# Two Approaches to Identifying Non-Surgical Controls for Bariatric Surgery Evaluation

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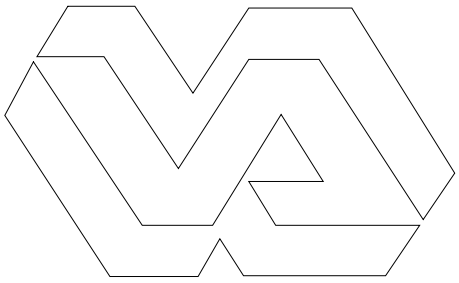

# Acknowledgements


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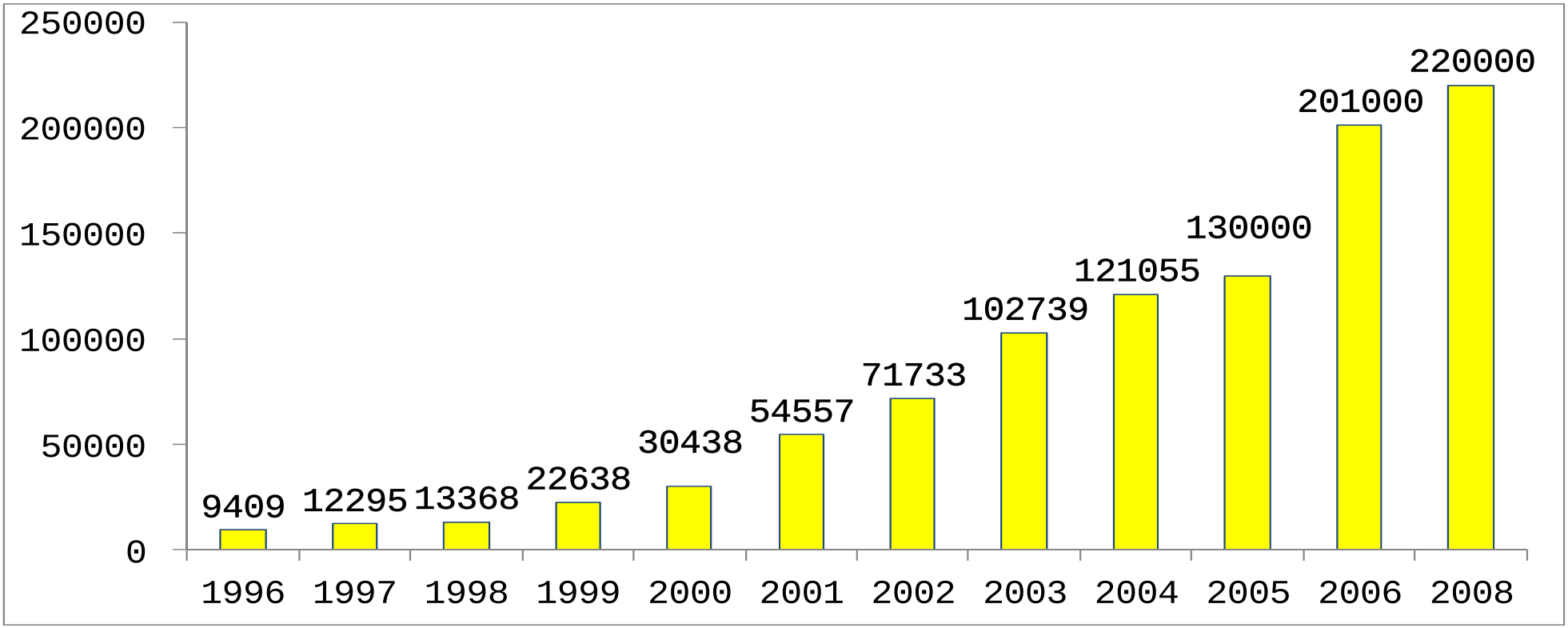
  - IIR 05-201, SHP 08-137
  - RCS 10-391

# Outline

- Prior aims and results
- Reaction to this work and scientific reflection due to reaction
- Cohort identification analysis
- Implications for evidence base?

# Evidence and Demand for Bariatric Surgery

- Most effective treatment for weight loss, comorbidity reduction, and improved QoL
- Low mortality (30-day: 0.28%, 1 yr: 1%)




Davis, Slish, 2006; Encinosa, Bernard, 2005; Santry, Gillen, Lauderdale, 2005; Thomson, 2007

# Prior Research Questions

## IIR 05-201

- Specific Aim 1: Compare survival rates of morbidly obese veterans who had bariatric surgery from 2000 to 2005 with those of a cohort of morbidly obese veterans who did not have surgery
  - *JAMA* June 2011
- Specific Aim 2: Compare the health care use and expenditures of morbidly obese veterans who had bariatric surgery with those of a cohort of morbidly obese veterans who did not have surgery
  - Under review at *Medical Care*
- Secondary Aim 1: Compare the preoperative and postoperative health care use and expenditures for morbidly obese veterans who had bariatric surgery in VA medical centers from 2000 to 2005
  - *Medical Care* Nov 2010
- Secondary Aim 2: Identify patient-level predictors of survival and adverse events among morbidly obese veterans who had bariatric surgery in VA medical centers from 2000 to 2005
  - *Archives of Surgery* Oct 2009

