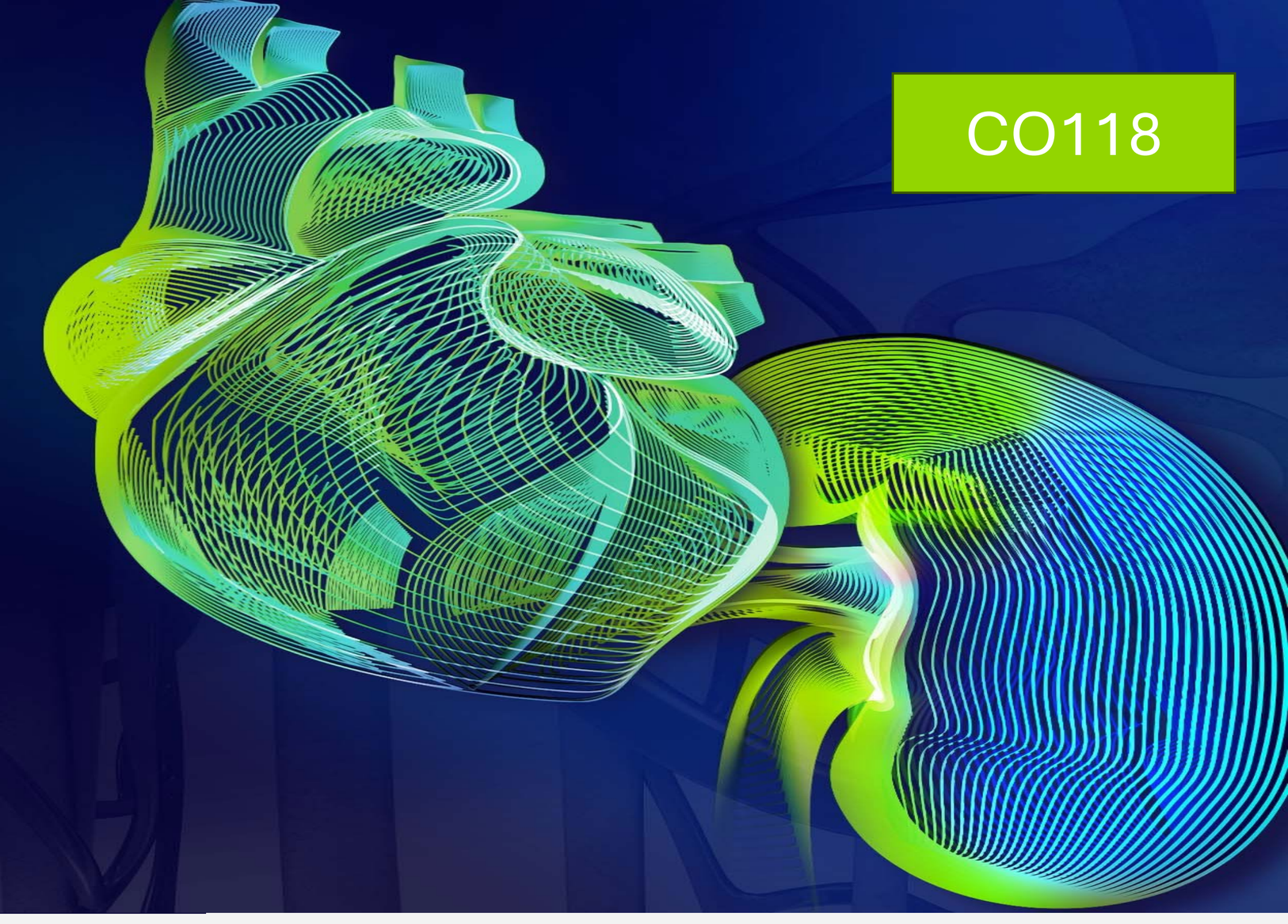
CO118

Clinical and Economic Impact of RBT-1 on Post-operative Complications and Costs of Cardiac Surgery



Frans van Wagenberg, MD[1], Lynn Cherry, PhD[2], Bhupinder Singh, MD[3], Stacey Ruiz, PhD[3], Raf Magar MBA[2]

1 Huntsville Heart Center, Huntsville Alabama, USA, 2 AHRM Inc., Raleigh, North Carolina, USA, 3 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] There remains an unmet need for novel pharmacologic agents that reduce post-operative complications and improve patient outcomes.

