**Annals of Internal Medicine**

ORIGINAL RESEARCH

# Effect of Social Vulnerability on Efficacy of Bariatric Surgery Versus Medical and Lifestyle Intervention for Type 2 Diabetes: Analysis of the ARMMS-T2D Consortium of Randomized Trials

**Mary Elizabeth Patti, MD; Bo Hu, PhD; Sarah Kirschling, MS; Hanna J. Wang; Kathleen Foster, BS, RN; Yael Sarig, BA; Donald C. Simonson, MD, MPH, ScD; Danielle Wolfs, MS; David Arterburn, MD, MPH; Matthew J. O'Brien, MD, MSc; Ashley H. Vernon, MD; John M. Jakicic, PhD; Lori Laffel, MD, MPH; Sando Ojukwu, MD, MPH; Sangeeta R. Kashyap, MD; Ali Aminian, MD; Philip R. Schauer, MD; David E. Cummings, MD; William F. Gourash, PhD, CRNP, RN; Anita Courcoulas, MD, MPH; and John P. Kirwan, PhD**

**Background:** Social determinants of health (SDOH) can affect metabolic health.

**Objective:** To determine the effect of social vulnerability on the comparative effectiveness of metabolic bariatric surgery or medical and lifestyle intervention on glycemia and weight outcomes in people with type 2 diabetes (T2D).

**Design:** Analysis of the effect modification of baseline Area Deprivation Index (ADI; a metric of social vulnerability) on longitudinal outcomes between randomized treatment groups using linear mixed-effects models. (ClinicalTrials.gov: NCT02328599)

**Setting:** 4 U.S. academic centers.

**Participants:** 258 participants with T2D enrolled in 4 randomized controlled trials of surgical versus medical management and a longitudinal observational follow-up study.

**Measurements:** ADI linked to ZIP code data at randomization; weight loss and hemoglobin $A_{1c}$ ($HbA_{1c}$) level at the end of the active intervention period (7 to 12 years).

**Results:** Baseline characteristics were well balanced between the surgical and medical therapy groups after adjustment for study site and stratification by high versus low ADI. Surgery was more effective than medical therapy in reducing $HbA_{1c}$ level among persons with high ADI (net difference, −1.29% [95% CI, −1.95% to −0.63%]) and those with low ADI (net difference, −0.95% [CI, −1.29% to −0.62%]). Surgery was also more effective than medical therapy at producing weight loss across ADIs, with respective net differences of −10.6% (CI, −15.2% to −5.9%) for high ADI and −13.3% (CI, −15.7% to −10.9%) for low ADI. The interaction between ADI and intervention group was not significant for either $HbA_{1c}$ ($P = 0.37$) or weight loss ($P = 0.31$).

**Limitations:** Small sample size; parent trials were not designed to address effect modification by ADI.

**Conclusion:** Surgery was superior to medical therapy for people with T2D regardless of social deprivation. This study did not detect statistically significant differences in the comparative advantage of surgery over medical therapy by ADI.

**Primary Funding Source:** National Institutes of Health.

*Ann Intern Med.* doi:10.7326/ANNALS-24-01882
For author, article, and disclosure information, see end of text.

---

Social determinants of health (SDOH), defined by the World Health Organization as the nonmedical factors that influence health outcomes (1), are major contributors to the prevalence and severity of chronic disease (2). It has been estimated that 50% to 60% of health outcomes are related to social, environmental, and behavioral factors independent of genetics and medical care (3). These relationships are well established in type 2 diabetes (T2D) (4, 5) and obesity (6, 7). High social vulnerability is associated with higher prevalence of T2D, poor glycemic control (8), elevated body mass index (BMI), and obesity-associated comorbidities such as cardiovascular disease (9) and premature mortality (10). The intersection of SDOH with obesity may particularly affect people with both T2D and obesity (11–14).

Current approaches targeting glycemic control and weight loss in patients with T2D include medical and lifestyle management, which involves medications and lifestyle interventions, or metabolic bariatric surgery, such as sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), or adjustable gastric banding (AGB) (15). Many studies have demonstrated the efficacy of surgery to achieve both metabolic control and weight loss (16–21), reduce diabetes-associated complications (19–25), and reduce overall mortality (20–23), with superior efficacy versus medical therapy seen in both randomized and observational studies.

Although adverse SDOH are recognized to contribute to health measures of both T2D and obesity,

**See also:**

*Web-Only*
Supplemental material

whether SDOH influence the long-term comparative efficacy of medical versus surgical therapeutic approaches for T2D is uncertain. Within a nonrandomized study or general clinical care, baseline differences in patients who choose surgery versus medical therapy may contribute to outcome differences. To test social vulnerability as an effect modifier within a randomized clinical trial setting, we analyzed data from the Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) consortium (19). We recently reported that people randomly assigned to metabolic bariatric surgery had greater hemoglobin $A_{1c}$ ($HbA_{1c}$) reductions, weight loss, and diabetes remission; lower use of antidiabetes medications; and reductions in several cardiovascular risk factors (19). Due to its framework of randomization, large sample size, and longitudinal follow-up, the ARMMS-T2D consortium provides a unique opportunity to study the independent influence of social vulnerability on the relative efficacy of surgery versus medical therapy on T2D outcomes. We hypothesized that patients with T2D who had high social vulnerability would have reduced response to diabetes and obesity-targeted therapy but would experience greater metabolic improvement after randomization to surgery. We tested these hypotheses by assessing the Area Deprivation Index (ADI), an address-based metric of neighborhood socioeconomic deprivation and social vulnerability, at baseline and the end of the study.

## METHODS

Written informed consent was obtained from participants at each center for the parent ARMMS-T2D trial, and the study was registered at ClinicalTrials.gov (NCT02328599). The Joslin Diabetes Center Committee on Human Studies approved this ancillary study. Electronically dated and signed informed consent was obtained from all participants before participation in the end-of-study survey.

### ARMMS-T2D and Intervention Groups

ARMMS-T2D is a pooled longitudinal follow-up study of participants with T2D initially enrolled in 4 randomized clinical trials. Details of the study methods and results were published previously (19, 26), and the study protocol is available at Annals.org. In brief, people with T2D were randomly assigned in 1 of the 4 parent trials (STAMPEDE [Cleveland, Ohio], SLIMM-T2D [Boston, Massachusetts], TRIABETES [Pittsburgh, Pennsylvania], or CROSSROADS [Seattle, Washington]) to undergo either medical and lifestyle management or 1 of 3 metabolic bariatric surgical procedures (RYGB, SG, or AGB) from 2007 to 2013. Participants self-identified their race and ethnicity based on fixed categories. Study eligibility criteria included diagnosis of T2D, BMI of 27 to 45 kg/$m^2$, and age 18 to 65 years.