## SHP 08-137

- Specific Aim 1: For obese veterans who had bariatric surgery in 2000-2006, how much did their weight and BMI change in the months after surgery? Did these changes persist over time?
  - Under review at *Obesity Research & Clinical Practice*
- Specific Aim 2: Compared to non-surgical controls, how much did weight and BMI of obese veterans who had bariatric surgery in 2000-2006 change in the months after surgery?
  - Not done
- Specific Aim 3: Among obese veterans with diabetes or dyslipidemia who had bariatric surgery in 2000-2006, what proportions were able to discontinue their oral hypoglycemic agents or statins in the months after surgery?
  - *SOARD* Nov/Dec 2010

# Study Design of Case Analyses

- Retrospective cohort

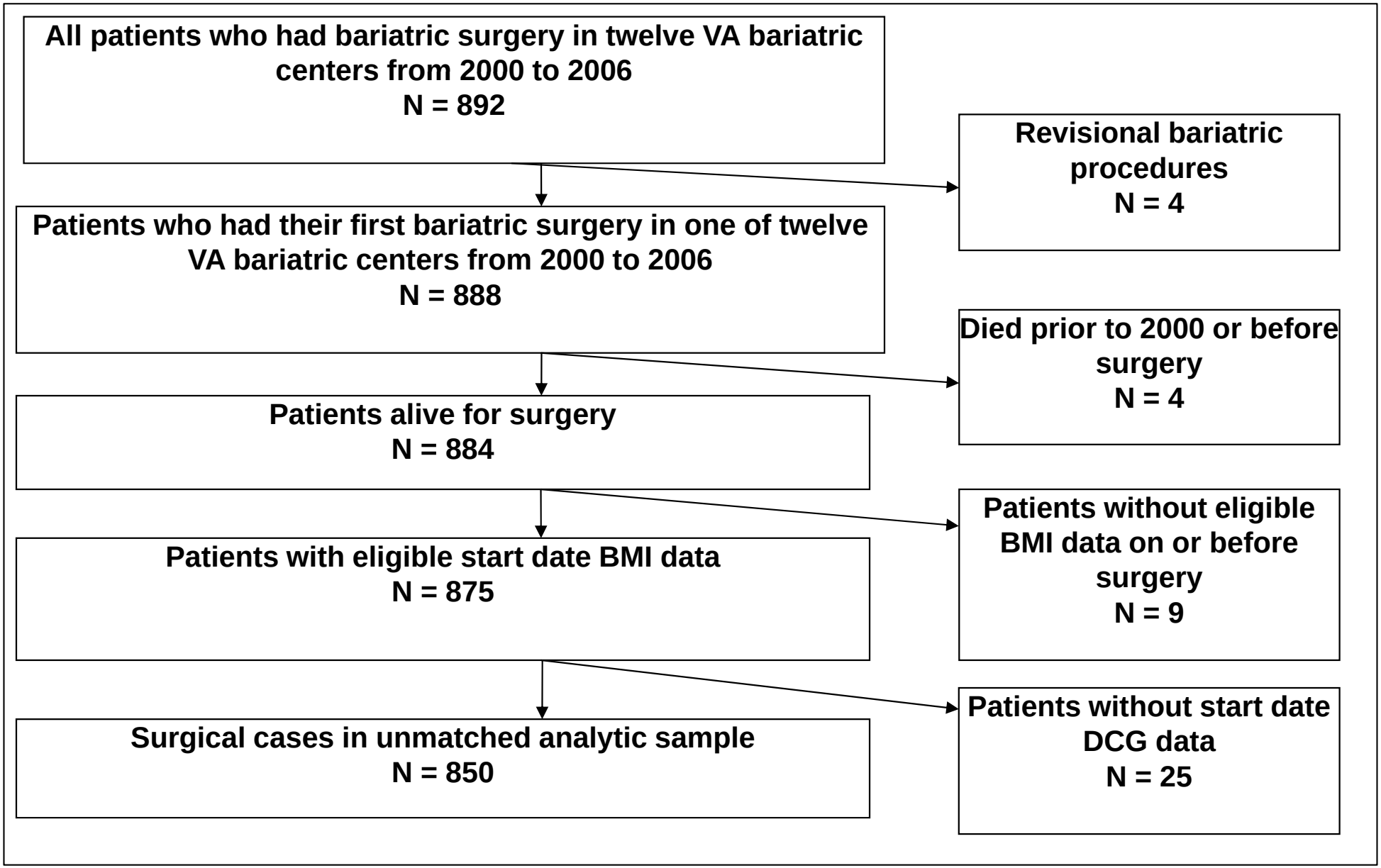
- Veterans who had bariatric surgery in one of 12 VA facilities (N=850)
  - Identified by CPT codes in 2000-2006
    - Sensitivity: 99.2%, Specificity: 99.9%

# Source for Cases: VA Surgical Quality Improvement Program

- VA Initiative to Monitor, Compare and Improve Surgical Quality
  - Founded in 1994

