Clinical and Economic Impact of RBT-1 on Post-operative Complications and Costs for CABG and Valve Surgery

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BACKGROUND

Post-operative complications in cardiac surgery (eg, CABG, valve, or combined CABG/valve) occur in ≥67% of patients.[1] Short- and long-term complications contribute to worse outcomes, a noticeable increase in healthcare utilization, and significantly more costs. There remains an unmet need for novel pharmacologic agents that reduce post-operative complications in cardiac surgery and improve patient outcomes.

A novel drug, RBT-1, has been evaluated in a Phase 2 clinical trial and demonstrated a substantial reduction in post-operative complications when administered prior to cardiac surgery (n=121: N=80, RBT-1, Placebo [Pbo] n=41]).[2] The most frequently reported post-operative complications were prolonged ICU stay, new-onset post-operative atrial fibrillation, and blood transfusion. Other complications assessed included AKI requiring dialysis, 30-day cardiopulmonary readmission, and death. We report on the magnitude of incremental cost savings based on complication rates between study groups (RBT-1 and Pbo).

OBJECTIVE

To evaluate incremental cost savings for RBT-1 vs. Pbo for combined CABG and valve surgery based on clinical trial results.

METHODS

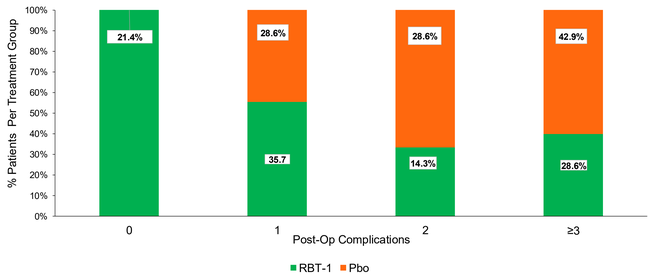
Complication rates from a clinical trial (NCT04564833) for RBT-1 were utilized in a decision-tree model to estimate the average expected cost of patients dosed with RBT-1 vs. Pbo. The decision tree model was constructed to represent the different pathways patients might experience based on the number of complications encountered during the 30-day post-operative period.

Complications were then categorized as 0, 1, 2, and ≥3 occurrences among patients in each treatment group (RBT-1 vs. Pbo). Thereafter, these rates were utilized in a decision-tree model to compute the average expected cost for patients who were dosed with RBT-1 or Pbo. Costs for each category were based on data culled from contemporary medical literature and adjusted for inflation to 2024 dollars.[3,4,5]

RESULTS

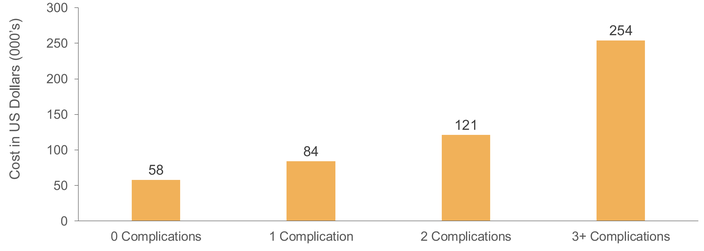
A total of 28 out of 121 (23.1%) patients had combined CABG and valve surgery (N=14, RBT-1; N=14, Pbo) and were evaluated for clinical outcomes in the Phase 2 trial. Rates for each complication category (0, 1, 2, ≥3 complications) per treatment group were: RBT-1: 21.4% (0), 35.7% (1), 14.3% (2), 28.6.3% (≥3) vs. Pbo: 0% (0), 28.6% (1), 26.8% (2), and 42.9% (≥3) as shown in Figure 1.

Figure 1. RBT-1 vs Pbo – Complication Rate Comparison



The cost of 0% complications was estimated at $58K[3,4,5], which is the average cost of the cardiac surgery procedures. The expected costs when 1, 2, and ≥3 complications occurred were $84K, $121K, and $254K, respectively (Figure 2).

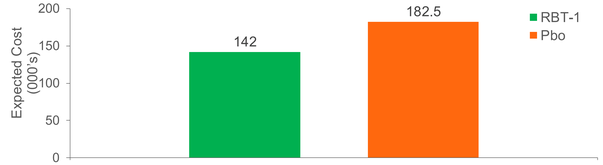
Figure 2. Estimated Costs Due to Complications



RESULTS (cont'd)

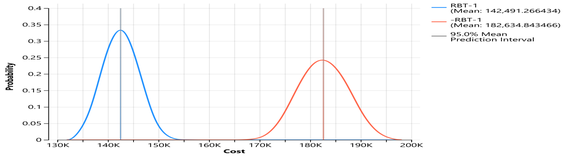
Based on this Phase 2 trial, the average expected cost of the RBT-1(excluding cost of RBT-1) treatment group was $142K vs $182.5K for Pbo, leading to a 22% ($40K) incremental cost savings in favor of RBT-1 (Figure 3).

Figure 3. Total Expected Cost of Complications



A probabilistic sensitivity analysis of 5000 samples showed that the only optimal pathway was the RBT-1 pathway 100% of the time (Figure 4).

Figure 4. Probabilistic Sensitivity Analyses of RBT-1 vs Pbo



CONCLUSIONS

Complications of combined CABG and valve surgery on CPB are common and costly to the healthcare system. For patients who have one or more complications, increased costs are not additive but rather exponential. Results from this expected-cost assessment of the Phase 2 trial suggest a protective effect of RBT-1, leading to lower complication rates and reduced average expected costs overall. Additional data from an ongoing Phase 3 trial, which includes a 1-year post-discharge follow-up, will contribute additional data to evaluate the impact of RBT-1 on clinical, economic, and qualitative outcomes compared to standard of care.

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