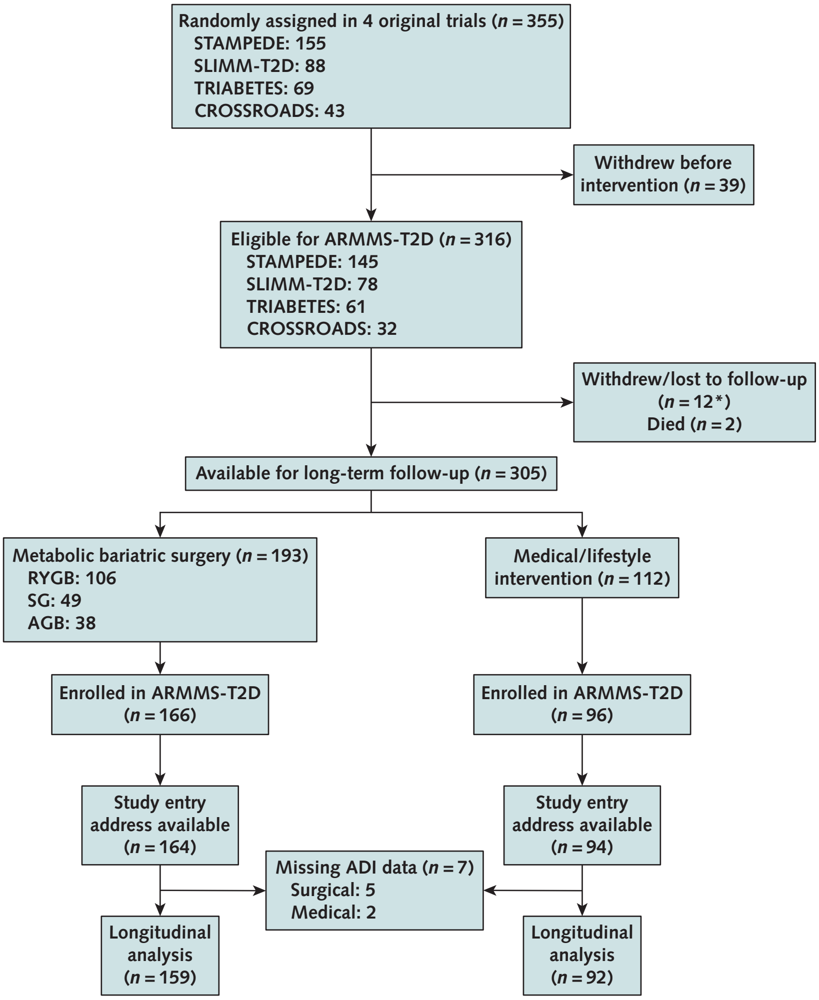
Randomization protocol and operation type options differed by site, as described previously (27) and summarized in **Supplement Table 1** (available at Annals.org). In brief, 1 site (CROSSROADS) randomly assigned participants in a 1:1 ratio to surgery (RYGB) versus medical management, whereas the other 3 sites (SLIMM-T2D, STAMPEDE, and TRIABETES) offered more than 1 surgical option. In SLIMM-T2D, participants chose their preferred surgical procedure (RYGB or AGB) and were then randomly assigned in a 1:1 allocation to that surgery versus medical therapy. The STAMPEDE trial randomly assigned participants in a 1:1:1 ratio to RYGB, SG, or medical therapy, and the TRIABETES trial assigned participants in a 1:1:1 ratio to RYGB, AGB, or medical therapy (27). This resulted in a larger number of participants in the ARMMS-T2D study who had been randomly assigned to surgery ($n = 166$) versus medical therapy ($n = 96$). Patients who underwent surgery had standard postoperative care, including guidance on diet and activity, at least monthly in the first year.

All medical and lifestyle interventions were based on the Diabetes Prevention Program (28) and Look AHEAD (29) interventions and included individualized nutrition counseling, instruction on exercise and self-monitoring of glucose, and behavioral education and counseling for at least 1 year after randomization (details are provided in **Supplement Table 1**). Although these interventions were intended to promote a healthy lifestyle and modest weight loss, specific pharmacologic therapy for weight loss was not part of the diabetes-focused medical intervention at the time of study initiation. After year 1, weight loss therapy could have been prescribed as part of usual care, and incretin-based agents were increasingly used for glycemic control with benefits for weight loss (37% of participants in the medical therapy groups and 27% in the surgical groups were receiving incretin-based therapy at the end of the study).

Participants who received their initially allocated intervention in one of the parent trials and provided consent for longitudinal follow-up were enrolled in the ARMMS-T2D study. Participants were followed for 7 to 12 years in annual visits (window from randomization date encompassing ±6 months) at each site, during which $HbA_{1c}$, weight, diabetes medication use (including incretin-based therapy but not nonincretin weight loss medications), and complications were assessed (19, 27). Observational follow-up within the ARMMS-T2D study was conducted through July 2022. Baseline $HbA_{1c}$ measurements were performed at each center, with standardization against a universal calibrator to reduce assay variability as per the National Glycohemoglobin Standardization Program. Thereafter, blood samples were analyzed using a central laboratory (Northwest Lipid Research Laboratories at the University of Washington until May 2020, and Advanced Research and Diagnostic Laboratory at the University of Minnesota thereafter). Wall-mounted stadiometers and calibrated scales were used for measurement of height and weight at each center.

An intention-to-treat analysis related to group assignment was performed. The primary outcome of the ARMMS-T2D trial was the between-group difference in the absolute change in $HbA_{1c}$ level and between-group differences in the relative change in

***Figure 1.*** Study flow diagram.



ADI = Area Deprivation Index; AGB = adjustable gastric banding; ARMMS-T2D = Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy.
* Three participants were successfully re-recruited.

BMI from baseline to 7 years, and up to 12 years for participants who reached that follow-up point before study closure. A study flow diagram is provided in Figure 1.

## Assessment of Social Vulnerability

To assess the impact of social vulnerability as an effect modifier for the comparative effectiveness of surgical versus medical weight loss interventions, we used addresses provided by participants before randomization and at completion of the ARMMS-T2D study to obtain a metric of social vulnerability based on geographic location and adjusted for year. Baseline addresses were collected during enrollment into the initial ARMMS-T2D clinical trials, and current addresses were extracted from surveys conducted at study completion.