- Trained surgical clinical nurses extract data on major surgical procedures using standardized protocol
  - Demographics, pre-op comorbidities & labs
  - 30-day post-op complications & mortality

# Sample Flow of Surgical Cases



# Survival Analysis of Cases

| | Hazard Ratio | 95% Confidence Interval | P-value |
|---|---|---|---|
| Age (continuous) | 1.02 | (0.98, 1.05) | 0.41 |
| Male | 1.26 | (0.58, 2.75) | 0.57 |
| Non-Caucasian Race** | 0.71 | (0.28, 2.36) | 0.71 |
| Unknown Race** | 1.51 | (0.85, 2.66) | 0.16 |
| BMI ≥ 50 | **1.77** | **(1.01, 3.09)** | **0.04** |
| ASA class 3*** | 2.13 | (0.50, 9.12) | 0.31 |
| ASA class 4*** | 4.65 | (0.95, 22.84) | 0.06 |
| DCG score ≥ 2**** | **3.40** | **(1.79, 6.48)** | **P<0.001** |
| Smoker | 1.24 | (0.61, 2.53) | 0.56 |
| Diabetes (oral/insulin) | 1.08 | (0.62, 1.90) | 0.78 |
| Laparoscopic procedure | 0.10 | (0.01, 0.74) | 0.02 |

Arterburn 2009 Arch Surg

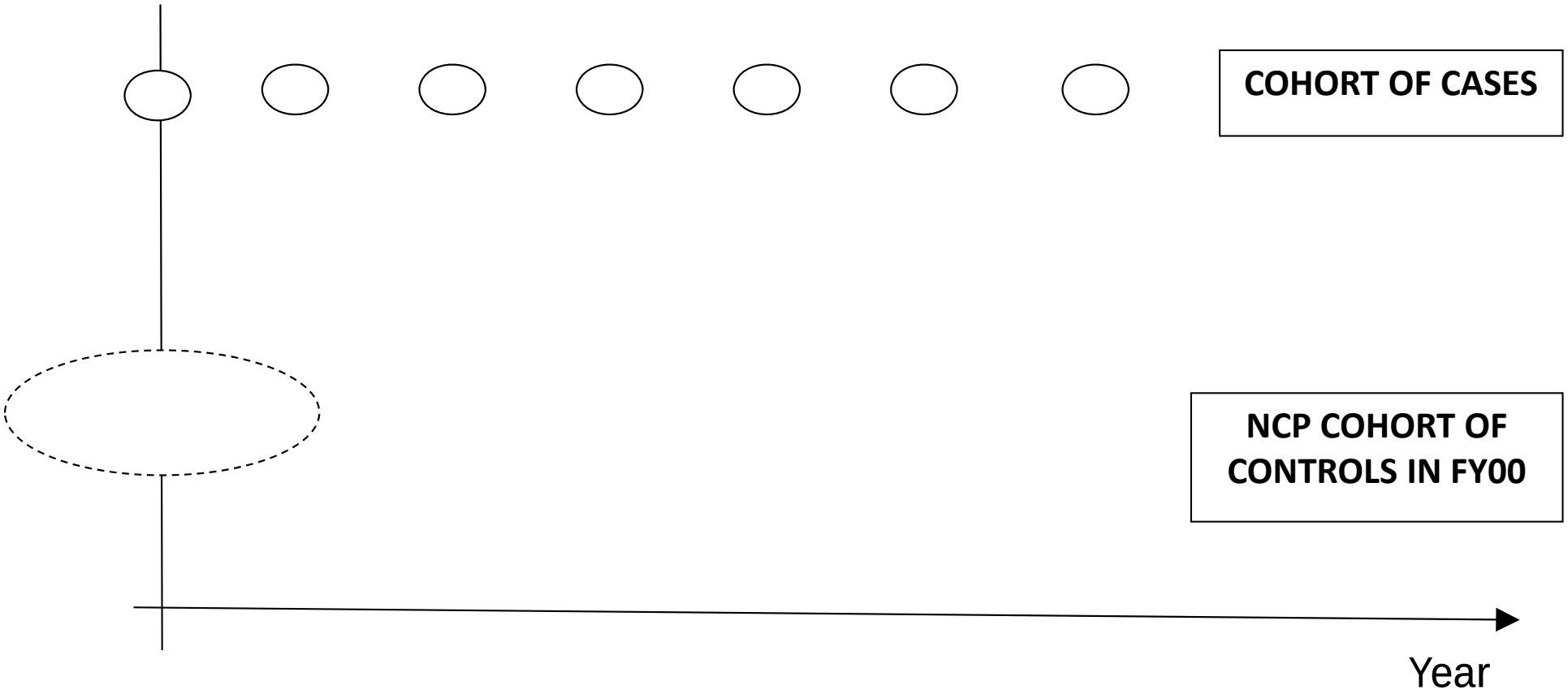
# Study Design of Case-Control Comparisons

- Retrospective cohort w/ non-equivalent controls

- 850 veterans who had bariatric surgery
  - Identified by CPT codes in 2000-2006
    - Sensitivity: 99.2%, Specificity: 99.9%

