Cost-Impact Analysis of Baroreflex Activation Therapy in Patients with Chronic Heart Failure in the United States

Michael R. Zile, MD[1], John E. Schneider, PhD[2], Shawn Davies, MA[2], Elizabeth Galle, MPH[3], Ivana Stojanovic, MA[3], John D. Bisognano, MD, PhD[4]

[1]Medical University of South Carolina, and Ralph H. Johnson Department of Veteran Affairs Medical Center, Charleston, SC, [2]Avalon Health Economics, Morristown, NJ, [3]CVRx Inc., Minneapolis, MN, [4]University of Rochester Medical Center, Rochester, NY

Funding: This study was funded by CVRx

OBJECTIVE

We evaluated the cost of baroreflex activation therapy (BAT) and guideline directed therapy (GDT) compared to GDT alone for chronic heart failure (CHF) patients with reduced ejection fraction and New York Heart Association Class II or III.

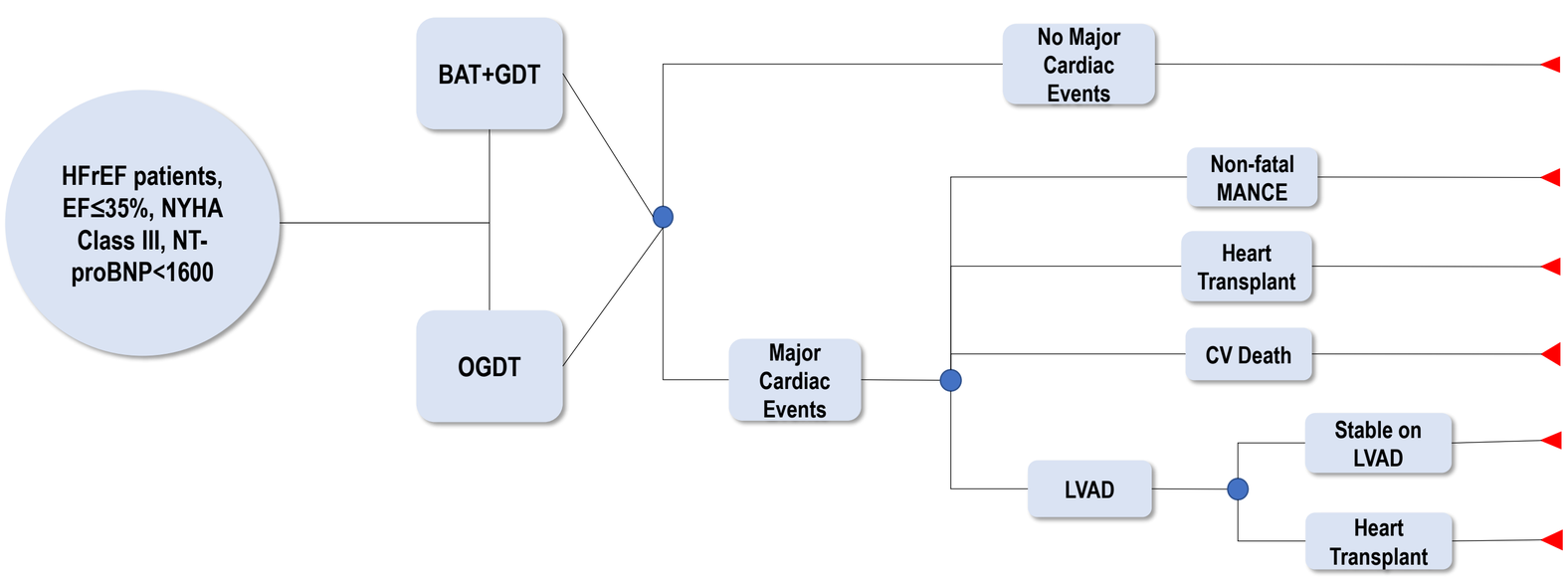
BACKGROUND

CHF affects roughly 5.7 million adults in the United States, accounting for $30.7 billion in medical spending each year. One approved therapy for CHF symptomatic treatment in these patients is BAT. BAT is delivered by an implantable device that stimulates the baroreceptors through an electrode attached to the outside of the carotid artery. The stimulation generates a reduction of sympathetic outflow and an increase of parasympathetic activity, thereby rebalancing the autonomic nervous system to regain cardiovascular (CV) homeostasis. The BeAT-HF trial evaluated the safety and effectiveness of BAT, resulting in FDA approval in August 2019.