Address information was processed using the Census Geocoder tool to obtain 12-digit Federal Information Processing Standards (FIPS) codes, which are directly linked to census blocks that uniquely identify geographic locations in the United States. Baseline addresses were geocoded to the 2010 FIPS as this is the oldest data benchmark available on the Census Geocoder tool; end-of-study addresses were geocoded to the most recent FIPS. The FIPS codes were then used to obtain values for the ADI, a defined measure of social vulnerability that is refined to the census block level and a composite of 17 variables based on the domains of education, income and employment, housing, and household characteristics derived from U.S. Census data (30). The ADI is a continuous variable that ranges from 1 to 100, with higher ADI indicating greater social vulnerability. ADI data were downloaded from the Neighborhood Atlas (https://www.neighborhoodatlas.medicine.wisc.edu), a University of Wisconsin–Madison website that publishes ADI data sets. Baseline FIPS codes, using Census Geocoder

2010 benchmark data, were matched to the 2015 ADI (31), the oldest ADI database available (based on 2011–2015 American Community Survey [ACS] 5-year data). End-of-study FIPS data were derived from the most up-to-date Census Geocoder data at the time of geocoding and matched to the most current ADI data available (based on 2015–2019 ACS 5-year data [32]). Seven participants were excluded: 5 due to missing information on their baseline address in the Census Geocoder, 1 with a baseline address that was contained within group quarters (not assigned an ADI value due to large populations) (33), and 1 due to missing information about their primary address.

### Outcome Measures

Our co–primary outcomes were glycemia, as measured by absolute change in $HbA_{1c}$ level, and weight loss, as measured by percentage change in BMI. These were measured at annual study visits at each consortium site using standardized protocols as described earlier and reported previously (19).

### Statistical Analysis

Participant characteristics were summarized as appropriate descriptive statistics. The *t* test, the Wilcoxon rank-sum test, or the $\chi^2$ test was used to compare characteristics between groups.

The ADI was considered as both a continuous variable and a dichotomized variable in separate analyses; for the dichotomized analysis, the third quartile (ADI >75) was used as a threshold for assignment to high ADI groups.

To test the comparative effectiveness of surgical versus medical intervention and its effect modification by ADI, linear mixed-effects models included intervention group, baseline ADI, and $HbA_{1c}$ level or BMI as covariates and an interaction term for intervention group and ADI category. For subject *i* and visit $t = 1,\ldots,12$, the mixed-effects model for change in $HbA_{1c}$ level is expressed as

$$Y_{it} = \alpha_t + \beta_1 G_i + \beta_2 ADI_i + \beta_3 G_i \times ADI_i + \gamma^T \mathbf{X}_i + b_i + e_{it},$$

where $Y_{it}$ represents the absolute change in $HbA_{1c}$ level ($HbA_{1c}$ at visit *t* minus baseline $HbA_{1c}$), $G_i$ represents the group (medical vs. surgical), $ADI_i$ represents ADI status (high vs. low), $X_i$ is a vector of baseline $HbA_{1c}$ and site, $b_i$ is a Gaussian random intercept at the subject level with mean 0, and $e_{it}$ is the residual that is independent of $b_i$. $\alpha$, $\beta$, and $\gamma$ are unknown parameters. The model for BMI change has the same format, with $Y_{it}$ being the percentage change in BMI and baseline $HbA_{1c}$ replaced by baseline BMI. Because the 4 trials began at different times, follow-up durations varied administratively. Missingness from shorter follow-up, death, or loss to follow-up was assumed to be at random (34, 35).

Statistical significance was established at a 2-sided *P* value less than 0.05. All analyses were conducted using RStudio (Posit Software).

### Role of the Funding Source

ARMMS-T2D is supported by the National Institutes of Health (U01 DK114156). The sponsor requested proposals for a randomized trial comparing surgery versus medical therapy for T2D but had no role in the design of the original trials. The National Institute of Diabetes and Digestive and Kidney Diseases was not involved in data collection but was involved in discussion of the planning of this ancillary study.

## RESULTS

### Study Sample Characteristics

Of 262 eligible participants from the 4 parent trials, 258 were available for analysis of social vulnerability, as measured by ADI, at study entry (**Figure 1**). Demographic and metabolic information at study entry for this cohort (164 in the surgery group and 94 in the medical therapy group), stratified by baseline ADI and randomization group, is shown in **Table 1**.

ADIs were higher in the surgery group at both baseline ($P = 0.008$) and the end of the study ($P = 0.003$), reflecting higher values at the Cleveland and Pittsburgh sites and the larger number of surgical participants from these sites due to the 2:1 treatment allocation in favor of surgery (2 surgical groups vs. 1 medical group) (**Supplement Figure**, available at Annals.org). Differences in ADI between surgery and medical therapy did not remain after adjustment for study site.

Stratification of the entire study population (both randomization groups) according to baseline ADI (>75 [high] vs. ≤75 [low]) (**Table 1**; **Supplement Table 2**, available at Annals.org) revealed that participants with high social vulnerability were younger; were more likely to be female; were more likely to be Black; and had higher BMI, $HbA_{1c}$ level, systolic blood pressure, and total, high-density lipoprotein, and low-density lipoprotein cholesterol levels. Baseline ADI was positively correlated with baseline $HbA_{1c}$ level ($r = 0.20$; $P = 0.001$) but not with BMI ($r = 0.11$; $P = 0.080$).

### Baseline ADI and Effectiveness of Surgical vs. Medical and Lifestyle Intervention on Glycemic Outcomes

**Table 2** and **Figure 2** (*top*) show the comparative effectiveness of surgery versus medical and lifestyle interventions, stratified by baseline ADI, on glycemic control over the 12 years of the study. Consistent with the primary results of the parent trials (19), reduction in $HbA_{1c}$ was greater for the surgical group than the medical group. Although the estimate of the surgical group's net advantage was numerically higher among those with high versus low ADI, the CIs were wide and the interaction effect (the difference of the differences between surgery and medical therapy in the high and low ADI groups) was not statistically significant over the 12 years of the study (interaction: −0.34% [95% CI, −1.08% to 0.40%]; $P = 0.37$). We note similar patterns

