Impact of RBT-1 a Novel Treatment to Reduce Post-operative Complication Rates and Costs for Coronary Artery Bypass Graft (CABG) Surgery

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BACKGROUND

Coronary artery bypass graft (CABG) surgery is used to treat diseased arteries in the coronary vasculature. Plaque build-up in the coronary arteries causes narrowing and obstruction of normal blood flow. CABG surgery can relieve obstructions and prevent symptoms such as chest pain and shortness of breath, as well as more serious events such as heart attacks. CABG surgeries are common procedures in the United States and are generally safe, but some complications do occur in a majority (≥66%) of patients.[1] No approved pharmacological therapies are available to reduce the risk of these post-operative complications.

A novel drug, RBT-1, has been evaluated in a Phase 2 clinical trial and has demonstrated a substantial reduction in post-operative complications[2] when administered prior to surgery. The most common post-operative complications reported include prolonged ICU stay, new-onset post-operative atrial fibrillation, and blood transfusion. We report on the magnitude of incremental cost savings for CABG surgery based on complication rates between study groups - RBT-1 vs. Placebo (PBO).

OBJECTIVE

To evaluate the incremental cost savings for RBT-1 when compared with PBO based on clinical trial results for CABG surgery.

METHODS

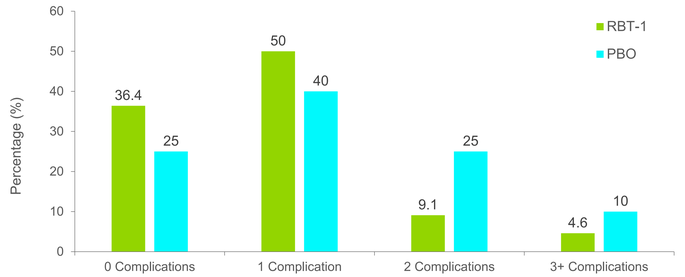
CABG complication rates from a clinical trial (NCT04564833) for RBT-1 were utilized in a decision-tree model to estimate the average expected cost of patients dosed with RBT-1 vs. PBO. The decision-tree model was constructed to represent the different pathways patients might experience based on the number 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

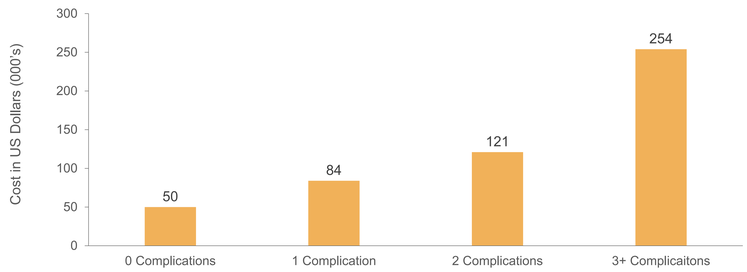
A total of 121 patients were assessed for clinical outcomes in the Phase 2 trial, in which 64 patients had CABG surgery alone (n=44 [RBT -1], n=20 [PBO]). Complication rates for each adverse event category per treatment group were: 36.4% (0), 50% (1), 9.1% (2), 4.6% (≥3) for RBT-1 vs. 25% (0), 40% (1), 25% (2), 10% (≥3) for PBO.

Figure 1. RBT-1 vs PBO – Complication Rate Comparison for CABG Only



The expected cost when 1, 2, and ≥3 complications occurred were $84K, $121K, and $254K, respectively (Figure 2).

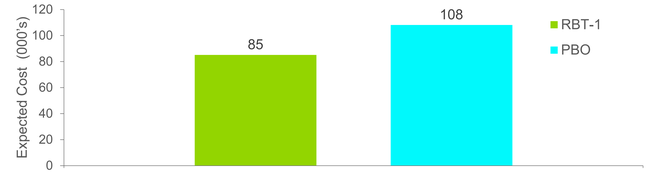
Figure 2. Estimated Costs due to Complications



RESULTS (cont'd)

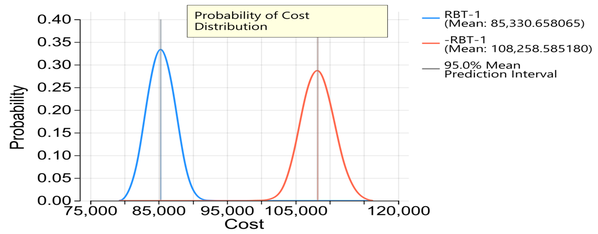
Based on this Phase 2 trial, the average expected cost of the RBT-1 treatment group was $85K vs. $108K for PBO, leading to a 21% ($23K) incremental cost savings in favor of RBT-1 (Figure 3).

Figure 3. Total Expected Cost of Complications for CABG



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

CABG surgery complications are common and costly to the healthcare system. For patients with one or more complications, costs were not additive but rather exponential. Results from the Phase 2 study demonstrated a protective effect related to RBT-1 utilization, leading to fewer complications, which also reduced the overall average expected cost for CABG surgery. Additional data from an ongoing Phase 3 trial will include 1-year post-discharge follow-up information for study patients in order to further evaluate the impact of RBT-1 on clinical, economic, and qualitative outcomes vs. standard of care.

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