METHODS

A Cost Impact Model was developed from a U.S. health care payer perspective over a 3-year period, based on 6-month outcome data that compares BAT + GDT to GDT alone. A visualization of the model structure is shown in **Figure 1**. The expected costs associated with each group were calculated by utilizing data from the BeAT-HF trial and existing literature. BAT implant related adverse events, progression to LVAD or heart transplantation, medication utilization and CV non-HF hospitalizations were based on BeAT-HF 6-month results and extrapolated beyond 6-months. HF hospitalization rates throughout the model were extrapolated based on assumptions within the BeAT-HF statistical analysis plan. HF hospitalizations and CV death rates remain blinded in BeAT-HF and were not used in this analysis.

Figure 1. Primary Conceptual Model



RESULTS

At 6 months, expected costs in BAT + GDT were $37,916/patient more expensive than GDT alone, reflecting initial BAT device and implantation costs. By 3 years, the predicted costs per patient was $1,682 lower for BAT + GDT versus GDT alone. This stems from an offset of higher short-term BAT + GDT costs with lower rates of significant non-HF CV hospitalizations, HF hospitalizations, and resource intensive late-stage procedures (LVADs and heart transplants) as compared to GDT alone. **Table 1** summarizes the expected costs by treatment and time period for both BAT + GDT and GDT alone.

Table 1.
Expected Costs per Patient by Treatment and by Time Period, BAT + GDT vs. GDT alone, 2018 US Dollars

Time Period (a)	**BAT + GDT**	**GDT**	**Difference**
6 Months	$51,990	$14,074	$37,916
1 Year	$61,420	$28,093	$33,327
2 Years	$75,384	$58,485	$16,900
3 Years	$88,405	$90,086	($1,682)

Notes: (a) time period is marked by the implantation of the BAT device; 6-month data pertains to the BeAT-HF clinical trial, whereas years 1, 2 and 3 are based on extrapolations.

CONCLUSION

BAT + GDT treatment starts to become less costly than GDT alone between years 2 and 3 and provides significant savings over time. As BeAT-HF trial outcome data past 6 months becomes available, the methodology and results of this model will be updated to give a more accurate representation of outcomes between BAT + GDT and GDT alone.

KEY REFERENCES

Doust, J.A., et al., *How well does B-type natriuretic peptide predict death and cardiac events in patients with heart failure: systematic review.* Bmj, 2005. **330**(7492): p. 625.
Deng, M.C., *Cardiac transplantation.* Heart (British Cardiac Society), 2002. **87**(2): p. 177-184.
Schumock, G.T., et al., *National trends in prescription drug expenditures and projections for 2018.* Am J Health Syst Pharm, 2018. **75**(14): p. 1023-1038.
Zile, M.R., et al., *Prognostic Implications of Changes in N-Terminal Pro-B-Type Natriuretic Peptide in Patients With Heart Failure.* J Am Coll Cardiol, 2016. **68**(22): p. 2425-2436.
CVRx. *Heart Failure Management*. Available from: http://www.barostimtherapy.com/en/patient/patient-heart-failure-management-view.
Abraham, W.T., et al., *Baroreflex Activation Therapy for the Treatment of Heart Failure With a Reduced Ejection Fraction.* JACC Heart Fail, 2015. **3**(6): p. 487-496.
Weaver, F.A., et al., *Surgical Experience and Long-term Results of Baroreflex Activation Therapy for Heart Failure With Reduced Ejection Fraction.* Semin Thorac Cardiovasc Surg, 2016. **28**(2): p. 320-328.
Zile, M.R., et al., *Baroreflex activation therapy for the treatment of heart failure with a reduced ejection fraction: safety and efficacy in patients with and without cardiac resynchronization therapy.* Eur J Heart Fail, 2015. **17**(10): p. 1066-74.
Abraham, W.T., et al., *A Randomized, Controlled Trial of Barorreflex Activation Therapy (BAT) in Patients with Heart Failure and Reduced Ejection Franction (HFrEF)*. 2019, CVRx, Inc.