*Table 1.* Baseline Characteristics of Participants, Overall and Stratified by Randomization and ADI Group

| Characteristic | Overall ($n = 258$) | ADI >75 | | ADI ≤75 | |
|---|---|---|---|---|---|
| | | Medical and Lifestyle Intervention ($n = 16$) | Metabolic Bariatric Surgery ($n = 39$) | Medical and Lifestyle Intervention ($n = 76$) | Metabolic Bariatric Surgery ($n = 120$) |
| Mean age (SD), *y* | 49.84 (8.35) | 49.90 (8.11) | 46.10 (9.25) | 51.86 (6.58) | 50.04 (8.63) |
| Female, *n (%)* | 176 (68) | 14 (88) | 33 (85) | 44 (58) | 81 (68) |
| Race, *n (%)* | | | | | |
| Black | 80 (31) | 9 (56) | 23 (59) | 25 (33) | 20 (17) |
| Other | 5 (1.9) | 0 (0) | 0 (0) | 3 (3.9) | 2 (1.7) |
| White | 173 (67) | 7 (44) | 16 (41) | 48 (63) | 98 (82) |
| Mean BMI (SD), $kg/m^2$ | 36.43 (3.51) | 36.94 (3.19) | 37.43 (3.38) | 36.07 (3.51) | 36.22 (3.61) |
| Mean weight (SD), *kg* | 104.26 (15.39) | 103.07 (11.49) | 102.75 (13.20) | 106.30 (16.27) | 103.35 (16.11) |
| Mean waist circumference (SD), *cm* | 114.55 (9.81) | 114.71 (7.40) | 115.59 (8.68) | 113.67 (10.06) | 114.65 (10.44) |
| Mean diabetes duration (SD), *y* | 8.45 (5.38) | 8.00 (5.35) | 7.92 (4.59) | 8.95 (5.28) | 8.45 (5.76) |
| Insulin dependence, *n (%)* | 116 (45) | 7 (44) | 20 (51) | 27 (36) | 61 (51) |
| Mean $HbA_{1c}$ level (SD), *%* | 8.51 (1.52) | 8.36 (0.98) | 9.08 (1.79) | 8.14 (1.21) | 8.56 (1.62) |
| Mean glucose level (SD), *mg/dL** | 165.39 (62.80) | 154.94 (44.33) | 178.95 (76.15) | 154.84 (51.14) | 167.54 (66.98) |
| Mean systolic blood pressure (SD), *mm Hg* | 132.64 (16.87) | 132.88 (19.97) | 138.23 (18.70) | 129.20 (14.70) | 133.12 (16.73) |
| Mean diastolic blood pressure (SD), *mm Hg* | 80.08 (9.88) | 78.19 (10.32) | 82.28 (11.48) | 79.87 (9.68) | 79.78 (9.60) |
| Mean total cholesterol level (SD), *mg/dL†* | 177.32 (42.72) | 177.94 (31.26) | 195.85 (41.81) | 171.44 (40.51) | 174.70 (45.20) |
| Mean HDL cholesterol level (SD), *mg/dL†* | 43.31 (12.23) | 49.56 (13.80) | 47.03 (11.44) | 43.23 (12.85) | 41.10 (10.91) |
| Mean LDL cholesterol level (SD), *mg/dL†* | 99.17 (33.74) | 97.38 (29.02) | 117.03 (37.47) | 96.24 (33.84) | 95.26 (31.85) |
| Mean triglyceride level (SD), *mg/dL‡* | 180.71 (138.46) | 155.13 (89.27) | 161.74 (88.01) | 162.16 (94.10) | 200.45 (173.94) |
| Median albumin–creatinine ratio (IQR) | 7.00 (4.00–21.75) | 6.00 (4.00–12.00) | 7.00 (4.00–17.00) | 6.00 (3.00–16.00) | 9.00 (4.00–23.50) |
| Mean ADI (SD)§ | 47.27 (29.12) | 87.75 (7.82) | 89.33 (7.05) | 31.00 (19.70) | 38.51 (21.60) |

ADI = Area Deprivation Index; BMI = body mass index; $HbA_{1c}$ = hemoglobin $A_{1c}$; HDL = high-density lipoprotein; LDL = low-density lipoprotein.
* To convert glucose values to millimoles per liter, multiply by 0.0555.
† To convert cholesterol values to millimoles per liter, multiply by 0.0259.
‡ To convert triglyceride values to millimoles per liter, multiply by 0.0113.
§ Seven patients were missing baseline ADI.

at 1 year after the intervention (**Supplement Table 3**, available at Annals.org).

We similarly assessed outcomes using ADI as a continuous variable (**Supplement Table 4**, available at Annals.org). Higher ADI was associated with significantly less decrease in $HbA_{1c}$ in the medical and lifestyle intervention group ($P = 0.038$); differences between the surgical and medical groups, stratified by ADI, were not significant in a test for interaction ($P = 0.192$).

Rates of remission and insulin use, or the number of medication classes prescribed, differed significantly between the high and low ADI groups, with estimates numerically favoring participants with low ADI (**Supplement Table 5**, available at Annals.org). The interaction between ADI and treatment group for incretin use was statistically significant ($P < 0.001$), with lower probability of use of incretins in the high ADI medical group and higher probability in the high ADI surgical group.

### Association With Weight Loss Outcomes

Stratification by both baseline ADI and randomization group (**Figure 2** [*bottom*]) showed greater weight loss in participants randomly assigned to surgery versus medical therapy in both the high and low vulnerability groups, although the interaction was not statistically significant. The difference in the percentage change in BMI between the surgical and medical groups was −10.6% (CI, −15.2% to −5.9%) in the high ADI group compared with −13.3% (CI, −15.7% to −10.9%) in the low ADI group over 12 years of follow-up. The difference in the differences (high ADI − low ADI) was 2.7% (CI, −2.5% to 7.9%; $P = 0.31$). The pattern was similar at 1 year (**Supplement Table 3**).

Likewise, assessment of baseline ADI as a continuous variable revealed that while higher ADI was significantly associated with less weight loss in the overall cohort, there was no significant interaction between group and ADI for weight loss outcomes (**Supplement Table 4**).

## DISCUSSION

Using pooled results of 4 randomized controlled trials comparing metabolic bariatric surgery versus medical interventions in participants with moderate to severe obesity, we explored the influence of SDOH on the comparative efficacy of surgical versus medical therapy. We found that surgery was more effective than medical therapy for both glycemic and weight loss outcomes, regardless of participants' social vulnerability as determined by ZIP code–linked ADI at study entry. Moreover, the relative comparative advantage of surgery over medical therapy did not definitively differ by ADI.

*Table 2.* Longitudinal Relationship Between Baseline ADI Category and Absolute Change in $HbA_{1c}$ Level or Percentage Change in BMI*

| Variable | $HbA_{1c}$ Level |  | BMI |  |
|---|---|---|---|---|
|  | **Absolute Change (95% CI), %** | ***P* Value** | **Relative Change (95% CI), %** | ***P* Value** |
| **Low ADI (≤75)** |  |  |  |  |
| Medical and lifestyle intervention | −0.50 (−0.79 to −0.22) | <0.001 | −8.6 (−10.6 to −6.7) | <0.001 |
| Metabolic bariatric surgery | −1.46 (−1.70 to −1.21) | <0.001 | −21.8 (−23.6 to −20.2) | <0.001 |
| Difference (surgery − medical) | −0.95 (−1.29 to −0.62) | <0.001 | −13.3 (−15.7 to −10.9) | <0.001 |
| **High ADI (>75)** |  |  |  |  |
| Medical and lifestyle intervention | 0.06 (−0.53 to 0.65) | 0.84 | −7.8 (−12.0 to −3.7) | <0.001 |
| Metabolic bariatric surgery | −1.23 (−1.63 to −0.83) | <0.001 | −18.4 (−21.3 to −15.5) | <0.001 |
| Difference (surgery − medical) | −1.29 (−1.95 to −0.63) | <0.001 | −10.6 (−15.2 to −5.9) | <0.001 |
| **Interaction (difference in high ADI group − difference in low ADI group)** | −0.34 (−1.08 to 0.40) | 0.37 | 2.7 (−2.5 to 7.9) | 0.31 |

ADI = Area Deprivation Index; BMI = body mass index; $HbA_{1c}$ = hemoglobin $A_{1c}$.

