Impact of RBT-1 on Post-operative Complication Rates and Costs for Cardiac Surgery

Frans van Wagenberg, MD[a] , Lynn Cherry, PhD[b], Bhupinder Singh, MD[c], Stacey Ruiz, PhD[c], Raf Magar MBA[b]

a Huntsville Heart Center, Huntsville Alabama, USA, b AHRM Inc., Raleigh, North Carolina, USA, c Department of Clinical Development, Renibus Therapeutics, Inc, Southlake, TX, USA

BACKGROUND

Post-operative complications of cardiac surgery (eg, CABG, valve, or combined CABG/valve) occur in ≥67% of patients.[1] To date, no pharmacological therapies have been approved to reduce the risk of these complications, neither during the hospital stay nor in the outpatient setting. Short- and long-term complications contribute to worse outcomes, a noticeable increase in healthcare utilization, and significantly more costs.

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.[2] The most common post-operative complications reported in the RBT-1 trial included prolonged ICU stay, new-onset post-operative atrial fibrillation, and need for blood transfusion. We report on the magnitude of incremental cost savings based on complication rates between study groups (RBT-1 and Placebo (PBO).

OBJECTIVE

To evaluate incremental cost savings for RBT-1 vs. PBO based on clinical trial results.

METHODS

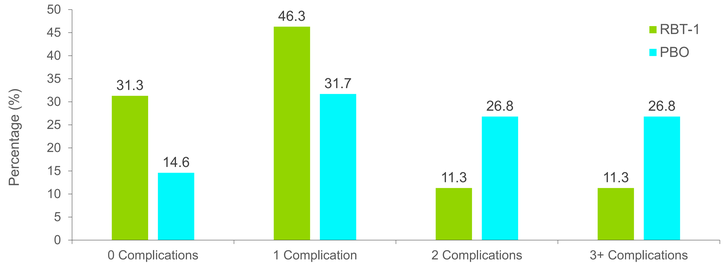
Complication rates from a clinical trial (NCT04564833) for RBT-1 were utilized in a decision-tree model to estimate the average expected cost of patients dosed with RBT-1 vs. PBO. The decision tree model was constructed to represent the different pathways patients might experience based on the number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

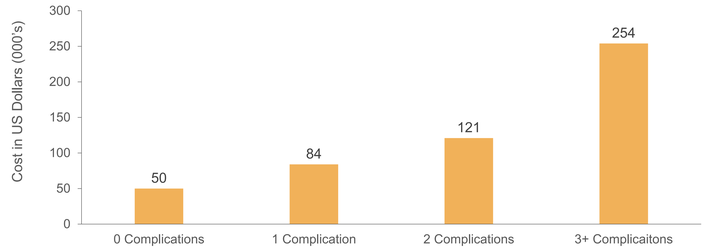
A total of 121 patients qualified for evaluation in this cost study: RBT-1, n=80 and PBO, n=41. Rates for each complication category (0, 1, 2, ≥3 complications) were established for each treatment group: RBT-1: 31.3% (0), 46.3% (1), 11.3% (2), 11.3% (≥3) vs. PBO: 14.6% (0), 31.7% (1), 26.8% (2), and 26.8% (≥3) as shown in Figure 1.

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



The cost of 0% complications was estimated at $50K, which is the average cost of the studied cardiac surgery procedures. The expected costs when 1, 2, and ≥3 complications occurred were $84K, $121K, and $254K, respectively (Figure 2).

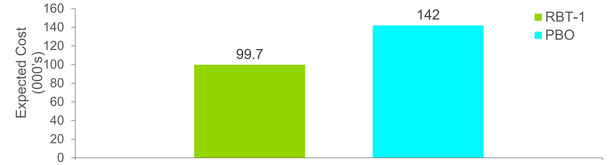
Figure 2. Estimated Costs Due to Complications



RESULTS (cont'd)

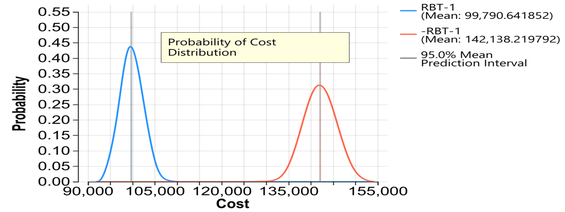
Based on this Phase 2 trial, the average expected cost of the RBT-1 treatment group was $99.7K vs. $142K for PBO, leading to a 30% ($42K) incremental cost savings in favor of RBT-1 (Figure 3).

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 CABG and/or 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.

Accepted for Presentation at the Annual AMCP Nexus 2024 Meeting – Las Vegas, Nevada (Oct. 14-17, 2024)

References

1 Patwa S, Bernabei A, Schaff H, et al. Impact of postoperative complications after cardiac surgery on long-term survival. J Card Surg. 2021;36:2045–2052.https://doi.org/10.1111/jocs.15471

2 Lamy A, Cherlow GM, Jessen M, Collar A, Brown CD, Mack CA, Marzouk M, Soave V, Washburn TB, Savage D, Smith J, Bennetts J, Asa R, Shutte C, Agrawal A, Butler J, Devereaux PJ, Zager R, Wang C, Snapinn S, Browne A, Rodriguez J, Ruiz S, Singh B; of START Investigators. Effects of RBT-1 on preconditioning response biomarkers in patients undergoing coronary artery bypass graft or heart valve surgery: a multicentre, double-blind, randomised, placebo-controlled phase 2 trial. EClinicalMedicine. 2024 Jan 8;68:102364. doi: 10.1016/j.eclinm.2023.102364. PMID: 38586479; PMCID: PMC10994983.

3 Mehaffey JH, Hawkins RB, Byler M, Charles EJ, Fonner C, Kron I, Quader M, Speir A, Rich J, Ailawadi G; Virginia Cardiac Services Quality Initiative. Cost of individual complications following coronary artery bypass grafting. J Thorac Cardiovasc Surg. 2018 Mar;155(3):875-882.e1. doi: 10.1016/j.jtcvs.2017.08.144. Epub 2017 Dec 14. PMID: 29248284.

4 Hadaya J, Sanaiha Y, Tran Z et al. Defining value in cardiac surgery: A contemporary analysis of cost variation across the United States. JTCVS Open 2022;10:256-81

5 Ferket BS, Thourani VH, Vassiw P, Hohmann SF, Chang HL, Smith PK, Michler RE, Ailawadi G, Perrault LP, Miller MA, O'Sullivan K, Mick SL, Bagiella E, Acker MA, Moquete E, Hung JW, Overbey JR, Lala A, Iraola M, Giammie JS, Gelijns AC, O'Gara PT, Moskowitz AJ; Cardiothoracic Surgical Trials Network Investigators. Cost -effectiveness of coronary artery bypass grafting plus mitral valve repair versus coronary artery bypass grafting alone for moderate ischemic mitral regurgitation. J Thorac Cardiovasc Surg. 2020 Jun;159(6):2230-2240.e15. doi: 10.1016/j.jtcvs.2019.06.040. Epub 2019 Jul 2. PMID: 31375378; PMCID: PMC6960356.