- Veterans who did not have surgery
  - Identified from NCP registry made in 2000

# Control Cohort



# Descriptive Statistics

| | Surgical Pts N=850 | Controls N=41,244 | Standardized Differences |
|---|---|---|---|
| Age (Mean, (SD)) | 49.5 (8.3) | 54.7 (10.2) | -55.92 |
| Age ≥ 65 years (%) | 18 (2.1) | 8,534 (20.7) | -61.20 |
| Male (%) | 628 (73.9) | 37,840 (91.7) | -48.54 |
| Caucasian (%) | 662 (77.9) | 27,967 (67.8) | 22.86 |
| Non-Caucasian (%) | 136 (16.0) | 7,977 (19.3) | -8.66 |
| Married (%) | 443 (52.1) | 23,808 (57.7) | -11.27 |
| Previously Married (%) | 258 (30.4) | 11,259 (27.3) | 6.85 |
| Never Married (%) | 139 (16.4) | 5,700 (13.8) | 7.00 |
| BMI (Mean, SD) | 47.4 (7.8) | 42.0 (5.0) | 82.43 |
| Super Obese (BMI ≥ 50) (%) | 266 (31.3) | 2,905 (7.0) | 64.93 |
| Diagnostic Cost Group (DCG) score | 0.60 (0.92) | 0.47 (0.75) | 15.49 |
| DCG score ≥ 2 (%) | 42 (4.9) | 1,633 (4.0) | 4.37 |
| Fiscal year of start time: 2000 | 339 (39.9) | 34,908 (84.6) | -104.24 |
| Fiscal year of start time: 2001 | 104 (12.2) | 4,921 (11.9) | 0.92 |
| Fiscal year of start time: 2002 | 110 (12.9) | 468 (1.1) | 47.21 |
| Fiscal year of start time: 2003 | 94 (11.1) | 342 (0.8) | 44.61 |
| Fiscal year of start time: 2004 | 87 (10.2) | 216 (0.5) | 44.14 |
| Fiscal year of start time: 2005 | 69 (8.1) | 212 (0.5) | 38.14 |
| Fiscal year of start time: 2006 | 47 (5.5) | 177 (0.4) | 30.49 |

# Covariate Imbalance Improved with 1:1 Propensity Matching

| | Unmatched | Matched |
|---|---|---|
| Age (Mean, (SD)) | -55.92 | 6.04 |
| Age ≥ 65 years (%) | -61.20 | -8.50 |
| Male (%) | -48.54 | 0.55 |
| Caucasian (%) | 22.86 | 2.25 |
| Non-Caucasian (%) | -8.66 | -1.92 |
| Married (%) | -11.27 | -1.90 |
| Previously Married (%) | 6.85 | 3.62 |
| Never Married (%) | 7.00 | -6.81 |
| BMI (Mean, SD) | 82.43 | 3.22 |
| Super Obese (BMI ≥ 50) (%) | 64.93 | 3.33 |
| Diagnostic Cost Group (DCG) score | 15.49 | 0.93 |
| Fiscal year of start time: 2000 | -104.24 | -111.41 |
| Fiscal year of start time: 2001 | 0.92 | 4.09 |
| Fiscal year of start time: 2002 | 47.21 | 49.81 |
| Fiscal year of start time: 2003 | 44.61 | 45.97 |
| Fiscal year of start time: 2004 | 44.14 | 45.36 |
| Fiscal year of start time: 2005 | 38.14 | 36.76 |
| Fiscal year of start time: 2006 | 30.49 | 34.28 |

# Matched & Unmatched Survival Outcomes

| | Unmatched | | Matched | |
|---|---|---|---|---|
| | Unadjusted | Covariate Adjusted | Unadjusted | Year Adjusted |
| Bariatric surgery | 0.638<br>0.511 - 0.797 | 0.795<br>0.634 - 0.995 | 0.833<br>0.607 - 1.144 | 0.939<br>0.635 - 1.389 |
| Sample size | 42,094 | | 1,694 | |

Maciejewski 2011 JAMA

# Reaction To These Results

- Survival results can't possibly be right
  - SOS, Utah studies (2007 NEJM) & systematic review show protective effect against death (Patterson, Belle & Wolfe JAMA 9/28/11)
- Absence of evidence isn't evidence of absence
- Explained by volume-outcome relationship?

# Reflection in Response to Reaction

- Initial response
  - Compare demographics
  - Compare follow-up time
  - Compare analytic methods

# Prior Mortality Comparisons

| Author Journal, Year | Patients | | Survival Results | Limitations |
|---|---|---|---|---|
| | Cases | Controls | | |
| MacDonald J Gastro'97 | 154 with diabetes | 78 with diabetes | 9% v. 28% at 6 years | High minority proportion |
| Christou AnnSurg'04 | 1035 pts in '86-02 | 5746 patients | 0.68% vs. 6.2% at 5 yrs | No BMI, ICD9 for control ID |
| Flum JACS '04 | 3328 pts in '87-01 | 62,781 patients | HR=0.67 (0.54-0.85) | No BMI, ICD9 for controls ID |
| SOS NEJM '07 | 2010 pts in '87-01 | 2037 patients | HR=0.76 (0.59-0.99) | Sweden, old surgical tech |
| Adams NEJM '07 | 7925 pts in '84-02 | 7925 patients | HR=0.60 (0.45-0.67) | No casemix, Driver's license control |