* Covariates include site and baseline $HbA_{1c}$ level or BMI. Estimates from a linear mixed-effects model are presented. A negative estimate indicates a decrease in $HbA_{1c}$ level or BMI.

Metrics of social vulnerability have previously been shown to moderate the effect of nonsurgical interventions on weight loss and diabetes care and prevention. Within a cluster randomized trial, an intensive behavioral weight loss intervention yielded more weight loss than usual care, but patients with food insecurity had a 2.5-kg lower weight loss than patients with food security (14, 36). Likewise, in a nonrandomized intervention designed to improve access to food resources for patients with T2D, those with poor glycemic control at baseline had greater improvement in $HbA_{1c}$, but this improvement was not seen in those with food insecurity (37). In the diabetes-focused Diabetes Prevention Program, there was a lower magnitude of diabetes risk reduction with either lifestyle intervention or metformin in participants with lower educational attainment, with a statistically significant education-by-treatment interaction (38).

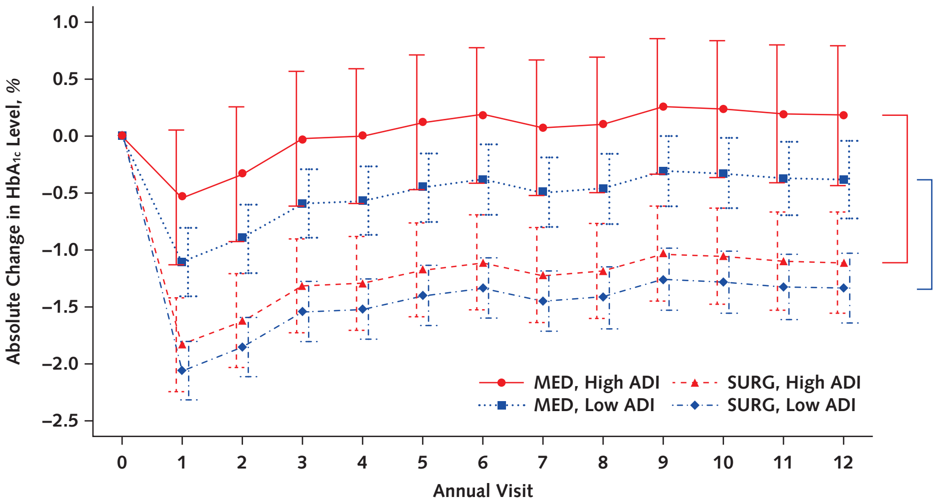
Prior investigations analyzing the relationship between SDOH and longitudinal outcomes of metabolic bariatric surgery in nonrandomized populations have yielded more mixed conclusions. A retrospective study using a sample of 13 275 patients who underwent gastric bypass from the Scandinavian Obesity Surgery Registry found that first-generation immigrants and patients residing in larger towns had lower weight loss than other groups, but associations with other factors, including income, education, and employment type, were weaker (39). In contrast, other studies have found no major effect of SDOH on surgical weight loss. There was no significant effect of insurance type (public Medicaid vs. non-Medicaid), ADI, or neighborhood urbanicity or walkability on weight loss in the University of Wisconsin bariatric surgery registry database (40, 41). Similarly, food accessibility and security were not associated with surgical weight loss (42, 43). These studies are limited in that weight loss associations were cross-sectional and were analyzed after a relatively short postoperative period, and the long-term effect on diabetes control was not assessed. Furthermore, the nonrandomized design could have introduced bias related to the effect of SDOH factors on patient selection and/or actual completion of surgical therapy (44).

Our randomized study allowed us to explore the influence of social deprivation on the comparative efficacy of surgical versus medical therapy. The comparative advantage of surgery over medical therapy was seen in populations with both high and low social deprivation over the long term. Notably, weight loss medications were not a component of medical therapy at study onset. Although incretin-based therapies for diabetes were implemented widely in both the surgical and medical groups during the course of the study as part of usual care, highly effective weight loss medications were not yet available to our participants during the early follow-up period of our study; thus, our findings related to the medical therapy group may not be generalizable to interventions where pharmacotherapy for weight loss was a core component.

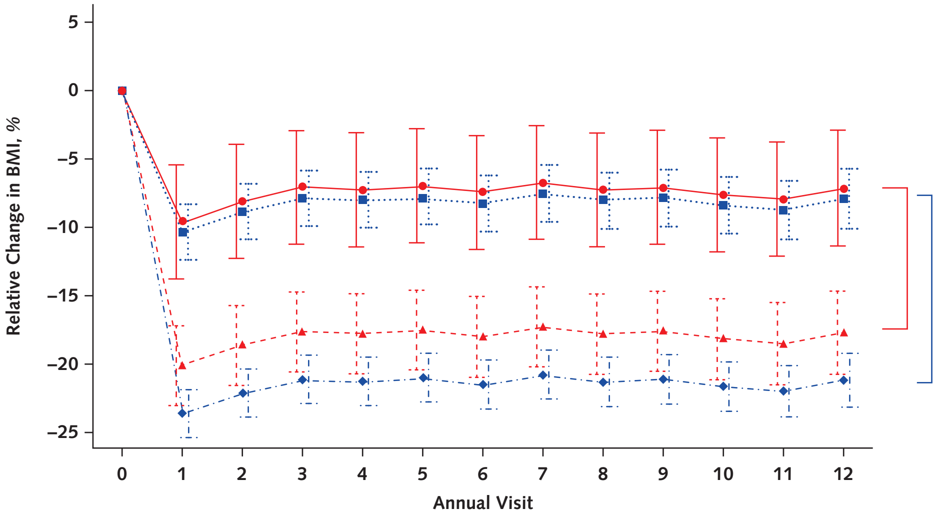
Although our measure of social vulnerability did not clearly affect the comparative advantage of surgery over medical intervention, social vulnerability metrics were associated with less reduction in BMI over the course of the study (**Supplement Table 4**). These data are consistent with reduced weight loss in people with high social vulnerability in some observational studies and in the cluster randomized trial cited earlier (14, 36). The potential role of food insecurity, lower health literacy, reduced medication access and adherence, and reduced physical activity as mediators of these relationships will need to be assessed in future studies (11, 45–47).

