing the frequency of complications is one method in which index costs can be reduced. While major vascular bleeds were cited with an incidence of 11.3%, disabling stroke 5.1%, and new pacemaker 5.7% in PARTNER 1A, the frequencies in Partner 2 were 8.4%, 5.0 %, and 9.9% respectively (all reduced other than incidence of new pacemaker, for one year follow up).[9,10] While the decrease in complications may be attributed to lower risk patients (intermediate rather than high risk), the decrease is also likely attributed to improved experience with the procedure and device advances such as a reduction in the size of the delivery sheath. Continued device innovation and operator experience will likely lead to further reduction in post-procedural complications and associated index hospitalization costs.

*Fast track and minimalist TAVR pathways*

A major contribution to cost, whether it be TAVR or SAVR, is the number of days spent in an ICU. Several groups have proposed and are now implementing a fast track or "minimalist" TAVR pathway for patient care. In a 2015 publication by the University of Pennsylvania, authors advocate for risk stratification based on pre and intra op variables to determine appropriate bed placement following TAVR – step down versus critical care. 39% of patients met their inclusion criteria for "fast track" which was associated with a $12,000 decrease in direct cost for the index admission.[11] In addition, in a review of recent STS data, a total of 10,997 patients were assessed who had undergone TAVR from 2014 to 2015, with 1,737 receiving moderate sedation -- approximately 15.8%. Technical success was not significantly different between the groups, but moderate sedation patients experienced lower rates of 30-day mortality and stroke, as well as shorter hospital stay.[12] These factors indicate that potentially 39% of TAVR patients do not need an ICU stay and many patients are candidates for moderate sedation. Furthermore, most patients can predictably do well without an ICU stay whatsoever, a major cost saving at the index admission.

**Coding and Reimbursement for TAVR**

Effective October 1, 2015 patients who undergo TAVR for aortic stenosis will be listed as carrying the ICD-10 diagnosis I35.0, indicative of "non rheumatic aortic (valve) disease." In addition, post-operatively, they will carry either the code 02RF38Z "replacement of aortic valve with zooplastic tissue, percutaneous approach" or if performed transapically the code 02RF38H. As of October 1, 2014, the MS-DRG for endovascular valve replacement falls under 266 if performed with MCC (major complications/comorbid conditions) and 267 if without. The associated hospital national average payment

is listed in Table 4. MS-DRG for surgical AVR encompass 216, 217, 218, and 219. Their reimbursement schedules are shown in contrast to TAVR. As discussed, while the valve costs are quite disparate, as shown in Table 4, for both types of interventions inpatient hospital reimbursement is approximately $40,000-$50,000.[13] Unlike SAVR, for TAVR, there is currently a zero day global period for TAVR follow-up care. Also, per CMS rules, both a cardiac surgeon and interventional cardiologist are required to be involved in patient assessment and intra-procedural care.

**How much does it cost to start a TAVR Program?**

While the DRG that accompanies TAVR may seem steep, the process of initiating a new TAVR program at an institution can be a significant economic undertaking. A consulting agency with expertise in cardiovascular medicine cited a $25,000 price tag to start a registry affiliated with the STS and regional agency, and at least another $10,000 annually to maintain the registry. In addition, this agency pointed out the requirements of the center.[14] At present over 1 million coronary angiograms are performed each year in the United States, 400,000 stents, and 100,000 valve surgeries. Approximately 15,000 Americans meet anatomic criteria for treatment with a transcatheter valve.[15] Therefore only large scale cardiovascular institutes should explore this option. Moreover, current guidelines recommend two cardiac surgeons at the institution be facile with the procedure, which is to be performed in a hybrid OR. A significant expense at most new centers will be the presence of a hybrid operating room or modified catheterization laboratory. Moreover $500,000 is required initially for infrastructure in terms of equipment and personnel. The hospital is required to front the money for the valves, which are $30,000 each. It is estimated a center will need to perform a minimum of 60-80 TAVRs per year to break even.[16]

**Is TAVR Cost Effective?**

Results from the Partner 1 trials as discussed yield nearly equivalent spending at the twelve month mark for those who undergo TF-TAVR and SAVR. In the CoreValve High Risk trial, TAVR was more costly than SAVR, although this finding is confounded by the fact that there was not a subgroup analysis for TF TAVR (which is less costly) and the CoreValve device was associated with a longer ICU stay due to higher rates of heart block. In PARTNER 2A, while the index admission was similarly higher for TAVR, the overall 2-year cost was $6,416 less due to decreased length of stay, lower follow up costs and fewer readmissions. For both Sapien and CoreValve devices in studies pertaining to high risk patients, the derived ICER is borderline in terms of being economically attractive. In PARTNER 2A involving intermediate risk patients, there was a clear QALY improvement of 0.15 out to two years for TAVR patients over SAVR with reduced total costs of $6,416 making the procedure unequivocally economically attractive for this group of patients when followed long term.