# Evidence about Survival associated with Bariatric Surgery

| | Patient Characteristics | | Follow-Up In Years | Survival HR |
|---|---|---|---|---|
| | Mean Age | Male | | |
| Flum 2004 | 43 | 19% | 4.4 | 0.67 |
| Adams 2007 | 40 | 16% | 7.1 | 0.63 |
| SOS 2007 | 47 | 29% | 10.9 | 0.76 |
| Maciejewski 2011 | 49 | 74% | 6.7 | 0.94 |

# Three Possibilities

- We are right and they are right
  - Non-VA:  Surgery good for 40-50 yr old women
  - VA:  Not as good for 50-60 yr old men
- We are wrong (in a sense) & they are right
  - Benefits of surgery takes longer to realize for men and our results will converge when we add 4-5 years of additional follow-up in new study
- We are right and they are wrong
  - VA results are unbiased, no evidence on women
  - Non-VA results are biased for several reasons
    - Poor covariate adjustment and/or no matching
    - Incorrect control identification

# Further Reflection in Response to Reaction

- Initial response
  - Compare demographics
  - Compare follow-up time
  - Compare analytic methods

- Most recent response
  - Examine control selection process
  - BMI in VA vs. obesity Dx everywhere else

# Scientific Objective

- Examine whether patients differ by strategy for identifying non-surgical controls
  - Demographics
  - Mortality
  - Expenditure trends

- Leverage cohort of 34,908 controls with who are eligible based on BMI≥35 in FY00
  - Find subset with obesity Dx

# Outcomes

- Survival Outcome:  Vital status file
  - Survival = Date of death or end of study period – 1st date with recorded BMI ≥ 35
  - Death data from VA, Medicare and Social Security

- Utilization & expenditures:  HERC data
  - OP, IP & total expenditures
  - 6-month blocks