Our study has both strengths and limitations. Our longitudinal analysis utilized baseline social vulnerability data from the randomized study population in the ARMMS-T2D clinical trial. A key strength of this approach is that analysis of baseline vulnerability on longitudinal outcomes within a randomized study

***Figure 2.*** Longitudinal absolute change in $HbA_{1c}$ level (*top*) and longitudinal percentage change in weight (*bottom*), stratified by ADI and randomization group.



| Participants, *n* | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MED, High ADI | 16 | 15 | 15 | 16 | 13 | 16 | 12 | 13 | 13 | 14 | 14 | 11 | 8 |
| MED, Low ADI | 76 | 73 | 70 | 67 | 63 | 66 | 64 | 67 | 56 | 55 | 52 | 42 | 22 |
| SURG, High ADI | 39 | 38 | 36 | 35 | 33 | 38 | 27 | 33 | 29 | 32 | 30 | 29 | 28 |
| SURG, Low ADI | 120 | 119 | 117 | 116 | 107 | 109 | 89 | 99 | 87 | 90 | 85 | 66 | 52 |



| Participants, *n* | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MED, High ADI | 16 | 15 | 14 | 16 | 14 | 14 | 13 | 13 | 12 | 16 | 14 | 13 | 8 |
| MED, Low ADI | 76 | 73 | 67 | 67 | 61 | 60 | 62 | 58 | 58 | 55 | 54 | 45 | 25 |
| SURG, High ADI | 39 | 38 | 37 | 37 | 34 | 36 | 30 | 36 | 28 | 34 | 30 | 29 | 28 |
| SURG, Low ADI | 120 | 119 | 117 | 115 | 103 | 109 | 89 | 100 | 90 | 88 | 83 | 72 | 53 |

Adjusted estimates from the linear mixed-effects models are shown along with 95% CIs. The numbers below the graphs indicate the number of participants in each group who were available for analysis at that time point. The brackets indicate comparative outcome differences between the medical and surgical groups for the high ADI group and the low ADI group; interaction differences were not significant. Results of statistical comparisons between groups are provided in Table 2. ADI = Area Deprivation Index; BMI = body mass index; $HbA_{1c}$ = hemoglobin $A_{1c}$; MED = medical and lifestyle intervention group; SURG = metabolic bariatric surgery group.

minimizes potential bias of these variables on patient-specific choice of therapy. However, given that analysis of social deprivation was not a primary outcome of ARMMS-T2D, the power to detect differences in outcomes as a function of baseline vulnerability was limited. Moreover, the ARMMS-T2D study did not include specific weight loss pharmacotherapy (beyond nutrition and physical activity) as a core element of medical therapy. Our study population may not be fully representative of patients from historically disadvantaged backgrounds who may be less likely to volunteer for medical research. Enrollment was also restricted to patients residing in the Northeast, Midwest, and Pacific Northwest regions of the United States, which tend to be more affluent on average (48). Finally, we relied on ADI as a metric of neighborhood-level social deprivation but recognize that no single available metric adequately captures the complete effect of social vulnerability for an individual.

In summary, the long-term efficacy of metabolic bariatric surgery for glycemic control and weight loss was superior to medical and lifestyle intervention for people with T2D, regardless of social vulnerability at randomization. We did not detect statistically significant differences in the comparative advantage of surgery over medical therapy by ADI. However, associations were stronger for the medical treatment group, suggesting that social vulnerability may modify outcomes, particularly when the ongoing need for medical therapy for diabetes and obesity is greater.

From Research and Clinic Division, Joslin Diabetes Center and Harvard Medical School, Boston, Massachusetts (M.E.P., H.J.W., K.F., Y.S., D.W., L.L., S.O.); Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, Ohio (B.H., S.K.); Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts (D.C.S., A.H.V.); Kaiser Permanente Washington Health Research Institute, Seattle, Washington (D.A.); Division of General Internal Medicine and Epidemiology, Northwestern University Feinberg School of Medicine, Chicago, Illinois (M.J.O.); Department of Internal Medicine, Division of Physical Activity and Weight Management, University of Kansas Medical Center, Kansas City, Kansas (J.M.J.); Weill Cornell Medicine-New York Presbyterian, Department of Medicine, Division of Endocrinology, Diabetes and Metabolism, New York, New York (S.R.K.); Bariatric and Metabolic Institute, Department of General Surgery, Cleveland Clinic, Cleveland, Ohio (A.A.); Metamor Institute, Pennington Biomedical Research Center, Baton Rouge, Louisiana (P.R.S., J.P.K.); Department of Medicine, University of Washington, and VA Puget Sound Health Care System, Seattle, Washington (D.E.C.); and Department of Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania (W.F.G., A.C.).

**Acknowledgment:** The authors thank all of the participants and staff who contributed to this research study.

**Grant Support:** ARMMS-T2D was supported by cooperative agreement U01 DK114156 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr. Patti acknowledges support from the Diabetes Research Center at Joslin Diabetes Center (P30-DK036836). Dr. O'Brien acknowledges support from the Chicago Center for Diabetes Translation Research (P30-DK092949). Dr. Kirwan was supported by the Louisiana Clinical and Translational Science Center (U54-GM104940).

**Disclosures:** Disclosure forms are available with the article online.

**Data Sharing Statement:** Available with the article online.

**Corresponding Author:** Mary Elizabeth Patti, MD, Research Division, Joslin Diabetes Center, 1 Joslin Place, Boston, MA 02215; e-mail, mary.elizabeth.patti@joslin.harvard.edu.

Author contributions are available at Annals.org.

