

PCORnet Bariatric Study (PBS): A PCORnet Demonstration Project

Kathleen McTigue, David Arterburn, Neely Williams, Jane Anau, Karen Coleman, Yates Coley, Andrea Cook, Anita Courcoulas, Roy Pardee, Cheri Janning, Darren Toh, and Rob Wellman, on behalf of the PCORnet Bariatric Study Collaborative*

*Caroline Apovian, Lydia Bazzano, Jeff Brown, Jeanne Clark, Nirav Desai, Elizabeth Doane, Emily Eckert, Ana Emiliano, John Holmes, Thomas Inge, Lingling Li, Elisha Malanga, Corrigan L. McBride, James McClay, Marc Michalsky, Sameer Murali, Joe Nadglowski, Rabih Nemr, Andrew Odegaard, Alberto Odor, Gabrielle Purcell, Laura Rasmussen-Torvik, Roz Saizan, David Schlundt, Steven R. Smith, Ali Tavakkoli, Tammy St. Clair, Julie Tice, Joseph Vitello, and Roni Zeiger



Study & Project Aims

- Bariatric procedures in use have shifted substantially (see Figure 1)
 - Most common US procedures:
 - Roux-en-y gastric bypass (RYGB)
 - Sleeve gastrectomy (SG)
 - Adjustable gastric banding (AGB)
 - Few CER studies evaluate bariatric procedures in large, diverse populations
- PBS uses electronic health record (EHR) data from >40 PCORnet-affiliated health systems
 - Will estimate 1-yr, 3-yr, and 5-yr benefits & risks of RYGB, AGB and SG
 - Researchers work closely with the PCORnet Coordinating Center to develop Common Data Model (CDM) queries
 - Queries identify bariatric patients and their health outcomes & return de-identified data
- Activities to benefit future PCORnet studies
 - Disease-specific coding lists & program code
 - Approaches for conducting analyses on de-identified data
 - Analyses of stakeholder and project management approaches

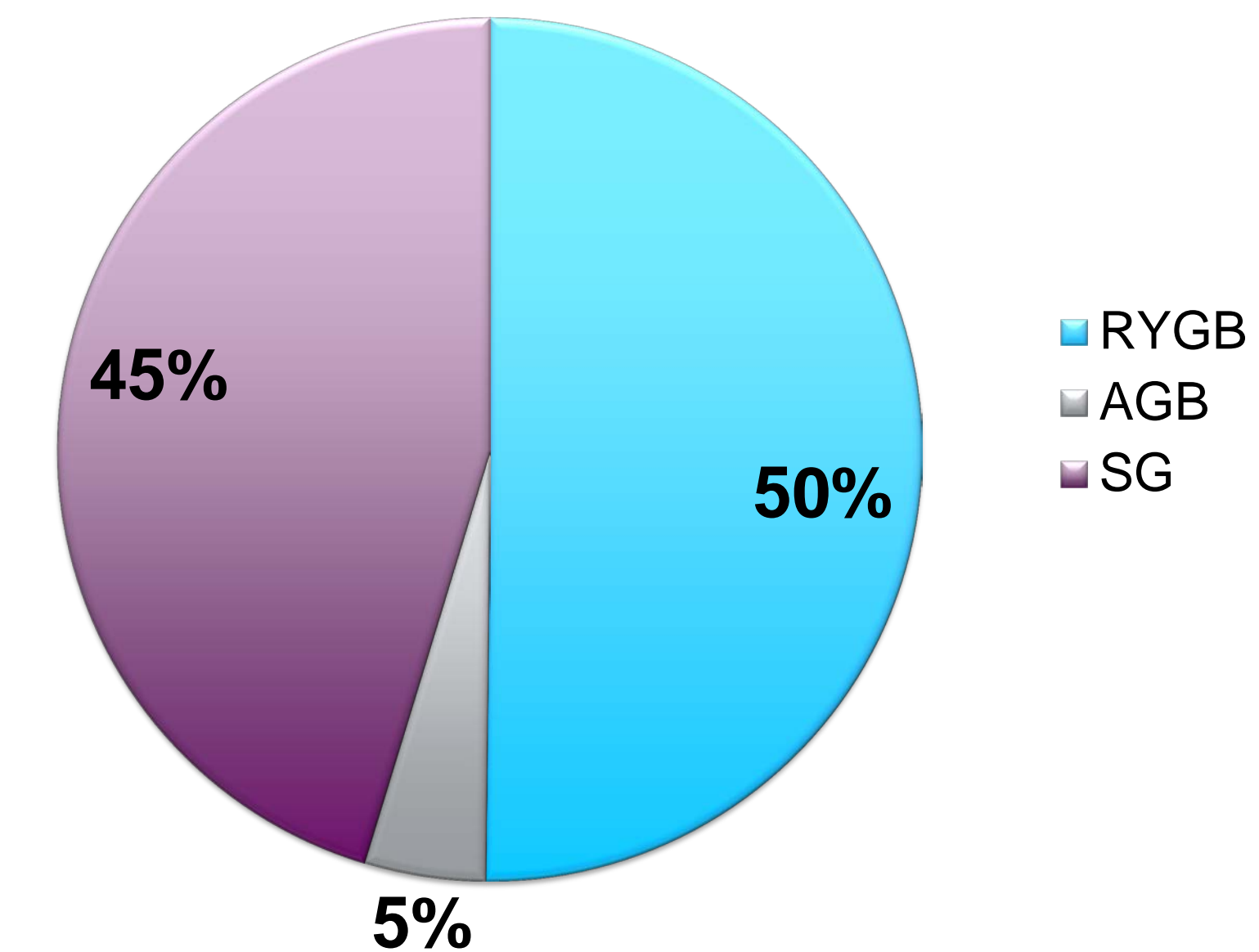
Methods

- Analyses will include:
 - Adjustment for potential confounders (e.g., age, sex, race/ethnicity, year of surgery, baseline BMI, location, comorbidities, insulin use)
 - Heterogeneity of treatment effects for important covariates (e.g., race, sex, age)
 - Comparison of individual-level & distributed analytic approaches
 - Qualitative work will examine patient perspectives on:
 - Whether to undergo surgery
 - Which bariatric procedure to use
 - Delivery of follow-up care after bariatric surgery