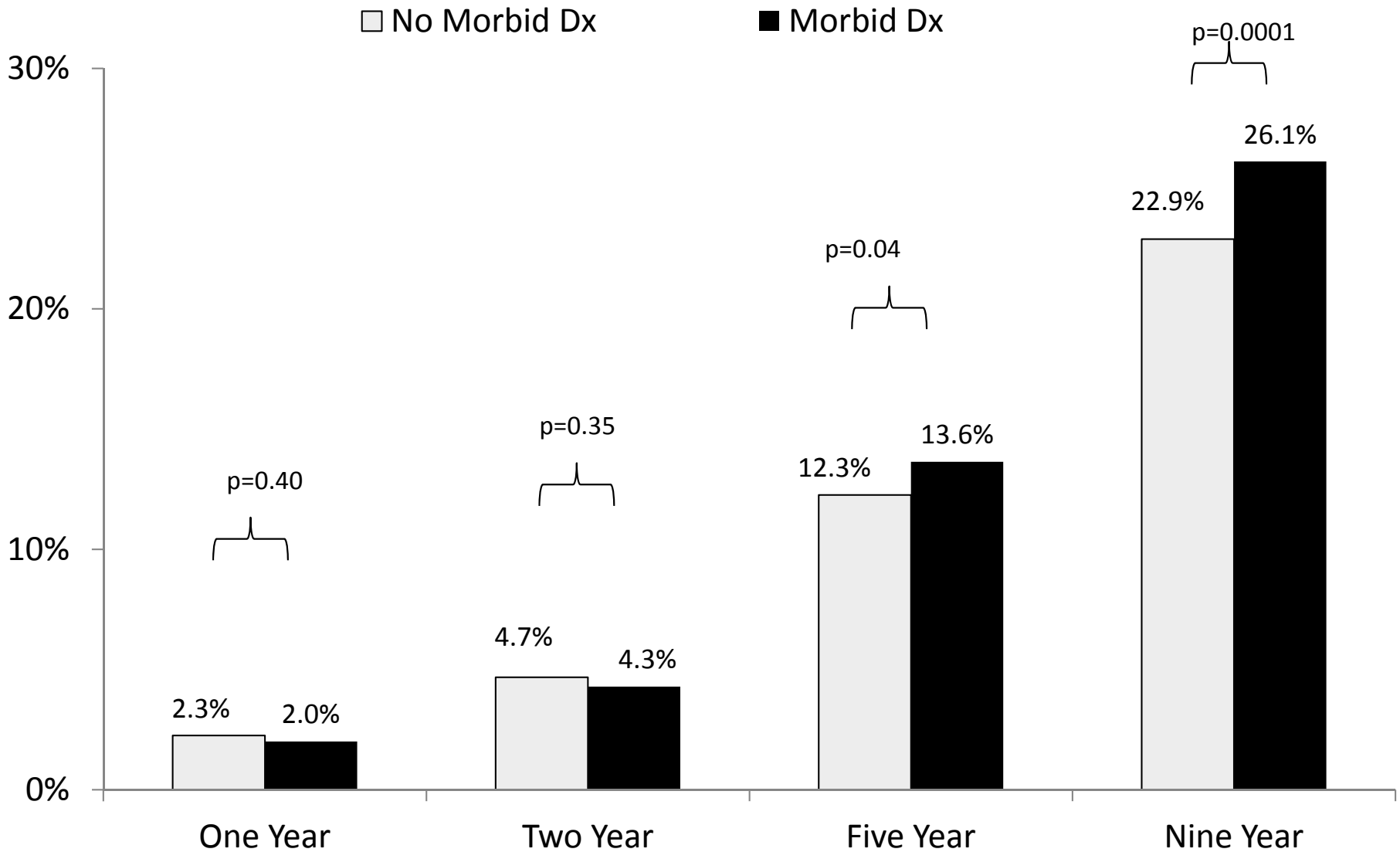
# Covariates

- Socio-demographic:  Age, gender, race, marital status
- BMI:  Corporate Data Warehouse
  - Super obese (BMI>50), binary
- Comorbidity burden:  Diagnostic Cost Group (DCG) score
  - As predictive of VA costs (Maciejewski 2005, 2009) & mortality (Fan, 2006) as other risk measures