A novel drug, RBT-1, has been evaluated in a Phase 2 clinical trial (NCT04564833) 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. Other complications assessed included AKI requiring dialysis, 30-day cardiopulmonary readmission, and death.

OBJECTIVE

To estimate incremental costs or savings for RBT-1 vs Placebo (PBO) based on clinical trial results for CABG, Valve, and Combined CABG/Valve surgery.

METHODS

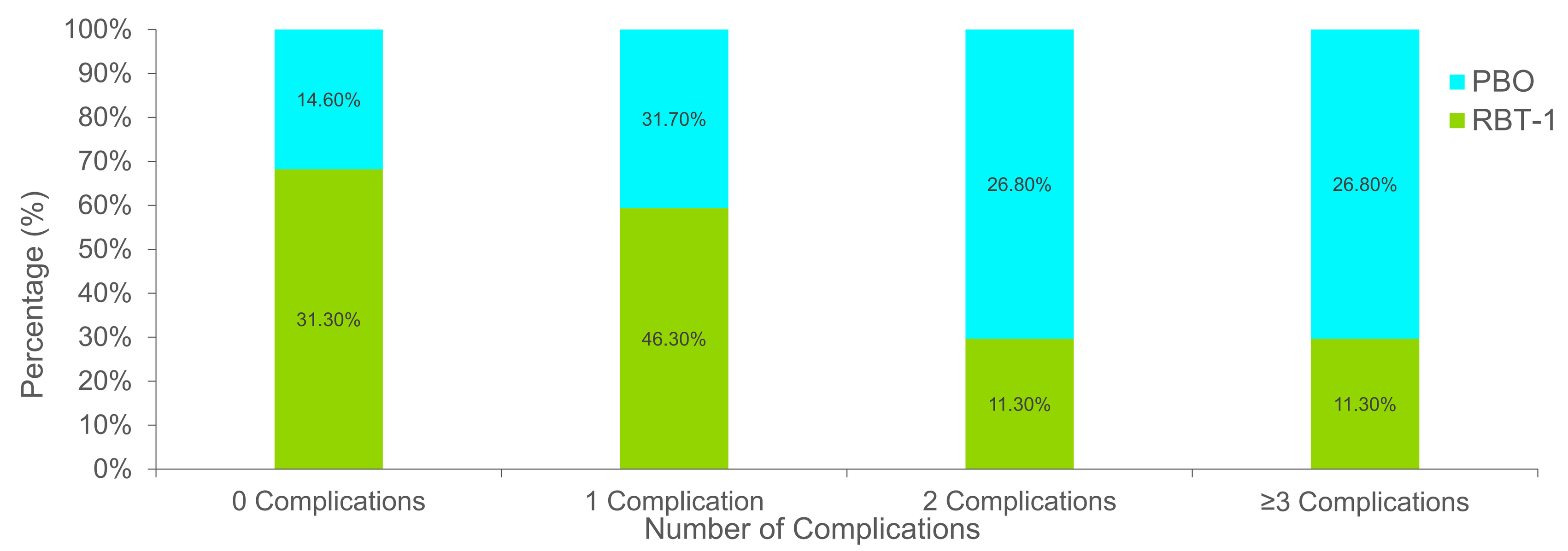
Complication rates from the Phase 2 clinical trial for RBT-1 were utilized in a decision-tree model to estimate the average expected cost of patients dosed with RBT-1 vs. PBO. The decision tree model was constructed to represent the different pathways patients might experience based on the number of 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