While the economic analyses from these prospective trials are robust, there are several factors that can be modified to reduce cost including type of anesthesia administered, trans-femoral versus alternate access, and fast track to a regular hospital bed rather than an ICU. The main driver of the index admission is the cost of the valve which is $30,000 in comparison with a standard bioprosthetic valve which is $5,000. While initial trials did not unequivocally demonstrate a cost advantage of TAVR, recent data would suggest with two-year follow up and recent streamlined pathways of care, the total cost of TAVR is trending toward less than traditional open repair for intermediate risk patients when followed

longitudinally. Continued cost effectiveness analyses will be necessary to assess shifts in ICER that reflect improvements in device innovation, operator experience, and device cost. Many await the fall in device cost as additional systems become FDA approved in the US.


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Table 1: Index Admission Resource Use and Costs ($)

| | TF-TAVR (PARTNER 1) | TA-TAVR (PARTNER 1) | SAVR, (PARTNER 1) | TAVR (CoreValve) | SAVR (CoreValve) | TAVR (PARTNER 2) | SAVR (PARTNER 2) |
|---|---|---|---|---|---|---|---|
| Procedural | 36,652 | 40,368 | 14,475-15,076 | 37,920 | 14,258 | 38,548 | 16,465 |
| Non Procedural | 31,705 | 44,909 | 53,834-57,827 | 27,654 | 38,399 | 19,417 | 37,409 |
| Physician Fees | 4,861 | 5,642 | 5,758-6,121 | 4,018 | 5,674 | 3,827 | 5,421 |
| Total | 73, 219 | 90,919 | 74,067-79,024 | 69,592 | 58,332 | 61,792 | 59,295 |

Table 2: Cumulative 1-Year Resource Use and Costs ($)

| | TF-TAVR (PARTNER) | TA-TAVR (PARTNER) | SAVR, (PARTNER) | TAVR (CoreValve) | SAVR (CoreValve) | TAVR (PARTNER 2) | SAVR (PART 2) |
|---|---|---|---|---|---|---|---|
| Index Admission | 71,955 | 90,548 | 74,452-79,540 | 69,592 | 58,332 | 61,792 | 59,295 |
| Re-admission | 18,122 | 11,733 | 15,645-11692 | 12,208 | 58,332 | | |
| Rehabilitation/Nursing facility | 5,539 | 6,249 | 7063-7111 | 14,335 | 10,831 | | |
| Outpatient services | 1,126 | 874 | 833-1156 | 2,224 | 18,216 | | |
| Total follow up | 24,787 | 18,856 | 19,959-23,540 | 28,766 | 1,772 | | 1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Total 12-month | 96,743 | 109,405 | 97,992-99499 | 98,358 | | 107,716 (*2 years) | 14,132 years) |

Table 3: Cost Effectiveness Results

| | TF TAVR | SAVR | Study Data |
|---|---|---|---|
| 12 month LYs | 0.878 | 0.813 | PARTNER A |
| 12 month QALY | 0.659 | 0.591 | PARTNER A |
| Lifetime LYs or QALYs | 4.101 | 3.887 | CoreValve |
| Lifetime ICER ($/QALY) | 52,897* | | CoreValve |
| 0.15 QALYs over 2 years realized in TAVR over SAVR (detailed quantitative data not yet released) | | | PARTNER 2A |

*70.9% bootstrap simulations in PARTNER and 42.6% in CoreValve showed TF TAVR ICER/QALY less than $50k

Table 4: Medicare DRG Payment for TAVR and SAVR

| MS-DRG | Description | FY 2016 National Average Payment | FY 2016 Mean LOS |
|---|---|---|---|
| TRANSCATHETER AORTIC VALVE REPLACEMENT | | | |
| 266 | Endovascular Cardiac Valve Replacement with MCC | $50,772 | 7.3 |
| 267 | Endovascular Cardiac Valve Replacement without MCC | $38,720 | 4.4 |
| SURGICAL AORTIC VALVE REPLACEMENT | | | |
| 216 | Cardiac valve procedures and other major cardiothoracic procedures with cardiac catheterization with MCC | $57,511 | |
| 217 | Cardiac valve procedures and other major cardiothoracic procedures with cardiac catheterization with CC | $37,688 | |
| 218 | Cardiac valve procedures and other major cardiothoracic procedures with cardiac | $33,800 | |

| | | | |
|---|---|---|---|
| | catheterization without MCC or CC | | |
| 219 | Cardiac valve procedures and other major cardiothoracic procedures without cardiac catheterization with MCC | $45,985 | |
| 220 | Cardiac valve procedures and other major cardiothoracic procedures without cardiac catheterization with CC | $30,744 | |
| 221 | Cardiac valve procedures and other major cardiothoracic procedures without cardiac catheterization without MCC or CC | $27,494 | |