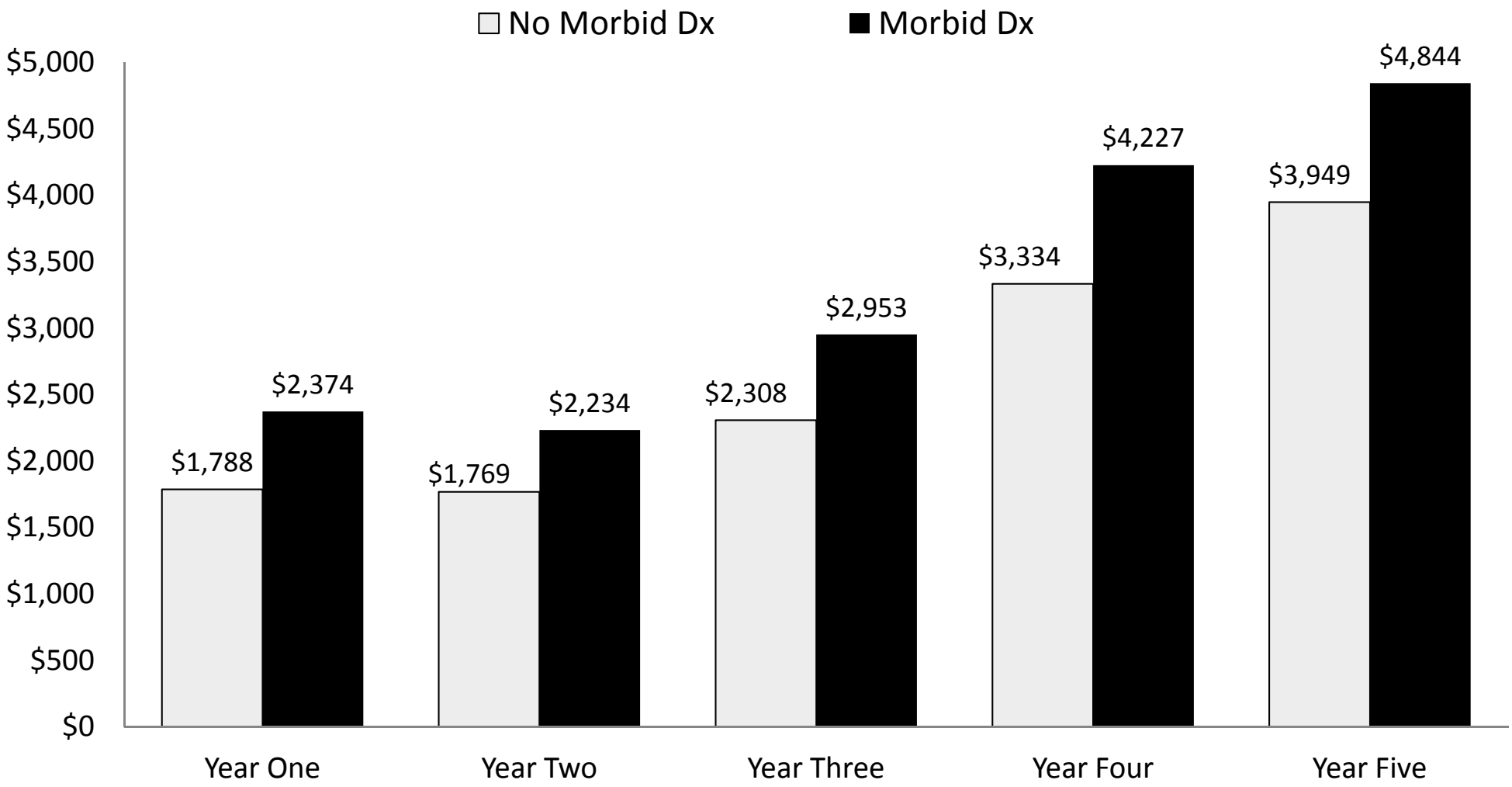
# Baseline Characteristics

| | *No Morbid Obesity Dx* (N=32,225) | *Primary or Secondary Dx of Morbid Obesity* (N=2,683) | *No Dx vs. Dx p-value* |
|---|---|---|---|
| Age (Mean, (SD)) | 54.4 (10.2) | 54.0 (9.5) | 0.0676 |
| Age ≥ 65 years (%) | 20.04 | 16.40 | <0.0001 |
| Male (%) | 91.56 | 92.69 | 0.0411 |
| Caucasian (%) | 68.59 | 70.59 | 0.0313 |
| Non-Caucasian (%) | 20.11 | 21.54 | 0.0755 |
| Unknown Race (%) | 11.30 | 7.86 | <0.0001 |
| Married (%) | 57.40 | 51.73 | <0.0001 |
| Previously Married (%) | 27.12 | 30.86 | <0.0001 |
| Never Married (%) | 14.25 | 16.73 | 0.0004 |
| Unknown Marital Status (%) | 1.23 | 0.67 | 0.0103 |
| BMI (Mean, (SD)) | 41.8 (4.7) | 45.9 (6.4) | <0.0001 |
| Super Obese (BMI≥50) | 5.95% | 22.14% | <0.0001 |
| Diagnostic Cost Group (DCG) score (Mean,(SD)) | 0.48 (0.75) | 0.59 (0.96) | <0.0001 |
| DCG score ≥ 2 (%) | 4.03 | 6.08 | <0.0001 |