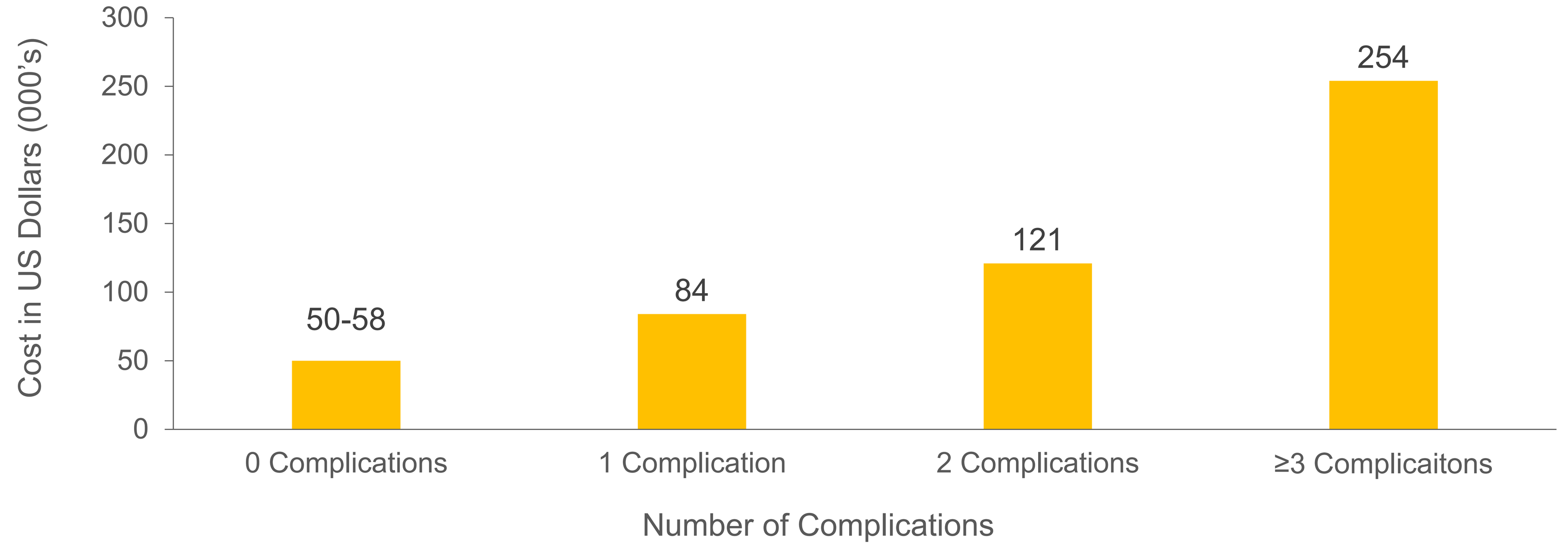
A total of 121 patients qualified for evaluation in this cost study: RBT-1, n=80 and PBO, n=41. Rates for each complication category (0, 1, 2, ≥3 complications) were established for each treatment group: RBT-1: 31.3% (0), 46.3% (1), 11.3% (2), 11.3% (≥3) vs. PBO: 14.6% (0), 31.7% (1), 26.8% (2), and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

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



The cost of surgery without any complications was estimated at $50-58K, which is the average cost of the cardiac surgery procedures. The expected cost when 1, 2, and ≥3 complications occurred was $84K, $121K, and $254K, respectively (Figure 2).