Research Objectives

- PBS examines 3 outcomes of importance to people affected by severe obesity:**
 - Weight Change
 - Diabetes remission & relapse
 - Major adverse events.
- PBS is timely due to rapid shift towards SG in the US**
 - Introduced in the late 2000s
 - 45% of bariatric procedures in participating CDRNs
 - Lacks long-term comparison data to RYGB & AGB
- Patients worked hand-in-hand with researchers & clinicians to develop the research questions, beginning with the initial topic brief (see quote box)**
- PBS' Executive Bariatric Stakeholder Advisory Group** includes patients, pediatric and adult bariatric surgeons, primary care and specialty physicians, researchers, and leaders of patient-level policy and advocacy organizations. This group works with our national research team to make decisions on how we collect data, analyze it, and share findings.
- The large study cohort will enable analysis of how different populations respond to bariatric procedures, allowing patients to see themselves in our study results.**
- Results from the PCORnet Bariatric Study will help to inform each person considering bariatric surgery and their clinicians as to which procedure might be best for them.**

Figure 2. Bariatric Procedures in the PBS Cohort



Initial Findings

- PBS identified 63,473 individuals who had a primary (initial) bariatric procedure for weight loss between 2005 – 2015.** These individuals also had BMI ≥ 35 kg/m² in the year before surgery.
- RYGB was the most common procedure, followed by SG, then AGB (see Figure 2)**
- Next Steps are to examine:**
 - Individuals' weight changes after bariatric surgery
 - How weight change differs across the 3 procedures.
- We are working to collect data on diabetes outcomes and adverse events following bariatric surgery.

DISCLOSURES

None.

FUNDING / ACKNOWLEDGEMENTS

This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (OBS-1505-30683). All statements in this poster, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

CONTACT INFORMATION

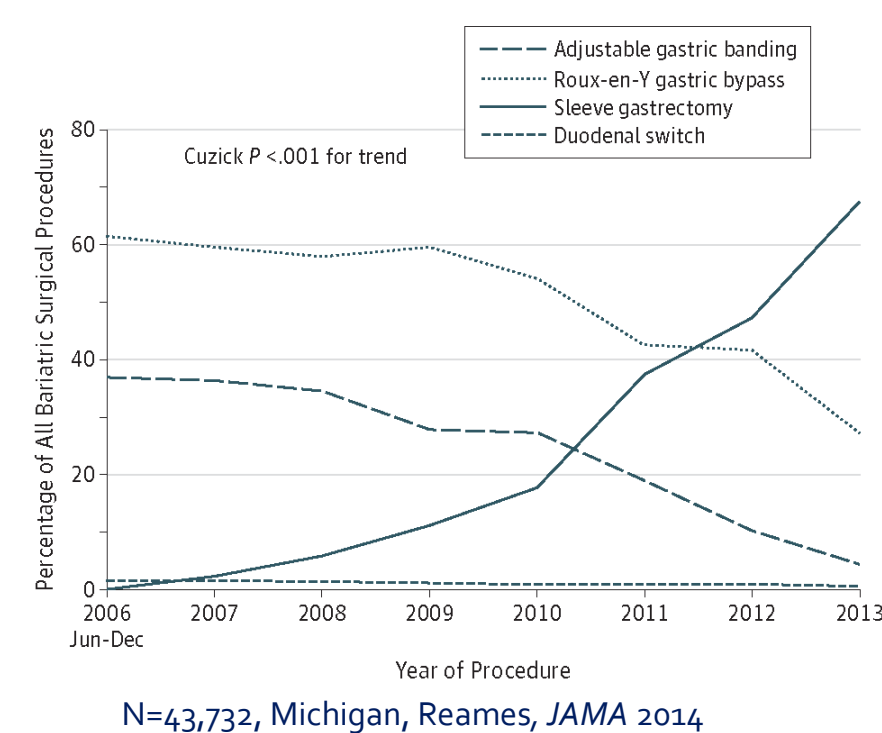
Kathleen McTigue - mctiguekm@upmc.edu



*“As a recent bariatric patient, I am very interested in research outcomes in later years. I also think it is important to look at the **outcome variances by the type of surgery selected.** Having access to statistics would be beneficial to the patient in making an informed decision.”*

- Patient member of the study's Executive Bariatric Stakeholder Advisory Group

Figure 1. Trends in Bariatric Procedures



Participating CDRNs

CAPriCORN
GPC
Mid-South
NYC-CDRN
OneFlorida
PaTH
PEDSnet
PORTAL
pSCANNER
REACHnet
SCILHS

Participating PPRNs

Ar-PoWER
COPD Foundation
Mood Network

N=43,732, Michigan, Reames, JAMA 2014