# Unadjusted Mortality Differences



# Unadjusted Outpatient Expenditures



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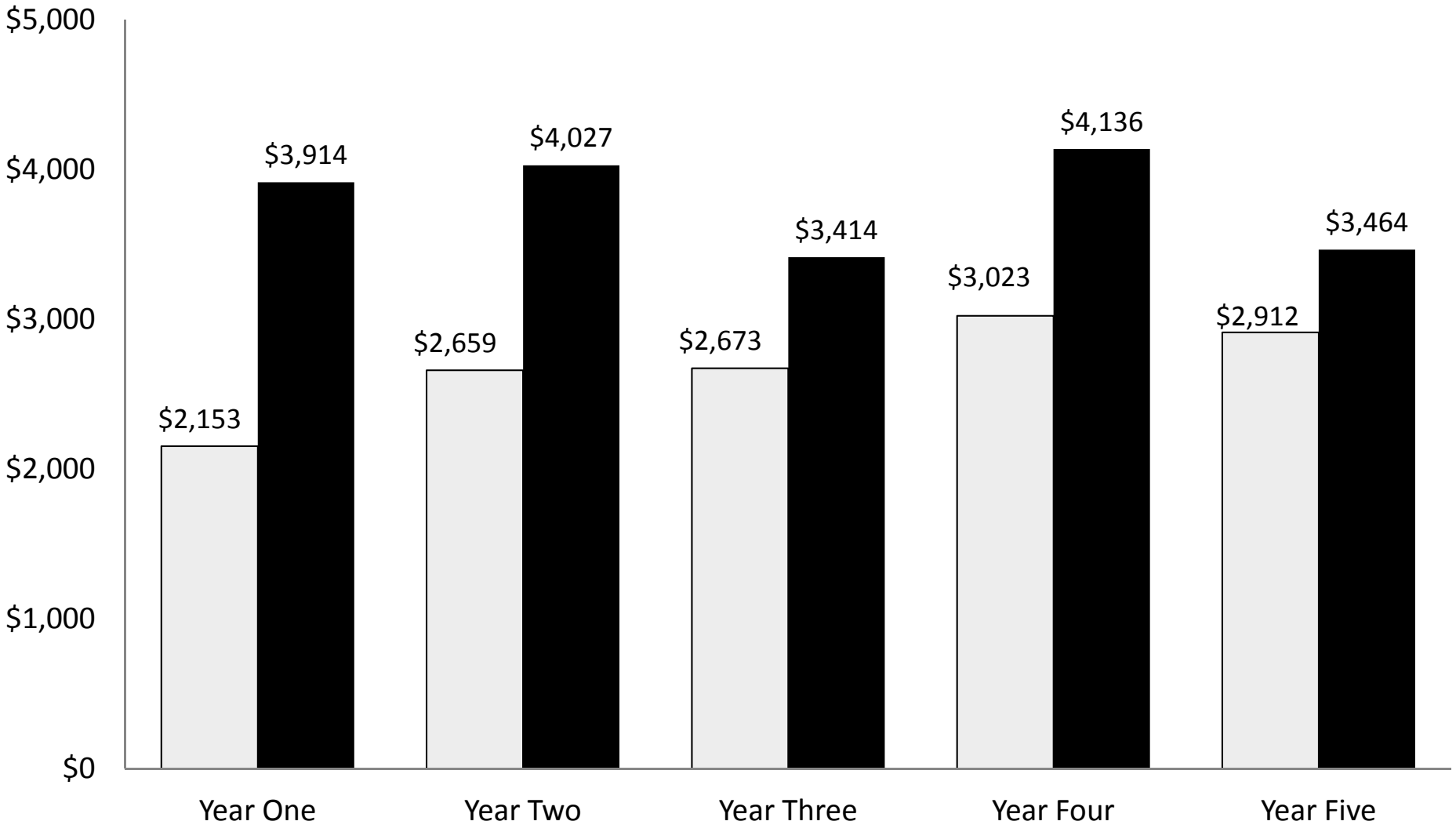
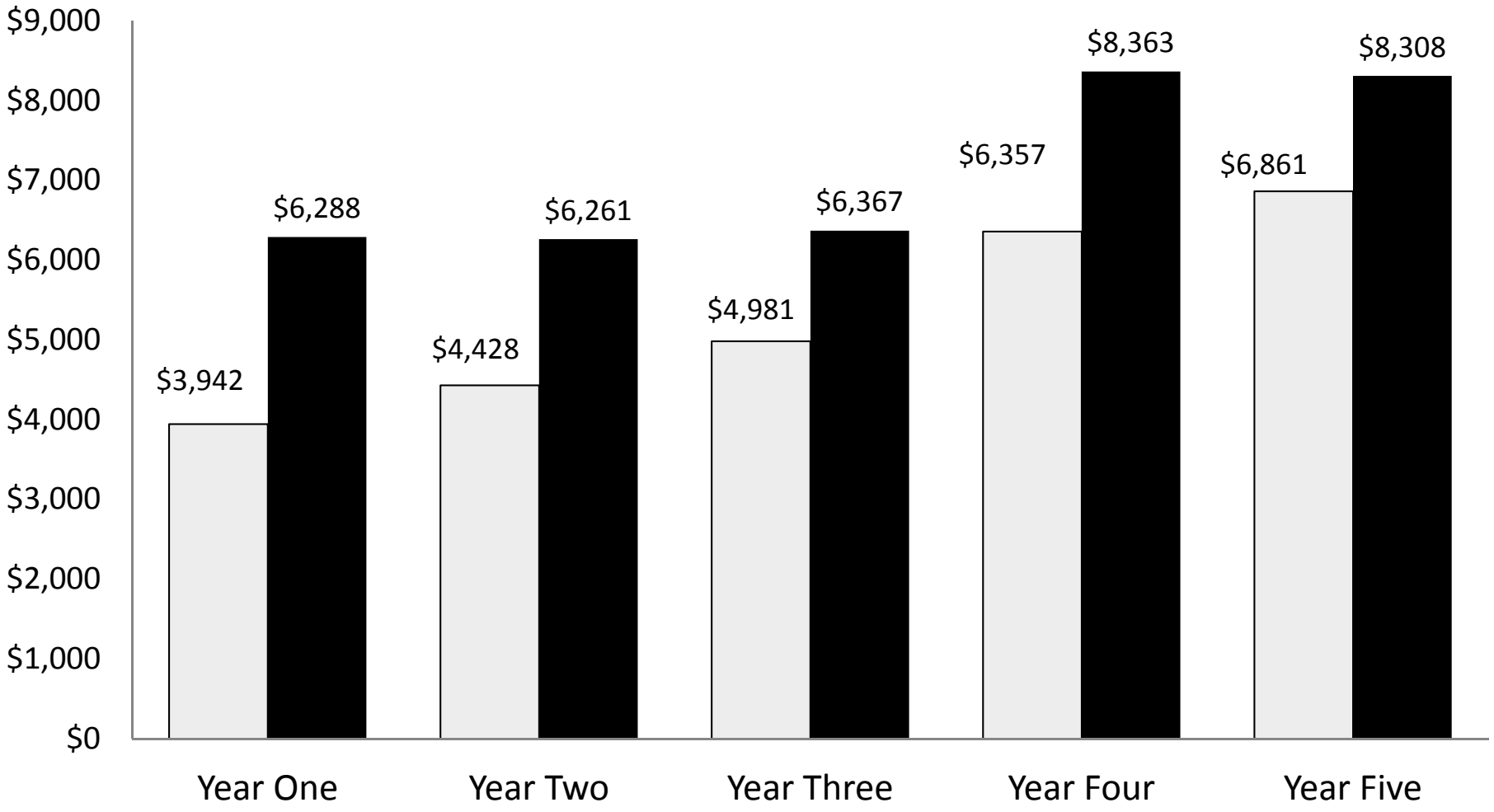


# Unadjusted Total Expenditures



# Conclusion

- Among controls identified from BMI data, 7.7% who had a Dx of morbid obesity
- Veterans with Dx were systematically different from veterans without Dx
  - Sicker and heavier
- Worse outcomes
  - Higher unadjusted mortality rates
  - Higher unadjusted VA expenditures

# Implication for Evidence Base of Bariatric Surgery?

- Potential issues with control identification via diagnosis codes
  - Smaller sample than BMI identification, so limits matching and subgroup analysis
  - Sicker and heavier than BMI-based cohort
- If sicker controls are identified but this bias isn't realized, is evidence base for bariatric surgery more favorable than it would be if BMI data was used to identify controls?

# Questions?