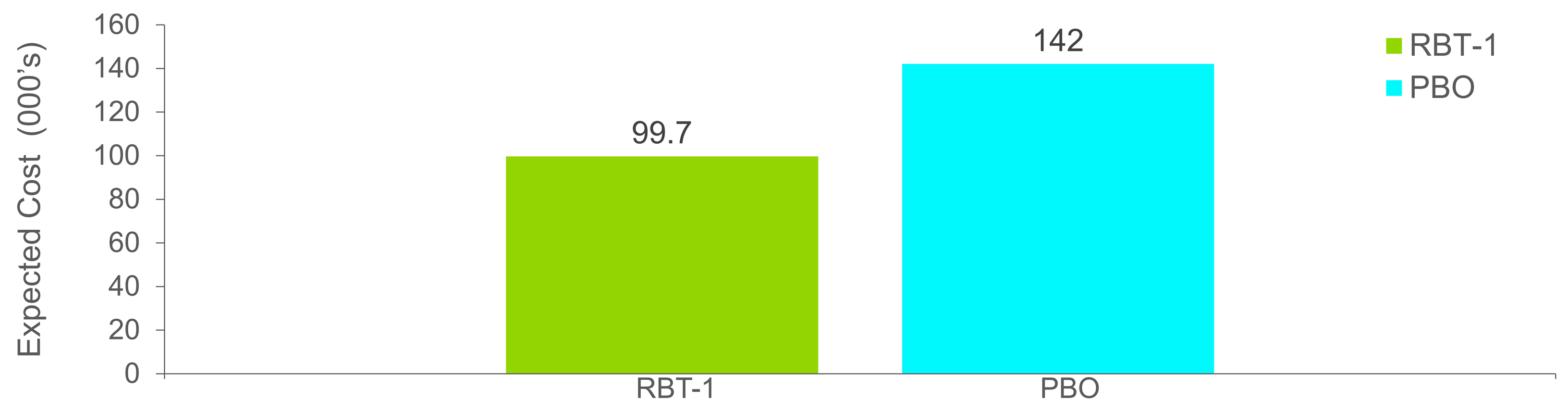
Figure 2. Estimated Costs Due to Complications



Based on this Phase 2 trial, the average expected cost of surgery was $99.7K for a patient receiving RBT-1 vs. $142K for a patient receiving PBO, leading to a 30% ($42K) incremental cost savings in favor of RBT-1 (Figure 3).[6]

RESULTS (cont'd)

Figure 3. Total Expected Cost of Complications



When expected costs were estimated by surgery type, incremental cost savings ranged from $23K for CABG to $63.4K for valve in favor RBT-1 and was influenced by the lower complication rates reported in the RBT-1 group in the Phase 2 trial (Table 1).

Table 1. Total Expected Cost by Surgery Type RBT-1 vs PBO

Number of Complications	CABG		Valve		Combined CABG/Valve	
	RBT-1 (N=44)	PBO (N=20)	RBT-1 (N=22)	PBO (N=7)	RBT-1 (N=14)	PBO (N=14)
0	36.4%	25.0%	27.3%	14.3%	21.4%	0%
1	50%	40.0%	45.5%	14.3%	35.7%	28.6%
2	9.1%	25.0%	13.6%	28.6%	14.3%	28.6%
≥3	4.6%	10%	13.6%	42.9%	28.6%	42.9 %
Total Expected Cost of Surgery	85K	108K	106.4K	169.8K	142.4K	182.5K
(Incremental Savings)	(23K)		(63.4K)		(40K)	

CONCLUSIONS

Cardiac surgery complications are common and costly to the healthcare system. For patients who have multiple complications, costs are not additive but rather exponential. Results from the Phase 2 trial suggest a protective effect of RBT-1, leading to lower complication rates and reduced average expected costs overall and by surgery type. Additional data from an ongoing Phase 3 trial, which includes a 1-year post-cardiac surgery follow-up, will contribute additional data to evaluate the impact of RBT-1 on clinical, economic, and qualitative outcomes compared to standard of care.

renibus therapeutics

ISPOR
Improving healthcare decisions

Accepted for Presentation at the Annual ISPOR 2025 Meeting – Montreal, QC Canada (May 13-16, 2025)

References

1 Pahwa 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, Chertow GM, Jessen M, Collar A, Brown CD, Mack CA, Marzouk M, Scavo V, Washburn TB, Savage D, Smith J, Bennetts J, Assi R, Shults C, Arghami 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: PMC10994969.

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;10:266-81

5 Ferket BS, Thourani VH, Voisine 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, Gammie 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.

6 van Wagenberg F, Cherry L, Singh B, Ruiz S, Magar R.. Impact of RBT-1 on Post-operative Complication Rates and Costs for Cardiac Surgery. AMCP Nexus 2024.