## References

1. **World Health Organization.** Social determinants of health. Accessed at https://www.who.int/health-topics/social-determinants-of-health on 8 July 2024.
2. **Cockerham WC, Hamby BW, Oates GR.** The social determinants of chronic disease. Am J Prev Med. 2017;52:S5-S12. [PMID: 27989293] doi:10.1016/j.amepre.2016.09.010
3. **Marmot M, Allen JJ.** Social determinants of health equity. Am J Public Health. 2014;104 Suppl 4:S517-S519. [PMID: 25100411] doi:10.2105/AJPH.2014.302200
4. **Hill-Briggs F, Adler NE, Berkowitz SA, et al.** Social determinants of health and diabetes: a scientific review. Diabetes Care. 2020; 44:258-279. [PMID: 33139407] doi:10.2337/dci20-0053
5. **Ogunwole SM, Golden SH.** Social determinants of health and structural inequities—root causes of diabetes disparities. Diabetes Care. 2021;44:11-13. [PMID: 33571949] doi:10.2337/dci20-0060
6. **Baez AS, Ortiz-Whittingham LR, Tarfa H, et al.** Social determinants of health, health disparities, and adiposity. Prog Cardiovasc Dis. 2023;78:17-26. [PMID: 37178992] doi:10.1016/j.pcad.2023.04.011
7. **Javed Z, Valero-Elizondo J, Maqsood MH, et al.** Social determinants of health and obesity: findings from a national study of US adults. Obesity (Silver Spring). 2022;30:491-502. [PMID: 35088551] doi:10.1002/oby.23336
8. **Bijlsma-Rutte A, Rutters F, Elders PJM, et al.** Socio-economic status and HbA1c in type 2 diabetes: a systematic review and meta-analysis. Diabetes Metab Res Rev. 2018;34:e3008. [PMID: 29633475] doi:10.1002/dmrr.3008
9. **Powell-Wiley TM, Baumer Y, Baah FO, et al.** Social determinants of cardiovascular disease. Circ Res. 2022;130:782-799. [PMID: 35239404] doi:10.1161/CIRCRESAHA.121.319811
10. **Kollia N, Caballero FF, Sánchez-Niubó A, et al.** Social determinants, health status and 10-year mortality among 10,906 older adults from the English Longitudinal Study of Aging: the ATHLOS project. BMC Public Health. 2018;18:1357. [PMID: 30526556] doi:10.1186/s12889-018-6288-6
11. **Kang H, Lobo JM, Kim S, et al.** Cost-related medication non-adherence among U.S. adults with diabetes. Diabetes Res Clin Pract. 2018; 143:24-33. [PMID: 29944967] doi:10.1016/j.diabres.2018.06.016
12. **Ngo-Metzger Q, Sorkin DH, Billimek J, et al.** The effects of financial pressures on adherence and glucose control among racial/ethnically diverse patients with diabetes. J Gen Intern Med. 2012;27:432-437. [PMID: 22005941] doi:10.1007/s11606-011-1910-7
13. **Pooler JA, Srinivasan M.** Association between Supplemental Nutrition Assistance Program participation and cost-related medication nonadherence among older adults with diabetes. JAMA Intern Med. 2019;179:63-70. [PMID: 30453334] doi:10.1001/jamainternmed.2018.5011
14. **Myers CA, Martin CK, Apolzan JW, et al; PROPEL Research Group.** Food insecurity and weight loss in an underserved primary care population: a post hoc analysis of a cluster randomized trial. Ann Intern Med. 2021;174:1032-1034. [PMID: 33683931] doi:10.7326/M20-6326
15. **American Diabetes Association Professional Practice Committee.** 8. Obesity and weight management for the prevention and treatment of type 2 diabetes: Standards of Care in Diabetes—2024. Diabetes Care. 2024;47:S145-S157. [PMID: 38078578] doi:10.2337/dc24-S008
16. **Sandoval DA, Patti ME.** Glucose metabolism after bariatric surgery: implications for T2DM remission and hypoglycaemia. Nat Rev Endocrinol. 2023;19:164-176. [PMID: 36289368] doi:10.1038/s41574-022-00757-5
17. **Clapp B, Ponce J, Corbett J, et al.** American Society for Metabolic and Bariatric Surgery 2022 estimate of metabolic and bariatric procedures performed in the United States. Surg Obes Relat Dis. 2024;20: 425-431. [PMID: 38448343] doi:10.1016/j.soard.2024.01.012

18. **Gebran SG, Knighton B, Ngaage LM, et al.** Insurance coverage criteria for bariatric surgery: a survey of policies. Obes Surg. 2020;30:707-713. [PMID: 31749107] doi:10.1007/s11695-019-04243-2

19. **Courcoulas AP, Patti ME, Hu B, et al.** Long-term outcomes of medical management vs bariatric surgery in type 2 diabetes. JAMA. 2024;331:654-664. [PMID: 38411644] doi:10.1001/jama.2024.0318

20. **Mingrone G, Panunzi S, De Gaetano A, et al.** Metabolic surgery versus conventional medical therapy in patients with type 2 diabetes: 10-year follow-up of an open-label, single-centre, randomised controlled trial. Lancet. 2021;397:293-304. [PMID: 33485454] doi:10.1016/S0140-6736(20)32649-0

21. **Gasoyan H, Alavi MH, Zajichek A, et al.** Macrovascular and microvascular outcomes of metabolic surgery versus GLP-1 receptor agonists in patients with diabetes and obesity. Nat Med. 2025;31:3341-3349. [PMID: 40957960] doi:10.1038/s41591-025-03893-3

22. **Sjöström L, Peltonen M, Jacobson P, et al.** Association of bariatric surgery with long-term remission of type 2 diabetes and with microvascular and macrovascular complications. JAMA. 2014;311:2297-2304. [PMID: 24915261] doi:10.1001/jama.2014.5988

23. **Arterburn DE, Olsen MK, Smith VA Jr, et al.** Association between bariatric surgery and long-term survival. JAMA. 2015;313:62-70. [PMID: 25562267] doi:10.1001/jama.2014.16968

24. **Arterburn D, Livingston EH, Schifftner T, et al.** Predictors of long-term mortality after bariatric surgery performed in Veterans Affairs medical centers. Arch Surg. 2009;144:914-920. [PMID: 19841358] doi:10.1001/archsurg.2009.134

25. **Wagen Hauge J, Borgeraas H, Birkeland KI, et al.** Effect of gastric bypass versus sleeve gastrectomy on the remission of type 2 diabetes, weight loss, and cardiovascular risk factors at 5 years (Oseberg): secondary outcomes of a single-centre, triple-blind, randomised controlled trial. Lancet Diabetes Endocrinol. 2025;13:397-409. [PMID: 40185112] doi:10.1016/S2213-8587(24)00396-6

26. **Courcoulas AP, Patti ME, Kirwan JP.** Medical management vs bariatric surgery in type 2 diabetes—reply. JAMA. 2024;332:76-77. [PMID: 38829663] doi:10.1001/jama.2024.8852

27. **Simonson DC, Hu B, Arterburn DE, et al.** Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D): study rationale, design, and methods. Diabetes Obes Metab. 2022;24:1206-1215. [PMID: 35233923] doi:10.1111/dom.14680

28. **Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group.** Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002;346:393-403. [PMID: 11832527] doi:10.1056/NEJMoa012512

29. **Ryan DH, Espeland MA, Foster GD, et al; Look AHEAD Research Group.** Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. Control Clin Trials. 2003;24:610-628. [PMID: 14500058] doi:10.1016/s0197-2456(03)00064-3

30. **Kind AJH, Buckingham WR.** Making neighborhood-disadvantage metrics accessible - the Neighborhood Atlas. N Engl J Med. 2018;378:2456-2458. [PMID: 29949490] doi:10.1056/NEJMp1802313

31. **University of Wisconsin School of Medicine and Public Health.** 2015 Area Deprivation Index, version 3.0. Accessed at www.neighborhoodatlas.medicine.wisc.edu on 8 July 2024.

32. **University of Wisconsin School of Medicine and Public Health.** 2019 Area Deprivation Index, version 3.1. Accessed at www.neighborhoodatlas.medicine.wisc.edu on 8 July 2024.

33. **United States Census Bureau.** Group Quarters and Residence Rules for Poverty. Accessed at https://www.census.gov/topics/income-poverty/poverty/guidance/group-quarters.html on 8 July 2024.

34. **Molenberghs G, Thijs H, Jansen I, et al.** Analyzing incomplete longitudinal clinical trial data. Biostatistics. 2004;5:445-464. [PMID: 15208205] doi:10.1093/biostatistics/5.3.445

35. **Schafer JL, Graham JW.** Missing data: our view of the state of the art. Psychol Methods. 2002;7:147-177. [PMID: 12090408]

36. **Katzmarzyk PT, Martin CK, Newton RL, et al.** Weight loss in underserved patients - a cluster-randomized trial. N Engl J Med. 2020;383:909-918. [PMID: 32877581] doi:10.1056/NEJMoa2007448

37. **Blitstein JL, Lazar D, Gregory K, et al.** Foods for health: an integrated social medical approach to food insecurity among patients with diabetes. Am J Health Promot. 2021;35:369-376. [PMID: 33043687] doi:10.1177/0890117120964144

38. **O'Brien MJ, Whitaker RC, Yu D, et al.** The comparative efficacy of lifestyle intervention and metformin by educational attainment in the Diabetes Prevention Program. Prev Med. 2015;77:125-130. [PMID: 26024851] doi:10.1016/j.ypmed.2015.05.017

39. **Stenberg E, Näslund I, Persson C, et al.** The association between socioeconomic factors and weight loss 5 years after gastric bypass surgery. Int J Obes (Lond). 2020;44:2279-2290. [PMID: 32651450] doi:10.1038/s41366-020-0637-0

40. **Liu N, Venkatesh M, Hanlon BM, et al.** Association between Medicaid status, social determinants of health, and bariatric surgery outcomes. Ann Surg Open. 2021;2:e028. [PMID: 33912867] doi:10.1097/AS9.0000000000000028

41. **Murtha JA, Venkatesh M, Liu N, et al.** Association between neighborhood food environments and bariatric surgery outcomes. Surg Obes Relat Dis. 2022;18:1357-1364. [PMID: 36123294] doi:10.1016/j.soard.2022.08.007

42. **Barr ML, Tabone LE, Brode C, et al.** Successful weight loss after bariatric surgery in Appalachian state regardless of food access ranking score. Surg Obes Relat Dis. 2020;16:1737-1744. [PMID: 32830059] doi:10.1016/j.soard.2020.06.040

43. **Wilkerson AD, Gentle C, Dewey EN, et al.** Association between geospatial disparities in food security with weight loss and nutritional outcomes of metabolic surgery. Surg Endosc. 2024;38:6827-6838. [PMID: 39168860] doi:10.1007/s00464-024-11175-1

44. **Noria SF, Pratt KJ, Abdel-Rasoul M, et al.** The impact of social determinants of health (SDOH) on completing bariatric surgery at a single academic institution. Surg Endosc. 2025;39:1234-1242. [PMID: 39537861] doi:10.1007/s00464-024-11364-y

45. **Seligman HK, Bindman AB, Vittinghoff E, et al.** Food insecurity is associated with diabetes mellitus: results from the National Health Examination and Nutrition Examination Survey (NHANES) 1999–2002. J Gen Intern Med. 2007;22:1018-1023. [PMID: 17436030] doi:10.1007/s11606-007-0192-6

46. **Marciano L, Camerini AL, Schulz PJ.** The role of health literacy in diabetes knowledge, self-care, and glycemic control: a meta-analysis. J Gen Intern Med. 2019;34:1007-1017. [PMID: 30877457] doi:10.1007/s11606-019-04832-y

47. **Umpierre D, Ribeiro PAB, Kramer CK, et al.** Physical activity advice only or structured exercise training and association with HbA1c levels in type 2 diabetes: a systematic review and meta-analysis. JAMA. 2011;305:1790-1799. [PMID: 21540423] doi:10.1001/jama.2011.576

48. **Centers for Disease Control and Prevention.** United States Diabetes Surveillance System. Accessed at https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html on 8 July 2024.

**Author Contributions:** Conception and design: M.E. Patti, K. Foster, D.C. Simonson, M.J. O'Brien, P.R. Schauer, J.P. Kirwan.

Analysis and interpretation of the data: M.E. Patti, B. Hu, S. Kirschling, H.J. Wang, Y. Sarig, D.C. Simonson, M.J. O'Brien, P.R. Schauer, D.E. Cummings, J.P. Kirwan.

Drafting of the article: M.E. Patti, H.J. Wang, D.C. Simonson, D. Arterburn, S.R. Kashyap, D.E. Cummings, J.P. Kirwan.

Critical revision for important intellectual content: M.E. Patti, H.J. Wang, D.C. Simonson, D. Arterburn, M.J. O'Brien, L. Laffel, S.R. Kashyap, A. Aminian, P.R. Schauer, D.E. Cummings, W.F. Gourash, A. Courcoulas, J.P. Kirwan.

Final approval of the article: M.E. Patti, B. Hu, S. Kirschling, H.J. Wang, K. Foster, Y. Sarig, D.C. Simonson, D. Wolfs, D. Arterburn, M.J. O'Brien, A.H. Vernon, J.M. Jakicic, L. Laffel, S. Ojukwu, S.R. Kashyap, A. Aminian, P.R. Schauer, D.E. Cummings, W.F. Gourash, A. Courcoulas, J.P. Kirwan.

Provision of study materials or patients: M.E. Patti, A.H. Vernon, S.R. Kashyap, A. Aminian, J.P. Kirwan.

Statistical expertise: B. Hu.

Obtaining of funding: M.E. Patti, D.C. Simonson, D. Arterburn, S.R. Kashyap, P.R. Schauer, D.E. Cummings, A. Courcoulas, J.P. Kirwan.

Administrative, technical, or logistic support: M.E. Patti, K. Foster, D. Wolfs, D. Arterburn, A.H. Vernon, S. Ojukwu, S.R. Kashyap, A. Aminian, J.P. Kirwan.

Collection and assembly of data: M.E. Patti, K. Foster, Y. Sarig, D.C. Simonson, D. Wolfs, S.R. Kashyap, A. Aminian, D.E. Cummings, W.F. Gourash, A. Courcoulas, J.P. Kirwan.